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Contents

Federal Register

Vol. 70, No. 18

Friday, January 28, 2005

Agricultural Marketing Service
RULES
Pistachios grown in—
California
Correction, 4191
PROPOSED RULES
Nectarines and peaches grown in—
California, 4041–4047

Agriculture Department
See Agricultural Marketing Service
See Animal and Plant Health Inspection Service
See Food and Nutrition Service
See Food Safety and Inspection Service
See Forest Service

Alcohol, Tobacco, Firearms, and Explosives Bureau
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 4150

Animal and Plant Health Inspection Service
RULES
Plant-related quarantine, domestic:
Asian longhorned beetle, 4003–4005
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 4084–4085
Environmental statements; availability, etc.:
Nonregulated status determinations—
Syngenta Seeds; genetically engineered cotton, 4085–4086

Army Department
NOTICES
Environmental statements; availability, etc.:
Fort Bliss, TX; brackish water desalination plant and support facilities; construction and operation, 4095–4096

Blind or Severely Disabled, Committee for Purchase From People Who Are
See Committee for Purchase From People Who Are Blind or Severely Disabled

Centers for Disease Control and Prevention
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 4126–4127

Centers for Medicare & Medicaid Services
RULES
Medicare and medicaid:
Medicare Advantage Program, 4587–4741
Medicare Prescription Drug Benefit, 4193–4585
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 4127–4129
Committees; establishment, renewal, termination, etc.:
Medicare Education Advisory Panel, 4129–4130
Medicare:
Medicare Prescription Drug, Improvement, and Modernization Act of 2003, implementation—
Chiropractic services; coverage demonstration, 4130–4132
Meetings:
Medicare—
Demonstration of Bundled Case-Mix Adjusted Payment System for End-Stage Renal Disease Services Advisory Board, 4132–4133
Medicare Coverage Advisory Committee; meeting, 4133–4134

Chemical Safety and Hazard Investigation Board
NOTICES
Meetings; Sunshine Act, 4090

Coast Guard
RULES
Drawbridge operations:
Delaware, 4014–4016
Florida, 4016–4019
Louisiana, 4013–4014
New York, 4014, 4019
Texas, 4013
PROPOSED RULES
Drawbridge operations:
Louisiana, 4074–4078

Commerce Department
See International Trade Administration
See National Oceanic and Atmospheric Administration

Committee for Purchase From People Who Are Blind or Severely Disabled
NOTICES
Procurement list; additions and deletions, 4090–4092

Corporation for National and Community Service
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 4094–4095

Defense Department
See Army Department
PROPOSED RULES
Restoration Advisory Boards; general, operating, administrative support, funding, and reporting requirements, 4061–4074
NOTICES
Federal Acquisition Regulation (FAR):
Agency information collection activities; proposals, submissions, and approvals, 4096–4097

Education Department
NOTICES
Grants and cooperative agreements; availability, etc.:
Elementary and secondary education—
Improving Literacy Through School Libraries Program, 4097–4101
Innovation and improvement—
Charter Schools Program, 4101–4107

Excellence in Economic Education Program, 4107–4111
Meetings:
Individuals with Disabilities Education Improvement Act; regulatory issues, 4111–4112
Privacy Act:
Systems of records, 4112–4115

Employment Standards Administration
NOTICES
Minimum wages for Federal and federally-assisted construction; general wage determination decisions, 4151–4152

Energy Department
See Federal Energy Regulatory Commission

Environmental Protection Agency
RULES
Air quality implementation plans; approval and promulgation; various States; air quality planning purposes; designation of areas:
Ohio, 4023–4026
Air quality implementation plans; approval and promulgation; various States:
Michigan, 4019–4023
Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:
Bifenazate, 4032–4037
Quinoxyfen, 4026–4032
PROPOSED RULES
Air quality implementation plans; approval and promulgation; various States:
Michigan, 4079–4080
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 4117–4118
Air programs:
State implementation plans; adequacy status for transportation conformity purposes—
Washington, 4118–4119
Environmental statements; availability, etc.:
Agency statements—
Weekly receipts, 4119–4120
Meetings:
Local Government Advisory Committee, 4120
Scientific Counselors Board, 4120–4122
Toxic and hazardous substances control:
New chemicals—
Receipt and status information, 4122–4126

Executive Office of the President
See Management and Budget Office
See Science and Technology Policy Office

Export-Import Bank
NOTICES
Meetings; Sunshine Act, 4126

Federal Aviation Administration
RULES
Airworthiness directives:
Raytheon; correction, 4191
Class E airspace; correction, 4191
Standard instrument approach procedures, 4010–4012
PROPOSED RULES
Airworthiness directives:
Boeing, 4048–4054
McDonnell Douglas, 4055–4058
NOTICES
Airport noise compatibility program:
Jackson International Airport; MS, 4186
Reports and guidance documents; availability, etc.:
Air Traffic Moderinization Cost-Share Program; program guidance, 4186–4190

Federal Communications Commission
RULES
Radio stations; table of assignments:
Indiana, 4038–4039
Oklahoma, 4037
Pennsylvania, 4038

Federal Emergency Management Agency
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 4137
Disaster and emergency areas:
Indiana, 4138
Ohio, 4138–4139

Federal Energy Regulatory Commission
NOTICES
Electric rate and corporate regulation filings, 4115–4117

Federal Transit Administration
PROPOSED RULES
School bus operations: tripper service; definition; withdrawn, 4081–4083

Food and Drug Administration
NOTICES
Human drugs:
New drug applications—
High Chemical Co., et al.; proposal to withdraw approval, 4134–4135
Meetings:
Antiviral Drugs Advisory Committee, 4136

Food and Nutrition Service
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 4086–4087

Food Safety and Inspection Service
PROPOSED RULES
Regulatory Flexibility Act:
Section 610 requirements; regulations review plan; amendment, 4047–4048
NOTICES
Meetings:
Codex Alimentarius Commission—
Food Additives and Contaminants Codex Committee, 4087–4089

Forest Service
NOTICES
Jurisdictional transfers:
Kisatchie National Forest, LA; interchange with Fort Polk Military Reservation, 4089–4090

General Services Administration
NOTICES
Federal Acquisition Regulation (FAR):
Agency information collection activities; proposals, submissions, and approvals, 4096–4097

Health and Human Services Department
See Centers for Disease Control and Prevention

See Centers for Medicare & Medicaid Services
See Food and Drug Administration
See National Institutes of Health
See Substance Abuse and Mental Health Services Administration
NOTICES
Meetings:
Vital and Health Statistics National Committee, 4126

Homeland Security Department
See Coast Guard
See Federal Emergency Management Agency

Housing and Urban Development Department
NOTICES
Grants and cooperative agreements; availability, etc.:
Homeless assistance; excess and surplus Federal properties, 4139

Interior Department
See Land Management Bureau
See National Park Service
See Reclamation Bureau

Internal Revenue Service
RULES
Income taxes:
New markets tax credit; correction, 4012–4013
PROPOSED RULES
Income taxes:
Relative values of optional forms of benefit; disclosure, 4058–4061
NOTICES
Meetings:
Taxpayer Advocacy Panels, 4190

International Trade Administration
NOTICES
Antidumping:
Frozen fish fillets from—
Vietnam, 4092–4093
Antidumping and countervailing duties:
Five year (sunset) reviews—
Initiation of reviews; correction, 4092
North American Free Trade Agreement (NAFTA); binational panel reviews:
Softwood lumber products from—
Canada, 4093–4094

International Trade Commission
NOTICES
Import investigations:
Sebacic acid from—
China, 4150

Justice Department
See Alcohol, Tobacco, Firearms, and Explosives Bureau
See Justice Programs Office

Justice Programs Office
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 4151

Labor Department
See Employment Standards Administration

Land Management Bureau
NOTICES
Closure of public lands:
California, 4139
Committees; establishment, renewal, termination, etc.:
Steens Mountian Advisory Council, 4139–4140
Environmental statements; availability, etc.:
Northeast National Petroleum Reserve, AK; integrated activity plan, 4140–4141
Oil and gas leases:
Utah, 4141
Wyoming, 4142
Opening of public lands:
Montana, 4142
Oregon, 4142–4143
Practice and procedure:
Credit and debit card payments; transaction limit, 4143
Realty actions; sales, leases, etc.:
Nevada, 4143–4145
Oregon, 4145
Resource management plans, etc.:
Little Snake Field Office, CO, 4145–4146
Sierra County et al., NM; White Sands planning area, 4146–4147

Management and Budget Office
NOTICES
Designated Federal Entities and Federal Entities; list, 4157–4158
Reports and guidance documents; availability, etc.:
Research and research-related grants; terms and conditions; policy issuance directive, 4159–4161

National Aeronautics and Space Administration
NOTICES
Federal Acquisition Regulation (FAR):
Agency information collection activities; proposals, submissions, and approvals, 4096–4097
Meetings:
Nuclear Systems Strategic Roadmap Committee, 4152–4153
Space Science Advisory Committee, 4153
Sun-Solar System Connection Strategic Roadmap Committee, 4153
Patent licenses; non-exclusive, exclusive, or partially exclusive:
Barton Medical Imaging, LLC, 4153–4154
Lake Shore Cryotronics, Inc., 4154

National Credit Union Administration
RULES
Credit unions:
Conversion of insured credit unions to mutual savings banks; information disclosure, 4005–4010

National Institutes of Health
PROPOSED RULES
Fellowships, internships, training:
Pediatric research training grants, 4080–4081

National Oceanic and Atmospheric Administration
RULES
Fishery conservation and management:
Alaska; fisheries of Exclusive Economic Zone—
Pacific cod, 4039–4040
Caribbean, Gulf, and South Atlantic fisheries—
Gulf of Mexico and South Atlantic coastal migratory pelagic resources, 4039

National Park Service
NOTICES
Environmental statements; availability, etc.:
Big Thicket National Preserve, TX, 4147–4148
Environmental statements; notice of intent:
Bureau of Mines, Twin Cities Research Center Main Campus, MN; disposition, 4148

National Science Foundation
NOTICES
Meetings:
Equal Opportunities in Science and Engineering Advisory Committee, 4154

Nuclear Regulatory Commission
NOTICES
Applications, hearings, determinations, etc.:
Energy Department, 4154–4157

Office of Management and Budget
See Management and Budget Office

Reclamation Bureau
NOTICES
Environmental statements; availability, etc.:
Humboldt Project, NV, 4149

Science and Technology Policy Office
NOTICES
Reports and guidance documents; availability, etc.:
Research and research-related grants; terms and conditions; policy issuance directive, 4159–4161

Securities and Exchange Commission
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 4161–4163
Self-regulatory organizations; proposed rule changes:
American Stock Exchange LLC, 4163–4165
Chicago Board Options Exchange, Inc., 4165–4167
Fixed Income Clearing Corp., 4167–4169
National Association of Securities Dealers, Inc., 4169–4171
New York Stock Exchange, Inc., 4171–4173
Pacific Exchange, Inc., 4173–4178
Philadelphia Stock Exchange, Inc., 4178–4185

Small Business Administration
NOTICES
Small business size standards:
Nonmanufacturer rule; waivers—
Petroleum and coal products manufacturing, 4185

State Department
NOTICES
Foreign terrorists and terrorist organizations; designation:
Kahane.net; revocation as alias, 4185–4186

Substance Abuse and Mental Health Services Administration
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 4136–4137

Transportation Department
See Federal Aviation Administration
See Federal Transit Administration
PROPOSED RULES
Air travel; nondiscrimination on basis of disability:
Regulation update, reorganization, and clarification; statutory requirement to cover foreign air carriers, 4058

Treasury Department
See Internal Revenue Service

Separate Parts In This Issue

Part II
Health and Human Services Department, Centers for Medicare & Medicaid Services, 4193–4585

Part III
Health and Human Services Department, Centers for Medicare & Medicaid Services, 4587–4741

Reader Aids

Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, reminders, and notice of recently enacted public laws.

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CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

7 CFR
301 4003
983 4193
Proposed Rules:
916 4041
917 4041

9 CFR
Proposed Rules:
Ch. III 4047

12 CFR
708a 4005

14 CFR
39 4191
71 4191
97 4010
Proposed Rules:
39 (4 documents) ...4048, 4050, 4052, 4055
382 4058

26 CFR
1 (2 documents) 4012, 4013
602 4013
Proposed Rules:
1 4058

32 CFR
Proposed Rules:
202 4061

33 CFR
117 (6 documents) 4013, 4014, 4016, 4019
Proposed Rules:
117 (2 documents) 4074, 4077

40 CFR
52 (2 documents) 4019, 4023
81 4023
180 (2 documents) 4026, 4032
Proposed Rules:
52 4079

42 CFR
400 4194
403 4194
411 4194
417 (2 documents) 4194, 4588
422 4588
423 4194
Proposed Rules:
63a 4080

47 CFR
73 (3 documents) 4037, 4038

49 CFR
Proposed Rules:
605 4081

50 CFR
622 4039
679 4039

Rules and Regulations

Federal Register
Vol. 70, No. 18
Friday, January 28, 2005

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. 04–130–1]

Asian Longhorned Beetle; Addition to Quarantined Areas

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the Asian longhorned beetle regulations by adding portions of Middlesex and Union Counties, NJ, to the list of quarantined areas and restricting the interstate movement of regulated articles from those areas. This action is necessary to prevent the artificial spread of the Asian longhorned beetle into noninfested areas of the United States.

DATES: This interim rule was effective January 24, 2005. We will consider all comments that we receive on or before March 29, 2005.

ADDRESSES: You may submit comments by any of the following methods:

- *EDOCKET:* Go to *http://www.epa.gov/feddocket* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once you have entered EDOCKET, click on the ''View Open APHIS Dockets'' link to locate this document.
- *Postal Mail/Commercial Delivery:* Please send four copies of your comment (an original and three copies) to Docket No. 04–130–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 04–130–1.
- *E-mail:* Address your comment to *regulations@aphis.usda.gov.* Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 04–130–1'' on the subject line.
- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the instructions for locating this docket and submitting comments.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: You may view APHIS documents published in the **Federal Register** and related information, including the names of groups and individuals who have commented on APHIS dockets, on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: Mr. Michael B. Stefan, Director of Emergency Programs, Pest Detection and Management Programs, PPQ, APHIS, 4700 River Road Unit 134, Riverdale, MD 20737–1236; (301) 734–7338.

SUPPLEMENTARY INFORMATION:

Background

The Asian longhorned beetle (ALB, *Anoplophora glabripennis*), an insect native to China, Japan, Korea, and the Isle of Hainan, is a destructive pest of hardwood trees. It attacks many healthy hardwood trees, including maple, horse chestnut, birch, poplar, willow, and elm. In addition, nursery stock, logs, green lumber, firewood, stumps, roots, branches, and wood debris of half an inch or more in diameter are subject to infestation. The beetle bores into the heartwood of a host tree, eventually killing the tree. Immature beetles bore into tree trunks and branches, causing heavy sap flow from wounds and sawdust accumulation at tree bases. They feed on, and over-winter in, the interiors of trees. Adult beetles emerge in the spring and summer months from round holes approximately three-eighths of an inch in diameter (about the size of a dime) that they bore through branches and trunks of trees. After emerging, adult beetles feed for 2 to 3 days and then mate. Adult females then lay eggs in oviposition sites that they make on the branches of trees.

A new generation of ALB is produced each year. If this pest moves into the hardwood forests of the United States, the nursery, maple syrup, and forest product industries could experience severe economic losses. In addition, urban and forest ALB infestations will result in environmental damage, aesthetic deterioration, and a reduction in public enjoyment of recreational spaces.

Addition to Quarantined Area

The ALB regulations in 7 CFR 301.51–1 through 301.51–9 (referred to below as the regulations) restrict the interstate movement of regulated articles from quarantined areas to prevent the artificial spread of ALB to noninfested areas of the United States. Portions of the State of Illinois, a portion of Hudson County in the State of New Jersey, and portions of New York City and Nassau and Suffolk Counties in the State of New York are already designated as quarantined areas.

On August 4, 2004, an ALB infestation was discovered in the Borough of Carteret in Middlesex County, NJ. Another ALB infestation was discovered in the City of Rahway, in Union County, NJ, on August 17, 2004. An additional ALB infestation was discovered in this area in late November 2004. Officials of the U.S. Department of Agriculture and officials of State, county, and city agencies in New Jersey are conducting intensive survey and eradication programs in the infested area, which includes sections of the City of Rahway and adjacent sections of the City of Linden in Union County and the Township of Woodbridge in Middlesex County. The State of New Jersey has quarantined the infested area and is restricting the intrastate movement of regulated articles from the quarantined area to prevent the further spread of ALB within that State. Federal regulations are necessary to restrict the interstate movement of regulated articles from the quarantined area to prevent the interstate spread of ALB.

The regulations in § 301.51–3(a) provide that the Administrator of the

Animal and Plant Health Inspection Service (APHIS) will list as a quarantined area each State, or each portion of a State, where ALB has been found by an inspector, where the Administrator has reason to believe that ALB is present, or where the Administrator considers regulation necessary because of its inseparability for quarantine purposes from localities where ALB has been found.

Less than an entire State will be quarantined only if (1) the Administrator determines that the State has adopted and is enforcing restrictions on the intrastate movement of regulated articles that are equivalent to those imposed by the regulations on the interstate movement of regulated articles and (2) the designation of less than an entire State as a quarantined area will be adequate to prevent the artificial spread of ALB.

In accordance with these criteria and the recent ALB findings described above, we are amending the list of quarantined areas in § 301.51–3(c) to include additional areas in Middlesex and Union Counties, NJ. The quarantined area is described in the rule portion of this document.

Emergency Action

This rulemaking is necessary on an emergency basis to help prevent the artificial spread of ALB to noninfested areas of the United States. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the **Federal Register**.

We will consider comments we receive during the comment period for this interim rule (*see* **DATES** above). After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review under Executive Order 12866.

We are amending the regulations by adding portions of Middlesex and Union Counties, NJ, to the list of areas regulated for ALB and restricting the interstate movement of regulated articles from those areas. This action is necessary to prevent the artificial spread of ALB into noninfested areas of the United States.

The Regulatory Flexibility Act (RFA) requires that agencies consider the economic impact of their rules on small entities, *i.e.,* small businesses, organizations, and governmental jurisdictions. This interim rule modifies the area in New Jersey that is regulated for ALB by adding an area that encompasses parts of Middlesex and Union Counties. The businesses potentially affected by modifications to the ALB quarantined area are nurseries, arborists, tree removal services, firewood dealers, garden centers, landscapers, recyclers of waste material, and lumber and building material outlets.

The newly quarantined area covers 12.1 square miles. Within that 12.1 square mile area, there are 10 firewood dealers, 50 landscapers and tree care companies, 3 private waste management companies, 3 developers/excavators, 1 wood recycler, and 1 garden center. While the size of those businesses is unknown, it is reasonable to assume that most would be classified as small entities, based on the U.S. Small Business Administration's size standards. There are also six governmental entities—two counties and four townships—within the 12.1 square mile area. Under the RFA, the term ''small governmental jurisdiction'' generally means cities, counties, townships, etc., with a population of less than 50,000. It is possible that some or all of the six governmental entities would qualify as small governmental jurisdictions.

Entities, large or small, could be affected by the regulations in two ways. First, if an entity wishes to move regulated articles interstate from a quarantined area, that entity must either: (1) Enter into a compliance agreement with APHIS for the inspection and certification of regulated articles to be moved interstate from the quarantined area; or (2) present its regulated articles for inspection by an inspector and obtain a certificate or a limited permit, issued by the inspector, for the interstate movement of regulated articles. The inspections may be inconvenient, but they should not be costly in most cases, even for entities operating under a compliance agreement that would perform the inspections themselves. For those entities that elect not to enter into a compliance agreement, APHIS would provide the services of the inspector without cost. There is also no cost for the compliance agreement, certificate, or limited permit for the interstate movement of regulated articles.

Second, there is a possibility that, upon inspection, a regulated article could be determined by the inspector to be potentially infested by ALB and, as a result, the inspector would not be able to issue a certificate. In this case, the entity's ability to move regulated articles interstate would be restricted. However, the affected entity could conceivably obtain a limited permit under the conditions of § 301.51–5(b). Whether an affected entity would be denied certificates as a result of inspections of regulated articles is unknown. However, because the newly regulated area is primarily urban, the entities located in that area are more likely to be receiving regulated articles from outside the quarantined area than they are to be shipping regulated articles interstate to nonquarantined areas. It is unlikely, therefore, that most entities located in the newly regulated area would be moving regulated articles that would require inspection in the first place.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (*See* 7 CFR part 3015, subpart V.)

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

■ Accordingly, we are amending 7 CFR part 301 as follows:

PART 301—DOMESTIC QUARANTINE NOTICES

■ 1. The authority citation for part 301 continues to read as follows:

Authority: 7 U.S.C. 7701–7772; 7 CFR 2.22, 2.80, and 371.3.

Section 301.75–15 also issued under Sec. 204, Title II, Pub. L. 106–113, 113 Stat. 1501A–293; sections 301.75–15 and 301.75–16 also issued under Sec. 203, Title II, Pub. L. 106–224, 114 Stat. 400 (7 U.S.C. 1421 note).

■ 2. In § 301.51–3, paragraph (c) is amended by adding, in alphabetical order under the heading New Jersey, an entry for Middlesex and Union Counties to read as follows:

§ 301.51–3 Quarantined areas.

* * * * *

(c) * * *

New Jersey

* * * * *

Middlesex and Union Counties. That portion of the counties bounded by a line drawn as follows: Beginning at the intersection of St. Georges Avenue and Stiles Street; then east along Stiles Street to Elizabeth Avenue; then north on Elizabeth Avenue to Wood Avenue; then east on Wood Avenue to the east side of the New Jersey Turnpike right-of-way; then south along the east side of the New Jersey Turnpike right-of-way to Marshes Creek; then southeast along Marshes Creek to the Rahway River; then west along the south side of the Rahway River to Cross Creek; then south along Cross Creek through the wetlands to Peter J. Sica Industrial Drive; then east and south on Peter J. Sica Industrial Drive to Roosevelt Avenue (State Route 602); then west on Roosevelt Avenue to Port Reading Avenue (State Route 604); then west southwest on Port Reading Avenue to the Conrail railroad; then north and west along the Conrail railroad right-of-way to the NJ Transit railroad right-of-way; then north and northwest along the NJ Transit railroad right-of-way to the south branch of the Rahway River; then west along the south branch of the Rahway River to St. Georges Avenue; then north on St. Georges Avenue to the point of beginning.

* * * * *

Done in Washington, DC, this 24th day of January 2005.

Elizabeth E. Gaston,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 05–1615 Filed 1–27–05; 8:45 am]

BILLING CODE 3410–34–P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 708a

Conversion of Insured Credit Unions to Mutual Savings Banks

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final rule.

SUMMARY: NCUA is updating its rule regarding conversion of insured credit unions to mutual savings banks (MSBs). The amendments require a converting credit union to provide its members with additional disclosures about the conversion before conducting a member vote. The amendments also require the vote to be by secret ballot and conducted by an independent entity. Finally, the amendments require a federally-insured State credit union to provide NCUA with conversion related information about the law of the State where the credit union is chartered.

DATES: This final rule is effective January 28, 2005.

FOR FURTHER INFORMATION CONTACT: Frank S. Kressman, Staff Attorney, at (703) 518–6540.

SUPPLEMENTARY INFORMATION:

A. Background

The Credit Union Membership Access Act (CUMAA) was enacted into law on August 7, 1998. Public Law 105–21. Section 202 of CUMAA amended the provisions of the Federal Credit Union Act concerning conversion of insured credit unions to MSBs. 12 U.S.C. 1785(b). CUMAA required NCUA to promulgate final rules regarding charter conversions that were: (1) Consistent with CUMAA; (2) consistent with the charter conversion rules promulgated by other financial regulators; and (3) no more or less restrictive than rules applicable to charter conversions of other financial institutions. NCUA issued rules in compliance with this mandate. 63 FR 65532 (November 27, 1998); 64 FR 28733 (May 27, 1999).

Since the enactment of CUMAA, NCUA has become concerned that many credit union members do not appreciate the effect a conversion may have on their ownership interests in the credit union and voting power in the MSB. In February 2004, NCUA amended part 708a to require a converting credit union to disclose additional information to its members to better educate them regarding the conversion. 69 FR 8548 (February 25, 2004). NCUA solicited public comment as part of that rulemaking. Some commenters suggested that, among other things, NCUA should have imposed more disclosures and requirements on converting credit unions. Many offered specific suggestions. NCUA noted at that time that many of those suggestions deserved further consideration but were beyond the scope of that rulemaking and would have to be considered in a future rulemaking. In July 2004, NCUA issued a proposed rule with request for comments to address some of those suggestions and other ongoing concerns NCUA has in connection with protecting members' interests in the conversion process. 69 FR 46111 (August 2, 2004).

B. Discussion

CUMAA provides that an insured credit union may convert to an MSB without the prior approval of NCUA, but it also requires NCUA to administer the member vote on conversion and review the methods and procedures by which the vote is taken. This is reflected in NCUA's conversion rule. The rule requires a converting credit union to provide its members with written notice of its intent to convert. 12 CFR 708a.4. It also specifies that the member notice must adequately describe the purpose and subject matter of the vote on conversion. *Id.* In addition, a converting credit union must notify NCUA of its intent to convert. 12 CFR 708a.5. The credit union must provide NCUA a copy of its member notice, ballot, and all other written materials it has provided or intends to provide to its members in connection with the conversion. *Id.*

A converting credit union has the option of submitting these materials to NCUA before it distributes them to its members. *Id.* This enables the credit union to obtain NCUA's preliminary determination on the methods and procedures of the member vote based on NCUA's review of the written materials. NCUA believes its review of these materials is a practical and unintrusive way of fulfilling, at least part of, its congressionally mandated responsibility to review the methods and procedures of the vote.

If NCUA disapproves of the methods and procedures of the member vote after the vote is conducted, then NCUA is authorized to direct a new vote be taken. 12 CFR 708a.7. NCUA interprets its responsibility to review the methods and procedures of the member vote to include determining that the member notice and other materials sent to the members are accurate and not misleading, all required notices are timely, and the membership vote is conducted in a fair and legal manner.

A charter conversion has consequences that may not surface for a

number of years and are often not apparent at the time of conversion to even the most astute members. As a result, members cannot make an informed decision about how the conversion will affect them unless their credit union provides them with this information.

NCUA is aware that credit unions are not providing some important conversion related information effectively to their members. This limits members' ability to make informed decisions about a conversion. NCUA also has become aware that many credit unions may not be equipped to conduct a proper member vote on conversion. Accordingly, NCUA is amending the conversion rule to require a converting credit union to provide additional disclosures to its members. Also, NCUA is providing guidelines to help converting credit unions better understand how they can satisfy the regulatory standard that the member vote be conducted in a fair and legal manner. In addition to the guidelines, NCUA is amending the rule to require the vote be conducted using secret ballots and an independent teller to ensure the integrity of the voting process and the privacy of each member's vote. Finally, NCUA is amending the conversion rule to require a federally-insured State credit union to provide NCUA with information about how the law of the State under which it is chartered relates to NCUA's conversion rule so that NCUA's review of the methods and procedures of the vote includes ensuring compliance with applicable State law.

C. Disclosures

A converting credit union can provide information to its members regarding any aspect of the conversion in any format it wishes, provided all communications are accurate and not misleading. NCUA only requires certain, minimal information be provided in the notice to members. Most converting credit unions choose to provide a great deal more information and, while NCUA recognizes this is a way to educate members, NCUA is concerned that members may be overwhelmed by the great volume of information. NCUA does not, however, wish to dissuade converting credit unions from communicating with their members or limit those communications.

To balance these competing interests, NCUA will continue to allow a converting credit union to communicate with its members as it sees fit, but will require that members receive a short, simple disclosure prepared by NCUA. This disclosure addresses: (1) Ownership and control of the credit union; (2) operating expenses and their effect on rates and services; (3) the effect of a subsequent conversion to a stock institution; and (4) the costs of conversion. NCUA believes members need to be particularly aware of these topics. NCUA recognizes these topics might be discussed elsewhere in a credit union's communications with its members, but NCUA is concerned that this information may get buried in the great volume of information being provided. Accordingly, a converting credit union must include this disclosure in a prominent place with each written communication it sends to its members regarding the conversion and must take specific steps to ensure that the disclosure is conspicuous to the member. To promote flexibility, a converting credit union may modify the disclosure with the prior consent of the Regional Director and, in the case of a State credit union, the appropriate State supervisory authority (SSA).

Officials of many converting credit unions indicate in their conversion materials that they are unable to raise capital quickly enough to operate their credit unions as they see fit, which often includes a desire to pursue rapid growth. These credit unions encourage their members to support the conversion to an MSB as a way to overcome this capital restraint. They do not, however, inform their members that the conversion process can be expensive and further deplete a credit union's capital. NCUA believes members deserve to know how much of their money will be spent on the conversion effort. Accordingly, NCUA is amending the conversion rule to require converting credit unions to disclose the costs of conversion as part of the above disclosure requirements. An accurate cost estimate must take into account conversion related expenses including printing fees, postage fees, advertising, consulting and professional fees, legal fees, staff time, the cost of holding a special meeting, conducting the vote, and other related expenses.

D. Guidelines for Conducting a Member Vote

A converting credit union must conduct its member vote on conversion in a fair and legal manner. A vote that does not satisfy this standard denies members their democratic right to decide the fate of their credit union and could result in a charter change without the true support of the members. The final rule includes guidelines to avoid these kinds of undesirable results. The guidelines address topics such as: (1) Understanding the relationship between Federal and State law; (2) determining voter eligibility; (3) holding a special meeting.

NCUA does not purport these guidelines are an exhaustive checklist that guarantees a fair and legal vote. Rather, the guidelines are suggestions that provide a framework that, if followed, will help a credit union fulfill its regulatory obligations. A converting credit union should use these guidelines in conjunction with its own independent analysis and planning to tailor the member vote to its particular circumstances.

E. Relationship Between State and Federal Law

Although NCUA's conversion rule applies to all conversions of federally-insured credit unions, federally-insured state credit unions may also be subject to State law on conversions. As stated in previous rulemakings, NCUA's position is that a State legislature or SSA may impose conversion requirements more stringent or restrictive than NCUA's. This position is included in the final rule. In fact, NCUA understands over half the States do not specifically permit conversions of credit unions to MSBs. Reflecting NCUA's support of the dual chartering system, NCUA will defer to a State regulator when appropriate on questions involving interpretation of State law.

When State law applies to a conversion, it can change the procedural and substantive requirements a converting credit union must satisfy. NCUA needs to understand how State law affects those requirements to fulfill its responsibility to review the methods and procedures of the member vote. Accordingly, NCUA requires a federally-insured state credit union to notify NCUA if the State law under which it is chartered permits it to convert to an MSB. The credit union also must inform NCUA if it relies for its authority to convert on a State law parity provision, a provision permitting a state credit union to operate with the same or similar authority as a federal credit union (FCU), and if its State regulatory authority agrees that it may rely on the parity provision for that purpose. Finally, if a federally-insured state credit union relies on a state parity provision for authority to convert, it is required to indicate its State regulatory authority's position as to whether Federal law or State law will control internal governance issues in the conversion such as the requisite membership vote for conversion and the determination of a member's eligibility to vote.

F. Secret Ballots and Third Party Tellers

NCUA understands that members, including those that are employees of the credit union, may be uncomfortable with a voting process that does not protect the privacy of their votes. NCUA is concerned this may lead some members to choose not to vote or to vote in a manner inconsistent with their true wishes. Accordingly, the final rule protects members' privacy by requiring a converting credit union to use a secret ballot and an independent entity to conduct the vote. NCUA requires that a converting credit union use a third party teller to conduct the vote meaning that a third party teller will be responsible for sending ballots, receiving and safe keeping ballots, verifying ballots, and tabulating the vote. Use of a third party teller enhances the integrity of the voting process and provides confidence that members, including employees, will have their votes remain confidential.

G. Written Materials

Since CUMAA, the conversion rule has required a converting credit union to provide NCUA with copies of all written materials it sends or intends to send to its members in connection with the conversion proposal. NCUA is not changing that requirement but is clarifying that it applies to all written materials, including electronic communications posted on Web sites.

H. Summary of Comments

NCUA received 42 comments regarding the proposed rule. Thirty commenters supported the proposal. One so strongly that it stated it was ''criminal'' for credit unions to convert and strip out of the credit union the reserves accumulated over time by many members and put them ''into the pockets of a very few individuals.'' All of the nine commenters who are members of a credit union whose recent conversion campaign failed supported the proposal and many of them indicated that, if the terms of the proposal were in place when their credit union was considering converting, they would have been better informed or the process would have been fairer to members.

Many of the proposal's supporters offered suggestions to improve the rule. For example, ten commenters offered various suggestions to revise the proposed disclosures. Six commenters suggested there should be more required disclosures beyond those proposed.

One of those commenters suggested that paid consultants and service providers be identified to the members and be required to disclose if they have opened an account at the credit union as a result of their involvement in the conversion. One of the conversion consultants stated that, if the costs of the conversion are to be disclosed, then the credit union should identify the name of the recipients of expenditures. NCUA believes the portion of the proposal that requires a converting credit union to disclose an itemized estimate of the costs of the conversion to its members helps to provide members with necessary information to understand and cast an informed vote on the conversion. NCUA also believes the suggestion that NCUA require a converting credit union to identify by name the recipients of expenditures as part of a detailed itemization of costs is worthy of further consideration. That requirement, however, as well as disclosure of the accountholder status of paid consultants and service providers, are beyond the scope of the proposal and are not adopted in this final rule.

One commenter suggested NCUA provide more voting guidelines than proposed. Another asked NCUA to clarify ''the extent to which the guidelines would be enforced.'' NCUA reiterates the voting guidelines are not regulatory requirements subject to enforcement. Rather, they are suggestions intended to help converting credit unions fulfill their regulatory obligation of conducting its member vote in a fair and legal manner.

Nine commenters stated that the proposed disclosure, which states ''Credit union directors and committee members serve on a volunteer basis,'' is not completely accurate because a number of States allow credit unions to compensate their board members while others are silent on the issue. NCUA is amending the disclosure to reflect these comments.

Seven commenters stated a converting credit union should not be legally required to use Robert's Rules of Order to conduct its special meeting on conversion or suggested there be flexibility to use other parliamentary procedures. One of these commenters also suggested NCUA require a converting credit union to hire an independent parliamentarian to run the meeting. Another commenter did not mention Robert's Rules of Order, but recommended the use of a certified parliamentarian. NCUA discusses the use of Robert's Rules of Order in the voting guidelines section of the proposal. As noted above, the guidelines are not regulatory requirements, and, therefore, a converting credit union is not legally required to follow them including using Robert's Rules of Order in conducting its special meeting relating to the member vote. NCUA recommends, however, that a converting credit union use appropriate parliamentary procedures to conduct its vote, and should enlist the services of an individual knowledgeable and skilled in those procedures. NCUA is revising the voting guidelines to clarify that Robert's Rules of Order are not the only parliamentary procedures a credit union should consider using for its member vote.

Twelve commenters, including the conversion consultants, banking trade organizations, and a bank that was formerly an FCU that had converted to an MSB and subsequently converted to a stock bank, opposed the proposal in general, stating it is inconsistent with CUMAA or obstructs credit unions' right to convert. NCUA fully supports a credit union's right to convert its charter but notes this right belongs to the members of the credit union. Members can only exercise that right in a meaningful way if their credit union provides them with information that is accurate and not misleading. NCUA is aware of the limitations CUMAA places on its authority to approve a conversion but is mindful of its responsibility to oversee the methods and procedures applicable to the member vote on conversion and protect the interests of credit union members.

Some of the commenters who opposed the proposal:

- Believe the disclosure regarding voting rights is inaccurate because an MSB could choose a ''one vote per member'' policy instead of allotting votes based on account balances,
- Highlighted that an MSB to stock conversion requires a number of steps scrutinized by other regulators and stated the disclosure regarding subsequent conversion to a stock institution is misleading and intended to discourage credit union members from voting for the conversion to an MSB,
- Believe NCUA acknowledges the proposal is intended to discourage conversions because NCUA reduced the estimated number of conversions per year in a Paperwork Reduction Act (PRA) filing associated with the proposed rulemaking, and
- Suggested the proposed requirement on state credit unions to provide NCUA with information about State laws affecting the conversion is burdensome or indicated NCUA does not have confidence in SSAs to perform their functions.

The fact that MSBs could choose a ''one vote per member'' policy instead

of allotting votes based on account balances is not what MSBs, in fact, usually choose to do. The disclosure regarding voting rights states that, in an MSB, account holders with larger balances ''usually'' have more votes and, thus, greater control. NCUA believes this is an accurate statement. Also, NCUA recognizes that additional steps and member votes are required to approve an MSB to stock institution conversion. This does not lessen NCUA's concern about protecting credit union members' interest in their credit union. Those additional steps and member votes, although possibly scrutinized by other regulators, occur only after the credit union has converted to an MSB and is on its way to converting to the stock form of ownership. Obviously, at that point, the credit union does not exist and the additional requirements can do nothing to enable a credit union member to make an informed decision on the initial conversion from a credit union to an MSB.

The disclosure regarding subsequent conversion to a stock institution is not misleading and not intended to discourage credit union members from voting for the conversion to an MSB. It states that, in a typical conversion to the stock form of ownership, the executives of the institution profit by obtaining stock far in excess of that available to the institution's members. This accurately reflects an executive's ability to obtain stock options, restricted stock or other forms of stock related compensation not available to members not employed by the credit union.

In the normal course of the rulemaking process, NCUA submitted a required PRA filing. In that filing, NCUA reduced the estimated number of conversions per year from a previous submission based on its experience with conversions over the past several years. NCUA would have made the same reduction in the PRA filing based on historical data even if this rule were not being considered.

The requirement on state credit unions to provide NCUA with information about State laws affecting the conversion is not burdensome and does not indicate any lack of confidence in SSAs to perform their functions. NCUA fully acknowledges that a State legislature or SSA may impose conversion requirements more stringent or restrictive than NCUA's. As noted above, when State law applies to a conversion, it can change drastically the procedural and substantive requirements a converting credit union must satisfy. It is essential for a converting credit union to understand both Federal and State requirements for compliance purposes and for NCUA to do the same to fulfill its responsibility to review the methods and procedures of the member vote as affected by State law. NCUA does not believe it is burdensome for a converting credit union to inform NCUA of State law that the credit union must obtain in any event to assure compliance with all applicable laws. NCUA works closely and cooperatively with SSAs in processing conversions and defers to SSAs in making determinations regarding State law. NCUA believes the subject requirement helps to promote cooperation among the regulators and a more informed converting credit union.

Three commenters disagreed with NCUA's statement that no conversion vote can be fair and legal if some members are improperly excluded. These commenters stated there is no statutory requirement for perfection and that a certain percentage of member exclusions should be tolerated if not the result of wrongful intent on the part of the converting credit union. Since CUMAA, NCUA has disapproved a converting credit union's methods and procedures applicable to the member vote on only one occasion. In that situation, voter disenfranchisement was widespread. NCUA will continue to take a pragmatic approach in reviewing member votes on conversion.

One commenter suggested a converting credit union should be required to prepare a comprehensive three-year business plan for the converted institution similar to the plan required by 12 CFR part 563b for MSBs proposing to convert to stock form. This commenter also stated the plan should be required to be sent to the credit union's members with the notice of intent to convert or the notice should explain how a member can obtain a free copy of the plan. This suggestion is beyond the scope of the proposal, but NCUA will consider it for future inclusion in the conversion rule.

Finally, commenters to previous amendments to the conversion rule have recommended NCUA require converting credit unions to provide members a meaningful way to share their opinions on the conversion and to disclose the views and concerns of the credit union's directors and officers who oppose the conversion. Four commenters to this rulemaking suggested there should be some mechanism in place for members to share their opinions on the conversion with each other and the credit union during the process. NCUA will continue to consider if this is practical and valuable and if it could be accomplished with minimal regulatory burden.

I. Effective Date of Final Rule

Generally, a final rule promulgated by NCUA is effective 30 days following its publication in the **Federal Register**. This final rule, however, is effective immediately upon publication because there is a strong public interest in having this consumer protection rule in place. First, this is necessary to ensure crucial disclosure information is provided to credit union members whose credit union has initiated or is about to initiate the conversion process, so the members may cast an informed and educated vote on the future existence of their credit union and their stake in it. Second, this will provide regulatory certainty to credit unions that are considering converting or beginning the conversion process within the next thirty days and enable them to better understand the regulatory requirements they must follow throughout the entirety of the process.

A converting credit union is required by statute and regulation to provide notice of its intent to convert to its members 90 days, 60 days, and 30 days before the member vote on conversion. 12 U.S.C. 205(b)(2)(C); 12 CFR 708a.4(b). It would be confusing for a converting credit union and its members if this rule became effective during that 90-day period as that would alter the regulatory requirements of the conversion in mid-process. That confusion about which regulatory requirements must be followed at a given point in the conversion process is eliminated for any recently initiated, soon to be initiated, and future conversions by making this rule immediately effective. Accordingly, for good cause, NCUA finds that, pursuant to 5 U.S.C. 553(d)(3), it would be impracticable and contrary to the public interest to delay the effective date of this rule for 30 days following publication. Therefore, this rule is effective immediately upon publication.

Regulatory Procedures

Regulatory Flexibility Act

The Regulatory Flexibility Act requires NCUA to prepare an analysis to describe any significant economic impact a rule may have on a substantial number of small credit unions, defined as those under ten million dollars in assets. This final rule amends the procedures an insured credit union must follow to convert to an MSB. Slightly over twenty credit unions have converted since 1995. NCUA anticipates no more than five credit unions per year will convert in the future and it is

unlikely that any will have less than ten million dollars in assets. Accordingly, the amendments would not have a significant economic impact on a substantial number of small credit unions, and, therefore, a regulatory flexibility analysis is not required.

Paperwork Reduction Act

Part 708a contains information collection requirements. As required by the PRA, 44 U.S.C. 3507(d), NCUA previously submitted a copy of this regulation in proposed form as part of an information collection package to the Office of Management and Budget (OMB) for its review and approval of a revision to Collection of Information, Conversion of Insured Credit Unions to Mutual Savings Banks, Control Number 3133–0153.

NCUA estimated the average annual burden per converting credit union to be between 20 and 23 hours and that no more than five credit unions will convert per year. As a result, NCUA estimated the total annual collection burden to be no more than 115 hours. NCUA did not receive any comments addressing the accuracy or methodology for computing the burden. OMB approved the revision.

Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on State and local interests. In adherence to fundamental federalism principles, NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order. The final rule would not have substantial direct effects on the States, on the connection between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. NCUA has determined that this final rule does not constitute a policy that has federalism implications for purposes of the executive order.

The Treasury and General Government Appropriations Act, 1999—Assessment of Federal Regulations and Policies on Families

The NCUA has determined that this final rule would not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, 1999, Public Law 105–277, 112 Stat. 2681 (1998).

Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) provides generally for congressional review of agency rules. A reporting requirement is triggered in instances where NCUA issues a final rule as defined by section 551 of the Administrative Procedure Act. 5 U.S.C. 551. The Office of Management and Budget has determined that this rule is not a major rule for purposes of the Small Business Regulatory Enforcement Fairness Act of 1996.

List of Subjects in 12 CFR Part 708a

Charter conversions, Credit unions.

By the National Credit Union Administration Board on January 13, 2005.

Mary F. Rupp,

Secretary of the Board.

■ For the reasons stated above, NCUA amends 12 CFR part 708a as follows:

PART 708a—CONVERSION OF INSURED CREDIT UNIONS TO MUTUAL SAVINGS BANKS

■ 1. The authority citation for part 708a continues to read as follows:

Authority: 12 U.S.C. 1766, 12 U.S.C. 1785(b).

■ 2. Section 708a.4 is amended by adding three sentences at the end of paragraph (a) and adding paragraph (e) to read as follows:

§ 708a.4 Voting procedures.

(a) * * * The vote on the conversion proposal must be by secret ballot and conducted by an independent entity. The independent entity must be a company with experience in conducting corporate elections. No official or senior manager of the credit union, or the immediate family members of any official or senior manager, may have any ownership interest in, or be employed by, the entity.

* * * * *

(e) A converting credit union must include the following disclosures with each written communication it sends to its members regarding the conversion. The disclosures must be offset from the other text by use of a border and at least one font size larger than any other text (exclusive of headings) used in the communication. Certain portions of the disclosures must be capitalized and bolded. A converting credit union may modify the disclosure with the prior consent of the Regional Director and, in the case of a state credit union, the appropriate state regulatory agency. The unmodified form of disclosure reads as follows:

The National Credit Union Administration, the federal government agency that supervises credit unions, requires [insert name of credit union] to provide the following disclosures.

1. **OWNERSHIP AND CONTROL.** In a credit union, every member has an equal vote in the election of directors and other matters concerning ownership and control. In a mutual savings bank, **ACCOUNT HOLDERS WITH LARGER BALANCES USUALLY HAVE MORE VOTES AND, THUS, GREATER CONTROL.**
2. **EXPENSES AND THEIR EFFECT ON RATES AND SERVICES.** Most credit union directors and committee members serve on a volunteer basis. Directors of a mutual savings bank are compensated. Credit unions are exempt from federal tax and most state taxes. Mutual savings banks pay taxes, including federal income tax. If [insert name of credit union] converts to a mutual savings bank, these **ADDITIONAL EXPENSES MAY CONTRIBUTE TO LOWER SAVINGS RATES, HIGHER LOAN RATES, OR ADDITIONAL FEES FOR SERVICES.**
3. **SUBSEQUENT CONVERSION TO STOCK INSTITUTION.** Conversion to a mutual savings bank is often the first step in a two-step process to convert to a stock-issuing bank or holding company. In a typical conversion to the stock form of ownership, the **EXECUTIVES OF THE INSTITUTION PROFIT BY OBTAINING STOCK FAR IN EXCESS OF THAT AVAILABLE TO THE INSTITUTION'S MEMBERS.**
4. **COSTS OF CONVERSION.** The costs of converting a credit union to a mutual savings bank are paid from the credit union's current and accumulated earnings. Because accumulated earnings are capital and represent members' ownership interests in a credit union, the conversion costs reduce members' ownership interests. As of [insert date], [insert name of credit union] estimates **THE CONVERSION WILL COST [INSERT DOLLAR AMOUNT] IN TOTAL.** That total amount is further broken down as follows: [itemize the costs of all expenses related to the conversion including printing fees, postage fees, advertising, consulting and professional fees, legal fees, staff time, the cost of holding a special meeting, conducting the vote, and any other expenses incurred].

■ 3. Section 708a.5 is amended by redesignating paragraph (b) as paragraph (b)(1), adding a sentence at the end of paragraph (b)(1), and adding paragraph (b)(2) to read as follows:

§ 708a.5 Notice to NCUA.

* * * * *

(b)(1) * * * The term ''written materials'' includes written documentation or information of any sort, including electronic communications posted on a Web site.

(b)(2) A federally-insured State chartered credit union must include in its notice to NCUA a statement as to whether the State law under which it is chartered permits it to convert to a mutual savings bank and include a legal citation to the State law providing this authority. A federally-insured State chartered credit union will remain subject to any State law requirements for conversion that are more stringent than those this chapter imposes, including any internal governance requirements, such as the requisite membership vote for conversion and the determination of a member's eligibility to vote. If a federally-insured State chartered credit union relies for its authority to convert to a mutual savings bank on a State law parity provision, meaning a provision in State law permitting a State chartered credit union to operate with the same or similar authority as a federal credit union, it must include in its notice a statement that its State regulatory authority agrees that it may rely on the State law parity provision as authority to convert. If a federally-insured state chartered credit union relies on a State law parity provision for authority to convert, it must indicate its State regulatory authority's position as to whether Federal law and regulations or State law will control internal governance issues in the conversion such as the requisite membership vote for conversion and the determination of a member's eligibility to vote.

* * * * *

■ 4. Add section 708a.11 to read as follows:

§ 708a.11 Voting guidelines.

(a) A converting credit union must conduct its member vote on conversion in a fair and legal manner. These guidelines are not an exhaustive checklist that guarantees a fair and legal vote but are suggestions that provide a framework to help a credit union fulfill its regulatory obligations.

(b) While NCUA's conversion rule applies to all conversions of federally insured credit unions, federally-insured State chartered credit unions (FISCUs) are also subject to State law on conversions. NCUA's position is that a State legislature or State supervisory authority may impose conversion requirements more stringent or restrictive than NCUA's. States that permit this kind of conversion could have substantive and procedural requirements that vary from Federal law. For example, there could be different voting standards for approving a vote. While NCUA's rule requires a simple majority of those who vote to approve a conversion, some States have higher voting standards requiring two-thirds or more of those who vote. A FISCU should be careful to understand both Federal and State law to navigate the conversion process and conduct a proper vote.

(c)(1) Determining who is eligible to cast a ballot is fundamental to any vote. No conversion vote can be fair and legal if some members are improperly excluded. A converting credit union should be cautious to identify all eligible members and make certain they are included on its voting list. NCUA recommends that a converting credit union establish internal procedures to manage this task.

(2) A converting credit union should be careful to make certain its member list is accurate and complete. For example, when a credit union converts from paper record keeping to computer record keeping, some members' names may not transfer unless the credit union is careful in this regard. This same problem can arise when a credit union converts from one computer system to another where the software is not completely compatible.

(3) Problems with keeping track of who is eligible to vote can also arise when a credit union converts from a federal charter to a State charter or vice versa. NCUA is aware of an instance where a federal credit union used membership materials that allowed two or more individuals to open a joint account and also allowed each to become a member. The federal credit union later converted to a State chartered credit union that, like most other State chartered credit unions in its State, used membership materials that allowed two or more individuals to open a joint account but only allowed the first person listed on the account to become a member. The other individuals did not become members as a result of their joint account. To become members, those individuals were required to open another account where they were the first or only person listed on the account. Over time, some individuals who became members of the federal credit union as the second person listed on a joint account were treated like those individuals who were listed as the second person on a joint account opened directly with the State chartered credit union. Specifically, both of those groups were treated as non-members not entitled to vote. This example makes the point that a credit union must be diligent in maintaining a reliable membership list.

(d) NCUA's conversion rule requires a converting credit union to permit members to vote by written mail ballot or in person at a special meeting held for the purpose of voting on the conversion. Although most members may choose to vote by mail, a significant number may choose to vote in person. As a result, a converting credit union should be careful to conduct its special meeting in a manner conducive to accommodating all members that wish to attend. That includes selecting a meeting location that can accommodate the anticipated number of attendees and is conveniently located. The meeting should also be held on a day and time suitable to most members' schedules. A credit union should conduct its meeting in accordance with applicable federal and State law, its bylaws, Robert's Rules of Order or other appropriate parliamentary procedures, and determine before the meeting the nature and scope of any discussion to be permitted.

[FR Doc. 05–1167 Filed 1–27–05; 8:45 am]

BILLING CODE 7535–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30435 ; Amdt. No. 3114]

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective January 28, 2005. The compliance date for each

SIAP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 28, 2005.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which the affected airport is located;

3. The Flight Inspection Area Office which originated the SIAP; or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

For Purchase—Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription—Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

FOR FURTHER INFORMATION CONTACT: Donald P. Pate, Flight Procedure Standards Branch (AMCAFS–420), Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd. Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK 73125) telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs). The complete regulatory description of each SIAP is contained in official FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of the Federal Aviation Regulations (FAR). The applicable FAA Forms are identified as FAA Forms 8260–3, 8260–4, and 8260–5. Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. The provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

The Rule

This amendment to part 97 is effective upon publication of each separate SIAP as contained in the transmittal. Some SIAP amendments may have been previously issued by the FAA in a National Flight Data Center (NFDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP amendments may require making them effective in less than 30 days. For the remaining SIAPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, and Navigation (air).

Issued in Washington, DC on January 14, 2005.

James J. Ballough,

Director, Flight Standards Service.

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

** * * Effective February 17, 2005*

Lufkin, TX, Angelina County, RNAV (GPS) RwY 7, Orig

** * * Effective March 17, 2005*

Perryville, AK, Perryville, RNAV (GPS) RwY 3, Orig
Scottsdale, AZ, Scottsdale, RNAV (GPS)-D, Orig
Scottsdale, AZ, Scottsdale, NDB OR GPS-B, Amdt 3A, Cancelled
California City, CA, California City Muni, RNAV (GPS) RwY 6, Orig
California City, CA, California City Muni, RNAV (GPS) RwY 24, Orig
San Jose, CA, Norman Y. Mineta San Jose Intl, RNAV (GPS) RwY 12R, Orig
San Jose, CA, Norman Y. Mineta San Jose Intl, RNAV (GPS) RwY 30L, Orig
San Jose, CA, Norman Y. Mineta San Jose Intl, GPS RwY 12R, Orig-A, Cancelled
San Jose, CA, Norman Y. Mineta San Jose Intl, GPS RwY 30L, Orig-A, Cancelled
Willimantic, CT, Windham, RNAV (GPS) RwY 9, Orig-A
Willimantic, CT, Windham, RNAV (GPS) RwY 27, Orig-A
Melbourne, FL, Melbourne Intl, ILS OR LOC RwY 9R, Amdt 11
Melbourne, FL, Melbourne Intl, LOC BC RwY 27L, Amdt 9

Agana, Guam, Guam International, RNAV (GPS) RwY 6R, Orig-B
Agana, Guam, Guam International, RNAV (GPS) Z RwY 6L, Orig-C
Agana, Guam, Guam International, RNAV (GPS) RwY 24L, Orig-B
Agana, Guam, Guam International, RNAV (GPS) RwY 24R, Orig-B
Elkhart, IN, Elkhart Muni, ILS OR LOC RwY 27, Amdt 2
Elkton, MD, Cecil County, RNAV (GPS) RwY 13, Orig-A
Frederick, MD, Frederick Muni, RNAV (GPS) Y RwY 23, Amdt 1
Ocean City, MD, Ocean City Muni, RNAV (GPS) RwY 14, Orig-D
Morganton, NC, Morganton-Lenoir, RNAV (GPS) RwY 3, Orig
Morganton, NC, Morganton-Lenoir, RNAV (GPS) RwY 21, Orig
Morganton, NC, Morganton-Lenoir, NDB RwY 3, Amdt 5
Statesville, NC, Statesville Regional, LOC RwY 10, Orig-A, Cancelled
Statesville, NC, Statesville Regional, NDB RwY 10, Orig-A, Cancelled
Wilmington, NC, Wilmington Intl, LOC BC RwY 17, Amdt 7C, Cancelled
Clayton, NM, Clayton Muni Airpark, RNAV (GPS) RwY 2, Amdt 1
Clayton, NM, Clayton Muni Airpark, RNAV (GPS) RwY 20, Amdt 1
Lovington, NM, Lea County-Zip Franklin Memorial, RNAV (GPS) RwY 3, Orig
Lovington, NM, Lea County-Zip Franklin Memorial, RNAV (GPS) RwY 21, Orig
Lovington, NM, Lea County-Zip Franklin Memorial, GPS RwY 21, Amdt 1, Cancelled
Lovington, NM, Lea County-Zip Franklin Memorial, GPS RwY 3, Amdt 1, Cancelled
Athens (Albany), OH, Ohio University Snyder Field, ILS OR LOC RwY 25, Amdt 1A
Athens (Albany), OH, Ohio University Snyder Field, RNAV (GPS) RwY 7, Orig
Athens (Albany), OH, Ohio University Snyder Field, RNAV (GPS) RwY 25, Orig
Athens (Albany), OH, Ohio University Snyder Field, NDB RwY 25, Amdt 9
Athens (Albany), OH, Ohio University , GPS RwY 7, Orig-A, Cancelled
Athens (Albany), OH, Ohio University , GPS RwY 25,Orig-A,Cancelled
Philadelphia, PA, Philadelphia Intl, NDB RwY 27L, Amdt 5C, Cancelled
Washington, PA, Washington County, VOR-B, Amdt 7
Washington, PA, Washington County, NDB RwY 27, Amdt 1
Washington, PA, Washington County, RNAV (GPS) RwY 9, Orig
Washington, PA, Washington County, GPS RwY 9, Orig-B, Cancelled
Washington, PA, Washington County, RNAV (GPS) RwY 27, Orig
Dallas-Fort Worth, TX, Dallas/Fort Worth International, NDB RwY 35C, Amdt 10B, Cancelled
Dallas-Fort Worth, TX, Dallas/Fort Worth International, ILS OR LOC RwY 35C, Orig
Dallas-Fort Worth, TX, Dallas/Fort Worth International, CONVERGING ILS RwY 35C, Orig
Dallas-Fort Worth, TX, Dallas/Fort Worth International, ILS RwY 35C, Amdt 7, Cancelled
Dallas-Fort Worth, TX, Dallas/Fort Worth International, CONVERGING ILS RwY 35C, Amdt 5A, Cancelled
Dallas-Fort Worth, TX, Dallas/Fort Worth International, LOC/DME RwY 17C, Orig
Galveston, TX, Scholes Intl at Galveston, ILS OR LOC RwY 13, Amdt 11
Galveston, TX, Scholes Intl at Galveston, RNAV (GPS) RwY 13, Orig
Galveston, TX, Scholes Intl at Galveston, GPS RwY 13, Amdt 1, Cancelled
Galveston, TX, Scholes Intl at Galveston, RNAV (GPS) RwY 17, Orig
Galveston, TX, Scholes Intl at Galveston, GPS RwY 17, Amdt 1, Cancelled
Warrenton, VA, Warrenton-Fauquier, VOR RwY 14, Amdt 4
Warrenton, VA, Warrenton-Fauquier, RNAV (GPS) RwY 14, Orig

[FR Doc. 05–1411 Filed 1–27–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9171]

RIN 1545–AY87; 1545–BC03

New Markets Tax Credit; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains corrections to final regulations (TD 9171), that were published in the **Federal Register** on Tuesday, December 28, 2004 (69 FR 77625) relating to the new markets tax credit under section 45D.

DATES: This correction is effective December 28, 2004.

FOR FURTHER INFORMATION CONTACT: Paul F. Handleman or Lauren R. Taylor, (202) 622–3040 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9171) that are the subject of these corrections are under section 45D of the Internal Revenue Code.

Need for Correction

As published, TD 9171 contains errors that may prove to be misleading and are in need of clarification.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

■ Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

§ 1.45D–1 [Corrected]

■ **Par. 2.** Section 1.45D–1(a), under the ''Table of contents'', the entry for paragraph (h)(2) ''(2) Exception for certain provisions'' is removed and the language ''(2) Exception'' is added in its place.

■ **Par. 3.** Section 1.45D–1(d)(4)(i)(E), second sentence, the language, ''For purposes the preceding'' is removed and the language ''For purposes of the preceding'' is added in its place.

■ **Par. 4.** Section 1.45D–1(d)(5)(ii) and (h)(2) are revised to read as follows:

§ 1.45D–1 New markets tax credit.

* * * * *

(d) * * *

(5) * * *

(ii) *Rental of real property.* The rental to others of real property located in any low-income community (as defined in section 45D(e)) is a qualified business if and only if the property is not residential rental property (as defined in section 168(e)(2)(A)) and there are substantial improvements located on the real property. However, a CDE's investment in or loan to a business engaged in the rental of real property is not a qualified low-income community investment under paragraph (d)(1)(i) of this section to the extent a lessee of the real property is described in paragraph (d)(5)(iii)(B) of this section.

(h) * * *

(2) *Exception.* Paragraph (d)(5)(ii) of this section as it relates to the restriction on lessees described in paragraph (d)(5)(iii)(B) of this section applies to qualified low-income community investments made on or after June 22, 2005.

* * * * *

■ **Par. 5.** Section 1.45D–1(d)(8)(ii), *Example* (ii), first sentence, the language, ''On November 1, 2004, W makes a'' is removed and the language ''On November 1, 2004, W makes an'' is added in its place.

Cynthia E. Grigsby,

Acting Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedures and Administration).

[FR Doc. 05–1552 Filed 1–27–05; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9171]

RIN 1545–AY87; 1545–BC03

New Markets Tax Credit; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final regulations.

SUMMARY: This document contains corrections to final regulations (TD 9171), that were published in the **Federal Register** on Tuesday, December 28, 2004 (69 FR 77625) relating to the new markets tax credit under section 45D.

DATES: This correction is effective December 28, 2004.

FOR FURTHER INFORMATION CONTACT: Paul F. Handleman or Lauren R. Taylor, (202) 622–3040 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9171) that are the subject of these corrections are under section 45D of the Internal Revenue Code.

Need for Correction

As published, TD 9171 contains errors that may prove to be misleading and are in need of clarification.

Correction of Publication

■ Accordingly, the publication of the final regulations (TD 9171), that were the subject of FR Doc. 04–28325, is corrected as follows:

■ 1. On page 77626, column 3, in the preamble, last full paragraph under paragraph heading ''Qualified Active Low-Income Community Business'', is removed.

■ 2. On page 77627, column 1, in the preamble under paragraph heading ''Recapture'', first paragraph, line 21 from the top of the column, the language, ''taxable year will be not treated as a'' is corrected to read ''taxable year will not be treated as a''.

Cynthia E. Grigsby,

Acting Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedures and Administration).

[FR Doc. 05–1551 Filed 1–27–05; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD08–05–009]

Drawbridge Operation Regulations; Corpus Christi—Port Aransas Channel—Tule Lake, Corpus Christi, TX

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eighth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Tule Lake Vertical Lift Span Highway and Railroad Bridge across the Corpus Christi—Port Aransas Channel, mile 14.0, at Corpus Christi, Nueces County, TX. This deviation allows the bridge to remain closed to navigation for four hours on two consecutive days. This temporary deviation is necessary for the maintenance of the rope sheaves and for the cleaning and lubrication of the haul and counterweight ropes of the drawbridge.

DATES: This deviation is effective from 7 a.m. on Thursday, February 10, 2005 through 11 a.m. on Friday, February 11, 2005.

ADDRESSES: Materials referred to in this document are available for inspection or copying at the office of the Eighth Coast Guard District, Bridge Administration Branch, Hale Boggs Federal Building, room 1313, 501 Magazine Street, New Orleans, Louisiana 70130–3396 between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (504) 589–2965. The Bridge Administration Branch of the Eighth Coast Guard District maintains the public docket for this temporary deviation.

FOR FURTHER INFORMATION CONTACT: David Frank, Bridge Administration Branch, telephone (504) 589–2965.

SUPPLEMENTARY INFORMATION: The Port of Corpus Christi Authority has requested a temporary deviation in order to perform required maintenance on the rope sheaves and for the cleaning and lubrication of the haul and counterweight ropes of the Tule Lake vertical lift span bridge across Corpus Christi—Port Aransas Channel, mile 14.0 at Corpus Christi, Nueces County, Texas. This temporary deviation will allow the bridge to remain in the closed-to-navigation position from 7 a.m. to 11 a.m. on Thursday, February 10, 2005 and from 7 a.m. to 11 a.m. on Friday, February 11, 2005.

The vertical lift span bridge has a vertical clearance of 9.0 feet above mean high water, elevation 1.0 feet Mean Sea Level and 11.0 feet above mean low water, elevation −1.0 Mean Sea Level in the closed-to-navigation position. Navigation at the site of the bridge consists mainly of oil tankers and tows with barges. There is no recreational pleasure craft usage at the bridge site. Due to prior experience, as well as coordination with waterway users, it has been determined that this two-day partial closure will not have a significant effect on these vessels. The bridge normally opens to pass navigation an average of 850 times per month. The bridge opens on signal as required by 33 CFR 117.5. The bridge will not be able to open for emergencies during the closure period. Alternate routes are not available.

In accordance with 33 CFR 117.35(c), this work will be performed with all due speed in order to return the bridge to normal operation as soon as possible. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: January 18, 2005.

Marcus Redford,

Bridge Administrator.

[FR Doc. 05–1559 Filed 1–27–05; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD08–05–007]

Drawbridge Operation Regulations; Gulf Intracoastal Waterway—Bayou Boeuf, Amelia, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eighth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the BNSF RR Swing Bridge across Bayou Boeuf, mile 10.2, at Amelia, St. Mary Parish, LA. This deviation allows the bridge to remain closed to navigation for eight hours on February 14, 2005, ten hours on February 15, 2005, and eight hours on February 16, 2005. The deviation is necessary to remove and replace the motor and transmission of the bridge.

DATES: This deviation is effective from 8 a.m. on Monday, February 14, 2005

until 4 p.m. on Wednesday, February 16, 2005.

ADDRESSES: Materials referred to in this document are available for inspection or copying at the office of the Eighth Coast Guard District, Bridge Administration Branch, Hale Boggs Federal Building, room 1313, 500 Poydras Street, New Orleans, Louisiana 70130–3310 between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (504) 589–2965. The Bridge Administration Branch of the Eighth Coast Guard District maintains the public docket for this temporary deviation.

FOR FURTHER INFORMATION CONTACT: David Frank, Bridge Administration Branch, telephone (504) 589–2965.

SUPPLEMENTARY INFORMATION: The BNSF RR has requested a temporary deviation in order to remove and replace the motor and transmission of the Bayou Boeuf Swing Bridge across Bayou Boeuf, mile 10.2, at Amelia, St. Mary Parish, LA. The repairs are necessary to ensure the proper operation of the bridge. This temporary deviation will allow the bridge to remain in the closed-to-navigation position from 8 a.m. until 4 p.m. on Monday, February 14, 2005, from 7 a.m. until 5 p.m. on Tuesday, February 15, 2005, and from 8 a.m. until 4 p.m. on Wednesday, February 16, 2005.

As the bridge has no vertical clearance in the closed-to-navigation position, vessels will not be able to transit through the bridge site when the bridge is closed. Navigation at the site of the bridge consists mainly of tows with barges and some recreational pleasure craft. Due to prior experience, as well as coordination with waterway users, it has been determined that this closure will not have a significant effect on these vessels. An alternate route is available by using the GIWW, Morgan City to Port Allen Alternate Route.

In accordance with 33 CFR 117.35(c), this work will be performed with all due speed in order to return the bridge to normal operation as soon as possible. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: January 13, 2005.

Marcus Redford,

Bridge Administrator.

[FR Doc. 05–1560 Filed 1–27–05; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD01–04–157]

Drawbridge Operation Regulations: Newtown Creek, Dutch Kills, English Kills, and Their Tributaries, NY

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the drawbridge operation regulations for the Metropolitan Avenue Bridge, mile 3.4, across English Kills at New York City, New York. Under this temporary deviation the bridge may remain closed from 6 a.m. to midnight on the following days: January 19 through January 21; January 26 through January 28; and January 31 through February 5, 2005. This temporary deviation is necessary to facilitate bridge maintenance.

DATES: This deviation is effective from January 19, 2005 through February 5, 2005.

FOR FURTHER INFORMATION CONTACT: Judy Leung-Yee, Project Officer, First Coast Guard District, at (212) 668–7195.

SUPPLEMENTARY INFORMATION: The Metropolitan Avenue Bridge has a vertical clearance in the closed position of 10 feet at mean high water and 15 feet at mean low water. The existing drawbridge operation regulations are listed at 33 CFR 117.801(e).

The owner of the bridge, New York City Department of Transportation (NYCDOT), requested a temporary deviation from the drawbridge operation regulations to facilitate rehabilitation repairs at the bridge. The bridge must remain in the closed position to perform these repairs.

Under this temporary deviation the NYCDOT Metropolitan Avenue Bridge may remain in the closed position from 6 a.m. through midnight on the following days: January 19 through January 21; January 26 through January 28; and from January 31 through February 5, 2005.

This deviation from the operating regulations is authorized under 33 CFR 117.35, and will be performed with all due speed in order to return the bridge to normal operation as soon as possible.

Dated: January 12, 2005.

Gary Kassof,

Bridge Program Manager, First Coast Guard District.

[FR Doc. 05–1561 Filed 1–27–05; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD05–04–168]

RIN 1625–AA09

Drawbridge Operation Regulations; Christina River, Wilmington, DE

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is changing the regulations that govern the operation of the Norfolk Southern (NS) Railroad Bridge across Christina River, at mile 1.4, in Wilmington, DE. The bridge will remain open for vessel traffic, closing only for train crossings and periodic maintenance by an operator at a remote location. The final rule will maintain the bridge's current level of operational capabilities and continue to provide for the reasonable needs of rail transportation and vessel navigation.

DATES: This rule is effective February 28, 2005.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket CGD05–04–168 and are available for inspection or copying at Commander (obr), Fifth Coast Guard District, Federal Building, 1st Floor, 431 Crawford Street, Portsmouth, VA 23704–5004 between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays. The Fifth Coast Guard District maintains the public docket for this rulemaking.

FOR FURTHER INFORMATION CONTACT: Anton Allen, Bridge Management Specialist, Fifth Coast Guard District, at (757) 398–6227.

SUPPLEMENTARY INFORMATION:

Regulatory History

On October 12, 2004, we published a notice of proposed rulemaking (NPRM) entitled ''Drawbridge Operation Regulations; Christina River, Wilmington, DE'' in the **Federal Register** (69 FR 60597). We received five letters commenting on the proposed rule. No public meeting was requested, and none was held.

Background and Purpose

Norfolk Southern Corporation (NSC), who owns and operates this swing-type bridge at mile 1.4 across the Christina River, in Wilmington, DE, requested a change to the current operating procedures set out in 33 CFR part 117.237(a)(2) which requires the draw to open on signal, except that the draw of a railroad bridge need not be opened when a train is in the bridge block, approaching the bridge, or within 5 minutes of the passage of a passenger train; but in no event shall the opening of the draw be delayed more than 10 minutes.

Under this rule, the NS Railroad Bridge will remain open to vessel traffic, closing only for train crossings and periodic maintenance. This rule would also allow the NS Railroad Bridge to be operated from a remote location at the Harrisburg, PA Dispatcher's Office.

NS has installed closed circuit cameras in the area of the bridge and directly beneath the bridge, mounted on the center pier fender systems on both sides. Infrared sensors have also been installed to cover the swing radius of the bridge. This equipment provides the controller the ability to monitor vessel traffic from the remote location. The controller will also monitor marine channel 13.

This change is being made to make the operation of the NS Railroad Bridge more efficient. It will save operational costs by eliminating the continuous presence of bridge tenders, and is expected to decrease maintenance costs. In addition, the draw being left in the open position most of the time will provide for greater flow of vessel traffic than the current regulation.

Discussion of Comments and Changes

The Coast Guard received five comments on the NPRM. Vane Line Bunkering and the U.S. Army Corps of Engineers both commented that they were concerned about marine radio traffic disruption from NS announcements on marine channel 13. The disruption was caused by excessive power for the transmitter and broadcasting horn blasts over the marine radio. NS has fixed all discrepancies. Announcements for bridge operations will only be broadcast over loudspeakers on the bridge, not over marine channel 13. Power to the marine radio transmitter has been reduced to an acceptable level.

The Coast Guard received a comment from the Delaware State Historical Preservation Office who indicated that they have no objection to this rule.

The remaining comments, from NSC, requested changes to their original submittal. NSC requested slight revisions to the language to be used in this rule. The Coast Guard has incorporated the following changes to this rule: In paragraph (b)(3), replaced ''less than ¾ of a mile'' with ''inhibited.'' Bends in the river near this bridge allow approximately ¼ of a mile visibility. Added the words ''Attention, Attention'' to the announcement in paragraph (b)(5). In paragraph (b)(6), removed the word ''automatically.'' The operation of this bridge is not intended to be automatic. Also in paragraph (b)(6), added the following statement: ''Vessels shall stay clear of both channels as to not interfere with the infrared detectors, until green lights are displayed on the swing span.''

The Coast Guard considers these changes necessary for safe navigation and the final rule was changed to reflect these proposals.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary. We reached this conclusion based on the fact that the changes have only a minimal impact on maritime traffic transiting the bridge. Although the NS Railroad Bridge will be untended and operated from a remote location, mariners can continue their transits because the bridge will remain open to mariners, only to be closed for train crossings or periodic maintenance.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking process. No assistance was requested from any small entity.

Collection of Information

This rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520.).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule would not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (32)(e) of the Instruction, from further environmental documentation because it has been determined that the promulgation of operating regulations for drawbridges are categorically excluded.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; Department of Homeland Security Delegation No. 0170.1; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

■ 2. In § 117.237 redesignate paragraphs (b) through (d) as paragraphs (c) through (e), add a new paragraph (b), and revise newly redesignated paragraph (d) to read as follows:

§ 117.237 Christina River.

* * * * *

(b) The draw of the Norfolk Southern Railroad Bridge, mile 1.4 at Wilmington, shall operate as follows:

(1) The draw shall remain in the open position for navigation. The draw shall only be closed for train crossings or periodic maintenance authorized in accordance with subpart A of this part.

(2) The bridge shall be operated by the controller at the Harrisburg, PA Dispatcher's Office. The controller shall monitor vessel traffic with closed circuit cameras and infrared sensors covering the swing radius. Operational information will be provided 24 hours a day on marine channel 13 and via telephone (717) 541–2140.

(3) The bridge shall not be operated from the remote location in the following events: Failure or obstruction of the infrared sensors, closed-circuit cameras or marine-radio communications, or anytime controller's visibility is inhibited. In these situations, a bridge tender with Norfolk Southern must be called and on-site within 30 minutes.

(4) Before the bridge closes for any reason, the remote operator will monitor waterway traffic in the area. The bridge shall only be closed if the off-site remote operator's visual inspection shows that the channel is clear and there are no vessels transiting in the area. While the bridge is moving, the operator shall maintain constant surveillance of the navigation channel.

(5) Before closing the draw, the channel traffic lights would change from flashing green to flashing red, the horn will sound five short blasts, and an audio voice warning stating, ''Attention, Attention. Norfolk Southern Railroad Bridge over Christina River at milepost 1.4 will be closing to river traffic.'' Five short blasts of the horn will continue until the bridge is seated and locked down to vessels. The channel traffic lights will continue to flash red.

(6) When the rail traffic has cleared, the horn will sound one prolonged blast followed by one short blast to indicate the draw is opening to vessel traffic. During the opening swing movement, the channel traffic lights would flash red until the bridge returns to the fully open position. In the full open position to vessels, the bridge channel lights will flash green followed by an announcement stating, ''Security, security, security. Norfolk Southern Railroad Bridge over Christina River at mile 1.4 is open for river traffic.'' Vessels shall stay clear of both channels as to not interfere with infrared detectors, until green lights are displayed on the swing span.

(c) * * *

(d) The draws of the Norfolk Southern Railroad bridges, at miles 4.1 and 4.2, both at Wilmington, shall open on signal from 6 a.m. to 8 p.m. if at least 24 hours notice is given. From 8 p.m. to 6 a.m., the draws need not be opened for the passage of vessels.

* * * * *

Dated: January 20, 2005.

Sally Brice-O'Hara,

Rear Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. 05–1660 Filed 1–27–05; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD07–04–108]

RIN 1625–AA09

Drawbridge Operation Regulations; Biscayne Bay, Atlantic Intracoastal Waterway, Miami River, and Miami Beach Channel, Miami-Dade County, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is temporarily changing the regulations governing the operation of the east and

west spans of the Venetian Causeway bridges across the Miami Beach Channel on the Atlantic Intracoastal Waterway, the Miami Avenue bridge and the Brickell Avenue bridge across the Miami River, Miami-Dade County. This temporary rule allows these bridges to remain in the closed position during the running of the Miami Tropical Marathon on January 30, 2005.

DATES: This temporary rule is effective from 6:05 a.m. until 12:05 p.m. on January 30, 2005.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket [CGD07–04–108] and are available for inspection or copying at Commander (obr), Seventh Coast Guard District, 909 SE 1st Avenue, Miami, Florida 33131–3050, between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays. Bridge Branch (obr), Seventh Coast Guard District, maintains the public docket for this rulemaking.

FOR FURTHER INFORMATION CONTACT: Mr. Gwin Tate, Project Manager, Seventh Coast Guard District, Bridge Branch, (305) 415–6747.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On November 30, 2004, we published a notice of proposed rulemaking (NPRM) entitled Drawbridge Operation Regulations; Biscayne Bay, Atlantic Intracoastal Waterway, Miami River, and Miami Beach Channel, Miami-Dade County, FL in the **Federal Register** (69 FR 69561). We received no comments on this proposed rule. No public hearing was requested, and none was held.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register.** No changes were made to the proposed regulatory text. The event for which the rule is necessary is scheduled to occur less than 30 days from the date of publication. Therefore, waiting an addtional 30 days from the date of publication to make this rule effective is both unnecessary and impracticable.

Background and Purpose

The Miami Marathon Director requested that the Coast Guard temporarily change the existing regulations governing the operation of the east and west spans of the Venetian Causeway bridges, the Brickell Avenue bridge and the Miami Avenue bridge to allow them to remain in the closed position during the running of the Miami Tropical Marathon on Sunday, January 30, 2005. The closure times range from 6:05 a.m. through 12:05 p.m. The marathon route will pass over these four bridges and any bridge opening would disrupt the race. Based on the limited amount of time the bridges will be closed, the proposed rule will still provide for the reasonable needs of navigation on the day of the event.

The east and west spans of the Venetian Causeway bridges are located between Miami and Miami Beach. The current regulation governing the operation of the east span of the Venetian Causeway bridge is published in 33 CFR 117.269 and requires the bridge to open on signal; except that, from November 1 through April 30 from 7:15 a.m. to 8:45 a.m. and from 4:45 p.m. to 6:15 p.m. Monday through Friday, the draw need not open. However, the draw opens at 7:45 a.m., 8:15 a.m., 5:15 p.m., and 5:45 p.m., if any vessels are waiting to pass. The draw opens on signal on Thanksgiving Day, Charistmas Day, New Year's Day and Washington's Birthday. The draw opens at anytime for public vessels of the United States, tugs with tows, regularly scheduled cruise vessels, and vessels in distress.

The regulation governing the west span of the Venetian Causeway bridge is published in 33 CFR 117.261(j)(4)(nn) and requires the bridge to open on signal; except that, from November 1 through April 30, Monday through Friday except Federal holidays, from 7 a.m. to 9 a.m. and 4:30 p.m. to 6:30 p.m., that the draw need open only on the hour and the half-hour.

The regulation governing the Miami Avenue bridge, mile 0.3, at Miami, is published at 33 CFR 117.305(c) and requires that the bridge open on signal; except that, from 7:35 a.m. to 8:59 a.m., 12:05 p.m. to 12:59 p.m. and 4:35 p.m. to 5:59 p.m., Monday through Friday, except Federal holidays, the draw need not open for the passage of vessels.

The regulation governing the draw of the Brickell Avenue bridge, mile 0.1. at Miami, is published in 33 CFR 117.305(d) and requires that the bridge open on signal; except that, from 7 a.m. to 7 p.m., Monday through Friday, except Federal holidays, the draw need open only on the hour and half-hour. From 7:35 a.m. to 8:59 a.m., 12:05 p.m. to 12:59 p.m. and 4:35 p.m. to 5:59 p.m., Monday through Friday except Federal holidays, the draw need not open for the passage of vessels.

This temporary rule will not advesely affect the reasonable needs of navigation due to the short duration that the bridges will be in the closed position.

Discussion of Comments and Changes

No comments were received in response to the notice of proposed rulemaking and there were no changes made to the proposed regulatory text.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assesssment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We expect the economic impact of this temporary rule to be so minimal that a full Regulatory Evaluation is unnecessary. The short duration of time during the morning of January 30, 2005, that the bridges will remain in the closed position to facilitate the running of the marathon will have little, if any, economic impact. This rule was preceded by a notice of proposed rulemaking and no comments were received.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the owners or operators of vessels that will require passage through these bridges during the morning hours of January 30, 2005. These vessels will not be able to pass through these bridges during the effective times of this rule. A notice of proposed rulemaking was published for this rule. No comments were received and no changes were made to the proposed regulatory test. Due to the limited effective times of this rule and the nominal amount of marine traffic expected during the early and late morning hours on a Sunday at this time of year, this rule would not have a significant economic impact on a substantial number of small entities.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking. The Coast Guard offered small businesses, organizations, or governmental jurisdictions that believed the rule would affect them, or that had questions concerning its provisions or options for compliance, to contact the person listed in **FOR FURTHER INFORMATION CONTACT**.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, Call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in the preamble.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from environmental Health Risks and Safety Risks. This rule is not an economically significant rule and will not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory affairs has not designated it as a significant energy action. Therefore, it does not require a statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.b.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (32)(e) of the Instruction, from further environmental documentation. This rule fits within paragraph (32)(e) because it pertains to operation regulations for drawbridges. Under figure 2–1, paragraph (32)(e), of the Instruction, an ''Environmental Analysis Check List'' and a ''Categorical Exclusion Determination'' are not required for this rule.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; Department of Homeland Security Delegation No. 0170.1; section 117.255 also issued under authority of Pub. L. 102–587, 106 Stat. 5039.

■ 2. From 6:15 a.m. until 9:20 a.m. on January 30, 2005, in § 117.261, paragraph (nn) is suspended and a new paragraph (tt) is added to read as follows:

§ 117.261 Atlantic Intracoastal Waterway from St. Marys River to Key Largo.

* * * * *

(tt) *West Span of the Venetian Causeway, mile 1088.6 at Miami.* The draw need not open from 6:15 a.m. until 9:20 a.m. on January 30, 2005. Public vessels of the United States and vessels in distress shall be passed at any time.

■ 3. From 6:05 a.m. until 8:40 a.m. on January 30, 2005, in § 117.269, temporarily designate the existing regulatory text as paragraph (a); suspend paragraph (a); and add a new paragraph (b) to read as follows:

§ 117.269 Biscayne Bay.

* * * * *

(b) The draw of the east span of the Venetian Causeway bridge across Miami Beach Channel need not open from 6:05

a.m. to 8:40 a.m. on January 30, 2005. Public vessesl of the United States and vessels in distress shall be passed at any time.

■ 4. From 6:25 a.m. until 10 a.m. on Sunday, January 30, 2005, in § 117.305, paragraphs (c) and (d) are suspended and new paragraphs (e) and (f) are added to read as follows:

§ 117.305 Miami River.

* * * * *

(e) The draw of each bridge from the mouth of the Miami River, to and including the NW. 27th Avenue bridge, mile 3.7 at Miami, except the Miami Avenue and Brickell Avenue bridges, shall open on signal.

(f) The Miami Avenue bridge, across the Miami River, need not open from 6:25 a.m. to 10 a.m. on Sunday, January 30, 2005, and the Brickell Avenue bridge, across the Miami River, need not open 7:10 a.m. to 12:05 p.m. on Sunday, January 30, 2005. Public vessels of the United States and vessels in an emergency involving danger to life or property shall be passed at any time.

Dated: January 11, 2005.

D. Brian Peterman,

Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District

[FR Doc. 05–1659 Filed 1–27–05; 8:45 am]

BILLING CODE 4910–15–M

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD01–05–004]

Drawbridge Operation Regulations: Newtown Creek, Dutch Kills, English Kills, and Their Tributaries, NY

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the drawbridge operation regulations for the Metropolitan Avenue Bridge, mile 3.4, across English Kills at New York City, New York. Under this temporary deviation the bridge may remain closed on the following days: February 14 through February 15; February 24 through February 25; March 3 through March 4; March 10 through March 11; March 17 through March 18; and March 24 through March 25, 2005. This temporary deviation is necessary to facilitate bridge maintenance.

DATES: This deviation is effective from February 14, 2005, through March 25, 2005.

FOR FURTHER INFORMATION CONTACT: Judy Leung-Yee, Project Officer, First Coast Guard District, at (212) 668–7195.

SUPPLEMENTARY INFORMATION: The Metropolitan Avenue Bridge has a vertical clearance in the closed position of 10 feet at mean high water and 15 feet at mean low water. The existing drawbridge operation regulations are listed at 33 CFR 117.801(e).

The owner of the bridge, New York City Department of Transportation (NYCDOT), requested a temporary deviation from the drawbridge operation regulations to facilitate rehabilitation repairs at the bridge. The bridge must remain in the closed position to perform these repairs.

Under this temporary deviation the NYCDOT Metropolitan Avenue Bridge may remain in the closed position on the following days: February 14 through February 15; February 24 through February 25; March 3 through March 4; March 10 through March 11; March 17 through March 18; and March 24 through March 25, 2005.

This deviation from the operating regulations is authorized under 33 CFR 117.35, and will be performed with all due speed in order to return the bridge to normal operation as soon as possible.

Dated: January 21, 2005.

Gary Kassof,

Bridge Program Manager, First Coast Guard District.

[FR Doc. 05–1658 Filed 1–27–05; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R05–OAR–2004–MI–0003; FRL–7865–2]

Approval and Promulgation of Maintenance Plan Revisions; Michigan

AGENCY: Environmental Protection Agency.

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a December 19, 2003 request from Michigan for a State Implementation Plan (SIP) revision of the Southeast Michigan carbon monoxide (CO) maintenance plan. The CO maintenance plan revision establishes a new on-road emissions inventory for the years 1996 and 2010. The revision also establishes a new transportation conformity motor vehicle emissions budget (MVEB) for the year 2010. The emission inventory and MVEB updates are designed to maintain the National Ambient Air Quality Standards (NAAQS) for CO as required by the Clean Air Act (CAA).

DATES: This rule is effective on March 29, 2005, unless EPA receives adverse written comments by February 28, 2005. If EPA receives adverse comments, EPA will publish a timely withdrawal of the rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit comments, identified by Regional Material in EDocket (RME) ID No. R05–OAR–2004–MI–0003, by one of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the on-line instructions for submitting comments.

Agency Web site: http://docket.epa.gov/rmepub/. Regional RME, EPA's electronic public docket and comments system, is EPA's preferred method for receiving comments. Once in the system, select ''quick search,'' then key in the appropriate RME Docket identification number. Follow the on-line instructions for submitting comments.

E-mail: mooney.john@epa.gov.

Fax: (312)886–5824.

Mail: You may send written comments to: John M. Mooney, Chief, Criteria Pollutant Section, (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Hand delivery: Deliver your comments to: John M. Mooney, Chief, Criteria Pollutant Section, (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, 18th floor, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

Instructions: Direct your comments to RME ID No. R05–OAR–2004–MI–0003. EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through RME, regulations.gov, or e-mail. The EPA RME Web site and the federal regulations.gov Web site are ''anonymous access'' systems, which means EPA will not know your identity

or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through RME or *regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional instructions on submitting comments, see ''How and to whom do I submit comments?'' of the **SUPPLEMENTARY INFORMATION** section of this rule.

Docket: All documents in the electronic docket are listed in the RME index at *http://docket.epa.gov/rmepub/*. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Publicly available docket materials are available either electronically in RME or in hard copy at Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. Please contact Anthony Maietta at (312) 353–8777 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Anthony J. Maietta, Life Scientist, Criteria Pollutant Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–8777, *maietta.anthony@epa.gov*.

SUPPLEMENTARY INFORMATION: This **SUPPLEMENTARY INFORMATION** section is arranged as follows:

I. General Information
A. Does This Action Apply to Me?
B. How Can I Get Copies of This Document and Other Related Information?
C. How and to Whom Do I Submit Comments?
II. What Action Is EPA Taking Today?
III. Did the State Properly Approve the Underlying State Rule?
IV. What Is Transportation Conformity?
V. What Is an On-Road Emissions Inventory?
VI. What Is an Emissions Budget?
VII. How Does This Action Change the Southeast Michigan CO Maintenance Plan?
VIII. Why Is This Request Approvable?
IX. Statutory and Executive Order Reviews

I. General Information

A. Does This Action Apply to Me?

Approval of the requested revision will mainly affect the entities responsible for transportation planning in the Southeast Michigan CO maintenance area. Those entities include, but are not limited to, the Southeast Michigan Council of Governments (SEMCOG), and the Michigan Department of Transportation. This action is approving non-regulatory changes to the state's CO maintenance plan.

B. How Can I Get Copies of This Document and Other Related Information?

The Regional Office has established an electronic public rulemaking file available for inspection at RME under RME ID No. R05–OAR–2004–MI–0003, and a hard copy file which is available for inspection at the Regional Office. The official public file consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public rulemaking file does not include CBI or other information whose disclosure is restricted by statute. The official public rulemaking file is the collection of materials that is available for public viewing at the Air Programs Branch, Air and Radiation Division, EPA Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604. EPA requests that, if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

Electronic Access. You may access this **Federal Register** document electronically through the regulations.gov Web site located at *http://www.regulations.gov* where you can find, review, and submit comments on Federal rules that have been published in the **Federal Register**, the Government's legal newspaper, and that are open for comment.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at the EPA Regional Office, as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in the official public rulemaking file. The entire printed comment, including the copyrighted material, will be available at the Regional Office for public inspection.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate rulemaking identification number by including the text ''Public comment on proposed rulemaking Region 5 Air Docket R05–OAR–2004–MI–0003'' in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

For detailed instructions on submitting public comments and on what to consider as you prepare your comments see the **ADDRESSES** section and the section I(B) of the **SUPPLEMENTARY INFORMATION** section of the related proposed rule which is published in the Proposed Rules section of this **Federal Register**.

II. What Action Is EPA Taking Today?

EPA is approving a December 19, 2003 request from the State of Michigan to revise the Southeast Michigan CO maintenance plan. The Southeast Michigan CO maintenance area consists of portions of Oakland, Macomb, and Wayne Counties. EPA designated Southeast Michigan as attainment in a June 30, 1999 **Federal Register** notice (64 FR 35017). At that time, an on-road CO emissions inventory was created for Southeast Michigan for the years 1996 and 2010. A 2010 MVEB was also created at that time. As a result of today's action, the 1996 base year on-road emissions inventory, forecast year, 2010, emissions inventory, and the 2010 MVEB will be updated to meet EPA's requirement to use the Mobile6 emissions factor model to determine mobile source emissions and conformity to the CO maintenance SIP. EPA required use of the Mobile6 model as of January 29, 2004. By approving the revision, EPA ensures that future emission forecasts for conformity

analyses in the Southeast Michigan CO maintenance area will be compared to budgets that are based on similar inputs and the same version of the Mobile model.

EPA is publishing this action without prior proposal because we view this as a noncontroversial SIP revision and anticipate no adverse comments. However, in the proposed rules of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the state plan revision if we receive relevant adverse comments and, therefore, withdraw this direct final rule. This rule will be effective March 29, 2005 without further notice unless we receive relevant adverse comments by February 28, 2005. If we receive such comments, we will withdraw this action before the effective date by publishing a document withdrawing the direct final approval action. EPA will not provide a second comment period on this action. Any person interested in commenting on this action should do so at this time.

III. Did the State Properly Approve the Underlying State Rule?

On December 19, 2003, Michigan submitted to EPA for approval, a SIP revision for the Southeast Michigan CO maintenance area. The Michigan Department of Environmental Quality (MDEQ) held a public hearing on the matter on September 9, 2003. Four people attended the hearing. MDEQ did not receive any comments on the proposed revision.

In the submittal, the State requests that the 1996 base year on-road CO emissions inventory be changed to 3,866.2 tons/day, and that the 2010 MVEB be changed to 3,842.7 tons/day. The State also added the forecast year 2010 emissions inventory of 1,942.5 tons/day. The MVEB, which is partly determined by using the base year on-road emissions inventory, is used for purposes of transportation conformity.

IV. What Is Transportation Conformity?

Transportation conformity is a mechanism for determining the amount of emissions created by a transportation project, plan, or program in a nonattainment or maintenance area, making sure that such emissions do not cause or contribute to violations of the NAAQS, or impede the rate of progress toward attaining or maintaining the NAAQS. Because the SIP contains measures that will help an area attain or maintain the NAAQS, transportation activities must ''conform'' to the goals outlined in the SIP. On November 24, 1993, EPA published a final rule establishing criteria and procedures for determining whether transportation plans, programs and projects funded or approved under Title 23 of the United States Code or the Federal Transit Act conform to the SIPs.

The transportation conformity rules require a CO maintenance area, like Southeast Michigan, to compare the actual projected emissions from cars, trucks and buses on the highway network, to the MVEB established by a maintenance plan. The Southeast Michigan area has an approved CO maintenance plan (see 64 FR 35017). Our approval of the original maintenance plan established the Southeast Michigan MVEB for transportation conformity purposes. At the time of approval, Mobile5 was the required computer model for estimating the amount of on-road emissions in an area. As of January 29, 2004, Mobile6 is the required model for estimating on-road emissions. By taking into account revised techniques for estimating motor vehicle emissions, Mobile6 provides a more accurate estimate of emissions than Mobile5.

V. What Is an On-Road Emissions Inventory?

General SIP provisions for nonattainment areas call for an inventory of all known emissions sources in that area to determine where emissions come from, and to provide a tool for evaluating potential emission control strategies. In a maintenance area, the emissions inventory shows the amount of a pollutant, in this case, CO, that an area can emit while still maintaining the CO air quality standards. Emissions from point, area, and mobile sources are estimated as part of this process. Forecasts of emissions in future years can then be calculated. These forecasts take into account emissions reductions from federal and state measures, as well as growth in emissions resulting from population growth and economic development. For purposes of transportation conformity, the emissions inventory and emissions forecast are used to determine the amount of on-road mobile source emissions an area can emit while still maintaining the NAAQS for that pollutant.

In the original CO maintenance plan, an emissions inventory was calculated for the base year 1986 and a forecast year of 1996. Point, area, off-road, and on-road sources were estimated. The on-road portions of the original inventory and forecast were created using the Mobile5 model. Michigan updated the on-road emissions inventory and forecast year inventory in June 1999. In the current submittal, Mobile6 is used to determine the on-road portions of the inventory and forecast. EPA policy requires this switch as of January 29, 2004 because EPA believes that the Mobile6 model more accurately predicts emissions levels. The State's action is simply an update of its original estimates of the on-road portion of the 1996 base year emissions inventory, using the newer model. The following Table shows the revised CO emissions inventory and forecast for Southeast Michigan.

TABLE 1.—SOUTHEAST MICHIGAN CO EMISSIONS INVENTORY

[Tons/day]

Source type	1996	2010	1996–2010 change	Percent change 1996–2010
Point	128.7	140.0	11.3	8.8
Area	129.7	137.6	7.9	6.0
Off-road Mobile	233.0	237.1	4.1	1.8
On-road Mobile	3,866.2	1942.5	−1923.7	−49.8
Total	4,357.6	2457.2	−1900.4	−43.6

VI. What Is an Emissions Budget?

A motor vehicle emissions budget (also known as a conformity budget) is the projected level of controlled emissions from the transportation sector (on-road mobile sources) that is estimated in the SIP. The SIP includes emissions control programs at the state and federal level, examples include requirements on motor vehicle fuels and exhaust standards for cars and trucks. The emissions budget concept is further explained in the preamble to the November 24, 1993, transportation conformity rule (58 FR 62188). The preamble also describes how to establish the MVEB in the SIP and how to revise the emissions budget. The transportation conformity rule provides for updates to the MVEB, and the revised MVEB is acceptable so long as the level of projected emissions from all sources (point, mobile, and area) remains at or below the level necessary to attain the NAAQS. Because that level of projected emissions will change as a result of today's actions, a new MVEB must be created. The following Table contains the new MVEB for Southeast Michigan.

TABLE 2.—2010 CO MOTOR VEHICLE EMISSIONS BUDGET (MVEB) FOR SOUTHEAST MICHIGAN

[Tons/day]

Total reductions from 1996 to 2010	1,900.4
2010 On-road Mobile Source Emissions	1,942.5
Total	3,842.9

VII. How Does This Action Change the Southeast Michigan CO Maintenance Plan?

When the budget was reassessed using Mobile6, the on-road CO estimates increased from earlier estimates. However, it is important to note that there is no actual increase of CO emissions in Southeast Michigan. The perceived increase is caused by changes in the estimation techniques, not by relaxation of control requirements.

VIII. Why Is This Request Approvable?

As noted above, the State's submittal is consistent with EPA policies and requirements, and is therefore approvable. EPA believes the revised emissions inventory and MVEB budgets are adequate for conformity purposes and are approvable as part of the maintenance plan.

IX. Statutory and Executive Order Reviews

Executive Order 12866; Regulatory Planning and Review

Under Executive Order 12866 (*58 FR 51735,* October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget.

Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

Because it is not a ''significant regulatory action'' under Executive Order 12866 or a ''significant energy action,'' this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (*66 FR 28355,* May 22, 2001).

Regulatory Flexibility Act

This action merely approves state regulations as meeting Federal requirements and imposes no additional requirements beyond those imposed by state regulations. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Unfunded Mandates Reform Act

Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Order 13175 Consultation and Coordination With Indian Tribal Governments

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (*59 FR 22951,* November 9, 2000).

Executive Order 13132 Federalism

This action also does not have Federalism implications because it does not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (*64 FR 43255,* August 10, 1999). This action merely approves a state rule implementing a federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act.

Executive Order 13045 Protection of Children From Environmental Health and Safety Risks

This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (*62 FR 19885,* April 23, 1997), because it is not economically significant.

National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTA), 15 U.S.C. 272, requires federal agencies to use technical standards that are developed or adopted by voluntary consensus to carry out policy objectives, so long as such standards are not inconsistent with applicable law or otherwise impracticable. In reviewing program submissions, EPA's role is to approve State choices, provided that they meet the criteria of the Act. Absent a prior existing requirement for the state to use voluntary consensus standards, EPA has no authority to disapprove a program submission for failure to use such standards, and it would thus be inconsistent with applicable law for EPA to use voluntary consensus standards in place of a program submission that otherwise satisfies the provisions of the Act. Therefore, the requirements of section 12(d) of the NTTA do not apply.

Civil Justice Reform

As required by section 3 of Executive Order 12988 (*61 FR 4729*, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct.

Governmental Interference With Constitutionally Protected Property Rights

EPA has complied with Executive Order 12630 (*53 FR 8859,* March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order, and has determined

that the rule's requirements do not constitute a taking.

Paperwork Reduction Act

This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 804 exempts from section 801 the following types of rules: (1) Rules of particular applicability; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. 5 U.S.C. 804(3). EPA is not required to submit a rule report regarding this action under section 801 because this is a rule of particular applicability. Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 15, 2004. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Intergovernmental relations.

Dated: January 14, 2005.

Norman Neidergang,

Acting Regional Administrator, Region 5.

■ Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart X—Michigan

■ 2. Section 52.1179 is revised to read as follows:

§ 52.1179 Control strategy: Carbon monoxide.

(a) Approval—On March 18, 1999, the Michigan Department of Environmental Quality submitted a request to redesignate the Detroit CO nonattainment area (consisting of portions of Wayne, Oakland and Macomb Counties) to attainment for CO. As part of the redesignation request, the State submitted a maintenance plan as required by 175A of the Clean Air Act, as amended in 1990. Elements of the section 175A maintenance plan include a base year (1996 attainment year) emission inventory for CO, a demonstration of maintenance of the ozone NAAQS with projected emission inventories to the year 2010, a plan to verify continued attainment, a contingency plan, and an obligation to submit a subsequent maintenance plan revision in 8 years as required by the Clean Air Act. If the area records a violation of the CO NAAQS (which must be confirmed by the State), Michigan will implement one or more appropriate contingency measure(s) which are contained in the contingency plan. The menu of contingency measures includes enforceable emission limitations for stationary sources, transportation control measures, or a vehicle inspection and maintenance program. The redesignation request and maintenance plan meet the redesignation requirements in sections 107(d)(3)(E) and 175A of the Act as amended in 1990.

(b) Approval—On December 19, 2003, Michigan submitted a request to revise its plan for the Southeast Michigan CO maintenance area (consisting of portions of Wayne, Oakland and Macomb Counties). The submittal contains updated emission inventories for 1996 and 2010, and an update to the 2010 motor vehicle emissions budget (MVEB). The 2010 MVEB is 3,842.9 tons of CO per day.

[FR Doc. 05–1633 Filed 1–27–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[OH 159–2; FRL–7862–8]

Approval and Promulgation of Implementation Plans; Ohio

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On September 27, 2003, Ohio requested revisions to the State Implementation Plan (SIP) for sulfur dioxide (SO_2) for several counties in Ohio, along with a request for redesignation of Cuyahoga County to attainment for SO_2. On July 8, 2004, at 69 FR 41344, EPA proposed to approve the requested revisions and to redesignate Cuyahoga County as requested. EPA also published a corresponding direct final rule on the same date, at 69 FR 41336, but EPA withdrew this direct final rule because it received an adverse comment. A citizen from New Jersey expressed concern about air pollution coming east from Ohio and urged EPA to require Ohio power plants to upgrade their pollution controls. EPA is satisfied that the SO_2 emission limits submitted by Ohio suffice to assure attainment of the SO_2 air quality standard. EPA notes further that a separate action proposed on January 30, 2004, at 69 FR 4566, known as the Clean Air Interstate Rule, would require significant reduction in the emissions of SO_2 and nitrogen oxides (NO_X) of power plants in Ohio and elsewhere for purposes of reducing their long-range transported contributions to fine particulate matter and ozone exposures. EPA also received a comment from an affected company clarifying the operational status of boilers affected by the relevant rule. EPA affirms this clarification. Thus, as proposed, EPA is approving the SO_2 rules Ohio submitted, removing the Federal Implementation Plan rules that these State rules supersede, and redesignating Cuyahoga County to attainment for SO_2.

DATES: This final rule is effective on February 28, 2005.

ADDRESSES: Copies of the Ohio's submittals and other information are available for inspection during normal business hours at the following address: (We recommend that you telephone John Summerhays at (312) 886–6067, before visiting the Region 5 Office.)

United States Environmental Protection Agency, Region 5, Air Programs Branch (AR–18J), Criteria Pollutant Section, 77 West Jackson Boulevard, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: John Summerhays at (312) 886–6067.

SUPPLEMENTARY INFORMATION: This supplemental information section is organized as follows:

I. Synopsis of Ohio's Submittal
II. Review of Comments
III. EPA Action
IV. Statutory and Executive Order Reviews

I. Synopsis of Ohio's Submittal

On September 27, 2003, Ohio requested numerous revisions to its

State Implementation Plan (SIP) for sulfur dioxide (SO_2). These revisions principally relate to the nature of the federally enforceable emission limits for SO_2 in several Ohio counties. For most of the sources affected by this request, the current limits are the federally promulgated Federal Implementation Plan (FIP) limits that EPA promulgated in 1976 (with selected subsequent amendments). Ohio requested that EPA approve numerous State-adopted emission limits as federally enforceable, which would allow EPA to delete the corresponding FIP limits.

Ohio's submittal addresses SO_2 limits for the following counties: Adams, Allen, Clermont, Cuyahoga, Lake, Lawrence, Mahoning, Monroe, Montgomery, Muskingum, Pike, Ross, Washington, and Wood Counties. For Cuyahoga, Mahoning, Monroe, and Washington Counties, the submitted limits differ from the current federally enforceable limits. Ohio provided evidence from modeling that the submitted limits would provide for attainment of the SO_2 standards. For the other counties, the submitted limits are largely equivalent to current federally enforceable limits. Finally, Ohio submitted selected revisions to generic rules with statewide applicability.

The second Ohio request is for EPA to redesignate the Cleveland area (Cuyahoga County) from a nonattainment area to an attainment area for SO_2. Among the prerequisites to redesignation is that EPA has approved State adopted rules sufficient to provide for attainment and to satisfy other planning requirements. Ohio's submittal and EPA's approval of State limits for Cuyahoga County for replacing FIP limits addresses this prerequisite. A related, third Ohio request is that EPA approve Ohio's plan for continuing to attain the SO_2 air quality standard in Cuyahoga County.

EPA published a direct final rule approving Ohio's requests and redesignating Cuyahoga County to attainment for SO_2 on July 8, 2004, at 69 FR 41336. EPA subsequently withdrew this action due to receipt of a relevant adverse comment. Nevertheless, readers seeking a more thorough description of Ohio's submittal, EPA's criteria for reviewing this submittal, and EPA's review of the submittal, may consult this notice of direct final rulemaking.

II. Review of Comments

In conjunction with its direct final rule, EPA simultaneously published a proposed rule proposing the same actions, published at 69 FR 41344. EPA received two comment letters in response to this proposed rule.

Comment: A citizen from New Jersey commented: ''This agency must examine this with a view to any Ohio poisonous air that comes east, impacting New Jersey, New York, and Connecticut. EPA has a duty and responsibility to guarantee clean air to those east of Ohio, as well as Ohio residents. We need the highest standards for Ohio.

Power plants have had at least fifty years to upgrade their plants. There is absolutely no reason if they have failed to upgrade, other than a desire to pollute. It is time to clean up our air.''

Response: In this action, EPA is evaluating the adequacy of Ohio's limits for assuring attainment of the SO_2 air quality standards. In general, the highest concentrations of SO_2 arise within a few kilometers of a source or sources that emit SO_2; nevertheless, EPA has examined evidence related to the longer range impacts and believes that Ohio sources are not causing violations of the SO_2 standards or interfering with attainment of the SO_2 standards in the cited eastern states. At the same time, EPA is taking separate actions to address the impacts of SO_2 emitted from power plants in Ohio and elsewhere on concentrations of other air pollutants. In particular, in order to address long-range impacts of power plant emissions on concentrations of fine particulate matter and ozone, EPA has proposed to require significant reductions of emissions of SO_2 and NO_X from power plants throughout the Eastern United States, including Ohio. This proposal was published on January 30, 2004, at 69 FR 4566, and EPA intends to publish final action on this proposal later this year.

Comment: MW Custom Papers commented to clarify the operational status of the boilers at a mill, formerly known as a Mead Corporation facility, which it operates in Ross County, Ohio. The commenter highlighted a statement in the preamble section of the direct final rulemaking discussing Ross County rules, stating ''The FIP limit for boilers at this source is 0.00#/MMBTU, based on anticipation that these boilers would be shut down; however, these boilers did not in fact shut down.'' The commenter explains that four boilers, corresponding to stacks 1, 2, 3, and 4, were in fact shut down as anticipated, but three other boilers (boilers 5, 7 and 8) were not shut down and were never intended to be shut down. Indeed, the commenter notes, while the FIP expressly requires zero emissions from stacks 1 through 4, the attainment analysis assumes nonzero emissions for the other three boilers. The commenter requests that EPA provide this explanation in its final rulemaking.

Response: The preamble to the direct final rulemaking reflected a confusion between boilers slated for shutdown and boilers (not mentioned in the FIP regulations but given explicit limits in Ohio's rules) that were slated for continued operation. EPA acknowledges its error and appreciates the clarification. Thus, Ohio's rules reflect the same operations as the FIP, *i.e.,* boilers for stacks 1 through 4 shut down and boilers 5, 7, and 8 operating with nonzero limits, and the company in fact shut down the boilers it intended to shut down. This explanation provides a clarified basis for approving Ohio's Ross County limits.

III. EPA Action

This rulemaking approves numerous SO_2 limits adopted and submitted by Ohio, many of which replace limits that EPA promulgated as part of a FIP. EPA is approving rules for Adams County (limits for Dayton Power & Light-Stuart Station), Allen County (limits for the Marsulex facility), Clermont County (limits for Cincinnati Gas & Electric-Beckjord Station), Cuyahoga County (full rule), Lake County (full rule), Lawrence County (limits for the Allied Chemical facility), Mahoning County (full rule), Monroe County (full rule), Montgomery County (limits for the Glatfelter and Miami Paper facilities), Muskingum County (Armco Steel), Pike County (limits for the Portsmouth Diffusion Plant), Ross County (limits for the MW Custom Papers facility), Washington County (full rule), and Wood County (Libby-Owens-Ford Plants 4 & 8 and Plant 6).

In those cases where the affected plants are subject to FIP limits, the approved State rules supersede the FIP limits. In today's action, EPA is removing the FIP rules that have thus been superseded.

EPA is redesignating Cuyahoga County to attainment for SO_2. EPA is also approving Ohio's plan for maintenance of the SO_2 air quality standard in Cuyahoga County.

IV. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional

requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves state rules implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 29, 2005. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Sulfur dioxide.

40 CFR Part 81

Air pollution control, National parks, Wilderness areas.

Dated: January 13, 2005.

Michael O. Leavitt,

Administrator.

■ For the reasons stated in the preamble, part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart KK—Ohio

■ 2. Section 52.1870 is amended by adding paragraph (c)(129) to read as follows:

§ 52.1870 Identification of plan.

* * * * *

(c) * * *

(129) On September 27, 2003, the Ohio Environmental Protection Agency submitted revised rules for sulfur dioxide. The submittal includes revised provisions in Rules 3745–18–01, 3745–18–04, and 3745–18–06, relating to natural gas use, as well as special provisions in Rule 3745–18–04 for compliance testing for Lubrizol in Lake County. The submittal includes recently revised Ohio limits in Cuyahoga, Lake, Mahoning, Monroe, and Washington Counties, as well as previously adopted source-specific limits in Adams, Allen, Clermont, Lawrence, Montgomery, Muskingum, Pike, Ross, and Wood Counties that had not previously been subject to EPA rulemaking.

(i) *Incorporation by reference.*

(A) Rules OAC 3745–18–01; OAC 3745–18–04(F); OAC 3745–18–04(J); OAC 3745–18–06; OAC 3745–18–24; OAC 3745–18–49; OAC 3745–18–56; OAC 3745–18–62; and OAC 3745–18–90. Adopted August 19, 2003, effective September 1, 2003.

(B) Rules OAC 3745–18–07(B); OAC 3745–18–08(H); OAC 3745–18–19(B); OAC 3745–18–66(C); OAC 3745–18–72(B);, effective May 11, 1987.

(C) OAC 3745–18–50(C); OAC 3745–18–77(B); effective December 28, 1979.

(D) OAC 3745–18–63(K) and (L); and OAC 3745–18–93(B) and (C); effective December 1, 1984.

(ii) *Additional material*—Letter from Robert Hodanbosi, Chief of the Division of Air Pollution Control of the Ohio EPA, to Thomas Skinner, Regional Administrator for Region 5 of USEPA, dated September 27, 2003.

* * * * *

■ 3. Section 52.1881 is amended as follows:

■ a. By revising paragraphs (a)(4) and (a)(8) and adding paragraph (a)(15).

■ b. By removing paragraphs (b)(7) through (b)(15), redesignating paragraph (b)(16) as (b)(7), removing paragraphs (b)(17) through (b)(25), redesignating paragraphs (b)(26), (b)(27) and (b)(28) as (b)(8), (b)(9), and (b)(10), respectively, and removing paragraphs (b)(29) and (b)(30).

§ 52.1881 Control strategy: Sulfur Oxides (sulfur dioxide).

(a) * * *

(4) Approval—EPA approves the sulfur dioxide emission limits for the following counties: Adams County, Allen County, Ashland County, Ashtabula County, Athens County, Auglaize County, Belmont County, Brown County, Butler County, Carroll County, Champaign County, Clark County, Clermont County, Clinton County, Columbiana County, Coshocton County, Crawford County, Cuyahoga County, Darke County, Defiance County, Delaware County, Erie County, Fairfield County, Fayette County, Fulton County, Gallia County, Geauga County, Greene County, Guernsey County, Hamilton County, Hancock County, Hardin County, Harrison County, Henry County, Highland County, Hocking County, Holmes County, Huron County, Jackson County, Jefferson County, Knox County, Lake County, Lawrence County, Licking County, Logan County, Lorain County, Lucas County, Madison County, Mahoning County, Marion County, Medina County, Meigs County, Mercer County, Miami County, Monroe County, Montgomery County, Morgan County, Morrow County, Muskingum County,

Noble County, Ottawa County, Paulding County, Perry County, Pickaway County, Pike County, Portage County, Preble County, Putnam County, Richland County, Ross County, Sandusky County (except Martin Marietta Chemicals), Scioto County, Seneca County, Shelby County, Trumbull County, Tuscarawas County, Union County, Van Wert County, Vinton County, Warren County, Washington County, Wayne County, Williams County, Wood County, and Wyandot County.

* * * * *

(8) No Action—EPA is neither approving nor disapproving the emission limitations for the following counties/sources pending further review: Franklin County, Sandusky County (Martin Marietta Chemicals), and Stark County.

* * * * *

(15) On September 27, 2003, Ohio submitted maintenance plans for sulfur dioxide in Cuyahoga County and Lucas County.

* * * * *

PART 81—[AMENDED]

■ 1. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. In § 81.336 the Ohio-SO_2 table is amended by revising the entry for Cuyahoga County to read as follows:

§ 81.336 Ohio.

OHIO-SO_2

Designated area	Does not meet primary standards	Does not meet secondary standards	Cannot be classified	Better than national standards
* * * * *				
Cuyahoga County				X
* * * * *				

* * * * *

[FR Doc. 05–1441 Filed 1–27–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0009; FRL–7695–3]

Quinoxyfen; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of quinoxyfen in or on vegetable, cucurbit, subgroup 9A; pumpkin; and squash, winter. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on melons, winter squash, and pumpkins. This regulation establishes a maximum permissible level for residues of quinoxyfen in these food commodities. These tolerances will expire and are revoked on December 31, 2007.

DATES: This regulation is effective January 28, 2005. Objections and requests for hearings must be received on or before March 29, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0009. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6463; e-mail address: *madden.barbara@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408 (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a,

is establishing tolerances for residues of the fungicide quinoxyfen, 5,7-dichloro-4-(4-fluorophenoxy)quinoline, in or on vegetable, cucurbit, subgroup 9A; pumpkin; and squash, winter at 0.30 parts per million (ppm). These tolerances will expire and are revoked on December 31, 2007. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 of the FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Section 18 of the FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Quinoxyfen on Melons, Winter Squash, and Pumpkins and FFDCA Tolerances

There are protectant fungicides registered that are effective in controlling powdery mildew on the upper leaf surfaces of melons, winter squash and pumpkins when the fungicide is in direct contact with the pathogen. However, these fungicides do not provide protection against the pathogen growing on the undersides of the leaves. During the 2003 growing season, resistance of powdery mildew control from the systemic registered alternatives (strobilurins and myclobutanil) was confirmed. The registered strobilurins and myclobutanil proved to be ineffective in controlling powdery mildew in melons, winter squash and pumpkins. The Agency believes that under high disease pressure and disease favorable weather conditions 20–30 percent yield losses are likely without the use of quinoxyfen. EPA has authorized under FIFRA section 18 the use of quinoxyfen on melons, winter squash, and pumpkins for control of powdery mildew in New York. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of quinoxyfen in or on cantaloupe, muskmelon, watermelon, watermelon juice, winter squash, pumpkin and pumpkin seed. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although this tolerance will expire and is revoked on December 31, 2007, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on melon subgroup 9A, pumpkin and winter squash after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether quinoxyfen meets EPA's registration requirements for use on melons, winter squash, and pumpkins or whether a permanent tolerance for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of quinoxyfen by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than New York to use this pesticide on these crops under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for quinoxyfen, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of quinoxyfen and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a time-limited tolerance for residues of quinoxyfen in or on vegetable, cucurbit, subgroup 9A; pumpkin; and squash, winter at 0.30 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Endpoints

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. The toxicology database for quinoxyfen is complete. EPA has considered available information concerning the variability of the sensitivities of major identifiable

subgroups of consumers, including infants and children. The nature of the toxic effects caused by quinoxyfen are fully discussed in a **Federal Register** Notice published on September 29, 2003 (68 FR 55849) that established tolerances for residues of quinoxyfen on cherries, grapes and hops. Please refer to that document for a complete discussion of the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

The dose, typically the NOAEL, from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological endpoint. However, the lowest dose at which adverse effects of concern are identified the LOAEL is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor (SF) is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (LOC). For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 $x10^{-6}$ or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In thisnon-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for Quinoxyfen used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR QUINOXYFEN FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13-50 years of age) and Acute dietary (general population including infants and children)	Not applicable	Not applicable	There were no toxic effects attributable to a single dose.Therefore, an endpoint of concern was not identified to quantitateacute-dietary risk to the general population or to the subpopulationfemales 13-50 years old
Chronic Dietary (All populations)	NOAEL = 20 milligram/kilogram/day (mg/kg/day)UF = 100 Chronic RfD = 0.20 mg/kg/day	FQPA SF = 1cPAD = chronic RfD/FQPA SF = 0.20 mg/kg/day	Combined chronic toxicity/carcinogenicity study in rat LOAEL = 80 mg/kg/day, based upon increases in severity ofchronic progressive glomerulonephropathy in the males and minimal decreasesin body weight and body weightgain in both sexes
Cancer (oral, dermal, inhalation)	classified as not likely to be carcinogenic to humans	Not applicable	No evidence of carcinogenicity in rats and mice

*The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.588) for the residues of quinoxyfen, in or on a variety of raw agricultural commodities including sweet and tart cherries, hops and grapes. Risk assessments were conducted by EPA to assess dietary exposures from quinoxyfen in food as follows:

i. *Acute exposure.* Quantitative Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. There were no toxic effects attributable to a single dose. Therefore, an endpoint of concern was not identified to quantitate acute-dietary risk to the general population or to the subpopulation females 13–50 years old. As a result, no acute risk is expected from exposure to quinoxyfen and hence no quantitative acute dietary risk assessment was performed.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™) which incorporates food consumption data as reported by respondents in the USDA 1994–1996

and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made: An unrefined, Tier 1 chronic-dietary exposure assessment using tolerance-level residues and assuming 100% CT for all proposed commodities, and default DEEM Version 7.76 processing factors for all commodities.

iii. *Cancer*. Quinoxyfen has been classified as not likely to be carcinogenic to humans. Therefore, a quantitative exposure assessment was not conducted to assess cancer risk.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for quinoxyfen in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of quinoxyfen.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentrations in Groundwater (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will generally use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to quinoxyfen they are further discussed in the aggregate risk sections below.

Based on the FIRST and SCI-GROW models the EECs of quinoxyfen for chronic exposures are estimated to be 0.8 parts per billion (ppb) for surface water and 0.006 ppb for ground water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Quinoxyfen is not registered for use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a common mechanism oftoxicity*. Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether quinoxyfen has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, quinoxyfen does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that quinoxyfen has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

C. Safety Factor for Infants and Children

1. *In general*. Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Developmental toxicity studies*. In a prenatal developmental study in rats the Maternal and Developmental NOAELs were 1,000 mg/kg/day and no LOAELs were identified. In a prenatal developmental study in rabbits the Maternal NOAEL was 80 mg/kg/day and the LOAEL was 200 mg/kg/day based on inanition, clinical signs, decreased body weights, body weight gains, and food consumption and on increased incidences of abortion. The Developmental NOAEL is 80 mg/kg/day and the LOAEL is 200 mg/kg/day based on increased incidences of abortion.

3. *Reproductive toxicity study*. In a reproduction toxicity study in rats the Parental/Systemic NOAEL was 100 mg/kg/day and no LOAEL was identified. The Reproductive NOAEL was 100 mg/kg/day and no LOAEL was identified. The Offspring NOAEL was 20 mg/kg/day and the LOAEL was 100 mg/kg/day based on a minimal decrease in F_{1a} pup weights.

4. *Prenatal and postnatal sensitivity.* There is no quantitative or qualitative evidence of increased susceptibility of rat and rabbit fetuses to *in utero* exposure in developmental studies. There is evidence of increased quantitative susceptibility (minimal decrease in F_{1a} pup weights) in the rat multi-generation reproduction study, but the concern is low since: (1) The effects in pups are well-characterized with a clear NOAEL; (2) the pup effects are minimal at the LOAEL and only noted in the first-generation offspring; and, (3) the doses and endpoints selected for regulatory purposes would address the concerns of the pup effects noted in the rat reproduction study. Therefore, there are no residual uncertainties for prenatal/postnatal toxicity in this study.

5. *Conclusion*. There is a complete toxicity data base for quinoxyfen and exposure data are complete or are estimated based on data that reasonably

accounts for potential exposures. There are no residual uncertainties for prenatal/postnatal toxicity. No additional safety factor is needed for database uncertainties. No clinical sign of neurotoxicity or neuropathology was seen in the data base. A developmental neurotoxicity study is not required. Therefore, EPA determined that the 10X SF to protect infants and children should be reduced to 1X.

D. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + chronic non-dietary, non-occupational exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to quinoxyfen in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of quinoxyfen on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. An endpoint of concern was not identified to quantitate acute-dietary risk to the general population or to the subpopulation females 13–50 years old. As a result, no acute risk is expected from exposure to quinoxyfen.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to quinoxyfen from food will utilize less than 1% of the cPAD for the U.S. population, 1% of the cPAD for all infants (<1 year old) and 2% of the cPAD for children (1–2 years old), the children subpopulation at greatest exposure. There are no residential uses for quinoxyfen that result in chronic residential exposure to quinoxyfen. In addition, there is potential for chronic dietary exposure to quinoxyfen in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 2 of this unit:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO QUINOXYFEN

Population Subgroup	cPAD mg/kg/day	% cPAD	(Food) Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.20	<1%	0.8	0.006	7000
All Infants (<1 year old)	0.20	1%	0.8	0.006	2000
Children (1-2 years old)	0.20	2%	0.8	0.006	2000

3. *Short-term and Intermediate-term risks*. Short- and intermediate-term aggregate exposure take into account non-dietary, non-occupational plus chronic exposure to food and water (considered to be a background exposure level). Quinoxyfen is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

4. *Aggregate cancer risk for U.S. population*. Quinoxyfen has been classified as not likely to be carcinogenic to humans. Therefore, quinoxyfen is expected to pose at most a negligible cancer risk.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to quinoxyfen residues.

V. Other Considerations

A. Analytical Enforcement Methodology

IR-4 has proposed a gas chromatography (GC) method with mass-selective detection (MSD) entitled Determination of DE-795 Residues in Grape Wine, Must, and Pomace ERC95.26 (and its supplement S1) for the enforcement of proposed tolerances for residues of quinoxyfen in/on grapes, cherries and hops. Method ERC 95.26 is classified as acceptable and conforms with the criteria of OPPTS GL 860.1340. The petitioner has submitted a study which investigated the behavior of quinoxyfen through MRMs outlined in FDA's Pesticide Analytical Manual (PAM), Volume I, Appendix II. The study summary reported that depending on spike levels, certain MRM Protocols (D, E, and F) yielded partial (incomplete) to complete recoveries of quinoxyfen in grapes (non-fatty matrix) and ground beef (fatty matrix).

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*..

B. International Residue Limits

There are no Mexican, Canadian or Codex Maximum Residue Limits (MRLs) established for quinoxyfen on sweet and tart cherries, grapes, or hops. Therefore, no compatibility problems exist for these tolerances.

VI. Conclusion

Therefore, tolerances are established for quinoxyfen, 5,7-dichloro-4-(4-fluorophenoxy)quinoline in or on vegetable, cucurbit, subgroup 9A; pumpkin; and squash, winter at 0.30 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2005–0009 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before March 29, 2005.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII..A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by the docket ID number OPP–2005–0009, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Statutory and Executive Order Reviews

This final rule establishes time-limited tolerances under section 408 of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under section 408 of the FFDCA, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States,

on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 14, 2005.

Betty Shackleford,

Acting Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—AMENDED

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.588 is amended by adding text to paragraph (b) to read as follows:

§ 180.588 Quinoxyfen; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the fungicide quinoxyfen, 5,7-dichloro-4-(4-fluorophenoxy)quinoline in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The time-limited tolerances will expire and are revoked on the date specified in the following table:

Commodity	Parts per million	Expiration/ revocation date
Pumpkin	0.30	12/31/07
Squash, winter ..	0.30	12/31/07
Vegetable, cucurbit, sub-group 9A	0.30	12/31/07

* * * * *

[FR Doc. 05–1638 Filed 1–27–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0012; FRL–7696–2]

Bifenazate; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for the combined residues of bifenazate in or on timothy hay and timothy forage. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on timothy. This regulation establishes a maximum permissible level for residues of bifenazate in these feed commodities. These tolerances will expire and are revoked on December 31, 2007.

DATES: This regulation is effective January 28, 2005. Objections and requests for hearings must be received on or before March 29, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under docket identification (ID) number OPP–2005–0012. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6463; e-mail address: *Madden.Barbara@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also

be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in the section above. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for the combined residues of the insecticide bifenazate, (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate) and diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl, 1-methylethyl ester, in or on timothy, hay at 150 parts per million (ppm) and timothy, forage at 50 ppm. These tolerances will expire and are revoked on December 31, 2007. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 of the FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Section 18 of the FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

EPA has received objections to a tolerance it established for bifenazate on a different food commodity. The objections were filed by the Natural Resources Defense Council (NRDC) and raised several issues regarding aggregate exposure estimates and the additional safety factor for the protection of infants and children. Although these objections concern separate rulemaking proceedings under the FFDCA, EPA has considered whether it is appropriate to establish this emergency exemption tolerance for bifenazate while the objections are still pending.

Factors taken into account by EPA included how close the Agency is to concluding the proceedings on the objections, the nature of the current action, whether NRDC's objections raised frivolous issues, and extent to which the issues raised by NRDC had already been considered by EPA. Although NRDC's objections are not frivolous, the other factors all support establishing this tolerance at this time. First, the objections proceeding is unlikely to conclude prior to when action is necessary on this petition. NRDC's objections raise complex legal, scientific, policy, and factual matters. EPA has published a notice describing the nature of the NRDC's objections in more detail. This notice offered an opportunity for the public to comment on this matter and published in the **Federal Register** of June 19, 2002 (67 FR 41628) (FRL–7167–7). EPA is now examining the extensive comments received. Second, the nature of the current action is extremely time-sensitive and addresses an emergency situation. Third, the issues raised by NRDC are not new matters but questions that have been the subject of considerable study by EPA and comment by stakeholders. Accordingly, EPA is proceeding with establishing the tolerance for bifenazate.

III. Emergency Exemption for Bifenazate on Timothy and FFDCA Tolerances

The banks grass mite became a pest of economic significance for timothy growers beginning in 2002 when it was recognized that the pest had developed resistance to the registered alternatives. Based on information submitted by the State, without the use of bifenazate to control banks grass mites, many timothy growers will experience significant economic losses. Dietary risk will be minimal because the bulk of the treated hay will be used as horse feed. EPA has authorized under FIFRA section 18 the use of bifenazate on timothy, hay and timothy, forage for control of banks grass mites in Nevada. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of bifenazate in or on timothy. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although these tolerances will expire and are revoked on December 31, 2007, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on timothy, hay and timothy, forage after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the

residues do not exceed a level that was authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether bifenazate meets EPA's registration requirements for use on timothy or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of bifenazate by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Nevada to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for bifenazate, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of bifenazate and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for time-limited tolerances for the combined residues of bifenazate, (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate) and diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl, 1-methylethyl ester, in or on timothy, hay at 150 ppm and timothy, forage at 50 ppm.

Timothy is a member of the grass, forage, fodder, and hay crop group. No timothy residue data were submitted for this specific emergency exemption request. The proposed use rate of bifenazate for timothy is similar to rates for registered uses. Based on data contained in the Food and Feed Crops of the United States (second edition; forage grass monograph), approximately 3,700 pounds of hay may be produced per acre. Based on the application rate of 0.50 lbs per acre and the expected hay production, a theoretical bifenazate residue of 135 ppm was calculated. Assuming 25% dry matter content for forage and a 80% dry matter content for hay, a theoretical residue of 42 ppm was calculated for timothy, forage. To ensure that the tolerance levels are adequate, the Agency is establishing levels slightly higher than estimated (150 ppm for timothy, hay and 50 ppm for timothy, forage).

Under the emergency exemption, timothy is being grown as a premium feed for race horses. However, it is possible that a fraction of the treated crop may be diverted to cattle (timothy is not a poultry feed crop). Timothy is not consumed by humans, any inadvertent exposure to residues of bifenazate from this emergency exemption will result from the consumption of meat or milk. Currently there are bifenazate tolerances established for residues of bifenazate in or on ruminant meat, meat byproducts, milk and fat. These tolerances are based on conservative assumptions that the entire livestock diet contains tolerance level residues of bifenazate. Therefore, the Agency has concluded that the established ruminant tolerances are sufficient to cover any dietary exposure to bifenazate resulting from the requested timothy use.

Residues of bifenazate in or on timothy are not expected to increase dietary exposure. The use of bifenazate on timothy is not expected to result in exceedances of the tolerances that already exist for meat and milk. Therefore, establishing the timothy tolerances will not increase the most recent estimated aggregate risks resulting from use of bifenazate, as discussed in the February 4, 2004 **Federal Register** (69 FR 5289, FRL–7335–6) Final Rule establishing tolerances for combined residues of bifenazate, (hydrazine carboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl-, 1-methylethyl ester) and diazenecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl-, 1-methylethyl ester in or on potatoes, because in that prior action, risk was estimated assuming all meat and milk products contained tolerance level residues. Refer to the February 4, 2004 **Federal Register** document for a detailed discussion of the aggregate risk assessments and determination of safety. EPA relies upon that risk assessment and the findings made in the **Federal Register** document in support of this action. Below is a brief summary of the aggregate risk assessment.

An endpoint for acute dietary exposure was not identified since no effects were observed that could be attributable to a single dose in oral toxicity studies, including developmental and maternal toxicity in the developmental toxicity studies. Therefore, an acute dietary risk assessment was not conducted.

Using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™) an analysis evaluated the individual food consumption as reported by respondents in the United States Department of Agriculture 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to bifenazate for each commodity. The chronic dietary exposure analysis assumed tolerance level residues and 100% crop treated for all registered and proposed crops excluding tomato where average field trial residues were used. DEEM™ (ver 7.73) default processing factors were assumed for all commodities excluding apple juice, grape juice, wine/sherry, tomato paste, and tomato puree. The processing factors for these commodities were reduced to 0.23, 0.17, 0.17, 5.0, and 5.0, respectively, based on data from processing studies.

Using the exposure assumptions described, EPA concluded that exposure to bifenazate from food will utilize 25% of the cPAD for the U.S. population, 60% of the cPAD for all infants <1 year old, 86% of the cPAD for children 1–2 years old (the most highly exposed population subgroup), and 17% of the cPAD for females 13–49 years old. Based on the use pattern, chronic residential exposure to residues of bifenazate is not expected. However, there is potential for chronic dietary exposure to bifenazate in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 1:

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO BIFENAZATE

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.01	25	6.4	<0.001	260
All Infants (<1 year old)	0.01	60	6.4	<0.001	75
Children (1–2 years old)	0.01	86	6.4	<0.001	14
Females (13–49 years old)	0.01	17	6.4	<0.001	290

Short-term and intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Bifenazate is currently registered for use on the following residential non-dietary sites: Commercial application to ornamental plants (including bedding plants, flowering plants, foliage plants, bulb crops, perennials, trees and shrubs; not turf) and all fruit trees which will not bear fruit for a minimum of 12 months as well as application by residents/homeowners. EPA anticipates only short-term dermal and short-term inhalation exposure from the residential uses. The Agency assumed that residential applications will be made via pump up sprayers, garden hose-end sprayers or similar ''homeowner'' pesticide devices. Exposure from a hose-end sprayer was assessed rather than that of a compressed air sprayer. For the treatment of shrubs and ornamentals, EPA assumed 100 gallons of finish spray are applied per day. The unit exposure value for a residential handler using open pour mixing/loading for a garden hose-end sprayer is 11 milligrams/pound (mg/lb) handled (dermal) and 0.013 mg/lb handled. Exposures were calculated using the Agency's draft Residential Standard Operating Procedures.

Using the exposure assumptions described for short-term exposures, EPA concluded that food and residential exposures aggregated result in aggregate MOEs of 2,000 for the U.S. population, 2,100 for youth 13–19 years old, 2,400 for adults 20–49 years old, 2,200 for females 13–49 years old, and 2,300 for adults 50+ years old. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of bifenazate in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERMEXPOSURE TO BIFENAZATE

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
U.S. population	2,000	100	6.4	<0.001	3,500
Youth, (13–19 years old)	2,100	100	6.4	<0.001	3,000
Adults, (20–49 years old)	2,400	100	6.4	<0.001	3,500
Females, (13–49 year old)	2,200	100	6.4	<0.001	3,000
Adults (50+ years old)	2,300	100	6.4	<0.001	3,500

Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). Residential intermediate-term aggregate exposure (30 days to 6 months) is not expected from use of this chemical. Thus, the intermediate-term risk for the public consists of food and water exposures which were previously addressed.

EPA has classified bifenazate as ''not likely'' to be a human carcinogen. Therefore, a cancer dietary exposure and risk assessment was not performed.

Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to bifenazate residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (example—gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

Canada, Codex, and Mexico do not have maximum residue limits for residues of bifenazate in/on the proposed crop. Therefore, harmonization is not an issue.

VI. Conclusion

Therefore, tolerances are established for the combined residues of bifenazate, (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate) and diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]3-yl, 1-methylethyl ester, in or on timothy, hay at 150 ppm and timothy, forage at 50 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2005–0012 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before March 29, 2005.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by the docket ID number OPP–2005–0012, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Statutory and Executive Order Reviews

This final rule establishes time-limited tolerances under section 408 of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under section 408 of the FFDCA, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not

alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 14, 2005.

Betty Shackleford,

Acting Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—AMENDED

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.572 is amended by alphabetically adding commodities to the table in paragraph (b) to read as follows:

§ 180.572 Bifenazate; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ Revocation Date
* *	* *	*
Timothy, forage	50	12/31/07
Timothy, hay	150	12/31/07
* *	* *	*

* * * * *

[FR Doc. 05–1624 Filed 1–27–05; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 05–36; MB Docket No. 03–181, RM–10758, and RM–11123]

Radio Broadcasting Services; Blanchard, Elmore City, Weatherford and Wynnewood, OK

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Audio Division, at the request of Wright Broadcasting Systems, Inc., licensee of FM Station KWEY, Channel 247C1, Weatherford, Oklahoma, deletes Channel 247C1 at Weatherford, Oklahoma, from the FM Table of Allotments, allots Channel 247A at Blanchard, Oklahoma, as the community's first local FM service, and modifies the license of FM Station KWEY to specify operation on Channel 247A at Blanchard. Channel 247A can be allotted to Blanchard, Oklahoma, in compliance with the Commission's minimum distance separation requirements with a site restriction of 2.1 km (1.3 miles) southwest of Blanchard. The coordinates for Channel 247A at Blanchard, Oklahoma, are 35–07–21 North Latitude and 97–40–18 West Longitude.

DATES: Effective February 25, 2005.

FOR FURTHER INFORMATION CONTACT: Deborah Dupont, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order*, MB Docket No. 03–181, adopted January 5, 2005, and released January 10, 2005. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. The complete text of this decision also may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, (800) 378–3160, or via the company's Web site, *http://www.bcpiweb.com*. The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the General Accountability Office pursuant to the Congressional Review Act, *see* U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

■ Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.202 [Amended]

■ 2. Section 73.202(b), the Table of FM Allotments under Oklahoma, is amended by removing Channel 247C1 at Weatherford and by adding Blanchard, Channel 247A.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 05–1605 Filed 1–27–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 05–44 MB Docket No. 03–231, RM–10818]

Radio Broadcasting Services; Centre Hall, Huntingdon, Mount Union, PA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Audio Division, at the request of Megahertz Licenses, LLC, licensee of FM Stations WXMJ, Channel 258A, Mount Union, Pennsylvania, and WLLY, Channel 292A, Huntingdon, Pennsylvania, deletes Channel 292A at Huntingdon, Pennsylvania, and Channel 258A at Mount Union, Pennsylvania, from the FM Table of Allotments, allots Channel 258A at Centre Hall, Pennsylvania, as the community's first local FM service, allots Channel 292A at Mount Union, Pennsylvania, modifies the license of FM Stations WXMJ to specify operation on Channel 258A at Centre Hall, Pennsylvania, and modifies the License of FM Station WLLY to specify operation Channel 292A at Mount Union. Channel 258A can be allotted to Centre Hall, Pennsylvania, in compliance with the Commission's minimum distance separation requirements without site restriction at center city reference coordinates. The coordinates for Channel 258A at Centre Hall, Pennsylvania, are 40–50–50 North Latitude and 77–51–41 West Longitude. Channel 292A can be allotted to Mount Union, Pennsylvania with a site restriction of 14.5 km (9.0 miles) south of Mount Union. The coordinates for Channel 292A at Mount Union, Pennsylvania, are 40–15–18 North Latitude and 77–51–41 West Longitude. Centre Hall, Mount Union, and Huntingdon, Pennsylvania, all are located within 320 kilometers (199 miles) of the Canadian border, and therefore Canadian concurrence in the allotment changes will be required. Although concurrence has been requested for these allotment changes, notification has not been received. If a construction permit is granted for Centre Hall or Mount Union prior to the receipt of formal concurrence in the corresponding channel allotment by the Canadian government, the construction permit will include the following condition. ''Operation with the facilities specified for [Centre Hall or Mount Union] herein is subject to modification, suspension, or termination without right to hearing, if found by the Commission to be necessary in order to conform to the USA-Canada FM Broadcast Agreement.''

DATES: Effective February 25, 2005.

FOR FURTHER INFORMATION CONTACT: Deborah Dupont, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MB Docket No. 03–231, adopted January 5, 2005, and released January 10, 2005. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. The complete text of this decision also may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, (800) 378–3160, or via the company's Web site, *http://www.bcpiweb.com*. The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the General Accountability Office pursuant to the Congressional Review Act, *see* U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

■ Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.202 [Amended]

■ 1. Section 73.202(b), the Table of FM Allotments under Pennsylvania, is amended by adding Centre Hall, Channel 258A, by removing Channel 292A at Huntingdon, by removing Channel 258A and adding Channel 292A at Mount Union.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 05–1606 Filed 1–27–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 05–34; MB Docket No.04–380; RM–11069]

Radio Broadcasting Services; Corydon and Lanesville, IN

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In response to a *Notice of Proposed Rule Making,* 69 FR 60604 (October 12, 2004), this document reallots Channel 243A from Corydon, Indiana, to Lanesville, Indiana, and modifies the license of Station WGZB–FM accordingly. The coordinates for Channel 243A at Lanesville are 38–12–52 North Latitude and 86–01–00 West Longitude, with a site restriction of 3.68 kilometers (2.29 miles) southwest of the community.

DATES: Effective February 25, 2005.

FOR FURTHER INFORMATION CONTACT: Helen McLean, Media Bureau, (202) 418–2738.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order,* MB Docket No. 04–380, adopted January 5, 2005, and released January 10, 2005. The full text of this Commission decision is available for inspection and copying during regular business hours at the FCC's Reference Information Center, Portals II, 445 Twelfth Street, SW., Room CY–A257, Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–378–3160 or *http://www.BCPIWEB.com.* The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the General Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

■ Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1.The authority citation for part 73 reads as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.202 [Amended]

■ 2. Section 73.202(b), the Table of FM Allotments under Indiana, is amended

by removing Channel 243A at Corydon, and by adding Lanesville, Channel 243A.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 05–1604 Filed 1–27–05; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 001005281–0369–02; I.D. 012105A]

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic; Trip Limit Increase

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Inseason action; trip limit increase.

SUMMARY: NMFS increases the trip limit in the commercial hook-and-line fishery for king mackerel in the Florida east coast subzone from 50 to 75 fish per day in or from the exclusive economic zone (EEZ). This trip limit increase is necessary to maximize the socioeconomic benefits of the quota.

DATES: This rule is effective 12:01 a.m., local time, February 1, 2005, through March 31, 2005.

FOR FURTHER INFORMATION CONTACT: Steve Branstetter, telephone: 727–570–5305, fax: 727–570–5583, e-mail: *Steve.Branstetter@noaa.gov*.

SUPPLEMENTARY INFORMATION: The fishery for coastal migratory pelagic fish (king mackerel, Spanish mackerel, cero, cobia, little tunny, and, in the Gulf of Mexico only, dolphin and bluefish) is managed under the Fishery Management Plan for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic (FMP). The FMP was prepared by the Gulf of Mexico and South Atlantic Fishery Management Councils (Councils) and is implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

Based on the Councils' recommended total allowable catch and the allocation ratios in the FMP, on April 30, 2001 (66 FR 17368, March 30, 2001) NMFS implemented a commercial quota of 2.25 million lb (1.02 million kg) for the eastern zone (Florida) of the Gulf migratory group of king mackerel. That quota is further divided into separate quotas for the Florida east coast subzone and the northern and southern Florida west coast subzones. The quota implemented for the Florida east coast subzone is 1,040,625 lb (472,020 kg) (50 CFR 622.42(c)(1)(i)(A)(*1*)).

In accordance with 50 CFR 622.44(a)(2)(i), beginning on February 1, if less than 75 percent of the Florida east coast subzone's quota has been harvested by that date, king mackerel in or from that subzone's EEZ may be possessed on board or landed from a permitted vessel in amounts not exceeding 75 fish per day. The 75–fish daily trip limit will continue until a closure of the subzone's fishery has been affected or the fishing year ends on March 31, 2005.

NMFS has determined that 75 percent of the quota for Gulf group king mackerel for vessels using hook-and-line gear in the Florida east coast subzone was not reached before February 1, 2005. Accordingly, a 75–fish trip limit applies to vessels in the commercial hook-and-line fishery for king mackerel in or from the EEZ in the Florida east coast subzone effective 12:01 a.m., local time, February 1, 2005. The 75–fish trip limit will remain in effect until the fishery closes or until the end of the current fishing season (March 31, 2005) for this subzone. From November 1 through March 31, the Florida east coast subzone of the Gulf group king mackerel is that part of the eastern zone north of 25°20.4′ N. lat. (a line directly east from the Miami-Dade County, FL, boundary).

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, (AA) finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth in 5 U.S.C. 553(b)(B), as such prior notice and opportunity for public comment is unnecessary and contrary to the public interest. Such procedures are unnecessary because the rule itself already has been subject to notice and comment, and all that remains is to notify the public of the trip limit increase. Allowing prior notice and opportunity for public comment is contrary to the public interest because it requires time, thus delaying fishermen's ability to catch more king mackerel than the present trip limit allows and preventing fishermen from reaping the socioeconomic benefits derived from this increase in daily catch.

As this actions allows fishermen to increase their harvest of king mackerel from 50 fish to 75 fish per day in or from the EEZ of the Florida east coast subzone, the AA finds it relieves a restriction and may go into effect on its effective date pursuant to 5 U.S.C. 553(d)(1). This action is taken under 50 CFR 622.43(a) and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: January 24, 2005.

Alan D. Risenhoover,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 05–1610 Filed 1–25–05; 3:08 pm]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 041202339–4339–01; I.D. 012405C]

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Vessels Catching Pacific Cod for Processing by the Inshore Component in the Central Regulatory Area of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by vessels catching Pacific cod for processing by the inshore component in the Central Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the 2005 interim total allowable catch (TAC) of Pacific cod apportioned to vessels catching Pacific cod for processing by the inshore component of the Central Regulatory Area of the GOA.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), January 26, 2005, until superseded by the notice of 2005 and 2006 final harvest specifications of groundfish of the GOA, which will be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone

according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2005 interim TAC of Pacific cod apportioned to vessels catching Pacific cod for processing by the inshore component of the Central Regulatory Area of the GOA is 13,733 metric tons (mt), as established by the 2005 interim harvest specifications for groundfish of the GOA (69 FR 74455, December 14, 2004).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2005 interim TAC of Pacific cod apportioned to vessels catching Pacific cod for processing by the inshore component of the Central Regulatory Area of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 12,733 mt, and is setting aside the remaining 1,000 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by vessels catching Pacific cod for processing by the inshore component in the Central Regulatory Area of the GOA.

After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of Pacific cod apportioned to vessels catching Pacific cod for processing by the inshore component of the Central Regulatory Area of the GOA.

The AA also finds good cause to waive the 30 day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: January 25, 2005.

Alan D. Risenhoover,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 05–1611 Filed 1–25–05; 3:08 pm]

BILLING CODE 3510–22–S

Proposed Rules

Federal Register
Vol. 70, No. 18
Friday, January 28, 2005

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 916 and 917

[Docket No. AO–90–A7; FV05–916–1]

Nectarines and Peaches Grown in California; Hearing on Proposed Amendment of Marketing Agreement Nos. 124 and 85 and Order Nos. 916 and 917

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice of hearing on proposed rulemaking.

SUMMARY: Notice is hereby given of a public hearing to receive evidence on proposed amendments to Marketing Agreement Nos. 124 and 85 and Orders Nos. 916 and 917, which regulate the handling of nectarines and peaches grown in California. The amendments are jointly proposed by the Nectarine Administrative Committee (NAC), the Peach Commodity Committee, and the Control Committee (part of M.O. No. 917) (committees), which are responsible for local administration of orders 916 and 917. The proposed amendments to order 917 only apply to peaches. The pear provisions of the order have been suspended since 1994. Because the Pear Commodity Committee and the pear provisions are suspended, the Pear Commodity Committee did not participate in any amendment discussions. The amendments would: update definitions and districts in both orders; increase committee membership of the NAC from eight to thirteen members and modify sections of the order to conform to the increased membership; eliminate the Shippers Advisory Committee (M.O. No. 916); allow the Control Committee under M.O. No. 917 to be suspended if the provisions of one commodity are suspended and transfer applicable duties and responsibilities to the remaining commodity committee; authorize interest and late payment charges on assessments paid late; add authority to recommend different quality and size regulations for different market destinations; and other related amendments. All of the proposals are intended to streamline industry organization and improve the administration, operation, and functioning of the programs.

DATES: The hearing will be held on February 15, 2005, in Fresno, California, beginning at 8:30 a.m. and ending at 4:30 p.m. The hearing will continue, if necessary, on February 16, 2005, commencing at 8:30 a.m.

ADDRESSES: The hearing location is: Fresno Metropolitan Flood Control District, 5469 East Olive Avenue, Fresno, CA 93727, telephone: (559) 456–3292.

FOR FURTHER INFORMATION CONTACT: Melissa Schmaedick, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, P.O. Box 1035, Moab, Utah; telephone: (435) 259–7988, Fax: (435) 259–4945; or Kathleen M. Finn, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue SW., Stop 0237, Washington, DC 20250–0237; telephone: (202) 720–2491, fax (202) 720–8938.

Small businesses may request information on this proceeding by contacting Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue SW., Stop 0237, Washington, DC 20250–0237; telephone: (202) 720–2491, fax: (202) 720–8938.

SUPPLEMENTARY INFORMATION: This administrative action is instituted pursuant to the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' This action is governed by the provisions of sections 556 and 557 of title 5 of the United States Code and, therefore, is excluded from the requirements of Executive Order 12866.

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) seeks to ensure that within the statutory authority of a program, the regulatory and informational requirements are tailored to the size and nature of small businesses. Interested persons are invited to present evidence at the hearing on the possible regulatory and informational impacts of the proposals on small businesses.

The amendments proposed herein have been reviewed under Executive Order 12988, Civil Justice Reform. They are not intended to have retroactive effect. If adopted, the proposed amendments would not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with the proposals.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review the USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

The hearing is called pursuant to the provisions of the Act and the applicable rules of practice and procedure governing the formulation of marketing agreements and orders (7 CFR part 900).

The proposed recommendations are the result of a task force appointed by the committees to conduct a review of the orders. The task force met several times in 2003 and drafted proposed amendments to the orders and presented the recommendations at industry meetings. The recommendations were then forwarded to the commodity committees and the Control Committee, each of which unanimously approved the proposed amendments. The amendments are intended to streamline organization and administration of the committees.

The Committees' request for a hearing was submitted to USDA on January 5, 2004. The hearing is called pursuant to the provisions of the Act and the applicable rules of practice and procedure governing the formulation of marketing agreements and orders (7 CFR part 900).

The Committees' proposed amendments to Marketing Orders Nos. 916 and 917 (orders) are summarized

below. Modifications from what was proposed by the committees on marketing order No. 917 have been made to some of the proposals. These modifications were made to provide clarity that no amendments are being proposed to the suspended pear provisions.

1a. Amend the order to allow hybrid fruit that exhibits the characteristics of nectarines and is subject to cultural practices common to nectarines be subject to marketing order regulations. This proposal would amend § 916.5.

1b. Amend the order to allow hybrid fruit that exhibits the characteristics of peaches and is subject to cultural practices common to peaches to be subject to marketing order regulations. This proposal would amend § 917.4.

2a. Amend the order by specifying that the act of packing nectarines is considered a handling function and clarifying that the word ''packer'' is synonymous with ''handler'' and ''shipper.'' This proposal would amend §§ 916.10, 916.11.

2b. Amend the order by specifying that the act of packing peaches is considered a handling function and clarifying that, for peaches, the word ''packer'' is synonymous with ''handler'' and ''shipper.'' This proposal would amend §§ 917.6 and 917.7.

3. Amend the nectarine order by changing the marketing season from May 1 through November 30 to April 1 through November 30. This proposal would amend § 916.15.

4. Amend the provisions relating to the Control Committee under marketing order No. 917 by allowing the duties and responsibilities of the Control Committee to be transferred to one commodity committee if the provisions of the other commodity committee are suspended. This proposal would amend § 917.18.

5a. Amend the nectarine order by increasing membership from eight members to thirteen members and revising the procedures that constitute quorum and voting requirements to conform to the increased committee. The proposal would also add that the committee may vote by facsimile and would specify that voting requirements for video conferencing would be the same as those for assembled meetings. This proposal would amend §§ 916.20 and 916.32.

5b. Amend the peach order by adding that the Peach Commodity Committee may vote by facsimile or video teleconference. This proposal would amend § 917.29(d).

6. Amend the nectarine order by eliminating the Shippers' Advisory Committee. This proposal would remove § 916.37.

7a. Amend the nectarine order by modifying the definition of grower to clarify that officers of corporations are considered growers for purposes of eligibility for membership on the committee. This proposal would amend § 916.9.

7b. Amend the order by modifying the definition of grower to clarify that, for peaches, officers of corporations are considered growers for purposes of eligibility for membership on the committees. This proposal would amend § 917.5.

8a. Amend the order by adding a definition of ''pure producer'' and ''pure grower'' for purposes of eligibility for membership on the committee. This proposal would add a new § 916.16.

8b. Amend the order by adding a definition for peaches of ''pure producer'' and ''pure grower'' for purposes of eligibility for membership on the committee. This proposal would add a new § 917.5a.

8c. Amend the nectarine order by allowing alternative methods to conduct nominations, changing the date that the nomination procedure should be held from February 15 to January 31, requiring at least 50 percent of the positions be pure producers and adding tenure requirements for committee members. This proposal would amend §§ 916.20 and 916.22.

8d. Amend the peach provisions of the order by allowing alternative methods to conduct nominations, changing the date that the nomination procedure should be held from February 15 to January 31, requiring at least 50 percent of the positions be pure producers, and adding tenure requirements for committee members. This proposal would amend § 917.24.

9a. Amend the order by authorizing the nominees to state their willingness to serve on the committee prior to the selection. This proposal would amend § 916.25.

9b. Amend the order by authorizing the peach nominees to state their willingness to serve on the committees prior to the selection. This proposal would amend § 917.25.

10a. Amend the order by changing the district boundaries under the nectarine order. This proposal would amend § 916.12.

10b. Amend the order by redefining the peach growing Fresno and Tulare districts under the order. This proposal would amend § 917.14.

11. Amend the order by changing the names and the composition of the districts of the Peach Commodity Committee. This proposal would amend § 917.22.

12a. Amend the order to allow for interest and/or late payments for assessments not paid timely. This proposal would amend § 916.41.

12b. Amend the order to allow for interest and/or late payments for peach assessments not paid timely and to authorize the committee to borrow money for administration of peach provisions of the order. This proposal would amend § 917.37.

13a. Amend the order to provide authority to recommend different regulations for different market destinations of the product. This proposal would amend § 916.52.

13b. Amend the order to provide authority to recommend different regulations for different market destinations of peaches. This proposal would amend § 917.41.

14. Amend the order to clarify that subcommittees may be established by the Peach Commodity Committee. This proposal would amend § 917.35.

15. Make such changes as may be necessary to the order to conform with any amendment thereto that may result from the hearing.

The committees work with USDA in administering the orders. These proposals have not received the approval of the Department. The Nectarine Administrative Committee, the Peach Commodity Committee, and the Control Committee believe that the proposed changes would improve the administration, operation, and functioning of the programs in effect for nectarines and peaches grown in California.

AMS also proposes to allow such changes to the order as may be necessary to conform to any amendment that may result from the hearing.

The public hearing is held for the purpose of: (i) Receiving evidence about the economic and marketing conditions which relate to the proposed amendments of the order; (ii) determining whether there is a need for the proposed amendments to the order; and (iii) determining whether the proposed amendments or appropriate modifications thereof will tend to effectuate the declared policy of the Act.

Testimony is invited at the hearing on all the proposals and recommendations contained in this notice, as well as any appropriate modifications or alternatives.

All persons wishing to submit written material as evidence at the hearing should be prepared to submit four copies of such material at the hearing and should have prepared testimony available for presentation at the hearing.

From the time the notice of hearing is issued and until the issuance of a final decision in this proceeding, USDA employees involved in the decisional process are prohibited from discussing the merits of the hearing issues on an *ex parte* basis with any person having an interest in the proceeding. The prohibition applies to employees in the following organizational units: Office of the Secretary of Agriculture; Office of the Administrator, AMS; Office of the General Counsel, except any designated employee of the General Counsel assigned to represent the Committee in this proceeding; and the Fruit and Vegetable Programs, AMS.

Procedural matters are not subject to the above prohibition and may be discussed at any time.

List of Subjects

7 CFR Part 916

Marketing agreements, Nectarines, Reporting and recordkeeping requirements.

7 CFR Part 917

Marketing Agreements, Peaches, Pears, Reporting and recordkeeping requirements.

PART 916—NECTARINES GROWN IN CALIFORNIA

PART 917—FRESH PEARS AND PEACHES GROWN IN CALIFORNIA

1. The authority citation for 7 CFR parts 916 and 917 continues to read as follows:

Authority: 7 U.S.C. 601–674.

2. Testimony is invited on the following proposals or appropriate alternatives or modifications to such proposals.

Proposals submitted by the Nectarine Administrative Committee, the Peach Commodity Committee, and the Control Committee are as follows:

Proposal Number 1a

3. Revise § 916.5 to read as follows:

§ 916.5 Nectarines.

Nectarines means:

(a) All varieties of nectarines grown in the production area; and

(b) Hybrids grown in the production area that exhibit the characteristics of a nectarine and are subject to cultural practices common to nectarines, as recommended by the committee and approved by the Secretary.

Proposal Number 1b

4. Revise § 917.4 to read as follows:

§ 917.4 Fruit.

Fruit means the edible product of the following kinds of trees:

(a) All varieties of peaches grown in the production area;

(b) All hybrids grown in the production area exhibiting the characteristics of a peach and subject to cultural practices common to peaches as recommended by the committee and approved by the Secretary; and

(c) All varieties of pears except Beurre Hardy, Beurre D'Anjou, Bosc, Winter Nelis, Doyenne du Comice, Beurre Easter, and Beurre Clairgeau.

Proposal Number 2a

5. Revise § 916.10 to read as follows:

§ 916.10 Handler.

Handler, shipper and *packer* are synonymous and mean any person (except a common or contract carrier transporting nectarines owned by another person) who handles nectarines.

6. Revise § 916.11 to read as follows:

§ 916.11 Handle.

Handle, ship and *pack* are synonymous and mean to place nectarines into containers, sell, consign, deliver, or transport nectarines, or to cause nectarines to be placed into containers, sold, consigned, delivered, or transported, between the production area and any point outside thereof, or within the production area: *Provided,* That the term *handle* shall not include the sale of nectarines on the tree, the transportation within the production area of nectarines from the orchard where grown to a packing facility located within such area for preparation for market, or the delivery of such nectarines to such packing facility for such preparation.

Proposal Number 2b

7. Revise § 917.6 to read as follows:

§ 917.6 Handle.

Handle and *ship* are synonymous and mean to place fruit into containers, sell, consign, deliver or transport fruit or to cause fruit to be placed into containers, sold, consigned, delivered or transported between the production area and any point outside thereof, or within the production area: *Provided,* That the term *handle* shall not include the sale of fruit on the tree, the transportation within the production area of fruit from the orchard where grown to a packing facility located within such area for preparation for market, or the delivery of such fruit to such packing facility for such preparation. For peaches, the term ''pack'' is also synonymous with ''handle'' and ''ship.''

8. Revise § 917.7 to read as follows:

§ 917.7 Handler.

Handler and *shipper* are synonymous and mean any person (except a common or contract carrier transporting fruit owned by another person) who handles fruit. For peaches, the term ''packer'' is also synonymous with the terms ''handler'' and ''shipper.''

Proposal Number 3

9. Revise § 916.15 to read as follows:

§ 916.15 Marketing season.

Marketing season means the period beginning on April 1 and ending on November 30 of any year.

Proposal Number 4

10. Revise § 917.18 to read as follows:

§ 917.18 Nomination of commodity committee members of the Control Committee.

Nominations for the 13 members of the Control Committee to represent the commodity committees shall be made in the following manner:

(a) A nomination for one member shall be made by each commodity committee selected pursuant to § 917.25. Nominations for the remaining members shall be made by the respective commodity committees as provided in this section. The number of remaining members which each respective commodity shall be entitled to nominate shall be based upon the proportion that the previous three fiscal periods' shipments of the respective fruit is of the total shipments of all fruit to which this part is applicable during such periods. In the event provisions of this part are terminated as to any fruit, the members of the commodity committee of the remaining fruit shall have all of the powers, duties, and functions given to the Control Committee under this part and sections of this part pertaining to the designation of the Control Committee shall be terminated. In the event provisions of this part are suspended as to any fruit, the members of the commodity committee of the remaining fruit shall have all the powers, duties, and functions given to the Control Committee under this part and sections of this part pertaining to the designation of the Control Committee shall be suspended.

(b) A person nominated by any commodity committee for membership on the Control Committee shall be an individual person who is a member or alternate member of the commodity committee which nominates him/her. Each member of each commodity committee shall have only one vote in

the selection of nominees for membership on the Control Committee.

Proposal Number 5a

11. Revise § 916.20 to read as follows:

§ 916.20 Establishment and membership.

There is hereby established a Nectarine Administrative Committee consisting of thirteen members, each of whom shall have an alternate who shall have the same qualifications as the member for whom he/she is an alternate. The members and their alternates shall be growers or authorized employees of growers. Six of the members and their respective alternates shall be producers of nectarines in District 1. Four members and their respective alternates shall be producers of nectarines in District 2; two of the members and their respective alternates shall be producers of nectarines in District 3; and one member and his/her alternate shall be producers of nectarines in District 4.

12. Revise § 916.32 to read as follows:

§ 916.32 Procedure.

(a) Nine members of the committee, or alternates acting for members, shall constitute a quorum and any action of the committee shall require the concurring vote of the majority of those present: *Provided, That* actions of the committee with respect to expenses and assessments, or recommendations for regulations pursuant to §§ 916.50 to 916.55, shall require at least nine concurring votes.

(b) The committee may vote by telephone, telegraph, or other means of communication, such as facsimile, and any votes so cast shall be confirmed promptly in writing: *Provided, That* if an assembled meeting is held, all votes shall be cast in person. A videoconference shall be considered an assembled meeting and all votes shall be considered as cast in person.

Proposal Number 5b

13. Revise paragraph (d) of § 917.29 to read as follows:

§ 917.29 Organization of Committees.

* * *

(d) The Control Committee or any commodity committee may, upon due notice to all of the members of the respective committee, vote by letter, telegraph or telephone: *Provided,* That any member voting by telephone shall promptly thereafter confirm in writing his/her vote so cast. The Peach Commodity Committee may, upon due notice to all of the members of the respective committee, vote by letter, telegraph, telephone, facsimile, or video teleconference; *Provided,* That any member voting by telephone shall promptly thereafter confirm in writing his/her vote so cast.

Proposal Number 6

14. Remove § 916.37.

§ 916.37 Shippers' Advisory Committee.

(a) A Shippers' Advisory Committee, consisting of five members and their respective alternates who shall be handlers, or employees of handlers, selected by the handlers in accordance with the provisions of this section, is hereby established. The members and their respective alternates shall be selected biennially for a term ending on the last day of February of odd numbered years. An alternate member shall, in the event of the member's absence from a meeting of the committee, act in the place and stead of such member, and, in the event of a vacancy in the office of such member, shall act in the place and stead of such member until a successor for the unexpired term of such member has been selected.

(b) The members and alternate members of the Shippers' Advisory Committee shall be elected by handlers at a general meeting of all handlers and shall serve in such capacities during the marketing seasons subsequent to such election. Such meeting shall be supervised by the Nectarine Administrative Committee which may prescribe such rules and procedures as may be necessary to assure a membership representative of all shippers.

(c) The Shippers' Advisory Committee may attend each meeting of the Nectarine Administrative Committee held to consider recommendations with respect to regulations of shipments pursuant to the provisions of this subpart. The Shippers' Advisory Committee may advise the committee on matters relating to such recommendations, but shall have no vote with such committee in any matter. Members of the Shippers' Advisory Committee shall serve without compensation but may be reimbursed for expenses necessarily incurred in attendance of meetings of the Nectarine Administrative Committee.

Proposal Number 7a

15. Revise § 916.9 to read as follows:

§ 916.9 Grower.

Grower is synonymous with *producer* and means any person who produces nectarines for the fresh market and who has a proprietary interest therein. Officers of corporations actively engaged in growing nectarines are considered to be growers.

Proposal Number 7b

16. Revise § 917.5 to read as follows:

§ 917.5 Grower.

Grower is synonymous with *producer* and means any person who produces fruit for market in fresh form, and who has a proprietary interest therein. Officers of corporations actively engaged in growing peaches are considered to be growers.

Proposal Number 8a

17. Revise § 916.16 to read as follows:

§ 916.16 Pure Grower or Pure Producer.

Pure grower means the grower is not an employee or officer of a packing business; or if he/she is an officer or employee of a packing business, that specific packing business packs 75% or more of its nectarines from said grower. A *pure producer* is synonymous with *pure grower.*

Proposal Number 8b

18. Add a new § 917.5a to read as follows:

§ 917.5a Pure Grower or Pure Producer.

For peaches, *pure grower* means the grower is not an employee or officer of a packing business; or if he/she is an officer or employee of a packing business, that specific packing business packs 75% or more of its fruit from said grower. A *pure producer* is synonymous with *pure grower.*

Proposal Number 8c

19. Remove the period after the phrase ''District 4'' in the proposed amendment of § 916.20 (Proposal Number 5), add a colon and the following:

§ 916.20 Establishment and membership.

* * * *Provided, That* at least 50% of the nominees from each presentation area shall be pure producers. Furthermore, no person shall serve more than three consecutive two-year terms of office or a total of six consecutive years; *Provided, That* an appointment to fill less than a two year term of office, or serving one term as an alternate, shall not be included in determining the three consecutive terms of office.

20. Revise paragraph (b) of § 916.22 to read as follows:

§ 916.22 Nominations.

* * *

(b) *Successor members.* (1) The committee shall appoint a nominating committee, which will hold or cause to be held, not later than January 31 of

each odd numbered year, a nomination procedure or a meeting or meetings of growers in each district for the purpose of designating nominees for successor members and alternate members of the committee. Meetings may be supervised by the nominating committee that shall prescribe such procedure as shall be reasonable and fair to all persons concerned. After the nomination procedure or meetings have concluded, the nominating committee by February 15 will verify consent to place the nominee's name on the ballot and will cause a ballot listing all of the nominees for a given district to be mailed to all growers within the district. Members and then alternates will be chosen based on a descending ranking of votes received. Once ballots have been tabulated, the Nectarine Administrative Committee will announce to the growers the nominees that have been selected and recommended to the Secretary.

(2) Nominations may only be by growers, or by duly authorized employees. At meetings only growers, who are present at such nomination meetings may participate in the nomination of nominees for members and their alternates. All known growers will then receive a ballot for the nominees in the district in which they produce and are entitled to vote accordingly. A grower who produces in multiple districts is allowed to vote only in one district, and may exchange his/her ballot for the nominees in another district provided the grower is producing in the district for which he/she wants to participate. Employees of such grower shall be eligible for membership as principal or alternate to fill only one position on the committee.

(3) A particular grower, including authorized employees of such grower, shall be eligible for membership as principal or alternate to fill only one position on the committee.

Proposal Number 8d

21. Revise § 917.24 to read as follows:

§ 917.24 Procedure for nominating members of various commodity committees.

(a) The Control Committee shall hold or cause to be held not later than January 31 for peaches and not later than February 15 for pears of each odd numbered year a nomination procedure or a meeting or meetings of the growers of the fruits in each representation area set forth in §§ 917.21 and 917.22 for purposes of designating nominees for successor members and alternate members of the commodity committees. These meetings shall be supervised by the Control Committee, which shall prescribe such procedure as shall be reasonable and fair to all persons concerned.

(b) With respect to each commodity committee only growers of the particular fruit who are present at such nomination meetings or represented at such meetings by duly authorized employees may participate in the nomination and election of nominees for commodity committee members and alternates. For peaches, those who may receive nomination forms if the nominations are conducted via a mail process may also participate in the nomination and election of nominees for Peach Commodity Committee members and alternates. All peach growers, or authorized employees, will receive a ballot for the nominees in the district in which they produce and are entitled to vote accordingly. A peach grower who produces in multiple districts is allowed to vote only in one district, and may exchange his/her ballot for the nominees in another district provided the grower is producing in the district for which he/she wants to participate. For both commodity committees, each such grower, including employees of such grower, shall be entitled to cast but one vote for each position to be filled for the representation area in which he/she produces such fruit.

(c) A particular grower, including employees of such growers, shall be eligible for membership as principle or alternate to fill only one position on a commodity committee. A grower nominated for membership on the Pear Commodity Committee must have produced at least 51 percent of the pears shipped by him/her during the previous fiscal period, or he/she must represent an organization that produced at least 51 percent of the pears shipped by it during such period. The members and alternates of the Peach Commodity Committee shall be growers, or shall be authorized employees of such growers and at least 50% of the nominees from each representation area shall be pure producers.

(d) For peaches, no person shall serve more than three (3) consecutive two-year terms of office or a total of six (6) consecutive years; *Provided, That* an appointment to fill less than a two year term of office, or serving one (1) term as an alternate, shall not be included in determining the three (3) consecutive terms of office. The members shall serve until their respective successors are selected and have qualified.

Proposal Number 9a

22. Revise § 916.25 to read as follows:

§ 916.25 Acceptance.

Each person to be selected by the Secretary as a member or as an alternate member of the committee shall, prior to such selection, qualify by advising the Secretary that he/she agrees to serve in the position for which nominated for selection.

Proposal Number 9b

23. Revise § 917.25 to read as follows:

§ 917.25 Acceptance.

(a) The Secretary shall select the members of each commodity committee, except for the Peach Commodity Committee, from nominations made by growers, as provided in §§ 917.21 through 917.24, or from among other eligible persons. Any person selected as a member of the Pear Commodity Committee shall qualify by filing with the Secretary a written acceptance of the appointment.

(b) For the Peach Commodity Committee, each person to be selected by the Secretary as a member or as an alternate member of the committee shall, prior to such selection, qualify by advising the Secretary that he/she agrees to serve in the position for which nominated for selection.

Proposal Number 10a

24. Revise paragraphs (a) and (b) of § 916.12 to read as follows:

§ 916.12 District.

* * *

(a) *District 1* shall include the counties of Madera and Fresno.

(b) *District 2* shall include the counties of Kings and Tulare.

* * * * *

Proposal Number 10b

25. Revise paragraphs (n) and (o) of § 917.14 to read as follows:

§ 917.14 District.

* * *

(n) *Fresno District* includes and consists of Madera County, Fresno County, and Mono County.

(o) *Tulare District* includes and consists of Tulare County and Kings County.

* * * * *

Proposal Number 11

26. Revise § 917.22 to read as follows:

§ 917.22 Nomination of Peach Commodity Committee members.

Nominations for membership on the Peach Commodity Committee shall be made by growers of peaches in the respective representation areas, as follows:

(a) *District 1* composed of the Fresno District: seven nominees.

(b) *District 2* composed of the Tulare District: three nominees.

(c) *District 3* composed of the Tehachapi District and Kern District: one nominee.

(d) *District 4* composed of the Stanislaus District, Stockton District and all of the production area not included in paragraphs (a) through (d) of this section: one nominee.

(e) *District 5* composed of the South Coast District and Southern California District: one nominee.

Proposal Number 12a

27. Revise § 916.41 to read as follows:

§ 916.41 Assessments.

(a) As his/her pro rata share of the expenses which the Secretary finds are reasonable and likely to be incurred by the committee during a fiscal period, each person who first handles nectarines during such period shall pay to the committee, upon demand, assessments on all nectarines so handled. The payment of assessments for the maintenance and functioning of the committee may be required under this part throughout the period it is in effect irrespective of whether particular provisions thereof are suspended or become inoperative.

(b) The Secretary shall fix the rate of assessment to be paid by each such person during a fiscal period in an amount designed to secure sufficient funds to cover the expenses which may be incurred during such period and to accumulate and maintain a reserve fund equal to approximately one fiscal period's expenses. At any time during or after the fiscal period, the Secretary may increase the rate of assessment in order to secure sufficient funds to cover any later finding by the Secretary relative to the expenses that may be incurred. Such increase shall be applied to all nectarines handled during the applicable fiscal period. In order to provide funds for the administration of the provisions of this part during the first part of a fiscal period before sufficient operating income is available from assessments on the current year's shipments, the committee may accept the payment of assessments in advance, and may also borrow money for such purposes. Furthermore, any assessment not paid by a handler within a period of time prescribed by the committee may be subject to an interest or late payment charge, or both. The period of time, rate of interest and late payment charge shall be as recommended by the committee and approved by the Secretary. Subsequent to such approval, all assessments not paid within the prescribed period of time shall be subject to an interest or late payment charge or both.

Proposal Number 12b

28. Revise § 917.37 to read as follows:

§ 917.37 Assessments.

(a) As his/her pro rata share of the expenses which the Secretary finds are reasonable and are likely to be incurred by the commodity committees during a fiscal period, each handler shall pay to the Control Committee, upon demand, assessments on all fruit handled by him/her. The payment of assessments for the maintenance and functioning of the committees may be required under this part throughout the period it is in effect irrespective of whether particular provisions thereof are suspended or become inoperative.

(b) The Secretary shall fix the respective rate of assessment which handlers shall pay with respect to each fruit during each fiscal period in an amount designed to secure sufficient funds to cover the respective expenses which may be incurred during such period. At any time during or after the fiscal period, the Secretary may increase the rates of assessment in order to secure funds to cover any later findings by the Secretary relative to such expenses, and such increase shall apply to all fruit shipped during the fiscal period. Furthermore, any assessment not paid by a peach handler within a period of time prescribed by the Control Committee may be subject to an interest or late payment charge, or both. The period of time, rate of interest and late payment charge shall be as recommended by the committee and approved by the Secretary. Subsequent to such approval, all assessments for peaches not paid within the prescribed period of time shall be subject to an interest or late payment charge or both.

(c) In order to provide funds to carry out the functions of the commodity committee prior to commencement of shipments in any season, shippers may make advance payments of assessments, which advance payments shall be credited to such shippers and the assessments of such shippers shall be adjusted so that such assessments are based upon the quantity of fruit shipped by such shippers during such season. Any shipper who ships fruit for the account of a grower may deduct, from the account of sale covering such shipment or shipments, the amount of assessments levied on said fruit shipped for the account of such grower. The Control Committee may also borrow money for such purposes for peaches.

Proposal Number 13a

29. Revise § 916.52 to read as follows:

§ 916.52 Issuance of regulations.

(a) The Secretary shall regulate, in the manner specified in this section, the handling of nectarines whenever he/she finds, from the recommendations and information submitted by the committee, or from other available information, that such regulations will tend to effectuate the declared policy of the act. Such regulations may:

(1) Limit, during any period or periods and/or by specific market destination, the shipment of any particular grade, size, quality, maturity, or pack, or any combination thereof, of any variety or varieties of nectarines grown in the production area;

(2) Limit the shipment of nectarines by establishing, in terms of grades, sizes, or both, minimum standards of quality and maturity during any period when season average prices are expected to exceed the parity level;

(3) Fix the size, capacity, weight, dimensions, markings, or pack of the container, or containers, which may be used in the packaging or handling of nectarines.

(b) The committee shall be informed immediately of any such regulation issued by the Secretary and the committee shall promptly give notice thereof to handlers.

Proposal Number 13b

30. Revise § 917.41 to read as follows:

§ 917.41 Issuance of regulations.

(a) The Secretary shall regulate, in the manner specified in this section, the handling of any variety or varieties of fruit whenever he/she finds, from the recommendations and information submitted by the commodity committee, or from other available information, that such regulations will tend to effectuate the declared policy of the act. Such regulations may:

(1) Limit, during any period or periods and/or for peaches only, by specific market destination, the total quantity of any grade, size, quality, maturity, or pack, or any combination thereof, of any variety or varieties of fruit;

(2) Limit the shipment of any variety or varieties of fruit by establishing, in terms of grades, sizes, or both, minimum standards of quality and maturity during any period when season average prices are expected to exceed the parity level;

(3) Fix the size, capacity, weight, dimensions, markings, or pack of the container, or containers, which may be used in the packaging or handling of any fruit.

(b) The commodity committee shall be informed immediately of any such regulation issued by the Secretary, and the commodity committee shall promptly give notice thereof to handlers.

Proposal Number 14

31. Add a sentence at the end of paragraph (d) of § 917.35 to read as follows:

§ 917.35 Powers and duties of each commodity committee.

* * * * *

(d) * * * To establish subcommittees to aid the Peach Commodity Committee in the performance of its duties under this part as may be deemed advisable.

* * * * *

Proposal Number 15

Make such changes as may be necessary to the order to conform with any amendment thereto that may result from the hearing.

Dated: January 25, 2005.

Kenneth Clayton,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 05–1614 Filed 1–27–05; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Ch. III

[Docket No. 04–040N]

Regulatory Flexibility Act; Amended Plan for Reviewing Regulations Under Section 610 Requirements

AGENCY: Food Safety and Inspection Service (FSIS), USDA.

ACTION: Schedule of regulations to be reviewed under section 610 requirements of the Regulatory Flexibility Act; amended.

SUMMARY: The Food Safety and Inspection Service (FSIS) is publishing an amended scheduling plan for reviewing regulations under Section 610 of the Regulatory Flexibility Act, as amended. These provisions require that all Federal agencies review existing regulations that have a significant economic impact on a substantial number of small entities to determine whether the associated impact can be minimized.

FOR FURTHER INFORMATION CONTACT: For further information contact Dr. Quita Bowman Blackwell, Director, Directives and Economic Analysis Staff, FSIS, U.S. Department of Agriculture, 300 12th Street, SW, Room 112, Washington, DC 20250–3700, (202) 720–5627.

SUPPLEMENTARY INFORMATION:

Background

Section 610 of the Regulatory Flexibility Act (RFA), as amended (5 U.S.C. 601–612), requires that all Federal agencies review any regulations that have been identified as having a significant economic impact upon a substantial number of small entities as a means to determine whether the associated impact can be minimized by considering the following factors: (1) The continued need for the rule; (2) the nature of the complaints or comments received concerning the rule from the public; (3) the complexity of the rule; (4) the extent to which the rule overlaps, duplicates, or conflicts with other Federal rules; and (5) the length of time since the rule has been initially evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

On April 2, 2002, FSIS published in the **Federal Register** (67 FR 15501) a scheduling plan for reviewing regulations under the 610 provisions. At that point, the Agency had determined to review all rules deemed economically significant, regardless of whether the Agency had stated that the rule would impose a significant economic impact on a substantial number of small entities or not. After further consideration, FSIS now believes that it would be more effective and beneficial if the Agency concentrated its reviews under Section 610 of the RFA on those final and interim final rules that the Agency has identified as having a significant economic impact on a substantial number of small entities.

Accordingly, FSIS has amended its plan for reviewing the Agency rules that it has identified as having a significant economic impact on a substantial number of small entities.

SCHEDULE OF FSIS' REGULATIONS IDENTIFIED FOR REVIEW UNDER THE RFA'S 610 PROVISIONS

CFR parts affected and legal authority	Regulation title	Publication citation and date	Review date
9 CFR 304, 308, 310, 320, 327, 381, 416, 417; 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.	Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems.	61 FR 38806; July 25, 1996.	2005
9 CFR 430; 7 U.S.C. 450; 7 U.S.C. 1901–1906; 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.	Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products.	68 FR 34208; June 6, 2003.	2007
9 CFR 309, 310, 311, 318, 319; 21 U.S.C. 601–695; 7 U.S.C. 138f, 450, 1901–1906; 7 CFR 2.17, 2.18, 2.53, 2.55.	Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle.	69 FR 1862; January 12, 2004.	2008
9 CFR 301, 318, 320; 21 U.S.C. 601–695; 7 U.S.C. 138f, 450, 1901–1906; 7 CFR 2.7, 2.18, 2.53.	Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems.	69 FR 1874; January 12, 2004.	2009

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and in particular minorities, women, and persons with disabilities, are aware of this notice, FSIS will announce it on-line through the FSIS Web page located at *http://www.fsis.usda.gov.*

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and other types of information that could affect or would be of interest to our constituents and stakeholders. The update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health

professionals, scientific professionals, and other individuals who have requested to be included.

The update also is available on the FSIS web page. Through Listserv and the web page, FSIS is able to provide information to a much broader, more diverse audience.

Done at Washington, DC, on January 24, 2005.

Barbara J. Masters,

Acting Administrator.

[FR Doc. 05–1613 Filed 1–27–05; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–20136; Directorate Identifier 2004–NM–185–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 747–200B, –200C, –200F, and –400F Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Boeing Model 747 series airplanes. This proposed AD would require repetitive detailed inspections for cracks in the crease beam and adjacent structure of the fuselage, and related investigative and corrective actions if necessary. This proposed AD is prompted by fatigue cracks found in the crease beam during a follow-on inspection of a previously installed modification. We are proposing this AD to find and fix fatigue cracking of the fuselage frame, which could result in reduced structural integrity of the frame and consequent rapid decompression of the airplane.

DATES: We must receive comments on this proposed AD by March 14, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- *DOT Docket Web site*: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- *Government-wide rulemaking Web site*: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, room PL–401, Washington, DC 20590.
- *By fax:* (202) 493–2251.
- *Hand Delivery:* Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207.

FOR FURTHER INFORMATION CONTACT: *Technical Information*: Nick Kusz, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6432; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION:

Docket Management System (DMS)

The FAA has implemented new procedures for maintaining AD dockets electronically. As of May 17, 2004, new AD actions are posted on DMS and assigned a docket number. We track each action and assign a corresponding directorate identifier. The DMS AD docket number is in the form ''Docket No. FAA–2005–99999.'' The Transport Airplane Directorate identifier is in the form ''Directorate Identifier 2005–NM–999–AD.'' Each DMS AD docket also lists the directorate identifier (''Old Docket Number'') as a cross-reference for searching purposes.

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES.** Include ''Docket No. FAA–2005–20136; Directorate Identifier 2004–NM–185–AD'' in the subject line of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments submitted by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of that Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You can review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you can visit *http://dms.dot.gov*.

We are reviewing the writing style we currently use in regulatory documents. We are interested in your comments on whether the style of this document is clear, and your suggestions to improve the clarity of our communications that affect you. You can get more information about plain language at *http://www.faa.gov/language* and *http://www.plainlanguage.gov*.

Examining the Docket

You can examine the AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

We have received a report indicating that cracking was found on a 747–200 series airplane during a follow-on inspection of a previously installed modification of the crease beam of the fuselage. The cracking is attributed to fatigue due to cabin pressurization cyclic loading. This condition, if not corrected, could result in reduced structural integrity of the fuselage frame and consequent rapid decompression of the airplane.

The crease beam of the fuselage on certain Model 747–200B, –200C, –200F, and –400F series airplanes is identical to that on the affected Model 747–200 series airplane. Therefore, all of these models may be subject to the same unsafe condition.

Other Related Rulemaking

On October 26, 1989, we issued AD 89–08–03 R1, amendment 39–6389 (54 FR 46367, November 3, 1989), applicable to certain Boeing Model 747 series airplanes, (line numbers 66 through 603 inclusive). That AD requires inspections for cracks of the fuselage between body station (BS) 940 and BS 1000, the body crown crease beam, and the intercostal structure; and repair if necessary. The newly reported fatigue cracking of the crease beam and adjacent structure of the fuselage that prompted this new proposed AD occurred at approximately 10,000 flight

cycles after the airplane had been modified per the repair procedures specified in Boeing Service Bulletin 747–53–2297, Revision 1, dated January 26, 1989 (referenced in AD 89–08–03 R1 for accomplishing the specified actions).

Although AD 89–08–03 R1 contains adequate post-modification/repair inspections, there are no such inspections required for airplanes with line numbers 604 and subsequent. This proposed AD would require inspections for airplanes that are not included in the applicability specified in AD 89–08–03 R1.

Relevant Service Information

We have reviewed Boeing Alert Service Bulletin 747–53A2504, dated August 19, 2004. The service bulletin describes procedures for repetitive detailed inspections for cracks in the crease beam and adjacent structure of the fuselage, and related investigative and corrective actions if necessary. The related investigative action is a high frequency eddy current inspection for additional cracking in adjacent skin panel fastener locations. The corrective action involves repairing any cracks found during any inspection. Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other airplanes of this same type design. Therefore, we are proposing this AD, which would require accomplishing the actions specified in the service information described previously, except as discussed under ''Differences Between Proposed AD and Service Bulletin.''

Differences Between Proposed AD and Service Bulletin

For certain airplanes, the service bulletin recommends reporting any discrepancies to the manufacturer; however, this proposed AD does not include that requirement.

Although the service bulletin specifies that operators may contact the manufacturer for disposition of certain repair conditions, this proposed AD would require operators to repair those conditions using a method that we approve or using data that meet the certification basis of the airplane, and that have been approved by an Authorized Representative for the Boeing Delegation Option Authorization (DOA) Organization whom we have authorized to make those findings.

Costs of Compliance

There are about 163 airplanes of the affected design in the worldwide fleet. This proposed AD would affect about 30 airplanes of U.S. registry. The proposed inspection would take about 8 work hours per airplane, at an average labor rate of $65 per work hour. Based on these figures, the estimated cost of the proposed inspection for U.S. operators is $15,600, or $520 per airplane, per inspection cycle.

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this proposed AD.

Regulatory Findings

We have determined that this proposed AD will not have federalism implications under Executive Order 13132. This proposed AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Boeing: Docket No. FAA–2005–20136; Directorate Identifier 200—-NM–185–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this AD action by March 14, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 747–200B, –200C, –200F, and –400F series airplanes, line numbers 604 and subsequent, certificated in any category; as listed in Boeing Alert Service Bulletin 747–53A2504, dated August 19, 2004.

Unsafe Condition

(d) This AD was prompted by fatigue cracks found in the crease beam during a follow-on inspection of a previously installed modification. We are issuing this AD to find and fix fatigue cracking of the fuselage frame, which could result in reduced structural integrity of the frame and consequent rapid decompression of the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Repetitive Inspections

(f) Accomplish a detailed inspection for cracks in the crease beam and adjacent structure of the fuselage by doing all the applicable actions in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 747–53A2504, dated August 19, 2004; at the applicable time specified in paragraph (f)(1) or (f)(2) of this AD. Repeat the inspection thereafter at intervals not to exceed 6,000 flight cycles.

(1) For Groups 1 and 2 airplanes as identified in the service bulletin: Before the accumulation of 10,000 total flight cycles, or within 1,500 flight cycles after the effective date of this AD, whichever is later.

(2) For Groups 3 and 4 airplanes as identified in the service bulletin: Before the

accumulation of 14,000 total flight cycles, or within 1,500 flight cycles after the effective date of this AD, whichever is later.

Related Investigative and Corrective Actions

(g) If any crack is found during any inspection required by paragraph (f) of this AD: Before further flight, repair the cracking in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 747–53A2504, dated August 19, 2004. If cracking of the crease beam or outer tee chord attachment is found: Before further flight, do a high frequency eddy current inspection for additional cracking, and repair any cracking found, in accordance with the service bulletin. Where the service bulletin specifies contacting the manufacturer for disposition of certain repair conditions, repair before further flight in accordance with a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA; or by an Authorized Representative for the Boeing Delegation Option Authorization (DOA) Organization, who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

No Reporting Required

(h) For certain airplanes, the service bulletin referenced in this AD recommends reporting any discrepancies to the manufacturer, but this AD does not include that requirement.

Alternative Methods of Compliance (AMOCs)

(i)(1) The Manager, Seattle ACO, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) An AMOC that provides an acceptable level of safety may be used for a repair required by this AD, if it is approved by an Authorized Representative for the Boeing DOA Organization who has been authorized by the Manager, Seattle ACO, to make such findings.

Issued in Renton, Washington, on January 18, 2005.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–1584 Filed 1–27–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–20138; Directorate Identifier 2004–NM–167–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 757–200, –200PF, and –200CB Series Airplanes Equipped With Pratt & Whitney or Rolls Royce Engines

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Boeing Model 757–200, –200PF, and –200CB series airplanes. This proposed AD would require inspecting to determine the part number of the upper link forward fuse pins of the engine struts; and replacing the fuse pins as necessary. This proposed AD is prompted by a report indicating that, due to an incorrect listing in the illustrated parts catalog, persons performing maintenance on the engine strut(s) could have installed an incorrect upper link forward fuse pin. We are proposing this AD to prevent a ruptured wing box, due to the engine not separating safely during certain emergency landing conditions, which could lead to a fuel spill and consequent fire.

DATES: We must receive comments on this proposed AD by March 14, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- *DOT Docket Web site:* Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW, Nassif Building, room PL–401, Washington, DC 20590.
- *By fax:* (202) 493–2251.
- *Hand Delivery:* Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street SW, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207.

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC. This docket number is FAA–2005–20138; the directorate identifier for this docket is 2004–NM–167–AD.

FOR FURTHER INFORMATION CONTACT: Dennis Stremick, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6450; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2005–20138; Directorate Identifier 2004–NM–167–AD'' in the subject line of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments submitted by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of that website, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You can review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you can visit *http://dms.dot.gov.*

Examining the Docket

You can examine the AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

We have received a report indicating that, due to an incorrect listing in the illustrated parts catalog, an operator performing maintenance on the engine strut(s) could have installed, as a replacement for an upper link forward fuse pin having part number (P/N) 311N5501–1, an incorrect fuse pin having P/N 311N5501–2. An incorrect fuse pin could prevent the engine from separating safely from the airplane upon abrupt contact with the ground or a massive ground object during an uncontrolled or wheels up emergency landing. This condition, if not corrected, could cause a ruptured wing box, due to the engine not separating safely during certain emergency landing conditions, which could lead to a fuel spill and consequent fire.

Relevant Service Information

We have reviewed Boeing Special Attention Service Bulletin 757–54–0048, dated May 13, 2004. The service bulletin describes procedures for inspecting to determine the part number of the upper link forward fuse pins of the engine struts and replacing the fuse pins with fuse pins having P/N 311N5501–1, if necessary. Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other airplanes of this same type design. Therefore, we are proposing this AD, which would require accomplishing the actions specified in the service information described previously, except as discussed under ''Differences Between the Proposed AD and Service Information.''

Differences Between the Proposed AD and Service Information

Boeing Special Attention Service Bulletin 757–54–0048 specifies to inspect the upper link forward fuse pin to determine the P/N; however, we have examined a fuse pin returned from service and found the P/N to be unreadable. Therefore, we are proposing one alternate method of identifying the fuse pin by measuring the inside diameter of the fuse pin bore. We have coordinated the alternate method with the manufacturer and included appropriate procedures in this proposed AD.

Boeing Special Attention Service Bulletin 757–54–0048 permits the use of an ''approved equivalent procedure'' for inspection and necessary replacement of the fuse pin(s); however, this proposed AD would require that inspection and replacement be done in accordance with the instructions of the aircraft maintenance manual (AMM) as specified in the service bulletin.

Clarification of Applicability

Boeing Special Attention Service Bulletin 757–54–0048 specifies that it is applicable to airplanes having line numbers 1 through 735 inclusive; however, airplanes having line numbers 1 through 618 inclusive were originally manufactured with upper link forward fuse pins P/N 311N5060–1. P/N 311N5060–1 fuse pins are replaced with P/N 311N5501–1 fuse pins when the strut improvement modification required by AD 2004–12–07, amendment 39–13666, (69 FR 33561, dated June 16, 2004); or AD 2003–18–05, amendment 39–13296, (68 FR 53496, dated September 11, 2003); as applicable, is incorporated on the airplane.

Clarification of Inspection Terminology

In this proposed AD, the ''detailed visual inspection'' specified in the Boeing service bulletin is referred to as a ''detailed inspection.'' We have included the definition for a detailed inspection in Note 1 of the proposed AD.

Costs of Compliance

There are about 735 airplanes of the affected design in the worldwide fleet. This proposed AD would affect about 478 airplanes of U.S. registry. The proposed inspection would take about 1 work hour per fuse pin (2 fuse pins per airplane), at an average labor rate of $65 per work hour. Based on these figures, the estimated cost of the proposed AD for U.S. operators is $62,140, or $130 per airplane.

Replacement of any upper link forward fuse pin, if required, would take about 26 work hours, at an average labor rate of $65 per work hour. Required parts would cost about $431. Based on these figures, the estimated cost of a proposed replacement is $2,121 per fuse pin.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Boeing: Docket No. FAA–2005–20138; Directorate Identifier 2004–NM–167–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this AD action by March 14, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 757–200, –200PF, and –300 series airplanes, line numbers 1 through 735 inclusive, certificated in any category; equipped with Pratt & Whitney or Rolls Royce engines.

Unsafe Condition

(d) This AD was prompted by a report indicating that, due to an incorrect listing in the illustrated parts catalog, persons performing maintenance on the engine strut(s) could have installed an incorrect upper link forward fuse pin having part number (P/N) 311N5501–2. We are issuing this AD to prevent a ruptured wing box, due to the engine not separating safely during certain emergency landing conditions, which could lead to a fuel spill and consequent fire.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Inspection of Fuse Pin

(f) Within 24 months after the effective date of this AD, perform a detailed inspection to determine the P/N of the upper link forward fuse pins of the engine struts, in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 757–54–0048, dated May 13, 2004, except as provided in paragraph (g) of this AD.

Note 1: For the purposes of this AD, a detailed inspection is: ''An intensive examination of a specific item, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at an intensity deemed appropriate. Inspection aids such as mirror, magnifying lenses, etc., may be necessary. Surface cleaning and elaborate procedures may be required.''

(1) If the fuse pin is P/N 311N5501–1 or P/N 311N5060–1, no further action is required for that fuse pin.

(2) If the fuse pin is P/N 311N5501–2, prior to further flight, replace the fuse pin with a new or serviceable fuse pin, P/N 311N5501–1, in accordance with the Accomplishment Instructions of the service bulletin.

(3) If the P/N of the fuse pin cannot be determined by inspection, use a tool such as an inside reading micrometer to determine the inside diameter (ID) of the fuse pin bore.

(i) If the ID of the fuse pin bore is greater than or equal to 0.850 inch, no further action is required for that fuse pin.

(ii) If the ID of the fuse pin bore is less than 0.850 inch, prior to further flight, replace the fuse pin as specified in paragraph (f)(2) of this AD.

(g) Where Boeing Special Attention Service Bulletin 757–54–0048 permits the use of an ''approved equivalent procedure'' for access and replacement of the fuse pin(s), this AD requires that access and replacement be done in accordance with the instructions of the aircraft maintenance manual (AMM) as specified in the service bulletin.

Parts Installation

(h) As of the effective date of this AD, no person may install a fuse pin, P/N 311N5501–2, on any airplane identified in the applicability of this AD.

Alternative Methods of Compliance (AMOCs)

(i)(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by a Boeing Company Designated Engineering Representative who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the approval must specifically refer to this AD.

Issued in Renton, Washington, on January 18, 2005.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–1586 Filed 1–27–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–20137; Directorate Identifier 2004–NM–96–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 757–200, –200PF, and –300 Series Airplanes, Powered by Pratt & Whitney PW2000 Series Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Boeing Model 757 series airplanes. This proposed AD would require repetitive inspections for loose or damaged components of the support brackets and associated fasteners for the hydraulic lines located in the nacelle struts, and any related investigative and corrective actions. This proposed AD is prompted by reports of damage and subsequent failure of the support brackets and associated fasteners for the hydraulic lines located internal to the upper fairing cavity of the nacelle struts. We are proposing this AD to prevent flammable fluids from leaking into the interior compartment of the nacelle struts where ignition sources exist, which could result in the ignition of flammable fluids and an uncontained fire.

DATES: We must receive comments on this proposed AD by March 14, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- *Government-wide rulemaking Web site*: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Nassif Building, room PL–401, Washington, DC 20590.
- *By fax:* (202) 493–2251.
- *Hand Delivery:* Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207.

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC.

FOR FURTHER INFORMATION CONTACT: *Technical information*: Tom Thorson, Aerospace Engineer, Propulsion Branch, ANM–140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6508; fax (425) 917–6590.

Plain language information: Marcia Walters, *marcia.walters@faa.gov.*

SUPPLEMENTARY INFORMATION:

Docket Management System (DMS)

The FAA has implemented new procedures for maintaining AD dockets electronically. As of May 17, 2004, new AD actions are posted on DMS and assigned a docket number. We track each action and assign a corresponding directorate identifier. The DMS AD docket number is in the form ''Docket No. FAA–2004–99999.'' The Transport Airplane Directorate identifier is in the form ''Directorate Identifier 2004–NM–999–AD.'' Each DMS AD docket also lists the directorate identifier (''Old

Docket Number'') as a cross-reference for searching purposes.

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES.** Include ''Docket No. FAA–2005–20137; Directorate Identifier 2004–NM–96–AD'' in the subject line of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments submitted by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of that website, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You can review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you can visit *http://dms.dot.gov.*

We are reviewing the writing style we currently use in regulatory documents. We are interested in your comments on whether the style of this document is clear, and your suggestions to improve the clarity of our communications that affect you. You can get more information about plain language at *http://www.faa.gov/language* and *http://www.plainlanguage.gov.*

Examining the Docket

You can examine the AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

We have received reports of damage and subsequent failure of the support brackets and associated fasteners for the hydraulic lines located internal to the upper fairing cavity of the nacelle struts. These failures occurred on certain Model 757 series airplanes powered by Pratt & Whitney PW2000 series engines. These failures resulted in damage to the adjacent fuel lines and fuel leaks in the engine strut due to a fastener migrating through a support bracket and retainer channel, allowing the fastener to wear through the fuel supply tube. The hydraulic lines supply pressure from the hydraulic pumps to the airframe and are subject to high frequency pressure oscillations/vibrations. Investigation by the manufacturer revealed that the operating pressure and surge loads from the hydraulic pumps are higher than originally expected and exceed the capability of the design for the support bracket structure.

The hydraulic lines are located in the upper fairing compartment of the nacelle struts. The upper fairing compartment is a flammable leakage zone and is isolated from other strut compartments by a protective vapor barrier. The vapor barrier acts as a seal to keep flammable fluids and vapors from hydraulic and fuel line leaks out of the interior portion of the strut where pneumatic bleed air ducts are located. The surface temperature of the bleed air ducts is hot enough to be an ignition source. The reported condition of sheared or loose fasteners, or damage to the strut webs adjacent to the support brackets and associated fasteners, compromises the vapor barrier, which in turn could allow flammable fluids to leak into the interior compartments of the nacelle struts. Such a condition, if not corrected, could result in ignition of flammable fluids and an uncontained fire.

Relevant Service Information

We have reviewed Boeing Service Bulletins 757–29–0064 (for Model 757–200 and –200PF series airplanes) and 757–29–0065 (for Model 757–300 series airplanes), both dated February 29, 2004. The service bulletins describe procedures for repetitive detailed inspections for loose or damaged components of the support brackets and associated fasteners for the hydraulic lines located in the nacelle struts, and related investigative and corrective actions. Evidence of damage includes excessive wear, fatigue cracks, or elongated fastener holes in the strut webs. If no damaged or loose parts are found, the service bulletins specify repeating the inspection of the support brackets and associated fasteners for the hydraulic lines at the intervals specified.

The procedures for the related investigative and corrective actions include:

- Inspecting the fuel and hydraulic lines and strut webs for evidence of damage (*e.g.*, chafing or holes) caused by a loose support bracket or line.
- Replacing or repairing damaged fuel lines.
- Replacing damaged hydraulic lines with new lines.
- Repairing damaged areas of the strut webs.
- Contacting the manufacturer for damage that is beyond the repair limitations specified in the service bulletin.
- Replacing damaged components with new, improved nickel alloy components.

The service bulletin also includes procedures for a functional test of the hydraulic and fuel systems.

Service Bulletin 757–29–0064 recommends prior or concurrent accomplishment of Boeing Service Bulletin 757–29–0043, dated June 21, 1990. Service Bulletin 757–29–0043 describes procedures for replacing aluminum brackets, retainer channels, and attachment hardware for the hydraulic lines located in the nacelle struts. Service Bulletin 757–29–0043 also describes procedures for replacing certain fuel and hydraulic lines with new lines if necessary.

Accomplishing the actions specified in the service information is intended to adequately address the identified unsafe condition.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other airplanes of this same type design. Therefore, we are proposing this AD, which would require accomplishing the actions specified in the service information described previously, except as discussed under ''Difference Between the Service Bulletins and Proposed AD.''

Difference Between the Service Bulletins and Proposed AD

Although the service bulletins specify that operators may contact the manufacturer for disposition of certain repair conditions, this proposed AD would require operators to repair those conditions per a method approved by the FAA.

Costs of Compliance

This proposed AD would affect about 432 airplanes worldwide and 377 airplanes of U.S. registry. The proposed

inspection/test would take about 35 work hours per airplane (including access and close-up), at an average labor rate of $65 per work hour. Based on these figures, the estimated cost of the proposed AD for U.S. operators is $857,675, or $2,275 per airplane, per inspection/test cycle.

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, the FAA is charged with promoting safety flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this proposed AD.

Regulatory Findings

We have determined that this proposed AD will not have federalism implications under Executive Order 13132. This proposed AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Boeing: Docket No. FAA–2005–20137; Directorate Identifier 2004–NM–96–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this AD action by March 14, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 757–200, –200PF, and –300 series airplanes; powered by Pratt & Whitney PW2000 series engines; certificated in any category.

Unsafe Condition

(d) This AD was prompted by reports of damage and subsequent failure of the support brackets and associated fasteners for the hydraulic lines located internal to the upper fairing cavity of the nacelle struts. We are issuing this AD to prevent flammable fluids from leaking into the interior compartment of the nacelle struts where ignition sources exist, which could result in the ignition of flammable fluids and an uncontained fire.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Repetitive Inspections

(f) Within 6,000 flight hours or 18 months after the effective date of this AD, whichever is first: Do a detailed inspection for loose or damaged components of the support brackets and associated fasteners for the hydraulic lines located in the nacelle struts by accomplishing all of the actions specified in Part 1, Part 2, and Part 3 of the Accomplishment Instructions of Boeing Service Bulletin 757–29–0064 (for Model 757–200 and –200PF series airplanes) or Boeing Service Bulletin 757–29–0065 (for Model 757–300 series airplanes), both dated February 29, 2004; as applicable. Repeat the inspection thereafter at intervals not to exceed 6,000 flight hours or 18 months, whichever is first.

Note 1: For the purposes of this AD, a detailed inspection is defined as: ''An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

Concurrent Service Bulletin

(g) Prior to or concurrently with the accomplishment of paragraph (f) of this AD: Accomplish all of the actions specified in the Accomplishment Instructions of Boeing Service Bulletin 757–29–0043, dated June 21, 1990.

Related Investigative and Corrective Actions

(h) Except as required by paragraph (i) of this AD: If any loose or damaged parts are found during any inspection required by paragraph (f) of this AD, before further flight, do all of the related investigative and corrective actions specified in Part 1 and Part 2 of the Accomplishment Instructions of Boeing Service Bulletin 757–29–0064, or Boeing Service Bulletin 757–29–0065, both dated February 29, 2004; as applicable.

Repair Information

(i) If any damage is found during any inspection required by this AD, and the service bulletin specifies contacting Boeing for appropriate action: Before further flight, repair per a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA. For a repair method to be approved, the approval letter must specifically refer to this AD.

Note 2: There is no terminating action currently available for the repetitive inspections required by paragraph (f) of this AD.

Alternative Methods of Compliance (AMOCs)

(j) The Manager, Seattle ACO, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Issued in Renton, Washington, on January 18, 2005.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–1587 Filed 1–27–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–20135; Directorate Identifier 2003–NM–231–AD]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model DC–8–33 and –43 Airplanes; Model DC–8F–54 and DC–8F–55 Airplanes; and Model DC–8–50, –60, –60F, –70, and –70F Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede an existing airworthiness directive (AD) for certain McDonnell Douglas series airplanes. That AD currently requires repetitive inspections of the electrical connectors of the explosive cartridge wiring of the engine fire extinguisher containers to verify if the identification number labels are installed and legible; repetitive electrical tests of all explosive cartridge wiring of the engine fire extinguisher containers to verify proper installation and function; and corrective actions if necessary. This proposed AD would also require an inspection of the emergency shut off wire assembly; installation of lanyards on the electrical connectors for the engine fire extinguishing agent containers and for the auxiliary power unit fire extinguishing agent containers if applicable; and related investigative/corrective actions, as applicable. This proposed AD is prompted by reports of cross-wired electrical connectors of the engine fire extinguishing agent containers. We are proposing this AD to detect and correct cross-wired electrical connectors of the fire extinguishing system, which could release fire extinguishing agent into the incorrect engine nacelle in the event of an engine fire.

DATES: We must receive comments on this proposed AD by March 14, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- *DOT Docket Web site:* Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street SW., Nassif Building, room PL–401, Washington, DC 20590.
- *Fax:* (202) 493–2251.
- *Hand Delivery:* Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024).

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC. This docket number is FAA–2005–20135; the directorate identifier for this docket is 2003–NM–231–AD.

FOR FURTHER INFORMATION CONTACT: William S. Bond, Aerospace Engineer, Propulsion Branch, ANM–140L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712–4137; telephone (562) 627–5253; fax (562) 627–5210.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES.** Include ''Docket No. FAA–2005–20135; Directorate Identifier 2003-NM–231-AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments received by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of our docket Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you may visit *http://dms.dot.gov*.

Examining the Docket

You can examine the AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

On November 29, 2001, we issued AD 2001–25–01, amendment 39–12553 (66 FR 63157, December 5, 2001), for certain McDonnell Douglas Model DC–8–33, –43, –51, –52, –53, and –55 series airplanes; Model DC–8F–54 and –55 series airplanes; and Model DC–8–61, –61F, –62, –62F, –63, –63F, –71, –71F, –72, –72F, –73, and –73F series airplanes airplanes. That AD requires repetitive inspections of the electrical connectors of the explosive cartridge wiring of the engine fire extinguisher containers to verify if the identification number labels are installed and legible; repetitive electrical tests of all explosive cartridge wiring of the engine fire extinguisher containers to verify proper installation and function; and corrective actions if necessary. That AD was prompted by reports of electrical connectors of the engine fire extinguishing agent containers being cross–wired on certain McDonnell Douglas DC–8 series airplanes. We issued that AD to detect and correct cross–wired electrical connectors of the fire extinguishing system, which could release fire extinguishing agent into the incorrect engine nacelle in the event of an engine fire.

Actions Since Existing AD Was Issued

The preamble to AD 2001–25–01 explains that we consider the requirements ''interim action'' and were considering further rulemaking. We now have determined that further rulemaking is indeed necessary, and this proposed AD follows from that determination.

Relevant Service Information

We have reviewed Boeing Service Bulletin DC8–26–047, Revision 1, dated

September 4, 2003. The service bulletin describes the following procedures:

1. Doing a general visual inspection of the emergency shut off wire assembly to determine if the length of wire harness AAG at P1–510 can be connected to R5–74 and to determine if the length of wire harness ABG at P1–511 can be connected to R5–73; and corrective action. The corrective action includes shortening wire harness AAG at P1–510, if cross connection is possible.

2. Installing lanyards on the electrical connectors for the engine fire extinguishing agent containers in the left and right wing front spar; and related investigative/corrective actions. The related investigative actions include inspecting the explosive cartridge electrical connectors for the engine fire extinguisher containers to determine if the identification number labels are installed and legible; and testing the installation of the engine fire extinguisher containers. The corrective actions include installing any missing label or replacing any illegible label with a new label, as applicable; and troubleshooting and repairing the wiring of the fire extinguishing (''firex'') discharge system if any cockpit warning lamp fails to light during any test of the engine fire extinguisher containers.

3. For airplanes equipped with an auxiliary power unit (APU) installation in the forward cargo compartment at station Y=640.000, installing lanyards on the electrical connectors for the APU fire extinguishing agent containers and related investigative/corrective actions. The related investigative action includes inspecting the explosive cartridge electrical connectors for the APU fire extinguisher containers to determine if the identification number labels are installed and legible. The corrective action includes installing any missing or replacing any illegible identification label with a new label, as applicable, on the explosive cartridge electrical connectors for the APU fire extinguisher containers. We have determined that accomplishment of the actions specified in the service information will adequately address the unsafe condition.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other products of this same type design. Therefore, we are proposing this AD, which would supersede AD 2001–25–01. This proposed AD would continue to require repetitive inspections of the electrical connectors of the explosive cartridge wiring of the engine fire extinguisher containers to verify if the identification number labels are installed and legible; repetitive electrical tests of all explosive cartridge wiring of the engine fire extinguisher containers to verify proper installation and function; and corrective actions if necessary. This proposed AD would also require an inspection of the emergency shut off wire assembly; installation of lanyards on the electrical connectors for the engine fire extinguishing agent containers and for the APU fire extinguishing agent containers if applicable; and related investigative/corrective actions, as applicable. Accomplishment of these new actions would terminate the requirement for repetitive inspections and electrical tests. This proposed AD would require you to use the service information described previously to perform these actions, except as discussed under ''Difference Between the Proposed AD and Service Bulletin.''

Difference Between the Proposed AD and Service Bulletin

Operators should note that, although the service bulletin recommends accomplishing the service bulletin ''at a scheduled maintenance period when manpower, materials, and facilities are available,'' we have determined that such an imprecise compliance time would not address the identified unsafe condition in a timely manner. In developing an appropriate compliance time for this proposed AD, we considered the degree of urgency associated with the subject unsafe condition, the average utilization of the affected fleet, and the time necessary to perform the modification (between 5 to 6 hours). In light of all of these factors, we find that an 18–month compliance time represents an appropriate interval of time for affected airplanes to continue to operate without compromising safety. We have coordinated this finding with the manufacturer and they concur.

Clarification Between the Proposed AD and Service Bulletin

Operators should note that, although the effectivity of the service bulletin includes McDonnell Douglas Model DC–8–54 airplanes, we have not included it in the applicability of the proposed AD because it is not listed on Type Certificate Data Sheet (TCDS) No. 4A25, Revision 37, or any other TCDS. In addition, the manufacturer has confirmed that its listing in the effectivity of the service bulletin is a typographical error. The manufacturer also indicated that Model DC–8F–54 and Model DC–8F–55 airplanes were misidentified in the effectivity of the service bulletin as Model DC–8–54F and Model DC–8–55F, respectively. The applicability of this AD references the correct model designations for these airplanes.

Change to Existing AD

This proposed AD would retain all requirements of AD 2001–25–01. Since AD 2001–25–01 was issued, the AD format has been revised, and certain paragraphs have been rearranged. As a result, the corresponding paragraph identifiers have changed in this proposed AD, as listed in the following table:

REVISED PARAGRAPH IDENTIFIERS

Requirement in AD 2001–25–01	Corresponding requirement in this proposed AD
paragraph (a)	paragraph (f).

Costs of Compliance

This proposed AD would affect about 233 worldwide airplanes. The following table provides the estimated costs, using an average labor rate of $65 per hour, for U.S. operators to comply with this proposed AD.

ESTIMATED COSTS

Action	Work hours	Parts	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
Inspection of the electrical connectors of the explosive cartridge wiring and electrical test of all explosive cartridge wiring (required by AD 2001–25–01).	3	$0	$195, per inspection/testing cycle.	177	$34,515

ESTIMATED COSTS—Continued

Action	Work hours	Parts	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
General visual inspection of the emergency shut off wire assembly (new proposed action).	1	0	65, per inspection cycle	177	11,505
Installation of lanyards on electrical connectors for engine fire extinguishing agent containers (new proposed action).	4	58 (For engine firex)	318	177	56,268
Installation of lanyards on electrical connectors for APU fire extinguishing agent containers if applicable (new proposed action).	1	52 (For APU firex)	117	177	20,709

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this AD.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by removing amendment 39–12553 (66 FR 63157, December 5, 2001) and adding the following new airworthiness directive (AD):

McDonnell Douglas: Docket No. FAA–2005–20135; Directorate Identifier 2003–NM–231–AD.

Comments Due Date

(a) The Federal Aviation Administration must receive comments on this airworthiness directive (AD) action by March 14, 2005.

Affected ADs

(b) This AD supersedes AD 2001–25–01, amendment 39–12553. Accomplishment of paragraph (g) and (h) of this AD terminates certain requirements of AD 2001–25–01, amendment 39–12553.

Applicability

(c) This AD applies to McDonnell Douglas Model DC–8–33, DC–8–43, DC–8–51, DC–8–52, DC–8–53, DC–8F–54, DC–8–55, DC–8F–55, DC–8–61, DC–8–61F, DC–8–62, DC–8–62F, DC–8–63, DC–8–63F, DC–8–71, DC–8–71F, DC–8–72, DC–8–72F, DC–8–73, and DC–8–73F airplanes, certificated in any category; as listed in Boeing Service Bulletin DC8–26–047, Revision 1, dated September 4, 2003.

Unsafe Condition

(d) This AD was prompted by reports of cross-wired electrical connectors of the engine fire extinguishing agent containers. We are issuing this AD to detect and correct cross-wired electrical connectors of the fire extinguishing system, which could release fire extinguishing agent into the incorrect engine nacelle in the event of an engine fire.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Requirements of AD 2001–25–01, Amendment 39–12553

Repetitive Inspections and Tests, and Corrective Action(s), If Necessary

(f) Within 30 days after December 20, 2001 (the effective date of AD 2001–25–01, amendment 39–12553), do the action(s) specified in paragraphs (f)(1) and (f)(2) of this AD, in accordance with Boeing Alert Service Bulletin DC8–26A046, dated November 7, 2001.

(1) Do an inspection of the electrical connectors of the explosive cartridge wiring of the engine fire extinguisher containers to verify if the identification number labels are installed and legible. If any identification number label is missing or is not legible, before further flight, install a label or replace the label with a new label, as applicable. Repeat the inspection after each maintenance action for the Firex Discharge system.

(2) Do an electrical test of all explosive cartridge wiring of the engine fire extinguisher containers to verify proper installation and function, using the cockpit warning lamps. If the lamp fails to illuminate, before further flight, troubleshoot and repair the wiring of the Firex Discharge system. Repeat the test after each maintenance action for the Firex Discharge system.

Note 1: Inspections, tests, and corrective actions, if necessary, done per Boeing BOECOM M–7200–01–02632, dated November 5, 2001, before December 20, 2001 (the effective date of AD 2001–25–01, amendment 39–12553), are considered acceptable for compliance with the requirements of paragraph (f) of this AD.

New Requirements of This AD

Inspection and Installation

(g) Within 18 months of the effective date of this AD, do a general visual inspection of the emergency shut off wire assembly to determine if the length of wire harness AAG at P1–510 can be connected to R5–74 and to determine if the length of wire harness ABG

at P1–511 can be connected to R5–73; and, before further flight, do the corrective action, as applicable; by accomplishing all of the actions specified in paragraph B.1.b. of the Accomplishment Instructions of Boeing Service Bulletin DC8–26–047, Revision 1, dated September 4, 2003.

Note 2: For the purposes of this AD, a general visual inspection is defined as: ''A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made from within touching distance unless otherwise specified. A mirror may be necessary to enhance visual access to all exposed surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked.''

(h) Within 18 months of the effective date of this AD, install lanyards on the electrical connectors for the engine fire extinguishing agent containers in the left and right wing front spar; and, before further flight, do all the related investigative/corrective actions, as applicable; by accomplishing all of the actions specified in paragraph B.1.c. of the Accomplishment Instructions of Boeing Service Bulletin DC8–26–047, Revision 1, dated September 4, 2003.

Installation If Applicable

(i) For airplanes equipped with an auxiliary power unit (APU) installation in the forward cargo compartment at station Y=640.000: Within 18 months of the effective date of this AD, install lanyards on the electrical connectors for the APU fire extinguishing agent containers; and, before further flight, do all the related investigative/corrective actions, as applicable; by accomplishing all of the actions specified in paragraph B.2. of the Accomplishment Instructions of Boeing Service Bulletin DC8–26–047, Revision 1, dated September 4, 2003.

Terminating Action

(j) Accomplishment of the actions specified in paragraphs (g) and (h) of this AD terminates the repetitive inspections and electrical tests required by paragraph (f) of this AD.

Credit for Previous Service Bulletin

(k) Actions done before the effective date of this AD in accordance with Boeing Service Bulletin DC8–26–047, dated April 2, 2003, is acceptable for compliance with the corresponding requirements in paragraphs (g), (h), and (i) of this AD.

Alternative Methods of Compliance (AMOCs)

(l) The Manager, Los Angeles Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

Issued in Renton, Washington, on January 18, 2005.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–1588 Filed 1–27–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Part 382

[Docket No. OST–2004–19482]

RIN 2105–AC97

Nondiscrimination on the Basis of Disability in Air Travel

AGENCY: Office of the Secretary (OST), U.S. Department of Transportation (DOT).

ACTION: Extension of comment period on proposed rule.

SUMMARY: The Department is extending through March 4, 2005, the period for interested persons to submit comments to its proposed rule to amend regulations implementing the Air Carrier Access Act.

DATES: Comments must be received by March 4, 2005. Comments received after this date will be considered to the extent practicable.

ADDRESSES: Please include the docket number of this document in all comments submitted to the docket. Written comments should be sent to Docket Clerk, Department of Transportation, 400 7th Street, SW., Room PL–401, Washington, DC 20590. For confirmation of the receipt of written comments, commenters may include a stamped, self-addressed postcard. The Docket Clerk will date-stamp the postcard and mail it back to the commenter. Comments will be available for inspection at this address from 10 a.m. to 5:30 p.m., Monday through Friday. Comments can also be reviewed through the Dockets Management System (DMS) pages of the Department's Web site (*http://dms.dot.gov*). Commenters may also submit comments electronically. Instructions appear on the DMS Web site.

FOR FURTHER INFORMATION CONTACT: Robert C. Ashby, Deputy Assistant General Counsel for Regulation and Enforcement, 400 7th Street, SW., Room 10424, Washington DC., 20590. Phone 202–366–9310; TTY: 202–755–7687; Fax: 202–366–9313. E-mail: *bob.ashby@ost.dot.gov*.

SUPPLEMENTARY INFORMATION: On November 4, 2004, the Department of Transportation issued a notice of proposed rulemaking (NPRM) that would amend 49 CFR Part 382, the Department's regulation implementing the Air Carrier Access Act (69 FR 64364). The NPRM would apply the requirements of Part 382 to foreign air carriers, require air carrier web sites to be accessible to persons with impaired vision, and generally update and improve the organization of the existing regulation. The original comment closing date was February 2, 2005.

The Air Transport Association (ATA) requested an extension of the comment period, in order to permit them to gather additional information from their members and present better-informed comments to the Department. They requested a 30-day extension of the comment period. This request was supported by comments from the International Air Transport Association, Regional Airline Association, and Air Carrier Association of America.

The Department is granting the requested extension, which we hope will result in more thorough comments to the docket than might otherwise be possible, not only from ATA. We also urge, given the additional time provided by this extension, that commenters make every effort to provide detailed data concerning the issues they raise.

Therefore, the Department of Transportation will extend the comment period 30 days, ending March 4, 2005. We do not anticipate the need for any further extensions.

Issued this 19th day of January, 2005, at Washington, DC.

Jeffrey A. Rosen,

General Counsel.

[FR Doc. 05–1562 Filed 1–26–05; 10:08 am]

BILLING CODE 4910–62–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–152914–04]

RIN 1545–BD97

Revised Regulations Concerning Disclosure of Relative Values of Optional Forms of Benefit

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations that would revise final regulations that were issued on

December 17, 2003, under section 417(a)(3) of the Internal Revenue Code concerning content requirements applicable to explanations of qualified joint and survivor annuities and qualified preretirement survivor annuities payable under certain retirement plans. These regulations affect plan sponsors and administrators, and participants in and beneficiaries of, certain retirement plans.

DATES: Written and electronic comments and requests for a public hearing must be received by April 28, 2005.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–152914–04), room 5203, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG–152914–04), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC, or sent electronically, via the IRS Internet site at *http://www.irs.gov/regs* or via the Federal eRulemaking Portal at *http://www.regulations.gov* (indicate IRS and REG–152914–04).

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Bruce Perlin at (202) 622–6090 (not a toll-free number); concerning submissions or hearing requests, Lanita Van Dyke, (202) 622–7180 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collections of information contained in this notice of proposed rulemaking have been previously reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1545–0928.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

Section 417(a) provides rules under which a participant (with spousal consent) may waive payment of the participant's benefit in the form of qualified joint and survivor annuity (QJSA). Specifically, section 417(a)(3) provides that a plan must provide to each participant, within a reasonable period before the annuity starting date, a written explanation that includes the following information: (1) The terms and conditions of the QJSA; (2) the participant's right to make an election to waive the QJSA form of benefit; (3) the effect of such an election; (4) the rights of the participant's spouse; and (5) the right to revoke an election to waive the QJSA form of benefit.

Section 205 of the Employee Retirement Income Security Act of 1974 (ERISA), Public Law 93–406 (88 Stat. 829) as subsequently amended, provides rules that are parallel to the rules of sections 401(a)(11) and 417 of the Internal Revenue Code. In particular, section 205(c)(3) of ERISA provides a rule parallel to the rule of section 417(a)(3) of the Code.

Section 1.401(a)–20, which provides rules governing the requirements for a waiver of the QJSA, was published in the **Federal Register** on August 19, 1988 (TD 8219) (53 FR 31837). Section 1.401(a)–20, Q & A–36, as published in 1988, set forth requirements for the explanation that must be provided under section 417(a)(3) as a prerequisite to waiver of a QJSA. Under those requirements, such a written explanation must contain a general description of the eligibility conditions and other material features of the optional forms of benefit and sufficient additional information to explain the relative values of the optional forms of benefit available under the plan (*e.g.*, the extent to which optional forms are subsidized relative to the normal form of benefit or the interest rates used to calculate the optional forms). In addition, § 1.401(a)–20, Q & A–36, as published in 1988, provided that the written explanation must comply with the requirements set forth in § 1.401(a)–11(c)(3). Section 1.401(a)–11(c)(3) was issued prior to the enactment of section 417, and provides rules relating to written explanations that were required prior to a participant's election of a preretirement survivor annuity or election to waive a joint and survivor annuity. Section 1.401(a)–11(c)(3)(i)(C) provides that such a written explanation must contain a general explanation of the relative financial effect of these elections on a participant's annuity.

For a married participant, the QJSA must be at least as valuable as any other optional form of benefit payable under the plan at the same time. *See* § 1.401(a)–20, Q & A–16. Further, the anti-forfeiture rules of section 411(a) prohibit a participant's benefit under a defined benefit plan from being satisfied through payment of a form of benefit that is actuarially less valuable than the value of the participant's accrued benefit expressed in the form of an annual benefit commencing at normal retirement age. These determinations must be made using reasonable actuarial assumptions. However, see section 417(e)(3) and § 1.417(e)–1(d) for actuarial assumptions required for use in certain present value calculations.

Final regulations under section 417(a)(3) regarding disclosure of the relative value and financial effect of optional forms of benefit as part of QJSA explanations provided to participants receiving qualified retirement plan distributions were published in the **Federal Register** on December 17, 2003. *See* § 1.417(a)(3)–1 (68 FR 70141). The 2003 regulations are generally effective for QJSA explanations provided with respect to annuity starting dates beginning on or after October 1, 2004.

The 2003 regulations were issued in response to concerns that, in certain cases, the information provided to participants under section 417(a)(3) regarding available distribution forms pursuant to § 1.401(a)–20, Q & A–36, does not adequately enable them to compare those distribution forms without professional advice. In particular, participants who are eligible for early retirement benefits in the form of both subsidized annuity distributions and unsubsidized single-sum distributions may be receiving explanations that do not adequately disclose the value of the subsidy that is foregone if the single-sum distribution is elected. In such a case, merely disclosing the amount of the single-sum distribution and the amount of the annuity payments would not adequately enable a participant to make an informed comparison of the relative values of those distribution forms. The 2003 regulations address this problem, as well as the problem of disclosure in other cases where there are significant differences in value among optional forms, and also clarify the rules regarding the disclosure of the financial effect of benefit payments.

A number of commentators requested that the effective date of the 2003 regulations be postponed. Among the reasons cited is the need in some plans for sponsors to complete an extensive review and analysis of optional forms of benefit in order to prepare proper comparisons of the relative values of those optional forms to the QJSA. They noted that recently proposed regulations under section 411(d)(6) would permit elimination of certain optional forms of benefit and that many plan sponsors can be expected to engage in a thorough

review of all of the optional forms of benefit under their plans following publication of the those regulations in final form. *See* § 1.411(d)–3, 69 FR 13769 (March 24, 2004). These commentators argued that it would be inefficient for plans to be required to incur the costs of two such extensive analyses in succession, rather than a single analysis of optional forms that might serve to some extent for purposes of both the relative value regulations and the section 411(d)(6) regulations. After consideration of these comments, Treasury and the IRS issued Announcement 2004–58 (2004–29 I.R.B. 66), which postponed the effective date of the 2003 regulations under § 1.417(a)(3)–1 for certain QJSA explanations.

Under section 101 of Reorganization Plan No. 4 of 1978 (43 FR 47713), the Secretary of the Treasury has interpretive jurisdiction over ERISA provisions that are parallel to the Code provisions addressed in these regulations. Therefore, these proposed regulations would apply for purposes of the parallel rules in section 205(c)(3) of ERISA, as well as for section 417(a)(3) of the Code.

Explanation of Provisions

Consistent with Announcement 2004–58, these proposed regulations would modify the 2003 regulations to provide that the 2003 regulations are generally effective for QJSA explanations provided with respect to annuity starting dates beginning on or after February 1, 2006. In the interim, plans that do not comply with § 1.417(a)(3)–1 would be required to comply with the 1988 regulations regarding disclosure of relative value and financial effect.

However, the existing effective date under § 1.417(a)(3)–1 of the 2003 regulations is retained for explanations with respect to any optional form of benefit that is subject to the requirements of section 417(e)(3) (*e.g.*, single sums, social security level income options, distributions in the form of partial single sums in combination with annuities, or installment payment options) if the actuarial present value of that optional form is less than the actuarial present value (as determined under section 417(e)(3)) of the QJSA. Thus, for example, a QJSA explanation provided with respect to an annuity starting date beginning on or after October 1, 2004, must comply with § 1.417(a)(3)–1 to the extent that the plan provides for payment to that participant in the form of a single sum that does not reflect an early retirement subsidy available under the QJSA. Where the existing effective date is retained, the plan must disclose the relative value of the QJSA for the participant even if the plan provides a disclosure of relative values that is not tailored to the participant's marital status. Accordingly, if a plan provides a relative value disclosure based on the single life annuity (the QJSA for a single participant) to a married participant, the plan must also include a comparison of the value of the QJSA to the value of the single life annuity.

The proposed regulations include a special rule that would enable a plan to use the delayed effective date rule even if there are minor differences between the value of an optional form and the value of the QJSA for a married participant that are caused by the calculation of the amount of the optional form of benefit based on the life annuity rather than on the QJSA. Under this special rule, solely for purposes of the effective date provisions, the actuarial present value of an optional form is treated as not being less than the actuarial present value of the QJSA if the following two conditions are met. First, using the applicable interest rate and applicable mortality table under §§ 1.417(e)–1(d)(2) and (3), the actuarial present value of that optional form is not less than the actuarial present value of the QJSA for an unmarried participant. Second, using reasonable actuarial assumptions, the actuarial present value of the QJSA for an unmarried participant is not less than the actuarial present value of the QJSA for a married participant.

These proposed regulations would also modify the 2003 regulations in several other respects. First, for purposes of disclosing the normal form of benefit as part of a disclosure made in the form of generally applicable information, reasonable estimates of the type permitted to be used to disclose participant-specific information may be used to determine the normal form of benefit, but only if the plan follows the requirements applicable to reasonable estimates used in disclosing participant-specific information (such as offering a more precise calculation upon request and revising previously offered information consistent with the more precise information). Second, a QJSA explanation does not fail to satisfy the requirements for QJSA explanations made in the form of disclosures of generally applicable information merely because the QJSA explanation contains an item of participant-specific information in place of the corresponding generally applicable information.

In addition, the proposed regulations would modify § 1.401(a)–20, Q&A–16, to clarify the interaction of the rule prohibiting a plan from providing an option to a married individual that is worth more than the QJSA with the requirement that certain optional forms of benefit be calculated using specified actuarial assumptions. Under that clarification, a plan would not fail to satisfy the requirements of § 1.401(a)–20, Q&A–16, merely because the amount payable under an optional form of benefit that is subject to the minimum present value requirement of section 417(e)(3) is calculated using the applicable interest rate (and, for periods when required, the applicable mortality table) under section 417(e)(3).

Dates of Applicability

The changes to § 1.401(a)–20, A–36, and § 1.417(a)(3)–1 are proposed to apply as if they had been included in TD 9099 (68 FR 70141). The change to § 1.401(a)–20, Q&A–16, is proposed to apply as if it had been included in TD 8219 (53 FR 31837). Taxpayers may rely on these proposed regulations for guidance pending the issuance of final regulations.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulation does not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any electronic or written comments (preferably a signed original and eight (8) copies) that are submitted timely to the IRS. In addition to the other requests for comments set forth in this document, the IRS and Treasury also request comments on the clarity of the proposed rule and how it may be made easier to understand. All comments will be available for public inspection and copying. A public hearing will be scheduled if one is requested.

Drafting Information

The principal authors of these regulations are Bruce Perlin and Linda S.F. Marshall of the Office of the Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities). However, other personnel from the IRS and Treasury participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAX; TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1986

Paragraph 1. The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 1.401(a)–20 is amended by:

1. Adding a sentence to the end of Q&A–16.
2. Adding a sentence to the end of Q&A–36.

The additions read as follows:

§ 1.401(a)–20 Requirements of qualified joint and survivor annuity and qualified preretirement survivor annuuity.

* * * * *

A–16 * * * A plan does not fail to satisfy the requirements of this Q&A–16 merely because the amount payable under an optional form of benefit that is subject to the minimum present value requirement of section 417(e)(3) is calculated using the applicable interest rate (and, for periods when required, the applicable mortality table) under section 417(e)(3).

* * * * *

A–36 * * * However, the rules of § 1.401(a)–20, Q&A–36, as it appeared in 26 CFR Part 1 revised April 1, 2003, apply to the explanation of a QJSA under section 417(a)(3) for an annuity starting date prior to February 1, 2006.

* * * * *

Par. 3. Section 1.417(a)(3)–1 is amended by:

1. Removing the language ''paragraph (c)(3)(iii) of'' from paragraph (c)(2)(ii)(A).
2. Adding a sentence to the end of paragraph (d)(2)(ii).
3. Adding paragraph (d)(5).
4. Revising paragraph (f).

The additions and revision read as follows:

§ 1.417(a)(3)–1 Required explanation of qualified joint and survivor annuity and qualified preretirement survivor annuity.

* * * * *

(d) * * *

(2) * * *

(ii) *Actual benefit must be disclosed.* * * * Reasonable estimates of the type described in paragraph (c)(3)(i) may be used to determine the normal form of benefit for purposes of this paragraph (d)(2)(ii) if the requirements of paragraphs (c)(3)(ii) and (iii) of this section are satisfied with respect to those estimates.

* * * * *

(5) *Use of participant-specific information in generalized notice.* A QJSA explanation does not fail to satisfy the requirements of this paragraph (d) merely because it contains an item of participant-specific information in place of the corresponding generally applicable information.

* * * * *

(f) *Effective date*—(1) *General effective date for QJSA explanations.* Except as provided in paragraph (f)(2) of this section, this section applies to a QJSA explanation with respect to any distribution with an annuity starting date that is on or after February 1, 2006.

(2) *Special effective date for certain QJSA explanations—(i) Application to QJSA explanations with respect to certain optional forms that are less valuable than the QJSA.* This section also applies to a QJSA explanation with respect to any distribution with an annuity starting date that is on or after October 1, 2004, and before February 1, 2006, if the actuarial present value of any optional form of benefit that is subject to the requirements of section 417(e)(3) (*e.g.*, single sums, distributions in the form of partial single sums in combination with annuities, social security level income options, and installment payment options) is less than the actuarial present value (as determined under § 1.417(e)–1(d)) of the QJSA. For purposes of this paragraph (f)(2)(i), the actuarial present value of an optional form is treated as not less than the actuarial present value of the QJSA if—

(A) Using the applicable interest rate and applicable mortality table under § 1.417(e)–1(d)(2) and (3), the actuarial present value of that optional form is not less than the actuarial present value of the QJSA for an unmarried participant; and

(B) Using reasonable actuarial assumptions, the actuarial present value of the QJSA for an unmarried participant is not less than the actuarial present value of the QJSA for a married participant.

(ii) *Requirement to disclose differences in value for certain optional forms.* A QJSA explanation with respect to any distribution with an annuity starting date that is on or after October 1, 2004, and before February 1, 2006, is only required to be provided under this section with respect to—

(A) An optional form of benefit that is subject to the requirements of section 417(e)(3) and that has an actuarial present value that is less than the actuarial present value of the QJSA (as described in paragraph (f)(2)(i) of this section); and

(B) The QJSA (determined without application of paragraph (c)(2)(ii) of this section).

(3) *Annuity starting date.* For purposes of paragraphs (f)(1) and (2) of this section, in the case of a retroactive annuity starting date under section 417(a)(7), as described in § 1.417(e)–1(b)(3)(vi), the date of commencement of the actual payments based on the retroactive annuity starting date is substituted for the annuity starting date.

(4) *Effective date for QPSA explanations.* This section applies to any QPSA explanation provided on or after July 1, 2004.

Mark E. Matthews,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 05–1553 Filed 1–27–05; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF DEFENSE

32 CFR Part 202

Restoration Advisory Boards (RABs)

AGENCY: Department of Defense, Office of the Deputy Under Secretary of Defense (Installations and Environment), DoD.

ACTION: Proposed rule.

SUMMARY: The Department of Defense (DoD) requests public comment on these proposed regulations regarding the scope, characteristics, composition, funding, establishment, operation, adjournment, and dissolution of Restoration Advisory Boards (RABs). DoD has proposed these regulations in response to 10 U.S.C. 2705(d)(2)(A), which requires the Secretary of Defense to prescribe regulations regarding RABs.

The propose of the RAB is to facilitate public participation in DoD environmental restoration activities and active and closing DoD installations and formerly used defense sites where local communities express interest in such activities. The proposed regulations are based on DoD's current policies for

reestablishing and operating RABs, as well as DoD's experience over the past ten years in using RABs.

DATES: Comments on this proposed rule must be submitted on or before March 29, 2005.

ADDRESSES: Comments on this proposal should be sent to the following address: RAB Rule, P.O. Box #5413, McLean, VA 22103–5413.

The public must send the original, and (whenever possible) a 3.5-inch computer disk containing comments in a common word processing format such as Microsoft Word. Public comments will also be collected via the Defense Environmental Network and Information eXchange (DENIX), located at the following Web site: *https://www.denix.osd.mil/rabruleTBD.*

FOR FURTHER INFORMATION CONTACT: Ms. Patricia Ferrebee, Office of the Deputy Under Secretary of Defense (Environmental Management), at (703) 695–6107.

SUPPLEMENTARY INFORMATION:

Preamble Outline

I. Authority
II. Background
III. Summary of the Proposed Rule
A. General Requirements
B. Operating Requirements
C. Administrative Support, Funding, and Reporting Requirements
IV. Section-by-Section Analysis of the Proposed Rule
A. General Requirements
1. Purpose, Scope, Definitions, and Applicability
a. Purpose
b. Purpose and Scope of Responsibilities of RABs
c. Definitions
d. Other Public Involvement Activities
e. Applicability of Regulations to Existing RABs
f. Guidance
2. Criteria for Establishment
a. Determining if Sufficient Interest Warrants Establishing a RAB
b. Responsibility for Forming and Operating a RAB
c. Converting Existing Technical Review Committees (TRCs) to RAB
3. Notification of Formation of a RAB
a. Public Notice and Outreach
b. RAB Information Meeting
4. Composition of a RAB
a. Membership
b. Government Representation
c. Community Representation
d. Chairmanship
e. Compensation for Community Members of the RAB
f. Roles and Responsibilities of Members
B. Operating Requirements
1. Creating a Mission Statement
2. Selecting Co-Chairs
3. Developing Operating Procedures
4. Training RAB Members
5. Conducting RAB Meetings
a. Public Participation
b. Nature of Discussions
c. Meeting Minutes
6. RAB Adjournment and Dissolution
a. RAB Adjournment
b. RAB Dissolution
c. Reestablishing an Adjourned or Dissolved RAB
d. Public Comment
7. Documenting RAB Activities
C. Administrative Support, Funding, and Reporting Requirements
1. Administrative Support and Eligible Expenses
a. Administrative Support
b. Eligible Administrative Expenses
c. Funding
2. Technical Assistance for Public Participation (TAPP)
3. Documenting and Reporting Activities and Expenses
V. Regulatory Analysis
A. Regulatory Impact Analysis Pursuant to Executive Order 12866
B. Regulatory Flexibility Act
C. Paperwork Reduction Act
VI. Unfunded Mandates

I. Authority

These regulations are proposed under the authority of section 2705 of title 10, United States Code (U.S.C.).

II. Background

The Defense Environmental Restoration Program (DERP) was established in 1986 to ''carry out a program of environmental restoration of facilities under the jurisdiction of the Secretary.'' Goals of the program include: ''(1) Identification, investigation, research and development, and cleanup of contamination from hazardous substances, and pollutants and contaminants. (2) Correction of other environmental damage (such as detection and disposal of unexploded ordnance) which creates an imminent and substantial endangerment to the public health or welfare or to the environment. (3) Demolition and removal of unsafe buildings and structures, including buildings and structures of the Department of Defense at sites formerly used by or under the jurisdiction of the Secretary.'' (10 U.S.C. 2701) DoD conducts these activities at active and closing Department of Defense (DoD) installations and formerly used defense sites (FUDS). DoD created distinct programs within the DERP to address sites environmentally impacted by DoD's past activities. The Installation Restoration program (IRP) established in 1986 covers environmental restoration activities to address hazardous substances, and, pollutants and contaminants. In September 2001, DoD established the Military Munitions Response program (MMRP) to manage cleanup of unexploded ordnance, discarded military munitions, and munitions constituents at areas other than operational ranges. The Building Demolition/Debris Removal (BD/DR) program category addresses the demolition and removal of unsafe buildings and structures at facilities or sites that are or were owned by, leased to, or otherwise possessed by the United States and under the jurisdiction of the Secretary of Defense.

During the early years of the DERP, the Office of the Secretary of Defense (OSD) managed the Defense Environmental Restoration Account (DERA) for the Department's Military Components—the Army, Navy, Air Force, Defense Logistics Agency (DLA), and Defense Threat Reduction Agency (DTRA)—who execute environmental restoration activities at their respective installations. In 1996, DoD decided to separate, or devolve, DERA into five Environmental Restoration (ER) accounts to better align each Military Component's DERP responsibilities and accountability for environmental cleanup efforts. Policy direction and oversight of the DERP is the responsibility of the Office of the Deputy Under Secretary of defense (Installations and Environment). The DoD Military Components are responsible for program implementation. The Army, Navy, and Air Force manage their own ER accounts. The U.S. Army Corps of Engineers manages the FUDS program for the Army, the Department's designated executive agent for FUDS. The FUDS program addresses environmental impacts on properties DoD once owned, leased, or operated and were under the jurisdiction of the Secretary of Defense. The final ER account, the Defense-Wide account, funds cleanup programs for DLA and DTRA in addition to providing the operating funds for OSD's oversight of the DERP. While DoD manages environmental restoration at Base Realignment and Closure (BRAC) installations as part of the DERP, it funds these environmental restoration activities through a separate BRAC Program account, which is part of DoD's overall Military Construction appropriation.

DoD recognizes the importance of public involvement at military installations. For the purposes of this proposed rule, the term installation means operating and closing DoD installations and FUDS that require environmental restoration. DoD has developed community involvement policies to ensure that local communities are provided the

opportunity as early as possible to obtain information about, and provide input to, the decisions regarding the environmental restoration activities at military installations. It is DoD policy to provide the public an opportunity to participate through the establishment of RABs, among other public involvement opportunities.

Based on statutory and regulatory requirements for community involvement and recommendations from the Federal Facilities Environmental Restoration Dialogue Committee (FFERDC), DoD has strengthened its community involvement efforts, including the RAB initiative, under its environmental restoration program. DoD believes that working in partnership with local communities and addressing the concerns of those communities early in the restoration process has enhanced its efforts under, and increased the credibility of, the environmental restoration program. DoD remains committed to involving communities neighboring its installations in environmental restoration decision processes that may affect human health, safety, and the environment. RABs have become a significant component of DoD's efforts to increase community involvement in DoD's environmental restoration program. RABs provide a continuous forum through which members of affected communities can provide input to an installation's ongoing environmental restoration activities. RAB members provide recommendations regarding environmental restoration to DoD, RABs are not Federal Advisory Committees and are specifically excluded from the requirements of the Federal Advisory Committee Act (10 U.S.C. 2705(d)(2)).

On September 27, 1994, DoD and the Environmental Protection Agency (EPA) jointly issued guidelines for the formation and operation of RABs (''Restoration Advisory Board Implementation Guidelines''). The guidelines describe how to implement the DoD RAB policy and identify each stakeholder's role with the RAB. The guidelines also state that existing Technical Review Committees (TRCs) or similar groups may be expanded or modified to become RABs, and that RABs may fulfill the statutory requirements for establishing TRCs (10 U.S.C. 2705(d)(1) grants DoD the authority to establish RABs instead of TRCs at installations undergoing environmental restoration).

As of September 30, 2003, DoD reported the existence of 298 active RABs across all of the Military Components' installations. Over the past several years, the number of RABs has remained fairly consistent, although the number fluctuates as some RABs adjourn and others form. RABs are one part of DoD's and the Military Components' extensive community outreach and public participation activities, which include compliance with the public notice and participation requirements of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), Resource Conservation and Recovery Act (RCRA), and other federal and state environmental laws as well as considerable consultation with our partners at federal, state and local government agencies. A RAB, however, may address only issues associated with environmental restoration activities under the DERP at DoD installations, including activities conducted under the MMRP category of the DERP to address unexploded ordnance, discarded military munitions, and the chemical constituents of munitions. If a RAB already exists at an installation and MMRP sites are identified, the RAB may be expanded to consider additional issues related to the MMRP sites. If the current RAB or DoD installation decides that it is necessary to involve new stakeholders, the installation should notify potential stakeholders of its intent to expand the RAB and solicit new members who have an interest in issues related to the MMRP. If there is no current RAB active at the installation and MMRP sites are identified, the installation will follow the prescribe guidance for determining sufficient community interest in forming a RAB.

The Secretary of Defense is required to ''prescribe regulations regarding the establishment, characteristics, composition, and funding of restoration advisory boards'' (10 U.S.C. 2705(d)(2)(A)). DoD's issuance of regulations is not, however, a precondition to the establishment of RABs (10 U.S.C. 2705(d)(2)(B)). Therefore, DoD proposes these regulations regarding the scope, characteristics, composition, funding, establishment, operation, adjournment, and dissolution of RABs. DoD recognizes that each RAB established will be a unique organization dealing with installation-specific issues. This proposal, developed consistent with the recommendations set forth in the FFERDC's Final Report, is consistent with existing DoD and EPA policy on RABs, and reflects over ten years of experience in establishing and operating RABs throughout the United States. DoD has structured this proposal to maximize flexibility for RAB members and installations nationwide.

III. Summary of the Proposed Rule

DoD is requesting public comment on these proposed regulations regarding the scope, characteristics, composition, funding, establishment, operation, adjournment, and dissolution of RABs. This section of the preamble provides a summary of the proposed regulations in 32 CFR part 202.

A. General Requirements

In this section of the proposed rule, DoD discusses the purpose, scope, relevant definitions, and applicability of the proposed regulations for RABs. DoD is required by 10 U.S.C. 2705(d)(2)(A) to issue regulations concerning the establishment, characteristics, composition, and funding of RABs. When issued as a final rule, the regulations will apply to all RABs, regardless of when they were established.

In this proposal, DoD defines the purposes of a RAB as follows:

- Provide an expanded opportunity for stakeholder involvement in the environmental restoration process at DoD installations.
- Act as a forum for the discussion and exchange of restoration program information, addressing the concerns of stakeholders and effectively reaching key groups and representatives from DoD, regulatory agencies, tribes, and the community.
- Provide an opportunity for RAB members to review progress and participate in a dialogue with the installation's decision makers concerning environmental restoration matters. Installations will listen, carefully-consider, and provide specific responses to the recommendations provided by the individual RAB members. While a RAB will complement other community involvement efforts the installation undertakes concerning environmental restoration, a RAB does not replace other types of community outreach and participation activities required by applicable federal and state laws.

A RAB may address issues associated with environmental restoration activities under the DERP at DoD installations. DoD funds RABs with money dedicated to supporting environmental restoration activities under the DERP. DoD understands that RABs may want to address environmental issues beyond the scope of environmental restoration activities. In these circumstances the installation co-chair should assist the interested individuals in finding the proper venue

to support a broader scope of issues. Environmental groups or advisory boards that address issues other than environmental restoration activities are not governed by this regulation.

The Office of the Deputy Under Secretary of Defense for Installations and Environment will issue guidance regarding the scope, characteristics, composition, funding, establishment, operation, adjournment, and dissolution of RABs pursuant to this rule. The issuance of the guidance is not a precondition to the establishment of RABs or the implementation of this rule.

This section of the proposed rule also discusses the criteria for establishment, notification of the formation, and composition of a RAB.

B. Operating Requirements

In this section of the proposed rule, DoD establishes basic requirements for the operation of a RAB. DoD proposes that each RAB will have a mission statement that describes its overall purpose and goals. DoD also specifies certain requirements regarding the selection process for co-chairs.

DoD proposes that each RAB will develop a set of operating procedures. Areas that may be addressed in the procedures include: clearly defined goals and objectives for the RAB, as determined by the DoD installation co-chair in consultation with the RAB; development and approval procedures for the RAB meeting minutes; attendance of members at meetings; meeting frequency and location; rules of order; frequency and procedures for conducting training; procedures for selecting, adding, or removing RAB members and co-chairs; specifics on the size of the RAB membership and the length of service for RAB members and co-chairs; methods for resolving disputes; processes for reviewing and responding to public comments on issues being addressed by the RAB; procedures for public participation in RAB activities; and keeping the public informed about RAB proceedings.

DoD is not proposing specified requirements concerning the conduct of RAB meetings because the meeting format of each RAB will vary and be dictated by the needs of the participants. DoD proposes, however, that all RAB meetings be open to the public; the installation will provide timely notice of each meeting in a local newspaper of general circulation; each RAB meeting will be held at a reasonable time and in a manner or place reasonably accessible to and usable by persons with disabilities; the installation co-chair will prepare meeting minutes of the RAB meetings; and the meeting minutes and other relevant documents will be available for public inspection and copying at a single, publicly accessible location. Additionally, the installation will document information on the activities of a RAB in the information repository.

In this section of the proposed rule, DoD also establishes requirements for adjourning a RAB. An Installation Commander may adjourn a RAB when there is no longer a need for a RAB or when community interest in the RAB declines. For FUDS, the Installation Commander may be the District Commander or equivalent.

Although Installation Commanders are expected to make every reasonable effort to ensure that a RAB performs its role as efficiently as possible, circumstances may prevent a RAB from operating efficiently or fulfilling its intended purpose. When this occurs, the Installation Commander will make a concerted attempt to resolve the issues that affect the RAB's effectiveness. If unsuccessful, the Installation Commander may elect to dissolve the RAB. The Installation Commander should discuss dissolution with regulators and the community as a whole before making a final decision. This section of the rule provides guidelines for how an Installation Commander may elect to dissolve a RAB.

In this section of the proposed rule, DoD sets forth requirements for adjourning a RAB, adjournment procedures, dissolving a RAB, dissolution procedures, reestablishing an adjourned or dissolved RAB, and public comment.

C. Administrative Support, Funding, and Reporting Requirements

In this section of the proposed rule, DoD sets forth requirements regarding administrative support for establishing, operating, and adjourning or dissolving a RAB, funding for administrative support, and reporting requirements regarding the activities and administrative expenses associated with RABs.

The Installation Commander, or if there is no such Commander, an appropriate DoD official, is authorized to pay for routine administrative expenses of a RAB established at an installation (10 U.S.C. 2705(d)(3)). To implement this provision, this proposed rule requires that the installation provide administrative support to establish and operate a RAB, subject to the availability of funds. The scope of this support corresponds to those activities that are eligible for DoD funding, including:

- RAB establishment
- Membership selection
- Training that meets certain criteria
- Meeting announcements
- Meeting facility, including accommodations necessary to comply with the Americans with Disabilities Act
- Meeting facilitators, including translators
- Meeting materials and minutes preparation
- RAB-member mailing list maintenance and RAB materials distribution
- RAB adjournment and dissolution.

The Secretaries of the Military Departments will make funds available for RAB administrative expenses (10 U.S.C. 2705(g)), subject to appropriations. The proposed rule establishes these requirements and specifies that active installations should pay for RAB administrative expenses using funds from their Military Component's ER accounts. The ER-FUDS account is used to pay for RAB administrative expenses at FUDS. At BRAC installations, the Base Closure account is used to pay for RAB administrative expenses.

This section of the rule also discusses the opportunities for the RAB to obtain technical assistance to facilitate members' understanding of the scientific and engineering issues underlying environmental restoration activities through DoD's Technical Assistance for Public Participation (TAPP) program. The DoD installation may also provide in-house assistance to discuss technical issues.

DoD is required to report annually to Congress on the activities of Technical Review Committees (TRCs) and RABs (10 U.S.C. 2706(a)(2)(J)). In order to fulfill this requirement, this proposed rule requires that where RABs are established the installation documents the activities of the RAB and tracks expenditures for administrative expenses of the RAB. This proposed rule does not prescribe specific procedures for the installation to follow as part of DoD's information collection when reporting to Congress. Rather, DoD will rely on existing internal reporting mechanisms within the Department and Military Components to collect this information annually.

IV. Section-by-Section Analysis of the Proposed Rule

This section of the preamble presents an analysis of each section of the proposed rule.

A. General Requirements

1. Purpose, Scope, Definitions, and Applicability

a. Purpose. The purpose of this part is to establish regulations regarding the characteristics, composition, funding, and establishment of RABs, as required by 10 U.S.C. 2705(d)(2)(A), and the operation, adjournment, and dissolution of RABs.

b. Purpose and Scope of Responsibilities of a RAB. DoD is proposing the purposes of a RAB be:

• To provide an expanded opportunity for stakeholder involvement in the environmental restoration process at DoD installations. DoD considers ''stakeholders'' to be parties that are actually or potentially affected by environmental restoration activities at an installation.

• To act as a forum for the discussion and exchange of restoration program information between DoD, regulatory agencies, and the community.

• To provide an opportunity for RAB members to review progress and participate in a dialogue with the installation's decision makers concerning environmental restoration matters. Installations will listen, give careful consideration, and provide specific responses to the recommendations provided by individual RAB members. Consensus is not a prerequisite for RAB member recommendations.

A RAB may address issues associated with environmental restoration activities under the DERP at DoD installations. DoD funds RABs with money dedicated to supporting environmental restoration activities under the DERP. DoD understands that RABs may want to address environmental issues beyond the scope of environmental restoration activities. In these circumstances the installation should assist the interested individuals in finding the proper venue to support a broader scope of issues. Environmental groups, advisory boards, or other entities that address issues other than environmental restoration activities are not RABs.

This proposed rule does not list specific responsibilities of RAB members, but DoD considers the following types of activities within the scope of RAB members' functions:

• Providing advice to the installation, EPA, state regulatory agency, and other government agencies on restoration activities and community involvement.

• Addressing important issues related to restoration, such as the scope of studies, cleanup levels, waste management, and remedial action alternatives.

• Reviewing and evaluating documents associated with environmental restoration activities, such as plans and technical reports.

• Identifying environmental restoration projects to be accomplished in the next fiscal year and beyond.

• Recommending priorities among environmental restoration sites or projects.

• Attending regular meetings that are open to the public and scheduled at convenient times and locations.

• Interacting with the local redevelopment authority (LRA) or other land use planning bodies to discuss future land use issues relevant to environmental restoration decision-making.

• Providing feedback to other community members on RAB activities and share community concerns and input with the RAB.

By establishing a RAB, DoD hopes to ensure that interested stakeholders have a voice and can actively participate in a timely and thorough manner in the planning and implementation of the environmental restoration process. A RAB will serve as one method for the expression and careful consideration of diverse points of view.

Installations will listen and give careful consideration to all advice provided by individual members.

DoD proposes that each installation undergoing environmental restoration activities establish a RAB where there is sufficient and sustained community interest. Where TRCs or similar advisory groups already exist, the TRC or similar advisory group will be considered for conversion to a RAB, provided there is sufficient and sustained interest within the community. DoD will recognize only one RAB or TRC per installation.

c. Definitions. In this section:

• Installation will include active and closing Department of Defense (DoD) installations and formerly used defense sites (FUDS).

• Community RAB member shall mean those individuals identified by community members and appointed by the Installation Commander to participate in a RAB who live and/or work in the affected community or are affected by the installation's environmental program.

• Environmental restoration shall include the identification, investigation, research and development, and cleanup of contamination from hazardous substances, and pollutants and contaminants.

• Installation Commander will include the Commanding Officer of an installation; the Installation Commander or other Military Department officials who close the facility and are responsible for its disposal at BRAC installations; or the U.S. Army Corps of Engineers Project Management District Commander at FUDS properties.

• Public participants shall include anyone else who may want to attend the RAB meetings, including those individuals who may not live and/or work in the affected community or may not be affected by the installation's environmental program but would like to attend and provide comments to the RAB.

• Stakeholders are those parties that may be affected by environmental restoration activities at an installation, including family members of military personnel and civilian workers, and tribal community members and indigenous people, as appropriate.

• Tribes means any federally recognized American Indian and Alaska Native government as defined by the most current Department of Interior/ Bureau of Indian Affairs list of tribal entities published in the Federal Register pursuant to Section 104 of the Federally Recognized Tribe Act.

• RAB adjournment means when an Installation Commander, in consultation with the EPA, state, tribes, RAB members, and the local community, as appropriate, closes the RAB based on a determination that there is no longer a need for a RAB or when community interest in the RAB declines sufficiently.

• RAB dissolution means when an Installation Commander disbands a RAB that is no longer fulfilling the intended purpose of advising and providing community input to an Installation Commander and decision makers on environmental cleanup projects. Installation Commanders are expected to make every reasonable effort to ensure that a RAB performs its role as effectively as possible and makes a concerted attempt to resolve issues that affect the RAB's effectiveness. There are circumstances, however, that may prevent a RAB from operating efficiently or fulfilling its intended purpose.

d. Other Public Involvement Activities. RABs are one part of DoD and the Military Components' extensive community outreach and public participation activities, which include compliance with the public notice and participation requirements of CERCLA, RCRA, and other federal and state environmental laws, as well as considerable consultation with our partners at federal, state, and local environmental and resource agencies.

e. Applicability of Regulations to Existing RABs. DoD is proposing these

regulations regarding the establishment, characteristics, composition, and funding of RABs (10 U.S.C. 2705(d)(2)A)) to formalize current Department policy. DoD intends that the final regulations will apply to all RABs, including RABs established prior to the effective date of the final rule. DoD does not consider that applying final regulations to RABs already established will pose any additional requirements or conflict because the proposed regulations are based on existing DoD policy that has been implemented since September 1994.

f. Guidance. The Office of the Deputy Under Secretary of Defense for Environment will issue guidance regarding the scope, characteristics, composition, funding, establishment, operation, adjournment, and dissolution of RABs pursuant to this rule. The issuance of the guidance is not a precondition to the establishment of RABs or the implementation of this rule.

2. Criteria for Establishment

a. Determining if Sufficient Interest Warrants Establishing a RAB. In this rule, RABs may only be established at installations undergoing environmental restoration. There may be only one RAB per installation. In accordance with existing policy, DoD proposes that a RAB be established when the Installation Commander finds sufficient and sustained community interest and any of the following criteria are met:

- The closure of an installation involves the transfer of property to the community;
- At least 50 local citizens petition for a RAB;
- Federal, state, tribal, or local government representatives request formation of a RAB; or
- The installation determines the need for a RAB.

To clarify how an installation will determine the need for a RAB, DoD proposes that the Installation Commander determine the level of interest within the community for establishing a RAB by:

- Reviewing correspondence files;
- Reviewing media coverage;
- Consulting community members;
- Consulting relevant government officials; and
- Evaluating responses to communication efforts, such as notices placed in local newspapers.

At the majority of installations that have an environmental restoration program, DoD expects that local communities will be interested in forming a RAB. DoD notes that installation efforts identify the level of community interest in establishing a RAB should not be limited to a one-time assessment of the criteria discussed above. In special circumstances it may be advantageous to establish a joint RAB for multiple installations. The decision to establish a joint RAB must be made in consultation with RAB members. Only one RAB, however, will be recognized per installation. If a RAB already exists at an installation and there will be MMRP sites, the RAB may be expanded to consider issues related to the MMRP sites. If the current RAB or DoD installation decides that it is necessary to involve new stakeholders, then installation should notify potential stakeholders of its intent to expand the RAB and solicit net members who have an interest in issues related to the MMRP.

Where RABs are not formed initially, installations undergoing environmental restoration activities will reassess community interest at least every 24 months. Reassessment of community interest should include public notice through local media, such as a local newspaper. Where the reassessment finds sufficient and sustained community interest, the installation should establish a RAB. Where the reassessment does not find sufficient and sustained community interest in a RAB, the installation will document, in a memorandum for the Administrative Record, the procedures followed in the reassessment and the findings of the reassessment.

When all environmental restoration decisions have been made and required remedies are in place and properly operating at an installation, reassessment of the community interest for establishing or reestablishing a RAB is not necessary every 24 months. When additional environmental restoration decisions have to be made resulting from subsequent actions, such as long-term monitoring and five-year reviews, the installation will reassess community interest for establishing or reestablishing a RAB.

b. Responsibility for Forming and Operating a RAB. Once the installation determines that a RAB will be established, DoD proposes that the Installation Commander have the lead responsibility for forming and operating the RAB. The Installation Commander should have lead responsibility because the RAB will be an integral part of the installation's community involvement and outreach programs. The Installation Commander may also delegate his or her duties to appropriate personnel but retains oversight authority and responsibility. DoD recommends that installations involve, as appropriate, EPA, and state, tribal, and local governments and community members in all phases of RAB planning and operation.

c. Converting Existing Technical Review Committees (TRCs) to RABs. Before the implementation of RABs, TRCs were established at DoD installations to provide interested parties with a forum to discuss and provide input into environmental restoration activities. In accordance with 10 U.S.C. 2705(d)(1), a RAB fulfills the requirements of 10 U.S.C. 2705(c), which directs DoD to establish TRCs. DoD recommends that, where TRCs or similar advisory groups already exist, provided there is sufficient and sustained interest within the community for a RAB, the TRC or similar advisory group should be considered for conversion to a RAB.

RABs expand the TRC initiative in the following ways: (1) RABs involve a greater number of community members than TRCs, thereby better incorporating the diverse needs and concerns of the community directly affected by environmental restoration activities; and (2) chairmanship of the RAB is shared between the installation and community, promoting partnership and careful consideration of the community's concerns in the decision-making process.

In order to convert a TRC to a RAB, DoD should increase community representation, evaluate and ensure the diversity of community representation, add a community co-chair, and open meetings to the public.

3. Notification of Formation of a RAB

a. Public Notice and Outreach. Prior to establishing a RAB or converting a TRC to a RAB, DoD proposes that an installation notify potential stakeholders of its intent to form a RAB. In announcing the formation of a RAB, the installation should describe the purpose of a RAB and discuss membership opportunities.

DoD recommends that every effort be made to ensure that a broad spectrum of individuals or groups representing the community's interests are informed about the RAB, its purposes, and membership opportunities. In some cases, it may necessary that the installation directly solicit some groups or organizations, particularly groups that may be traditionally under represented, such as low-income and minority segments of the population. It is important that RAB memberships are fairly balanced in terms of points of view represented and functions to be performed. Installations should consult the existing TRC, EPA, and state, tribal, and local government representatives

for information or other comments before providing this notice.

b. RAB Information Meeting. While not required in the proposed rule, DoD suggests that an installation sponsor an informational meeting prior to establishing a RAB. The focus of this meeting will be to introduce the concept of RABs to the community and to begin the membership solicitation process.

4. Composition of a RAB

a. Membership. RAB membership shall be well balanced and reflect the diverse interests within the local community. Therefore, DoD proposes that each RAB should consist of representatives of the Military Component (the U.S. Army Corps of Engineers for FUDS), members of the community, EPA, and state, tribal, or local government representatives, as appropriate. RAB meetings will be widely publicized and open to all. Representatives of organizations and agencies who lie and work outside the affected area are encouraged to voice their opinions at RAB meetings within the rules of conduct established by the RAB.

b. Government Representation. In addition to the Military Component, DoD proposes that EPA and state, tribal, and local governments should be represented on the RAB, as they fulfill important roles because of their regulatory oversight of DoD environmental restoration activities. Potential candidates may include the Remedial Project Manager (RPM) from the installation, EPA at the discretion of the EPA Administrator, as well as representatives from the state, tribal, or local government agencies. In the case of closing military installations, members of the BRAC Cleanup Team (BCT) may serve on the RAB as government representatives. It is important that any government representative chosen for RAB membership dedicate the time necessary, and have sufficient authority, to fulfill all RAB responsibilities.

Ideally, DoD believes that RABs should have only one representative from each government agency, so as to prevent an inordinate representation by government and DoD officials. While DoD encourages other government representatives to attend RAB meetings, these representatives' role will be strictly one of providing information and support.

c. Community Representation. While DoD is not proposing specific procedures to be used for selecting community members of the RAB, DoD notes that one of the most sensitive issues facing installations that establish a RAB concerns the selection of community members. When members of the community feel the selection process for RAB members, particularly of community members, is conducted in an objective and unbiased manner, it enhances their perception that the RAB can be a credible forum for the discussion of their issues and concerns. If the selection of community members is not approached carefully, the result can be a loss of trust.

To support the objective selection of community RAB members, installations will use a selection panel comprised of community members to nominate community RAB members. The Installation Commander in consultation with the state, tribal, and local governments and EPA, as appropriate, will identify community interests and solicit names of individuals who can represent these interests on the selection panel. The panel will establish and announce the following:

- Procedures for nominating community RAB members,
- Process for reviewing community interest,
- Criteria for selecting community RAB members, and
- List of RAB nominees.

Following the panel nominations, the Installation Commander, in consultation with the state and EPA as appropriate, will review the nominations to ensure the panel fairly represents the local community. The Installation Commander will then appoint the community RAB members.

Some installations are located in close proximity to American Indian and Alaska Native communities. While DoD encourages individual tribal members to participate on RABs, RABs in no way replace or serve as a substitute forum for the government-to-government relationship between DoD and federally-recognized tribes, as defined by the most current Department of Interior/Bureau of Indian Affairs list of tribal entities published in the **Federal Register** pursuant to Section 104 of the Federally Recognized Indian Tribe List Act.

RAB community members should live and/or work in the affected community or be affected by the installation's environmental restoration program. DoD will not limit participation in the RAB of potential members who have or may bid on DoD contracts, if proper and appropriate assurances to avoid any potential conflicts of interest are issued. DoD will, however, apply applicable conflict of interest rules, pursuant to the Federal Acquisition Regulation.

At closing installations, members of the LRA, as defined under BRAC, are included as stakeholders and are encouraged to attend RAB meetings. There is not a specific requirement, however, that LRA members be invited to be a member of the RAB.

d. Chairmanship. DoD proposes that chairmanship of the RAB be shared between the installation and the community. DoD believes this will promote partnering between DoD and the community and reflect DoD's commitment to consider the community's concerns when making decisions about the environmental restoration process. Together, the installation and community co-chairs jointly will determine meeting agendas, run meetings, and ensure that issues related to environmental restoration are raised and adequately considered.

e. Compensation for Community RAB Members. DoD also is specifying in the proposed rule that the community co-chair and community RAB members are expected to serve without compensation for their services. DoD considers community membership on a RAB to be voluntary, and, therefore, DoD will not pay these members for their participation.

f. Roles and Responsibilities of Members. DoD is not proposing specific requirements concerning the roles and responsibilities of individual members of a RAB. DoD considers the issuance of such regulations to be overly burdensome to the formation and operation of RABs, and, therefore, unnecessary.

B. Operating Requirements

1. Creating a Mission Statement

DoD proposes that each RAB should have a mission statement that articulates the overall purpose of the RAB. DoD considers this necessary to provide focus and objectives for the group. In addition, when members of the RAB understand their mission from the onset, it provides a framework for discussions. Without the framework, discussions may become hampered with issues that are not relevant to the environmental restoration process. The DoD installation co-chair in conjunction with the RAB members will determine the RAB mission statement consistent with guidance provided by the DoD Component. The mission statement should be discussed with the RAB and the DoD installation co-chair will listen to and consider the RAB members' comments before finalizing.

2. Selecting Co-Chairs

DoD proposes that the installation co-chair be selected either by the Installation Commander or equivalent,

or defined by military service-specific guidance, while the community members of the RAB will select the community co-chair. DoD considers it necessary for the community members to select their co-chair to ensure their active participation in the operation of the RAB and to help ensure that the RAB can be a credible forum for discussing community issues and concerns. Public participants are not afforded the opportunity to vote for the community co-chair.

3. Developing Operating Procedures

DoD considers a formal and agreed-upon set of operating procedures necessary to manage the business of RABs. While DoD will allow each RAB to customize or tailor its operating procedures as it sees fit, DoD proposes that the co-chairs be responsible for the operating procedures, to include:

- Setting clearly defined goals and objectives for the RAB. These should be discussed with the RAB, and the DoD installation co-chair will listen to, consider, and provide specific responses to the RAB members' comments before finalizing the goals and objectives.
- Ensuring that an agenda is developed for RAB meetings. The agenda is considered an important organizational tool that should be developed to reflect the interests and concerns of RAB members.
- Announcing meetings.
- Establishing attendance requirements of members at meetings.
- Developing and approving procedures for the minutes of RAB meetings.
- Meeting frequency and location.
- Establishing the Rules of Order.
- Announcing the frequency and procedures for conducting training.
- Establishing procedures for selecting or replacing the community co-chair and selecting, replacing, or adding community RAB members.
- Specifying the size of the RAB membership and the periods for membership and co-chair length of service.
- Reviewing and responding to public comments.
- Establishing the participation of the public.
- Keeping the public informed about proceedings of the RAB.
- Discussing the agenda for the next meeting and issues to be addressed.

4. Training RAB Members

DoD is not proposing a requirement for training members of the RAB. DoD believes, however, that RAB members may need some initial orientation training to enable them to fulfill their responsibilities. DoD recommends that the installation should work with EPA, the state, tribes, and environmental groups to develop methods to quickly inform and educate the RAB members and to promote the rapid formation of a fully functioning RAB.

DoD notes that under this proposed rule, only certain types of training will be considered within the scope of administrative support for RABs, and therefore, may be financed using funds allocated to the administrative expenses of RABs. DoD further discusses training in context of administrative support eligible for available funding in section IV.C.1.b. of this preamble.

5. Conducting RAB Meetings

a. Public Participation. DoD believes the meeting format of each RAB will vary and be dictated by the needs of the participants. Therefore, DoD is not proposing specific procedures for conducting RAB meetings. All RAB meetings, however, shall be open to the public. The installation co-chair should prepare and publish a timely public notice in a local newspaper of general circulation announcing each RAB meeting. Each RAB meeting will be held at a reasonable time and in a manner or place reasonably accessible to and usable by persons with disabilities. Interested persons will be permitted to attend, appear before, or file statements with any RAB, subject to such reasonable rules or regulations that may be prescribed.

b. Nature of Discussions. Regarding the nature of discussions at RAB meetings, the installation will listen and give careful consideration to all advice provided by the individual RAB members. While voting or polling the members may facilitate RAB discussions, such votes are advisory only and not binding on agency decision makers. It is a RAB's decision on how to propose and debate recommendations; and this decision should be agreed upon by the RAB. Group consensus is not a prerequisite for RAB input; each member of the RAB may provide advice as an individual.

c. Meeting Facilitator: RABs may recommend to use a trained facilitator who is a neutral third-party and is acceptable to all members of the board. The facilitator's role is to guide the RAB through a cooperative communication process in order to fulfill the group's stated purpose or agenda as easily as possible. The facilitator has no substantive decision-making authority. The facilitator focuses on the group's communication process rather than the technical content of what is discussed.

d. Meeting minutes. DoD proposes that the installation co-chair, in coordination with the community co-chair, will prepare minutes of each RAB meeting. The RAB meeting minutes will be kept and will contain a record of the persons present, a complete and accurate description of matters discussed and opinions voiced, and copies of all reports received, issued, or considered by the RAB. At the installation's discretion, a court reporter or electronic taping is allowable, whether through live transmission or video or audiotape. The accuracy of all minutes will be certified by the RAB co-chairs. Although not required, DoD recommends that the installation consider mailing copies of the minutes to all community members who attended the meeting and/or to people identified on the installation's community relations mailing list. This is to ensure dissemination of the results to community members and interested parties.

6. RAB Adjournment and Dissolution

In this section of the proposed rule, DoD sets forth requirements for adjourning a RAB, adjournment procedures, dissolving a RAB, dissolution procedures, reestablishing an adjourned or dissolved RAB, and public comment.

a. RAB Adjournment

(1) Requirements for RAB Adjournment. An Installation Commander may adjourn a RAB when there is no longer a need for a RAB or when community interest in the RAB declines.

RABs may adjourn in the following situations:

- A record of decision has been signed for all DERP sites on the installation.
- An installation has achieved response complete at all sites and no further environmental restoration decisions are required.
- An installation has all remedies in place. When all environmental restoration decisions have been made and required remedies are in place and properly operating at an installation, the RAB may adjourn or decide to become inactive. The installation (or the designated authority at closure installations) will establish a mechanism to inform the community, including former RAB members, about subsequent actions, such as long-term monitoring and five-year reviews, that may interest the RAB and allow the community to address this information as appropriate. At a minimum, the installation will provide this

information to the community through status report mailings, Web sites, or local information repositories.

• The RAB has achieved its objectives as defined in the RAB Operating Procedures.

• If there is no longer sufficient, sustained community interest, as documented by the installation with RAB community members and community-at-large input, to sustain the RAB. The Installation Commander will be responsible for reassessing community interest that could warrant reactivating or reestablishing the RAB.

• The installation has been transferred out of DoD control and DoD is no longer responsible for making restoration response decisions.

(2) Adjournment Procedures. The Installation Commander should consult with EPA, states, tribes, RAB members, and the local community, as appropriate, regarding adjourning the RAB before making a final decision. The Installation Commander should consider all responses when determining the appropriate action.

If the Installation Commander decides to adjourn the RAB, the Installation Commander will document the rationale for adjournment in a memorandum for inclusion in the Administrative record, notify the public of the decision through written notice to the RAB members and through publication of a notice in a local newspaper of general circulation, and describe other ongoing public involvement opportunities that are available.

b. RAB Dissolution

(1) Requirements for RAB Dissolution. An Installation Commander may recommend dissolution of a RAB when a RAB is no longer fulfilling the intended purpose of advising and providing community input to an Installation Commander and decision makers on environmental cleanup projects as described in IV.A.1.b. Although Installation Commanders are expected to make every reasonable effort to ensure that a RAB performs its role as effectively as possible, circumstances may prevent a RAB from fulfilling the intended purpose as described in this rule. When this occurs, the Installation Commander will make a concerted attempt to resolve the issues that affect the RAB's effectiveness. If unsuccessful, the Installation Commander may elect to recommend dissolution of the RAB. In making such a decision, if environmental restoration activities are not complete, the Installation Commander should ensure that the community involvement program detailed in the Community Relations Plan provides for continued effective stakeholder input.

(2) Dissolution Procedures. The installation co-chair should consult with the community, EPA and state, tribal and local government representatives as appropriate, regarding dissolving the RAB. The installation co-chair should notify the RAB community co-chair and members in writing of the intent to dissolve the RAB and the reasons for doing so, and provide the RAB members 30 days to respond in writing. The installation co-chair should consider RAB member responses, and in consultation with EPA and state, tribal and local government representatives, as appropriate, determine the appropriate action.

If the Installation Commander decides to proceed with recommending the RAB for dissolution, the Installation Commander should notify the public of the proposal to dissolve the RAB and provide a 30-day public comment period on the proposal (see section d. Public Comment for further discussion). At the conclusion of the public comment period, the Installation Commander will review the public comments, consult with EPA, state, tribal and local government representatives, as appropriate, and render a recommendation.

The recommendation, responsiveness summary, and all supporting documentation should be sent via the chain-of-command to the Military Component's Environmental Deputy Assistant Secretary (or equivalent) for approval or disapproval. The Military Component's Environmental Deputy Assistant Secretary (or equivalent) will notify the Office of the Deputy Under Secretary of Defense (Installations & Environment) (or equivalent) of the decision to approve or disapprove the request to dissolve the RAB and the rationale for that decision.

Once the Military Component's Environmental Deputy Assistant Secretary (or equivalent) makes a final decision, the Installation Commander will document the rationale for dissolution in a memorandum for inclusion in the Administrative Record, notify the public of the decision through written notice to the RAB members and through publication of a notice in a local newspaper of general circulation, and describe other ongoing public involvement opportunities that are available.

c. Reestablishing an Adjourned or Dissolved RAB. An installation may reestablish an adjourned or dissolved RAB if there is sufficient and sustained community interest in doing so and there are environmental restoration activities still ongoing at the installation. Where a RAB is adjourned or dissolved and environmental restoration activities continue, the installation should reassess community interest at least every 24 months. When all environmental restoration decisions have been made and required remedies are in place and properly operating at an installation, reassessment of the community interest for reestablishing the RAB is not necessary. When additional environmental restoration decisions have to be made resulting from subsequent actions, such as long-term monitoring and five-year reviews, the installation will reassess community interest for reestablishing the RAB.

Reassessment should include, at a minimum, consultation with the chain-of-command, EPA, state, tribes, and the local community as appropriate, and a 30-day public comment period (see section d. Public Comment for further discussion). Where the reassessment finds sufficient and sustained community interest, at a previously adjourned RAB the Installation Commander should reestablish a RAB.

If there is interest for reestablishment at a previously dissolved RAB, but the Installation Commander determines that the same conditions exist that required the original dissolution, he or she will request, through the chain of command to the service component deputy assistant secretary, an exception to reestablishing the RAB. If those conditions no longer exist at a previously dissolved RAB, and there is interest in reestablishment the Installation Commander should notify the deputy assistant secretary of their recommendation for the RAB to be reestablished. The deputy assistant secretary will take the Installation Commander's recommendation under advisement and may approve that RAB for reestablishment.

Where the reassessment does not find sufficient and sustained community interest in reestablishing the RAB, the Installation Commander should document (in a memorandum for the record) the procedures followed in the reassessment and the findings of the reassessment. This document will be included in the Administrative Record for the installation.

d. Public Comment. If the Installation Commander intends to recommend dissolution of a RAB or reestablish a dissolved RAB, the Installation Commander will notify the public of the proposal to dissolve or reestablish the RAB and provide a 30-day public comment period on the proposal. The Installation Commander will notify the public of the decision through

publication of a notice in a local newspaper of general circulation and distribute the notice to community members. The installation's Public Affairs Office should have an updated mailing list. At the conclusion of the public comment period, the Installation Commander will review public comments, consult with the RAB, EPA, and state, tribal, or local government representatives, as appropriate, prepare a responsiveness summary, and render a recommendation. The Installation Commander will notify the public of the decision.

7. Documenting RAB Activities

Additionally, the installation will document the relevant information on the activities of a RAB in the Administrative Record. These activities will include, but are not limited to:

- Installation's efforts to survey community interest in forming a RAB,
- Steps taken to establish a RAB where there is sustained community interest,
- How the RAB relates to the overall community involvement program, and
- Steps taken to adjourn the RAB.

The records, reports, minutes, appendixes, working papers, drafts, studies, agenda, or other documents that were made available to or prepared for or by each RAB will be available for public inspection and copying at a single, publicly accessible location, such as the information repositories established under the installation's Community Relations Plan, a public library, or in the offices of the installation to which the RAB reports, until the RAB ceases to exist.

To the extent that RAB input is considered in a decision regarding environmental restoration activities, relevant information on the RAB activities will be included in the Administrative Record.

C. Administrative Support, Funding, and Reporting Requirements

1. Administrative Support and Eligible Expenses

a. Administrative Support. The Installation Commander, or if there is no such Commander, an appropriate DoD official, is authorized to pay for routine administrative expenses of a RAB established at an installation (10 U.S.C. 2705(d)(3)). To implement this provision, this proposed rule requires that the installation provide administrative support to establish, operate, and adjourn a RAB, subject to the availability of funds. Securing ongoing administrative support is especially important for closing or closed installations.

DoD proposes to define the scope of activities that are unique to the establishment and operation of RABs, and therefore eligible as a RAB administrative expense.

b. Eligible Administrative Expenses. In order for an activity to be considered as an eligible RAB administrative cost, the activity must be unique to and directly associated with establishing and operating the RAB. For example, an advertisement for a RAB meeting is an eligible RAB administrative cost. However, producing a fact sheet as part of obtaining a hazardous waste storage permit under RCRA or hosting an installation open house as specified by the Community Relations Plan under CERCLA, may not necessarily be relevant to a RAB's mission statement or operations. The costs incurred in preparing and distributing such a fact sheet or holding the open house would not be considered administrative support required for a RAB.

While DoD cannot identify all possible examples of activities unique to and directly associated with establishing and operating a RAB, DoD proposes to consider the following activities as typical of administrative support required for a RAB:

- RAB establishment.
- Membership selection.
- Training if it is unique to and mutually benefits the establishment and operation of a RAB and relevant to the environmental restoration activities occurring at the installation.
- Meeting announcements.
- Meeting facility.
- Meeting facilitators, including translators.
- Meeting agenda materials and minutes preparation.
- RAB-member mailing list maintenance and RAB materials distribution.
- RAB adjournment.

Training for RAB members is considered an eligible administrative cost if it mutually benefits all members of a RAB and is relevant to the environmental restoration activities occurring at the installation. For example, if the installation were to hold an orientation training for members of a RAB, costs incurred in preparing training manuals, slides, or other presentation materials would be considered an allowable administrative expense because such training is mutually beneficial to all members of the RAB. A type of training that would not qualify as a RAB administrative support includes specialized training for an individual member of a RAB, such as an off-site workshop on building leadership capabilities. However, DoD notes that types of training that are not eligible for funding as a RAB administrative expense may qualify and be eligible for funding as technical assistance.

RAB administrative support is for RAB purposes only. RAB administrative expenses do not include general community involvement expenses, such as preparation of public outreach materials, responses to public comment, or repository costs. RAB administrative support does not include efforts to determine community interest in forming a RAB that does not result in the actual formation of a RAB. These items will be categorized as a community involvement expense.

Additional types of expenses ineligible as RAB administrative costs include, but are not limited to:

- Salaries for DoD personnel.
- Dedicated equipment such as computers, software, facsimile machines, telephone lines, or electronic mail for community RAB members.
- Renting dedicated office space for community RAB members.
- Administrative support to community members of the RAB.
- Printed stationery and personal business cards.
- Temporary duty/travel, conference attendance, or fees, except where prior approval has been granted by DoD.
- Compensation to RAB members for meeting attendance, work hours lost, time reviewing and commenting on documents, travel to meetings, or long distance telephone calls.

c. *Funding.* The Secretaries of the Military Departments will make funds available for RAB administrative expenses (10 U.S.C. 2705(g)), subject to the availability of funds. Funds requested for environmental restoration activities that were appropriated to Military Components' ER or BRAC accounts or the ER–FUDS account may be used to provide administrative support to RABs. Such funds will not be used to support the activities of environmental groups or advisory boards in addressing issues other than environmental restoration activities. The Installation Commander is authorized to pay routine administrative expenses of the RABs, in accordance with 10 U.S.C. § 2705(d)(3). The activities of the RAB and expenditures of such funds for administrative expenses will be reported to ODUSD(I&E), at a minimum, on an annual basis.

2. Technical Assistance for Public Participation (TAPP)

Community members of a RAB may request technical assistance from the

private sector to assist their understanding of the scientific and engineering issues underlying eligible DoD environmental restoration activities. Technical assistance may be made available to community members of RABs or TRCs in accordance with 10 U.S.C. 2705(e) and the TAPP regulations found at 32 CFR part 203. RABs may submit TAPP requests to the Installation Commander, or to an appropriate DoD official. The DoD installation may also provide in-house assistance to discuss technical issues.

3. Documenting and Reporting Activities and Expenses

DoD is required to report to Congress on the activities of TRCs and RABs (10 U.S.C. 2706(a)(2)(J)). In order to fulfill this requirement, this proposed rule requires that, where RABs are established, the installation documents the activities of the RAB and tracks expenditures for administrative expenses of the RAB. With regards to tracking expenses, DoD recommends that installations tally costs according to the specific activities identified above (see section IV.C.1.b. of this rule) that are typical of administrative support required for RAB.

Although this proposed rule requires installations to document RAB activities and track expenditures, DoD is not prescribing specific procedures to accomplish this. In addition, DoD will use internal Department and Military Component-specific reporting mechanisms to obtain required information from installations on RAB activities and expenditures when reporting to Congress.

V. Regulatory Analysis

A. Regulatory Impact Analysis Pursuant to Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), as amended, DoD must determine whether a regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order.

DoD has determined that this proposed rule is not a ''significant regulatory'' action because it is unlikely to:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, productivity, competition, jobs, environment, public health, or safety of state, local, or tribal governments or communities;

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan program or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

B. Regulatory Flexibility Act

It has been certified that this proposed rule is not subject to the Regulatory Flexibility Act of 1980, 5 U.S.C. 601 *et seq.* because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. The primary effect of the proposed rule will be to increase community involvement in DoD's environmental restoration program.

C. Paperwork Reduction Act

It has been certified that the proposed rule does not impose any reporting or recordkeeping requirements subject to the Paperwork Reduction Act of 1995 (Pub. L. 104–13).

VI. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995, DoD must prepare a statement to accompany any rule where the estimated costs to state, local, or tribal governments in the aggregate, or to the private sector, will be $100 million or more in any one year.

DoD has determined that this proposed rule will not include a federal mandate that may result in estimated costs of $100 million or more to either state, local, or tribal governments in the aggregate, or to the private sector.

List of Subjects in 32 CFR Part 202

Administrative practice and procedure, Environmental protection—restoration, Federal buildings and facilities, Organization and functions (Government agencies).

Title 32 of the Code of Federal Regulations, Chapter I, Subchapter M, is proposed to be amended by adding part 202 to read as follows:

PART 202—RESTORATION ADVISORY BOARDS (RABs)

Subpart A—General Requirements

Sec.
202.1 Purpose, scope, definitions, and applicability.
202.2 Criteria for establishment.
202.3 Notification of formation of a Restoration Advisory Board.
202.4 Composition of a RAB.

Subpart B—Operating Requirements

202.5 Creating a mission statement.
202.6 Selecting co-chairs.
202.7 Developing operating procedures.
202.8 Training RAB members.
202.9 Conducting RAB meetings.
202.10 RAB adjournment and dissolution.
202.11 Documenting RAB activities.

Subpart C—Administrative Support, Funding, and Reporting Requirements

202.12 Administrative support and eligible expenses.
202.13 Technical assistance for public participation (TAPP).
202.14 Documenting and reporting activities and expenses.

Authority: 5 U.S.C. 551 *et seq.* and 10 U.S.C. 2705.

Subpart A—General Requirements

§ 202.1 Purpose, scope, definitions, and applicability.

(a) *Purpose.* The purpose of this part is to establish regulations regarding the scope, characteristics, composition, funding, establishment, operation, adjournment, and dissolution of Restoration Advisory Boards (RABs).

(b) *Purpose and scope of responsibilities of RABs.* The purpose of a RAB is to provide:

(1) An opportunity for stakeholder involvement in the environmental restoration process at Department of Defense (DoD) installations. Stakeholders are those parties that may be affected by environmental restoration activities at the installation.

(2) A form for the discussion and exchange of environmental restoration program information between DoD installations, regulatory agencies, tribes and the community.

(3) An opportunity for RAB members to review progress, participate in a dialogue with, and provide comments and advice to the installation's decision makers concerning environmental restoration matters. Installations shall give careful consideration to the comments provided by the RAB members.

(c) *Definitions.* In this section:

(1) *Community RAB member* shall mean those individuals identified by community members and appointed by the Installation Commander to participate in a RAB who live and/or work in the affected community or are affected by the installation's environmental program.

(2) *Environmental restoration* shall include the identification, investigation, research and development, and cleanup of contamination from hazardous substances, and pollutants and contaminants.

(3) *Installation* shall include active and closing Department of Defense (DoD) installations and formerly used defense sites (FUDS).

(4) *Installation Commander* shall include the Commanding Officer or the equivalent of a Commanding Officer at active installations; the Installation Commander or other Military Department officials who close the facility and are responsible for its disposal at Base Realignment and Closure (BRAC) installations; or the U.S. Army Corps of Engineers Project Management District Commander at FUDS.

(5) *Public participants* shall include anyone else who may want to attend the RAB meetings, including those individuals may not live and/or work in the affected community or may not be affected by the installation's environmental program but would like to attend and provide comments to the RAB.

(6) *Stakeholders* are those parties that may be affected by environmental restoration activities at an installation, including family members of military personnel and civilian workers, and tribal community members and indigenous people, as appropriate.

(7) *Tribes* shall mean any federally recognized American Indian and Alaska Native government as defined by the most current Department of Interior/Bureau of Indian Affairs list of tribal entities published in the **Federal Register** pursuant to Section 104 of the Federally Recognized Tribe Act.

(8) *RAB adjournment* shall mean when an Installation Commander, in consultation with the Environmental Protection Agency (EPA), state, tribes, RAB members, and the local community, as appropriate, closes the RAB based on a determination that there is no longer a need for a RAB or when community interest in the RAB declines.

(9) *RAB dissolution* shall mean when an Installation Commander disbands a RAB that is no longer fulfilling the intended purpose of advising and providing community input to an Installation Commander and decision makers on environmental restoration projects. Installation Commanders are expected to make every reasonable effort to ensure that a RAB performs its role as effectively as possible and a concerted attempt to resolve issues that affect the RAB's effectiveness. There are circumstances, however, that may prevent a RAB from operating effectively or fulfilling its intended purpose.

(d) *Other public involvement activities.* A RAB should complement other community involvement efforts occurring at an installation; however, it does not replace other types of community outreach and participation activities required by applicable laws and regulations.

(e) *Applicability of regulations to existing RABs.* The regulations in this part apply to all RABs regardless of when the RAB was established.

(f) *Guidance.* The Office of the Deputy Under Secretary of Defense for Environment shall issue guidance regarding the scope, characteristics, composition, funding, establishment, operation, adjournment, and dissolution of RABs pursuant to this rule. The issuance of any such guidance shall not be a precondition to the establishment RABs or the implementation of this rule.

§ 202.2 Criteria for establishment.

(a) *Determining if sufficient interest warrants establishing a RAB.* A RAB should be established when there is sufficient and sustained community interest, and any of the following criteria are met:

(1) The closure of an installation involves the transfer of property to the community;

(2) At least 50 local citizens petition the installation for creation of a RAB;

(3) Federal, State, tribal, or local government representatives request the formation of a RAB; or

(4) The installation determines the need for a RAB. To determine the need for establishing a RAB, an installation should:

(i) Review correspondence files;

(ii) Review media coverage;

(iii) Consult local community members;

(iv) Consult relevant government officials; and

(v) Evaluate responses to communication efforts, such as notices placed in local newspapers.

(b) *Responsibility for forming or operating a RAB.* The installation shall have lead responsibility for forming and operating a RAB.

(c) *Converting existing Technical Review Communittees (TRCs) to RABs.* In accordance with 10 U.S.C. 2705(d)(1), a RAB may fulfill the requirements of 10 U.S.C. 2705(c), which directs DoD to establish TRCs. DoD recommends that, where TRCs or similar advisory groups already exist, the TRC or similar advisory group be considered for conversion to a RAB, provided there is sufficient and sustained interest within the community.

§ 202.3 Notification of formation of a Restoration Advisory Board.

Prior to establishing a RAB, an installation shall notify potential stakeholders of its intent to form a RAB. In announcing the formation of a RAB, the installation should describe the purpose of a RAB and discuss opportunities for membership.

§ 202.4 Composition of a RAB.

(a) *Membership.* At a minimum, each RAB shall include representatives from DoD and the community. RAB community membership shall be well balanced and reflect the diverse interests within the local community.

(1) *Government representation.* The RAB may also include representatives from the EPA at the discretion of the Administrator of the appropriate EPA regional office, and state, tribal, and local governments, as appropriate. At closing installations, representatives of the BRAC Cleanup Team (BCT) may also serve as the government representative(s) of the RAB.

(2) *Community representation.* Community RAB members should live and/or work in the affected community or be affected by the installation's environmental restoration program. While DoD encourages individual tribal members to participate on RABs, RABs in no way replace or serve as a substitute forum for the government-to-government relationship between DoD and federally-recognized tribes.

(b) *Chairmanship.* Each RAB established shall have two co-chairs, one representing the DoD installation and the other the community. Co-chairs shall be responsible for directing and managing the RAB operations.

(c) *Compensation for community members of the RAB.* The community co-chair and community RAB members serve voluntarily; therefore, DoD will not compensate them for their participation.

Subpart B—Operating Requirements

§ 202.5 Creating a mission statement.

The DoD installation co-chair in conjunction with the RAB members shall determine the RAB mission statement in accordance with guidance provided by the DoD Component.

§ 202.6 Selecting co-chairs.

(a) *DoD installation Co-chair.* The DoD installation co-chair shall be selected by the Installation Commander or equivalent, or in accordance with Military Service-specific guidance.

(b) *Community Co-chair.* The Community co-chair shall be selected by the community RAB members.

§ 202.7 Developing operating procedures.

(a) Each RAB shall develop a set of operating procedures. Areas that should be addressed in the procedures include:

(1) Clearly defined goals and objectives for the RAB, as determined by

the DoD installation co-chair in consultation with the RAB.

(2) Meeting announcements.

(3) Attendance requirements of members at meetings.

(4) Development and approval procedures for the minutes of RAB meetings.

(5) Meeting frequency and location.

(6) Rules of order.

(7) The frequency and procedures for conducting training.

(8) Procedures for selecting or replacing co-chairs and selecting, replacing, or adding RAB members.

(9) Specifics on the size of the RAB, periods of membership, and co-chair length of service.

(10) Review and responses to public comments.

(11) Participation of the general public.

(12) Keeping the public informed about proceedings of the RAB.

(13) Discussing the agenda for the next meeting and issues to be addressed.

(b) [Reserved].

§ 202.8 Training RAB members.

Training is not required for RAB members. It may be advisable, however, to provide RAB members with some initial orientation training to enable them to fulfill their responsibilities. Funding for training activities must be within the scope of administrative support for RABs, as permitted in § 202.12.

§ 202.9 Conducting RAB meetings.

(a) *Public participation.* RAB meetings shall be open to the public.

(1) The installation co-chair shall prepare and public a timely publish notice in a local newspaper of general circulation announcing each RAB meeting.

(2) Each RAB meeting shall be held at a reasonable time and in a manner or place reasonably accessible to and usable by persons with disabilities.

(3) Interested persons shall be permitted to attend, appear before, or file statements with any RAB, subject to such reasonable rules or regulations as may be prescribed.

(b) *Nature of discussions.* The installation shall give careful consideration to all comments provided by the individual RAB members.

(c) *Meeting minutes.* The installation co-chair, in coordination with the community co-chair, shall prepare minutes of each RAB meeting.

(1) The RAB meeting minutes shall be kept and shall contain a record of the persons present, a complete and accurate description of matters discussed and comments received, and copies of all reports received, issued, or approved by the RAB. The accuracy of all minutes shall be certified by the RAB co-chairs.

(2) The records, reports, minutes, appendixes, working papers, drafts, studies, agenda, or other documents that were made available to or prepared for or by each RAB shall be available for public inspection and copying at a single, publicly accessible location, such as the information repositories established under the installation's Community Relations Plan, a public library, or in the offices of the installation to which the RAB reports, until the RAB ceases to exist.

§ 202.10 RAB adjournment and dissolution.

(a) *RAB adjournment.* (1) Requirements for RAB adjournment. An Installation Commander may adjourn a RAB when there is no longer a need for a RAB or when community interest in the RAB declines. RABs may adjourn in the following situations:

(i) A record of decision has been signed for all DERP sites on the installation.

(ii) An installation has achieved response complete at all sites and no further environmental restoration decisions are required.

(iii) An installation has all remedies in place.

(iv) The RAB has achieved the desired end goal as defined in the RAB Operating Procedures.

(v) There is no longer sufficient, sustained community interest, as documented by the installation with RAB community members and community-at-large input, to sustain the RAB. The installation shall continue to monitor for any changes in community interest that could warrant reactivating or reestablishing the RAB.

(vi) The installation has been transferred out of DoD control and DoD is no longer responsible for making restoration response decisions.

(2) Adjournment procedures. If the Installation Commander is considering adjourning the RAB, the Installation Commander shall:

(i) Consult with the EPA, state, tribes, RAB members, and the local community, as appropriate, regarding adjourning the RAB and consider all responses before making a final decision.

(ii) Document the rationale for adjournment in a memorandum for inclusion in the Administrative Record, notify the public of the decision through written notice to the RAB members and through publication of a notice in a local newspaper of general circulation, and describe other ongoing public involvement opportunities that are available, if the Installation Commander decides to adjourn the RAB.

(b) *RAB dissolution.* (1) *Requirements for RAB dissolution.* An Installation Commander may recommend dissolution of a RAB when a RAB is no longer fulfilling the intended purpose of advising and providing community input to an Installation Commander and decision makers on environmental restoration projects as described in § 202.1(b).

(2) *Dissolution procedures.* If the Installation Commander is considering dissolving the RAB, the Installation Commander shall:

(i) Consult with EPA, state, tribal and local government representatives, as appropriate, regarding dissolving the RAB.

(ii) Notify the RAB community co-chair and members in writing of the intent to dissolve the RAB and the reasons for doing so and provide the RAB members 30 days to respond in writing. The Installation Commander shall consider RAB member responses, and in consultation with EPA, state, tribal and local government representatives, as appropriate, determine the appropriate action.

(iii) Notify the public of the proposal to dissolve the RAB and provide a 30-day public comment period on the proposal, if the Installation Commander decides to proceed with dissolution. At the conclusion of the public comment period, the Installation Commander will review the public comments, consult with EPA, state, tribal and local government representatives, as appropriate, and render a recommendation.

(iv) Send the recommendation, responsiveness summary, and all supporting documentation via the chain-of-command to the Military Component's Environmental Deputy Assistant Secretary (or equivalent) for approval or disapproval. The Military Component's Environmental Deputy Assistant Secretary (or equivalent) shall notify the Office of the Deputy Under Secretary of Defense (Installations & Environment) (or equivalent) of the decision to approve or disapprove the request to dissolve the RAB and the rationale for that decision.

(v) Document the rationale for dissolution in a memorandum for inclusion in the Administrative Record, notify the public of the decision through written notice to the RAB members and through publication of a notice in a local newspaper of general circulation, and describe other ongoing public involvement opportunities that are

available, once the Military Component's Environmental Deputy Assistant Secretary (or equivalent) makes a final decision.

(c) *Reestablishing an adjourned or dissolved RAB.* An Installation Commander may reestablish an adjourned or dissolved RAB if there is sufficient and sustained community interest in doing so and there are environmental restoration activities still ongoing at the installation. Where a RAB is adjourned and environmental restoration activities continue, the Installation Commander should reassess community interest at least every 24 months. When all environmental restoration decisions have been made and required remedies are in place and properly operating at an installation, reassessment of the community interest for reestablishing the RAB is not necessary. When additional environmental restoration decisions have to be made resulting from subsequent actions, such as long-term monitoring and five-year reviews, the installation will reassess community interest for reestablishing the RAB. Where the reassessment finds sufficient and sustained community interest at previously adjourned RAB, the Installation Commander should reestablish a RAB. Where the reassessment does not find sufficient and sustained community interest in reestablishing the RAB, the Installation Commander shall document in a memorandum for the record the procedures followed in the reassessment and the findings of the reassessment. This document shall be included in the Administrative Record for the installation. If there is interest for reestablishment at a previously dissolved RAB, but the Installation Commander determines that the same conditions exist that required the original dissolution, he or she will request, through the chain of command to the service component deputy assistant secretary, an exception to reestablishing the RAB. If those conditions no longer exist at a previously dissolved RAB, and there is interest in reestablishment the Installation Commander should notify the deputy assistant secretary of the recommendation for the RAB to be reestablished. The deputy assistant secretary will take the Installation Commander's recommendation under advisement and may approve that RAB for reestablishment.

(d) *Public comment.* If the Installation Commander intends to recommend dissolution of a RAB or reestablish a dissolved RAB, the Installation Commander shall notify the public of the proposal to dissolve or reestablish the RAB and provide a 30-day public comment period on the proposal. At the conclusion of the public comment period, the Installation Commander shall review public comments, consult with EPA, and state, tribal, or local government representatives, as appropriate, prepare a responsiveness summary, and render a recommendation. The recommendation, responsiveness summary, and all supporting documentation should be sent via the chain-of-command to the Military Component's Environmental Deputy Assistant Secretary (or equivalent) for approval or disapproval. The Installation Commander shall notify the public of the decision.

§ 202.11 Documenting RAB activities.

The installation shall document information on the activities of a RAB in the Information Repository. When RAB input has been used in decision-making, it should be documented as part of the Administrative Record. These activities shall include, but are not limited to:

(a) Installation's efforts to survey community interest in forming a RAB;

(b) Steps taken to establish a RAB where there is sustained community interest;

(c) How the RAB relates to the overall community involvement program; and

(d) Steps taken to adjourn, dissolve, or reestablish the RAB.

Subpart C—Administrative Support, Funding, and Reporting Requirements

§ 202.12 Administrative support and eligible expenses.

(a) *Administrative support.* Subject to the availability of funding, the installation shall provide administrative support to establish and operate a RAB.

(b) *Eligible administrative expenses for a RAB.* The following activities specifically and directly associated with establishing and operating a RAB shall qualify as an administrative expense of a RAB:

(1) RAB establishment.

(2) Membership selection.

(3) Training if it is:

(i) Unique to and mutually benefits the establishment and oeration of a RAB; and

(ii) Relevant to the environmental restoration activities occurring at the installation.

(4) Meeting announcement.

(5) Meeting facility.

(6) Meeting facilitators, including translators.

(7) Preparation of meeting agenda materials and minutes.

(8) RAB-member mailing list maintenance and RAB materials distribution.

(c) *Funding.* Subject to the availability of funds, administrative support to RABs may be funded as follows:

(1) At active installations, administrative expenses for a RAB shall be paid for using funds from the Military Component's Environmental Restoration accounts.

(2) At BRAC installations, administrative expenses for a RAB shall be paid using BRAC funds.

(3) At FUDS, administrative expenses for a RAB shall be paid using funds from the Environmental Restoration account for the Formerly Used Defense Sites program.

§ 202.13 Technical assistance for public participation (TAPP).

Community members of a RAB or TRC may request technical assistance for interpreting scientific and engineering issues with regard to the nature of environmental hazards at the installation and environmental restoration activities conducted, or proposed to be conducted at the installation in accordance with 10 U.S.C. 2705(e) and the TAPP regulations found at 32 CFR part 203.

§ 202.14 Documenting and reporting activities and expenses.

The installation at which a RAB is established shall document the activities and record the administrative expenses associated with the RAB. Installations shall use internal department and Military Component-specific reporting mechanisms to submit required information on RAB activities and expenditures.

Dated: January 19, 2005

Jeannette Owings-Ballard,

Federal Register Liaison Officer, Department of Defense.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD08–05–003]

RIN 1625–AA09

Drawbridge Operation Regulation; Gulf Intracoastal Waterway, Houma, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to change the regulation governing the operation of the SR 315 (Bayou Dularge) bascule bridge across the Gulf Intracoastal Waterway, mile 59.9 west of Harvey Lock, in Houma, Louisiana. An increase in traffic during the noontime time period has facilitated a request to allow the bridge to remain closed to navigation for two (2), 30-minute periods in the middle of the day. These closures will allow local workers to transit the area with minimal delays during the noontime lunch period.

DATES: Comments and related material must reach the Coast Guard on or before March 29, 2005.

ADDRESSES: You may mail comments and related material to Commander (obc), Eighth Coast Guard District, 500 Poydras Street, New Orleans, Louisiana 70130–3310. The Commander, Eighth Coast Guard District, Bridge Administration Branch maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at the Bridge Administration office between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: David Frank, Bridge Administration Branch, telephone 504–589–2965.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking [CGD08–05–003], indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know they reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Public Meeting

We do not now plan to hold a public meeting. You may submit a request for a meeting by writing to Commander, Eighth Coast Guard District, Bridge Administration Branch at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register.**

Background and Purpose

The U.S. Coast Guard, at the request of the State of Louisiana, Department of Transportation and Development (LDOTD), and supported by the Terrebonne Parish Council, proposes to modify the existing operating schedule of the SR 315 (Bayou Dularge) bascule bridge across the Gulf Intracoastal Waterway, mile 59.9 west of Harvey Lock, in Houma, Terrebonne Parish, Louisiana. The modification of the existing regulations will allow the bridge to remain closed to navigation for two (2), 30-minute periods in the middle of the day to allow for local workers to transit the area with minimal delays during the noontime lunch period.

Currently, the bridge opens on signal; except that, the draw need not open for the passage of vessels Monday through Friday except Federal holidays from 6:30 a.m. to 8:30 a.m. and from 4:30 p.m. to 6 p.m.

Approximately 11,500 vehicles cross the bridge daily, 7% of which cross the bridge during the requested noon closure times. The bridge averages 288 openings a month. The requested two (2), 30-minute closures will delay approximately 35 additional tows a month for a maximum of 30 minutes. The average length of a bridge opening is approximately seven minutes, delaying an average of 92 vehicles per opening during the noontime bridge openings.

Navigation at the site of the bridge consists primarily of tugboats with barges. Alternate routes east and west through the bridge are not readily accessible; however, the bridge, in the closed-to-navigation position provides a vertical clearance of 40 feet above high water, elevation 3.8 feet Mean Sea Level.

Discussion of Proposed Rule

The proposed rule would modify the existing regulation in 33 CFR 117.451(c) to facilitate the movement of high volumes of vehicular traffic across the bridge during noontime lunch periods. The change would allow the SR 315 (Bayou Dularge) bridge, mile 59.9 west of Harvey Lock, at Houma, to remain closed to navigation from 11:45 a.m. to 12:15 p.m. and from 12:45 p.m. to 1:15 p.m. in addition to the presently published times of 6:30 a.m. to 8:30 a.m. and 4:30 p.m. to 6 p.m. Monday through Friday except Federal holidays.

Regulatory Evaluation

This proposed rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security. We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary.

This proposed rule allows vessels ample opportunity to transit this waterway with proper notification before and after the peak vehicular traffic periods. According to the vehicle traffic surveys, the public at large is better served by the additional closure times during the noontime lunch periods.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. This proposed rule would affect the following entities: the owners and operators of vessels needing to transit the bridge from 11:45 a.m. to 12:15 p.m. and from 12:45 p.m. to 1:15 p.m. on weekdays.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this proposed rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding this proposed rule so that

they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the Eighth Coast Guard District Bridge Administration Branch at the address above. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this proposed rule will not result in such an expenditure, we do discuss the effects of this proposed rule elsewhere in this preamble.

Taking of Private Property

This proposed rule would not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This proposed rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed rule under Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this proposed rule is categorically excluded, under figure 2–1, paragraph (32)(e), of the Instruction, from further environmental documentation. Paragraph (32)(e) excludes the promulgation of operating regulations or procedures for drawbridges from the environmental documentation requirements of NEPA. Since this proposed rule will alter the normal operating conditions of the drawbridge, it falls within this exclusion.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; Department of Homeland Security Delegation No. 0170.1; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. § 117.451(c) is revised to read as follows:

§ 117.451 Gulf Intracoastal Waterway.

* * * * *

(c) The draw of the SR 315 (Bayou Dularge) bridge, mile 59.9 west of Harvey Lock, at Houma, shall open on signal; except that, the draw need not open for the passage of vessels Monday through Friday except Federal holidays from 6:30 a.m. to 8:30 a.m., from 11:45 a.m. to 12:15 p.m., from 12:45 p.m. to 1:15 p.m. and from 4:30 p.m. to 6 p.m.

* * * * *

Dated: January 13, 2005.

R.F. Duncan,

Rear Admiral, U.S. Coast Guard, Commander, Eighth Coast Guard District.

[FR Doc. 05–1654 Filed 1–27–05; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD08–05–004]

RIN 1625–AA09

Drawbridge Operation Regulation; Houma Navigation Canal, Houma, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to change the regulation governing the operation of the SR 661 (Houma Nav Canal) swing bridge across the Houma Navigation Canal, mile 36.0, in Houma, Louisiana. An increase in traffic during the noontime time period has facilitated a request to allow the bridge to remain closed to navigation for two (2), 30-minute periods in the middle of the day. These closures will allow local workers to transit the area with minimal delays during the noontime lunch period.

DATES: Comments and related material must reach the Coast Guard on or before March 29, 2005.

ADDRESSES: You may mail comments and related material to Commander (obc), Eighth Coast Guard District, 500 Poydras Street, New Orleans, Louisiana 70130–3310. The Commander, Eighth Coast Guard District, Bridge Administration Branch maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at the Bridge Administration office between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: David Frank, Bridge Administration Branch, telephone 504–589–2965.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking [CGD08–05–004], indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know they reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Public Meeting

We do not now plan to hold a public meeting. You may submit a request for a meeting by writing to Commander, Eighth Coast Guard District, Bridge Administration Branch at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The U.S. Coast Guard, at the request of the State of Louisiana, Department of Transportation and Development (LDOTD), and supported by the Terrebonne Parish Council, proposes to modify the existing operating schedule of the SR 661 (Houma Nav Canal) swing bridge across the Houma Navigation Canal, mile 36.0, in Houma, Terrebonne Parish, Louisiana. The modification of the existing regulations will allow the bridge to remain closed to navigation for two (2), 30-minute periods in the middle of the day to allow for local workers to transit the area with minimal delays during the noontime lunch period.

Currently, the bridge opens on signal; except that, the draw need not open for the passage of vessels Monday through Friday except Federal holidays from 6:30 a.m. to 8:30 a.m. and from 4:30 p.m. to 6 p.m.

Approximately 9,500 vehicles cross the bridge daily, 6% of which cross the bridge during the requested noon closure times. The bridge averages 932 openings a month. The requested two (2), 30-minute closures will delay approximately 133 additional tows a month for a maximum of 30 minutes. The average length of a bridge opening is approximately nine minutes, delaying an average of 44 vehicles per opening during the noontime bridge openings.

Navigation at the site of the bridge consists primarily of tugboats with barges. Alternate routes are available but not readily accessible.

Discussion of Proposed Rule

The proposed rule would modify the existing regulation in 33 CFR 117.455 to facilitate the movement of high volumes of vehicular traffic across the bridge during noontime lunch periods. The change would allow the SR 661 (Houma Nav Canal) bridge, mile 36.0, at Houma, to remain closed to navigation from 11:45 a.m. to 12:15 p.m. and from 12:45 p.m. to 1:15 p.m. in addition to the presently published times of 6:30 a.m. to 8:30 a.m. and 4:30 p.m. to 6 p.m. Monday through Friday except Federal holidays.

Regulatory Evaluation

This proposed rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security. We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary.

This proposed rule allows vessels ample opportunity to transit this waterway with proper notification before and after the peak vehicular traffic periods. According to the vehicle traffic surveys, the public at large is better served by the additional closure times during the noontime lunch periods.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. This proposed rule would affect the following entities: the owners and operators of vessels needing to transit the bridge from 11:45 a.m. to 12:15 p.m. and from 12:45 p.m. to 1:15 p.m. on weekdays.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this proposed rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the Eighth Coast Guard District Bridge Administration Branch at the address above. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this proposed rule will not result in such an expenditure, we do discuss the effects of this proposed rule elsewhere in this preamble.

Taking of Private Property

This proposed rule would not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This proposed rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed rule under Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this proposed rule is categorically excluded, under figure 2–1, paragraph (32)(e), of the Instruction, from further environmental documentation. Paragraph (32)(e) excludes the promulgation of operating regulations or procedures for drawbridges from the environmental documentation requirements of NEPA. Since this proposed rule will alter the normal operating conditions of the drawbridge, it falls within this exclusion.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; Department of Homeland Security Delegation No. 0170.1; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. § 117.455 is revised to read as follows:

§ 117.455 Houma Navigation Canal.

The draw of SR 661 (Houma Nav Canal) bridge, mile 36.0, at Houma, shall open on signal; except that, the draw need not open for the passage of vessels Monday through Friday except Federal holidays from 6:30 a.m. to 8:30 a.m., from 11:45 a.m. to 12:15 p.m., from 12:45 p.m. to 1:15 p.m. and from 4:30 p.m. to 6 p.m.

Dated: January 13, 2005.

R. F. Duncan,

Rear Admiral, U. S. Coast Guard, Commander, Eighth Coast Guard District.

[FR Doc. 05–1657 Filed 1–27–05; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R05–OAR–2004–MI–0003; FRL–7865–1]

Approval and Promulgation of Maintenance Plan Revisions; Michigan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a December 19, 2003 request from Michigan for a State Implementation Plan (SIP) revision of the Southeast Michigan carbon monoxide (CO) maintenance plan. The CO maintenance plan revision establishes a new on-road emissions inventory for the years 1996 and 2010. The revision also establishes a new transportation conformity motor vehicle emissions budget (MVEB) for the year 2010. The emission inventory and MVEB updates are designed to maintain the National Ambient Air Quality Standards (NAAQS) for CO as required by the CAA.

In the final rules section of this **Federal Register**, EPA is approving the SIP revision as a direct final rule without prior proposal, because EPA views this as a noncontroversial revision and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If we do not receive any adverse comments in response to these direct final and proposed rules, we do not contemplate taking any further action in relation to this proposed rule. If EPA receives adverse comments, we will withdraw the direct final rule and will respond to all public comments in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

DATES: Written comments must be received on or before February 28, 2005.

ADDRESSES: Submit comments, identified by Regional Material in EDocket (RME) ID No. R05–OAR–2004–IL–0003 by one of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the on-line instructions for submitting comments.

Agency Web site: http://docket.epa.gov/rmepub/index.jsp. RME, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Once in the system, select ''quick search,'' then key in the appropriate RME Docket identification number. Follow the online instructions for submitting comments.

E-mail: mooney.john@epa.gov.

Fax: (312) 886–5824.

Mail: You may send written comments to: John M. Mooney, Chief, Criteria Pollutant Section, (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Hand delivery: Deliver your comments to: John M. Mooney, Chief, Criteria Pollutant Section (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, 18th floor, Chicago, Illinois 60604.

Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding federal holidays.

Instructions: Direct your comments to RME ID No. R05-OAR–2004–IL–0003. EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through RME, regulations.gov, or e-mail. The EPA RME Web site and the *federal regulations.gov* Web site are ''anonymous access'' systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through RME or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional instructions on submitting comments, go to Section I(B) of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the electronic docket are listed in the RME index at *http://www.epa.gov/rmepub/index.jsp.* Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Publicly available docket materials are available either electronically in RME or in hard copy at Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. (Please telephone Anthony Maietta at (312) 353–8777 before visiting the Region 5 Office.)

FOR FURTHER INFORMATION CONTACT: Anthony Maietta, Life Scientist, Criteria Pollutant Section, Air Programs Branch (AR–18J), USEPA, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–8777. *maietta.anthony@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information
A. Does This Action Apply to Me?
B. What Should I Consider as I Prepare my Comments for EPA?
II. What Action Is EPA Taking Today?
III. Where Can I Find More Information About This Proposal and the Corresponding Direct Final Rule?

I. General Information

A. Does This Action Apply to Me?

This action applies to the Southeast Michigan CO maintenance area, which consists of portions of Macomb, Wayne, and Oakland Counties.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit CBI to EPA through RME, regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

a. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).

b. Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

c. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

d. Describe any assumptions and provide any technical information and/or data that you used.

e. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

f. Provide specific examples to illustrate your concerns, and suggest alternatives.

g. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

h. Make sure to submit your comments by the comment period deadline identified.

II. What Action Is EPA Taking Today?

EPA is proposing to approve a December, 19, 2003 request from Michigan to revise the Southeast Michigan CO maintenance plan. In a separate Direct Final Rule in today's **Federal Register**, EPA is approving the December 19, 2003 request. The Southeast Michigan CO maintenance area consists of portions of Oakland, Macomb, and Wayne Counties. As a result of today's action, the 1996 base year on-road emissions inventory, forecast year 2010 emissions inventory, and the 2010 MVEB will be updated to meet EPA's requirement to use the Mobile6 emissions factor model to determine conformity to the CO maintenance SIP. By approving the revision, EPA ensures that future emission forecasts for conformity analyses in the Southeast Michigan CO maintenance area will be compared to budgets that are based on similar inputs and the same version of the Mobile model.

III. Where Can I Find More Information About This Proposal and the Corresponding Direct Final Rule?

For additional information, see the Direct Final Rule which is located in the Rules section of this **Federal Register**. Copies of the request and the EPA's analysis are available electronically at RME or in hard copy at the above address. (Please telephone Anthony Maietta at (312) 353–8777 before visiting the Region 5 Office.)

Dated: January 14, 2005.

Norman Niedergang,

Acting Regional Administrator, Region 5.

[FR Doc. 05–1634 Filed 1–27–05; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

42 CFR Part 63a

RIN 0925–AA28

National Institutes of Health Training Grants

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice of proposed rulemaking.

SUMMARY: The National Institutes of Health (NIH) proposes to amend the existing regulations governing its training grants to reflect applicability of the regulations to institutional training grants supporting pediatric research training.

DATES: Comments must be received on or before March 29, 2005, in order to assure that NIH will be able to consider all comments when preparing the final rule.

ADDRESSES: You may submit comments, identified by RIN number 0925–AA28, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- E-mail: *jm40z@nih.gov*. Include RIN number 0925–AA28 in the subject line of the message.
- Fax: 301–402–0169.
- Mail: Jerry Moore, NIH Regulations Officer, Office of Management Assessment, National Institutes of Health, 6011 Executive Boulevard, Suite 601, MSC 7669, Rockville, Maryland 20892.
- Hand Delivery/Courier: 6011 Executive Boulevard, Suite 601, MSC 7669, Rockville, Maryland 20892.

FOR FURTHER INFORMATION CONTACT: Jerry Moore at the address above, or telephone 301–496–4607 (not a toll-free number).

SUPPLEMENTARY INFORMATION: On October 17, 2000, Congress enacted the Children's Health Act of 2000, Public Law 106–310. Title X, section 1002, of this law amended the Public Health Service (PHS) Act by adding section 452G (42 U.S.C. 285g–10). Section 452G directs the Director of the National Institute of Child Health and Human Development, after consultation with the Administrator of the Health Resources and Services Administration, to support activities to provide for and increase in the number and size of institutional training grants to institutions supporting pediatric training. We propose to amend the present regulations codified at 42 CFR part 63a, National Institutes of Health Training Grants, to implement this pediatric research training grants authority. More specifically, we propose to amend part 63a to reference section 452G of the PHS Act in the authority section and in paragraph (2) of § 63a.1 of the regulations, and update information in unnumbered paragraphs 17 and 18 of § 63a.11.

The purpose of this notice is to invite public comment on this proposed action. We provide the following as public information.

Executive Order 12866

Executive Order 12866, Regulatory Planning and Review, requires that all regulatory actions reflect consideration of the costs and benefits they generate, and that they meet certain standards, such as avoiding the imposition of unnecessary burdens on the affected public. If a regulatory action is deemed to fall within the scope of the definition of the term ''significant regulatory action'' contained in section 3(f) of the Order, prepublication review by the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA) is necessary. The OIRA reviewed this proposed rule under Executive Order 12866 and deemed it not a significant regulatory action as defined by the Executive Order.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. chapter 6) requires that regulatory proposals be analyzed to determine whether they create a significant impact on a substantial number of small entities. The Secretary of Health and Human Services (Secretary) certifies that any final rule resulting from this proposed rule will not have such impact.

Executive Order 13132

Executive Order 13132, Federalism, requires that Federal agencies consult with State and local government officials in the development of regulatory policies with federalism implications. The Secretary reviewed the proposed rule as required under the Executive Order and determined that it does not have federalism implications. The Secretary certifies that this proposed rule will not have an effect on the States, or on the distribution of power and responsibilities among the various levels of government.

Paperwork Reduction Act

This proposed rule does not contain information collection requirements which are subject to Office of

Management and Budget (OMB) approval under the Paperwork Reduction Act of 1995, as amended (44 U.S.C. chapter 35).

Catalogue of Federal Domestic Assistance

The Catalogue of Federal Domestic Assistance numbered program affected by the proposed regulation is: 93.865.

List of Subjects in 42 CFR Part 63a

Grant programs—health, Health-medical research.

Dated: May 27, 2004.

Elias A. Zerhouni,

Director, National Institutes of Health.

Approved: January 14, 2005.

Tommy G. Thompson,

Secretary.

For the reasons set forth in the preamble, we propose to amend chapter 1 of title 42 of the Code of Federal Regulations as set forth below.

PART 63a—NATIONAL INSTITUTES OF HEALTH TRAINING GRANTS

1. The authority citation of part 63a would be revised to read as follows:

Authority: 42 U.S.C. 216, 242*l*(b)(3), 284(b)(1)(C), 285g–10, 287c(b), 300cc–15(a)(1), 300cc–41(a)(3)(C), 7403(h)(2).

2. Section 63a.1 would be amended by revising paragraph (a)(2) to read as follows:

§ 63a.1 To what programs do these regulations apply?

* * * * *

(a) * * *

(1) * * *

(2) Grants awarded by NIH for research training with respect to the human diseases, disorders, or other aspects of human health or biomedical research for which the institute or other awarding component was established, for which fellowship support is not provided under section 487 of the Act and which is not residency training of physicians or other health professionals, as authorized by sections 405(b)(1)(C), 452G, 485B(b), 2315(a)(1), and 2354(a)(3)(C) of the Act; and

* * * * *

3. Section 63a.11 would be amended by revising the 17th and 18th undesignated paragraphs to read as follows:

§ 63a.11 Other HHS regulations and policies that apply.

* * * * *

''NIH Grants Policy Statement,'' NIH Publication No. 99–8 (October 1998). (*NOTE:* this policy is subject to change, and interested persons should contact the Extramural Outreach and Information Resources Office (EOIRO), Office of Extramural Research, 6701 Rockledge Drive, Room 6208, MSC 7910, Bethesda, Maryland 20892–7910, telephone 301–435–0714 (not a toll-free number), to obtain references to the current version and any amendments. Information may also be obtained by contacting the EOIRO via e-mail address (*nih@odrockm1.od.nih.gov*) and browsing the NIH Home Page site on the World Wide Web (*http://www.nih.gov*).)

''Public Health Service Policy on Humane Care and Use of Laboratory Animals,'' Office of Laboratory Animal Welfare (Amended August, 2002). (*NOTE:* This policy is subject to change, and interested persons should contact the Office of Laboratory Animal Welfare, 6705 Rockledge Drive, Suite 360, MSC 7982, Bethesda, Maryland 20892–7982, telephone 301–594–2382 (not a toll-free number), to obtain references to the current version and any amendments. Information may also be obtained by browsing the Office of Laboratory Animal Welfare Home Page site on the World Wide Web (*http://www.grants.nih.gov/grants/olaw/olaw.htm*).)

[FR Doc. 05–1621 Filed 1–27–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

49 CFR Part 605

[Docket No. FTA–99–5082]

RIN 2131–AA67

School Bus Operations; Amendment of Tripper Service Definition

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Withdrawal of rulemaking.

SUMMARY: This document withdraws the rulemaking in which the Federal Transit Administration (FTA) proposed to amend its tripper service definition to clarify which student transportation operations are inconsistent with FTA requirements. The rulemaking is being withdrawn because after consideration of the comments, FTA has concluded that no regulatory clarification is necessary.

FOR FURTHER INFORMATION CONTACT: Elizabeth S. Martineau, Office of Chief Counsel, Federal Transit Administration, (202) 366–1936 or (202) 366–3809 (fax).

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this document may be downloaded using a modem and suitable communication software from the Government Printing Office's Electronic Bulletin Board Service at (202) 512–1661. Internet users may reach the **Federal Register**'s home page at: *http://www.archives.gov* and the Government Printing Office's database at: *http://www.access.gpo.gov/nar.*

Background

On May 3, 1999, the Federal Transit Administration published a Notice of Proposed Rulemaking proposing to amend its tripper service definition to clarify that buses used in tripper service may not carry destination signs such as ''student'' or any other marking indicating that they are carrying school children. Further, the rule would have clarified that, as consistent with the current regulation, these buses may only stop at stops that are accessible to the public and that are clearly marked as available to the public. 64 FR 23590, May 3, 1999.

Discussion of Comments on the NPRM

FTA received sixty comments on its proposal to amend the definition of tripper service.

Comments Supporting the Proposed Changes

Three commenters expressed support for FTA's proposed amendment to the tripper service definition. One commenter suggested that destination signs be permitted to inform the rider where the bus route goes. Another commenter was concerned that those who opposed the changes were confusing the issue of safety of school children with the tripper service definition. The commenter stated that the issue of safety of school children on public transportation is an important one that merits its own separate rulemaking. One other commenter recommended that if FTA is not going to eliminate tripper service, it should ensure timely and aggressive enforcement of the regulations.

Comments Opposing the Proposed Changes

Stopping at Marked Public Stops

Twenty-three commenters objected to the proposed amendment to the tripper service definition that would clarify that buses may stop only at stops that are accessible to the public and that are clearly marked as available to the public. Although the law currently prohibits stops on property that is not accessible to the general public,

nineteen commenters cited the risk to student safety from not being picked up and discharged on school property as a reason for objecting to the proposed amendment.

Commenters also raised non-safety-related objections to the requirement that buses providing tripper service may only stop at marked public stops. Eight commenters objected to the requirement because buses in suburban and rural areas often stop at unmarked flag stops that are known to the public. Seven commenters stated that loading and unloading students on school property prevents impediments to traffic flow on public streets. Seven commenters noted that in other situations buses are allowed to drop-off and pickup passengers at stops to which the general public may not have access, such as secured work sites, private business parks, and college campuses. Two commenters opposed the requirement that buses providing tripper service may only stop at clearly marked stops because they thought it would impose a higher standard than that generally required of fixed route transit services.

Six commenters asserted that the proposed changes would require cities to purchase new signs to mark each stop, which would be a significant cost. The American Public Transportation Association (APTA) commented that the marked bus stop requirement would impose an undue financial burden on numerous transit authorities.

Signage and Markings on Buses

The proposal to clarify that tripper buses may not carry any signs or markings indicating the presence of school children onboard raised objections from eleven commenters, all of whom cited safety as their primary concern. Two commenters noted that without signs and markings, drivers would not be alerted to the presence of school children who may be crossing the road. One commenter also noted that without signs and markings, there would be increased public ridership, which could pose additional safety risks to children onboard. One commenter added that there was no objective evidence that existing signage regarding school children caused the public to believe that buses used for tripper service were not open to the general public.

Two commenters who did not support FTA's proposed amendment did support the prohibition on signs and markings on transit buses that indicate the presence of school children. One of these commenters stated that the public becomes confused when equipment from yellow school buses is placed on transit buses.

Enlarge Scope To Address Safety Generally

Eleven commenters suggested that, rather than focus on one aspect of the tripper service definition, FTA should work with the school transportation and public transit communities to address the safety needs of school students on public transit vehicles. Nine of the commenters opposed the proposed amendment entirely, arguing that it is shortsighted. The National Association of State Directors of Pupil Transportation Services (NASDPTS) argued that while ensuring that tripper buses remain open to the public is an important objective of the tripper rule, providing for student safety is an equally important objective. Consequently, they argued, amending only one element of the rule at the expense of the other is ''inappropriate.'' NASDPTS suggested that FTA ''with the assistance of the school transportation community and the public transit community, develop a list of acceptable safety practices to accommodate the needs of school students.'' Six other commenters concurred in NASDPTS's suggestion.

One commenter, a private citizen from Altoona, Pennsylvania, noticed that tripper buses lack many of the safety features found in traditional school buses, such as forward facing seats and additional emergency exits. This difference in the level of passenger safety prompted the National Association for Pupil Transportation (NAPT) to suggest temporarily suspending tripper service altogether. NAPT suggested that tripper service be disallowed until ''it is clear that children who ride a transit bus to school receive the equivalent level of operational safety as children who ride a school bus to school.''

Forced Elimination or Reduction of Tripper Service

Ten commenters asserted that the proposed amendment would cost cities significant amounts of money, because to the extent that the proposed change eliminates or reduces tripper service, cities would be required to purchase and maintain a yellow bus fleet or to contract for those services.

Four commenters opposed the proposed amendments because they would either reduce or eliminate tripper service, which would increase the time that it takes students to get to and from school. Without tripper service, they asserted, some students would have to transfer buses one or more times, thus adding to the time it takes the student to reach the school.

Agency Response

Given the comments on the proposed rulemaking, FTA has decided to withdraw this rulemaking as unnecessary. FTA believes that the proposed amendments to the regulation were merely clarifying in nature, and not necessary to the enforcement of current law and regulation. The comments received generally indicated objections to the underlying law and current regulations, rather than to the clarifying amendments, indicating that confusion about the intent of the current regulation was not the primary issue.

The proposed amendment to the destination sign language was intended only to give additional information about language that is inappropriate on a tripper service bus by specifically prohibiting use of the word ''student'' and adding the language ''or any other marking indicating that they are carrying school children.'' FTA proposed this added language because it believed that grantees were interpreting the term ''such as'' in the existing regulation as an exclusive listing of prohibited signs, rather than a representative listing of prohibited signs that could also include other signs. However, based on the comments received, it appears that there is no general misunderstanding of the existing regulation. Indeed, commenters objected to the underlying prohibition on signs or markings that indicate the presence of school children on board, arguing that such a prohibition is unsafe. However, under the current regulation, tripper service cannot be operated in a way that would call into question its availability to the public. Moreover, FTA believes that allowing transit buses to carry such signs actually poses a greater threat to safety because the widespread use of these signs on transit buses could engender a false belief by parents or guardians that transit buses are the equivalent of school buses in terms of safety. In FTA's view, the comments opposing the prohibition on signage based on safety concerns failed to account for the fact that tripper service is intended to make ordinary transit bus service available to school children; it is not intended to substitute for school bus transportation.

Grantees that honor flag stops in suburban and rural areas expressed concern regarding the requirement that tripper buses stop only at clearly marked public bus stops. The proposed rulemaking was not intended to eliminate the use of flag stops for tripper service when such stops are generally

used for public transportation service. Commenters who opposed this clarification generally expressed concerns about student safety if buses were not allowed to stop on school property. This comment seemed to reflect a lack of clarity or misunderstanding of the proposed amendment; consistent with the current regulation, the proposed amendment would not have prohibited stops on school property, as long as those stops were clearly marked, accessible to the general public, and included in published bus schedules.

APTA also opposed the public bus stop amendment based on the fact that FTA allows grantees to make stops on private work sites, which are generally inaccessible to the public. However, the statute singles out school bus service for special attention and the current implementing regulation requires that tripper buses stop only at clearly marked stops that are open to the public.

List of Subjects in 49 CFR Part 605

Mass transit, Grants, School bus.

■ For the reasons set forth above, FTA is withdrawing its proposed amendments to title 49 of the Code of Federal Regulations, part 605.

* * * * *

Issued on: January 4, 2005.

Jennifer L. Dorn,

Administrator.

[FR Doc. 05–1644 Filed 1–27–05; 8:45 am]

BILLING CODE 4910–57–U

Notices

Federal Register
Vol. 70, No. 18
Friday, January 28, 2005

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 04–135–1]

Notice of Request for Extension of Approval of an Information Collection

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request an extension of approval of an information collection for self-certification medical statements.

DATES: We will consider all comments that we receive on or before March 29, 2005.

ADDRESSES: You may submit comments by any of the following methods:

EDOCKET: Go to *http://www.epa.gov/feddocket* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once you have entered EDOCKET, click on the ''View Open APHIS Dockets'' link to locate this document.

Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 04–135–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 04–135–1.

E-mail: Address your comment to *regulations@aphis.usda.gov*. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 04–135–1'' on the subject line.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: You may view APHIS documents published in the **Federal Register** and related information, including the names of groups and individuals who have commented on APHIS dockets, on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html*.

FOR FURTHER INFORMATION CONTACT: For information on self-certification medical statements, contact Ms. Linda L. Lane, Human Resources Specialist, Human Resources Division, MRPBS, room 1726, South Building, 14th Street and Independence Avenue SW., Washington, DC 20250; (202) 720–3519. For copies of more detailed information on the information collection, contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

SUPPLEMENTARY INFORMATION:

Title: Self-Certification Medical Statement.

OMB Number: 0579–0196.

Type of Request: Extension of approval of an information collection.

Abstract: The Marketing and Regulatory Programs (MRP) agencies of the U.S. Department of Agriculture facilitate the domestic and international marketing of U.S. agricultural products and protect the health of domestic animal and plant resources. The MRP agencies are the Agricultural Marketing Service (AMS), the Animal and Plant Health Inspection Service (APHIS), and the Grain Inspection, Packers and Stockyards Administration (GIPSA). Resource management and administrative services, including human resource management, for the three MRP agencies are provided by the MRP Business Services unit of APHIS, which is the lead agency in providing administrative support for MRP.

In accordance with 5 CFR part 339, Federal agencies are authorized to obtain medical information from applicants for positions that have approved medical standards. Medical standards may be established for positions for which the duties are arduous or hazardous or require a certain level of health status or fitness.

Certain positions in MRP agencies have medical standards. An example of such a position is the agricultural commodity grader position in AMS. Each year, AMS hires a number of agricultural commodity graders. These employees work under dusty conditions, around moving machinery and slippery surfaces, and in areas with high noise levels. They have direct contact with meat and dairy products, fresh and processed fruits and vegetables, and poultry products intended for human consumption or cotton and tobacco products intended for human use.

The MRP agencies require a self-certification statement from applicants for these positions regarding their fitness for the positions. The MRP agencies need this information to determine whether the applicants can perform the duties of the positions. Inability to collect this information would adversely affect the MRP agencies' ability to recruit and hire qualified individuals and carry out their missions.

We are asking the Office of Management and Budget (OMB) to approve our use of this information collection activity for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond, through use, as appropriate, of automated, electronic, mechanical,

and other collection technologies, *e.g.*, permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 0.1666 hours per response.

Respondents: Applicants for MRP positions with approved medical standards.

Estimated annual number of respondents: 300.

Estimated annual number of responses per respondent: 1.

Estimated annual number of responses: 300.

Estimated total annual burden on respondents: 50 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 24th day of January 2005.

Elizabeth E. Gaston,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E5–329 Filed 1–27–05; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 04–051–1]

Syngenta Seeds, Inc.; Availability of Petition and Environmental Assessment for Determination of Nonregulated Status for Cotton Genetically Engineered for Insect Resistance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has received a petition from Syngenta Seeds, Inc., seeking a determination of nonregulated status for cotton designated as transformation Event COT102, which has been genetically engineered for insect resistance. The petition has been submitted in accordance with our regulations concerning the introduction of certain genetically engineered organisms and products. In accordance with those regulations, we are soliciting public comments on whether this cotton presents a plant pest risk. We are also making available for public comment an environmental assessment for the proposed determination of nonregulated status.

DATES: We will consider all comments we receive on or before March 29, 2005.

ADDRESSES: You may submit comments by any of the following methods:

- EDOCKET: Go to *http://www.epa.gov/feddocket* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once you have entered EDOCKET, click on the ''View Open APHIS Dockets'' link to locate this document.
- Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 04–051–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 04–051–1.
- E-mail: Address your comment to *regulations@aphis.usda.gov*. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 04–051–1'' on the subject line.

Reading Room: You may read the petitions, the environmental assessment, and any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: You may view APHIS documents published in the **Federal Register** and related information, including the names of groups and individuals who have commented on APHIS dockets, on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html*.

FOR FURTHER INFORMATION CONTACT: Dr. Margaret Jones, Biotechnology Regulatory Services, APHIS, Suite 5B05, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 734–4880. To obtain copies of the petition or the environmental assessment, contact Ms. Terry Hampton at (301) 734–5715; e-mail: *Terry.A.Hampton@aphis.usda.gov*. The petition and the EA are also available on the Internet at *http://www.aphis.usda.gov/brs/aphisdocs/03_15501p.pdf* and *http://www.aphis.usda.gov/brs/aphisdocs/03_15501p_ea.pdf*.

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR part 340, ''Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests,'' regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered organisms and products are considered ''regulated articles.''

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

On June 4, 2003, APHIS received a petition (APHIS Petition Number 03–155–01p) from Syngenta Seeds, Inc., (Syngenta) of Research Triangle Park, NC, requesting a determination of nonregulated status under 7 CFR part 340 for cotton (*Gossypium hirsutum* L.) designated as transformation Event COT102, which has been genetically engineered for selective lepidopteran insect resistance. The Syngenta petition states that the subject cotton should not be regulated by APHIS because it does not present a plant pest risk.

As described in the petition, Event COT102 cotton has been genetically engineered to contain an insecticidal *vip3A(a)* gene derived from *Bacillus thuringiensis* (Bt) strain AB88 under the control of the actin-2 promoter derived from *Arabidopsis thaliana,* which confers expression of the VIP3A(a) protein throughout the plant with the exception of the fiber. Event COT102 cotton also contains the selectable marker gene *aph4* derived from *Escherichia coli.* The *aph4* gene encodes the enzyme hygromycinB phosphotransferase and its expression is controlled by the ubiquitin-3 promoter from *A. thaliana.* Agrobacterium-mediated gene transfer was used to transfer the added genes into the recipient Coker 312 cotton variety. The petitioner states that while the VIP3A protein shares no homology with known Cry proteins, testing has shown that VIP3A is similarly specific in toxicity

only to the larvae of certain lepidopteran species. However, the VIP3A apparently targets a different receptor than the Cry1 proteins in sensitive species and therefore may be useful in the management of pest resistance.

Event COT102 has been considered a regulated article under the regulations in 7 CFR part 340 because it contains gene sequences from the plant pathogen *Agrobacterium tumefaciens.* This cotton event has been field tested since 2000 in the United States under APHIS notifications. In the process of reviewing the notifications for field trials of the subject cotton, APHIS determined that the vector was disarmed and that the trials, which were conducted under conditions of reproductive and physical confinement or isolation, would not present a risk of plant pest introduction or dissemination.

In § 403 of the Plant Protection Act (7 U.S.C. 7701–7772), plant pest is defined as any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: A protozoan, a nonhuman animal, a parasitic plant, a bacterium, a fungus, a virus or viroid, an infectious agent or other pathogen, or any article similar to or allied with any of the foregoing. APHIS views this definition very broadly. The definition covers direct or indirect injury, disease, or damage not just to agricultural crops, but also to plants in general, for example, native species, as well as to organisms that may be beneficial to plants, for example, honeybees, rhizobia, etc.

The U.S. Environmental Protection Agency (EPA) is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 *et seq.*). FIFRA requires that all pesticides, including herbicides, be registered prior to distribution or sale, unless exempt by EPA regulation. In cases in which genetically modified plants allow for a new use of a pesticide or involve a different use pattern for the pesticide, EPA must approve the new or different use. Accordingly, Syngenta has submitted a request for commercial registration of VIP3A as a plant-incorporated protectant.

When the use of the pesticide on the genetically modified plant would result in an increase in the residues in a food or feed crop for which the pesticide is currently registered, or in new residues in a crop for which the pesticide is not currently registered, establishment of a new tolerance or a revision of the existing tolerance would be required. Residue tolerances for pesticides are established by EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 *et seq.*), and the Food and Drug Administration (FDA) enforces tolerances set by EPA under the FFDCA. Syngenta has submitted a request to EPA for a tolerance exemption for both the VIP3A and APH4 proteins as expressed in the subject cotton event. Subsequently, EPA granted a time-limited exemption from tolerance for the VIP3A protein and an exemption from tolerance for residues of the APH4 protein.

FDA published a statement of policy on foods derived from new plant varieties in the **Federal Register** on May 29, 1992 (57 FR 22984 23005). The FDA statement of policy includes a discussion of FDA's authority for ensuring food safety under the FFDCA, and provides guidance to industry on the scientific considerations associated with the development of foods derived from new plant varieties, including those plants developed through the techniques of genetic engineering. Syngenta has begun consultation with FDA on the subject cotton event.

To provide the public with documentation of APHIS' review and analysis of the environmental impacts and plant pest risk associated with a proposed determination of nonregulated status for Syngenta's Event COT102 cotton, an environmental assessment has been prepared. The EA was prepared in accordance with (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

In accordance with § 340.6(d) of the regulations, we are publishing this notice to inform the public that APHIS will accept written comments regarding the petition for a determination of nonregulated status from interested persons for a period of 60 days from the date of this notice. We are also soliciting written comments from interested persons on the environmental assessment prepared to examine any environmental impacts of the proposed determinations for the subject cotton event. The petition and the environmental assessment and any comments received are available for public review, and copies of the petitions and the environmental assessment are available as indicated in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

After the comment period closes, APHIS will review the data submitted by the petitioner, all written comments received during the comment period, and any other relevant information. After reviewing and evaluating the comments on the petition and the environmental assessment and other data and information, APHIS will furnish a response to the petitioner, either approving the petition in whole or in part, or denying the petition. APHIS will then publish a notice in the **Federal Register** announcing the regulatory status of Syngenta's insect-resistant cotton event COT102 and the availability of APHIS' written decision.

Authority: 7 U.S.C. 1622n and 7701–7772; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 19th day of January 2005.

Elizabeth E. Gaston,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E5–328 Filed 1–27–05; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection; Comment Request—Feasibility of Computer Matching in the National School Lunch Program

AGENCY: Food and Nutrition Service, Department of Agriculture.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Food and Nutrition Service's intention to request Office of Management and Budget approval of a new information collection from State Child Nutrition (CN), Education, and Medicaid agencies, as well as School Food Authorities (SFAs). The study will collect information to examine the feasibility of using computer matching in the National School Lunch Program (NSLP) to help improve program integrity and operational efficiency.

DATES: Written comments on this notice must be received by March 29, 2005, to be assured of consideration.

ADDRESSES: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate

of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to Alberta Frost, Director, Office of Analysis, Nutrition, and Evaluation, Food and Nutrition Service, Department of Agriculture, 3101 Park Center Drive, Room 1014, Alexandria, VA 22302.

All responses to this notice will be summarized and included in the request for Office of Management and Budget (OMB) approval of the information collection. All comments will also become a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the proposed information collection forms should be directed to Alberta Frost at (703) 305–2017.

SUPPLEMENTARY INFORMATION:

Title: Feasibility of Computer Matching in the National School Lunch Program.

OMB Number: Not yet assigned.

Expiration Date: Not applicable.

Type of Request: New collection of information.

Abstract: The Food and Nutrition Service (FNS) is seeking to improve the process by which SFAs determine and verify the children eligible for free and reduced-price school meals. Recent studies suggest that a significant number of ineligible children are being approved for free and reduced-price meals. Congress expressed concern about these issues in the Child Nutrition and WIC Reauthorization Act of 2004 (Pub. L. 108–265) (the Act). Section 105(a) requires USDA to conduct a study on the feasibility of using computer technology to reduce errors, waste, fraud, and abuse in the NSLP. The study will collect and analyze data through mail surveys of all states and in-depth telephone interviews with six selected States to: Assess current and planned use of computer matching for NSLP certification and application verification; identify benefits, challenges, and barriers to computer matching; collect information on statewide student information systems and education matches with Medicaid and wage data; and identify the types of information maintained by the Medicaid program that could be useful for NSLP certification and verification.

Estimate of Burden: The public reporting burden for the survey of State CN Program directors is estimated at 40 minutes for the mail survey. The public reporting burden for the survey of State Education Agency (SEA) liaisons to the National Center for Education Statistics (NCES) is estimated to be 15 minutes for the mail survey. The public reporting burden for the survey of State Medicaid Directors is estimated to be 30 minutes for the mail survey.

For the in-depth telephone interviews, the burden estimates per respondent in each of the six States are: State CN officials, 60 minutes; State Student Information Systems administrators, 60 minutes; State Food Stamp Program (FSP) agency officials, 60 minutes; State Medicaid agency officials, 60 minutes; State Wage Information Collection Agency (SWICA) officials, 60 minutes; and SFA administrators, 60 minutes.

Respondents: Respondents for the mail survey are State CN Directors, SEA NCES liaisons, and State Medicaid Directors. Respondents for the in-depth telephone interviews include: State CN officials; State Student Information Systems administrators; State FSP agency officials; State Medicaid agency officials, SWICA officials, and SFA administrators.

Estimated Number of Respondents: Mail surveys will be conducted with 51 State CN Program Directors, 51 SEA NCES liaisons, and 51 State Medicaid Directors.

In-depth telephone interviews will be conducted with: 12 State CN agency officials; 12 State Student Information Systems administrators; 12 State FSP agency officials; 12 State Medicaid agency officials; 12 SWICA officials; and 12 SFA administrators.

Number of Responses per Respondent: One response per respondent per data collection effort.

Estimated Time per Response:

Respondents	Number	Minutes	Total minutes
State CN Directors: Mail Survey	51	40	2,040
SEA NCES Liaisons: Mail Survey	51	15	765
State Medicaid Directors: Mail Survey	51	30	1,530
State CN Officials: Telephone Interview	12	60	720
State Student Information System Administrators: Telephone Interview	12	60	720
State FSP Officials: Telephone Interview	12	60	720
State Medicaid Officials: Telephone Interview	12	60	720
SWICA Officials: Telephone Interview	12	60	720
SFA Administrators: Telephone Interview	12	60	720
Total Respondent Burden			8,655

Estimated Total Annual Burden on Respondents: 144 hours.

Dated: January 21, 2005.

Roberto Salazar,

Administrator.

[FR Doc. 05–1616 Filed 1–27–05; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 04–045N]

Codex Alimentarius Commission: Thirty-Seventh Session of the Codex Committee on Food Additives and Contaminants

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of public meeting, request for comments.

SUMMARY: The Office of the Under Secretary for Food Safety, United States Department of Agriculture (USDA), and the Food and Drug Administration (FDA), United States Department of Health and Human Services, are sponsoring a public meeting on March 9, 2005, to provide information and receive public comments on agenda items that will be discussed at the

Thirty-seventh Session of the Codex Committee on Food Additives and Contaminants (CCFAC), which will be held in The Hague, The Netherlands, on April 25–29, 2005. The Under Secretary and FDA recognize the importance of providing interested parties the opportunity to obtain background information on the agenda items that will be discussed at this forthcoming session of the CCFAC.

DATES: The public meeting is scheduled for Wednesday, March 9, 2005, from 1 p.m. to 4 p.m.

ADDRESSES: The public meeting will be held in the Auditorium (Room 1A–003), Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, Maryland. Documents related to the 37th Session of the CCFAC will be accessible via the World Wide Web at the following address: *http://www.codexalimentarius.net/current.asp*.

FSIS invites interested persons to submit comments on this notice. Comments may be submitted by any of the following methods:

- Mail, including floppy disks or CD–ROM's and hand-or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 300 12th Street, SW., Room 102, Cotton Annex, Washington, DC 20250–3700.

All comments received must include the Agency name and docket number #04–045N.

All comments submitted in response to this notice, will be available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday. The comments also will be posted on the Agency's Web site at *http://www.fsis.usda.gov/regulations/2005_Notices_Index/*.

FOR FURTHER INFORMATION CONTACT: About the 37th session of the CCFAC: U.S. Delegate, Dr. Terry Troxell, Director, Office of the Plant and Diary Foods and Beverages, Center for Food Safety and Applied Nutrition, FDA, Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway (HFS–300), College Park, MD 20740, phone: (301) 436–1700, fax: (301) 436–2632, e-mail: *terry.troxell@fda.hhs.gov*.

About the public meeting: Ellen Matten, U.S. Codex Office, Food Safety and Inspection Service, Room 4861, South Building, 1400 Independence Avenue, SW., Washington, DC 20250–3700, phone: (202) 205–7760, fax: (202) 720–3157. Attendees are requested to pre-register as soon as possible by e-mail to (e-mail address: *ccfac@cfsan.fda.gov*.)

SUPPLEMENTARY INFORMATION:

Background

The Codex Alimentarius Commission (Codex) was established in 1962 by two United Nations organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Codex is the major international standard-setting organization for protecting the health and economic interests of consumers and encouraging fair international trade in food. Through adoption of food standards, codes of practice, and other guidelines developed by its committees, and by promoting their adoption and implementation by governments, Codex seeks to ensure that the world's food supply is sound, wholesome, free from adulteration, and correctly labeled. In the United States, USDA, FDA, and the Environmental Protection Agency (EPA) manage and carry out U.S. Codex activities.

The Codex Committee on Food Additives and Contaminants (CCFAC) establishes or endorses maximum or guideline levels for individual food additives, for contaminants (including environmental contaminants) and for naturally occurring toxicants in foodstuffs and animal feeds. In addition, the Committee prepares priority lists of food additives and contaminants for toxicological evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA); recommends specifications of identity and purity for food additives for adoption by the Commission; considers methods of analysis for the determination of food additives and contaminants in food; and considers and elaborates standards or codes for related subjects such as the labeling of food additives when sold as such, and food irradiation. The Committee is chaired by The Netherlands.

Issues To Be Discussed at the Public Meeting

Items on the provisional agenda of the 37th session of CCFAC to be discussed during the public meeting:

1. Matters referred or of interest to the committee arising from the Codex Alimentarius Commission and other Codex committees, including the endorsement or revision of maximum levels for food additives and contaminants in Codex commodity standards.

2. Summary reports of the 63rd and 64th meetings of the Joint Expert Committee for Food Additives (JECFA) and any actions required as a result of changes in the acceptable daily intake (ADI) status and other toxicological recommendations.

3. Consideration of the Codex General Standard for Food Additives (GSFA) including:

(a) Progress report of the working group on the working principles of the GSFA,

(b) Report of the electronic working group on the GSFA,

(c) Draft and proposed draft food additives provisions requiring information on their use, and

(d) Proposed draft food additive provisions at Step 3 and proposals for new uses.

4. Proposals for additions or amendments to the International Numbering System for Food Additives, including discussion papers on harmonizing the food additive class names used by Codex and JECFA, and a proposed definition of food additive carriers.

5. An updated Inventory of Processing Aids (IPA).

6. A discussion paper on flavoring agents with risk management options for CCFAC to consider.

7. Terms of reference for a Joint FAO/WHO expert group to conduct a comprehensive assessment of the use of active chlorine in food processing.

8. Specifications for the identity and purity of food additives.

9. Schedule 1 of the Codex General Standard for Contaminants and Toxins (GSCT) with proposed draft revisions.

10. Draft code of practice for the prevention and reduction of aflatoxin contamination in tree nuts.

11. Proposed draft maximum levels for aflatoxin in unprocessed and processed almonds, hazelnuts, and pistachios.

12. Proposed draft sampling plan for aflatoxin contamination in almonds, Brazil nuts, hazelnuts, and pistachios.

13. Discussion paper on aflatoxin contamination in Brazil nuts with risk management options for CCFAC to consider.

14. Information on deoxynivalenol (DON) contamination in cereal grains.

15. Information on mycotoxin contamination in sorghum.

16. Draft maximum levels for lead in fish, including a list of the major internationally traded fish species with proposals for lead maximum levels.

17. Proposed draft maximum levels for tin in food.

18. Draft code of practice for the prevention and reduction of inorganic tin contamination in canned foods.

19. Draft and proposed draft maximum levels for cadmium in rice, potatoes, wheat, vegetables, and mollusks.

20. Proposed draft code of practice for source directed measures to reduce dioxin and dioxin-like polychlorinated biphenyls (PCB) contamination of foods.

21. A discussion paper and proposed draft maximum levels for chloropropanols in food.

22. Discussion paper on acrylamide in food with risk management options for CCFAC to consider.

23. Discussion paper on polycyclic aromatic hydrocarbons in food with risk management options for CCFAC to consider.

24. Discussion paper on guideline levels for methylmercury in fish with risk management options for CCFAC to consider.

25. Draft revised guideline levels for radionuclides in foods for use in international trade.

26. Priority list of food additives, contaminants and naturally occurring toxicants proposed for evaluation by JECFA.

Each issue listed will be fully described in documents distributed, or to be distributed, by The Netherlands' Secretariat to the Meeting. Members of the public may access or request copies of these documents (*see* **ADDRESSES**).

Public Meeting

At the March 9, 2005, public meeting, the agenda items will be described and discussed, and attendees will have the opportunity to pose questions and offer comments. Written comments may be offered at the meeting or sent to the U.S. Delegate, for the 37th Session of the CCFAC, Dr. Terry Troxell (*see* **ADDRESSES**). Written comments should state that they relate to activities of the 37th Session of the CCFAC.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and in particular minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it on-line through the FSIS Web page. The Agency Web page is located at *http://www.fsis.usda.gov.*

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and other types of information that could affect or would be of interest to our constituents and shareholders. The update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. The update also is available on the FSIS Web page. Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience.

Done in Washington, DC on January 24, 2005.

F. Edward Scarbrough,

U.S. Manager for Codex Alimentarius.

[FR Doc. 05–1612 Filed 1–27–05; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Forest Service

Transfer of Administrative Jurisdiction: Joint Readiness Training Center (JRTC), Fort Polk Military Reservation Interchange and the Kisatchie National Forest, LA

AGENCY: Forest Service, USDA.

ACTION: Notice of joint interchange of lands.

SUMMARY: The Act of July 26, 1956 (70 Stat. 656; 16 U.S.C. 505a–b) authorizes the interchange of land between the Department of Agriculture and the Department of Defense through its various services. On August 10, 2004, and November 12, 2004, respectively, the Secretary of the Army and the Secretary of Agriculture signed a Joint Order authorizing the transfer of administrative jurisdiction from the Department of Agriculture to the Department of the Army of 480.00 acres, more or less, located in Natchitoches Parish, Louisiana and generally described as: Parts of Sections 26, 28, 30, 34, and 35, Township 5 North, Range 8 West, Louisiana Meridian, lying within the Joint Readiness Training Center (JRTC), Fort Polk Military Reservation, and the Kisatchie National Forest and more particularly described according to the map and legal description on file in the Forest Service office noted in the **ADDRESSES** section of this notice.

Furthermore, the Joint Order transfers from the Department of the Army to the Department of Agriculture for inclusion in the Kisatchie National Forest 481.33 acres, more or less, located in Vernon Parish, Louisiana, and generally described as: Parts of Section 18 and 34, Township 1 North, Range 6 West, Louisiana Meridian, being 120 acres, more or less; Parts of Sections 16 and 32, Township 1 North, Range 5 West, Louisiana Meridian, being 51.33 acres, more or less; Parts of Sections 32 and 33, Township 1 North, Range 8 West, Louisiana Meridian, being 310 acres, more or less, within the boundaries of the Kisatchie National Forest, and more particularly described according to the map and legal description on file in the Forest Service office noted in the **ADDRESSES** section of this notice. A copy of the Joint Order is set out at the end of this notice.

EFFECTIVE DATE: The 45-day Congressional oversight requirement of the Act of July 26, 1956 has been met. The Joint Order is effective January 28, 2005.

ADDRESSES: Copies of the maps with adjoining legal descriptions showing the lands included in this joint interchange are on file and available for public inspection in the Office of the Director of Lands, 4th Floor South, Sidney R. Yates Federal Building, Forest Service, USDA, 201 14th Street, SW., Washington, DC 20250, between the hours of 8:30 a.m. and 4:30 p.m. on business days. Those wanting to inspect the maps with adjoining legal descriptions are encouraged to call ahead to (202) 205–1248 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: A.L. Richard, Lands Staff, at (202) 205–1792. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 twenty-four hours a day, every day of the year, including holidays.

Dated: January 25, 2005.

Gloria Manning,

Associate Deputy Chief.

Department of the Army

Department of Agriculture

Fort Polk, Louisiana Joint Order; Interchanging Administrative Jurisdiction of Department of the Army Lands and National Forest System Lands

By virtue of the authority vested in the Secretary of the Array and the Secretary of Agriculture by the Act of July 26, 1956 (70 Stat. 656; 16 U.S.C. 505a) it is ordered as follows:

1. The lands under the jurisdiction of the Department of the Army described in Exhibit A and shown on the attached maps which are on file and available for public inspection in the Office of the Chief, U.S. Department of Agriculture (USDA), Forest Service, Washington, DC, which lie within the boundary of Joint Readiness Training Center (JRTC) and Fort Folk's military reservation, Vernon and Natchitoches Parishes, Louisiana, are hereby transferred from the jurisdiction of the Secretary of the Army to the jurisdiction of the Secretary of Agriculture, subject to outstanding rights or interests of record.

2. The lands under the jurisdiction of the USDA Forest Service described in Exhibit B

and shown on the attached map which are on file and available for public inspection in the Office of the Chief, USDA Forest Service, Washington, DC, which lie within the Kisatchie National Forest (KNF), Louisiana, are hereby transferred from the jurisdiction of the Secretary of Agriculture to the jurisdiction of the Secretary of the Army, subject to outstanding rights or interests of record.

3. Pursuant to Section 2 of the aforementioned Act of July 26, 1956, the National Forest lands transferred to the Secretary of Army by this Joint Interchange order, are hereby subject only to the laws applicable to the Department of the Army lands comprising JRTC and Fort Polk, Louisiana. The Department of the Army lands transferred to the Secretary of Agriculture by this order are hereafter subject only to the laws applicable to lands acquired under the Act of March 1, 1911 (36 Stat. 961) as amended.

4. After the effective date of this Joint Interchange Order, the Department of the Army shall remain responsible for the response to any ordnance, explosives, hazardous substances, or pollutants or contaminants discovered on the lands described in Exhibits A and B, that are the result of past Army operations on those lands or that occurred during the Army's administration of those lands.

This joint Interchange Order will be effective as of the date of publication in the **Federal Register**.

Dated: August 10, 2004.

R.L. Brownlee,

Acting Secretary of the Army.

Dated: November 12, 2004.

Ann M. Veneman,

Secretary of Agriculture.

[FR Doc. 05–1623 Filed 1–27–05; 8:45 am]

BILLING CODE 3410–11–P

CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD

Sunshine Act Meeting

In connection with its investigation into the cause of an dust explosion and fire that occurred at the CTA Acoustics manufacturing plant in Corbin, Kentucky, on February 20, 2003, the United States Chemical Safety and Hazard Investigation Board (CSB) announces that it will convene a Public Meeting starting at: 7 p.m. on February 15, 2005 at the London Community Center, 529 South Main Street, London, KY 40741; Telephone: (606) 864–7777.

At the meeting CSB staff will present to the Board the results of their investigation into this incident, including an analysis of the incident together with a discussion of the key findings, root and contributing causes, and draft recommendations. The CSB staff presentation will focus on four key safety issues: Combustible Dust Hazard Awareness, Work Practices, Building Design, and Product Stewardship.

The 2003 incident damaged the CTA Acoustics manufacturing plant in Corbin, Kentucky, fatally injuring seven workers. The facility produced fiberglass insulation for the automotive industry. CSB investigators have found that the explosion was fueled by a phenolic resin dust accumulated in a production area, likely ignited by flames from a malfunctioning oven. The resin was used in producing fiberglass mats.

After the staff presentation, the Board will allow a time for public comment. Following the conclusion of the public comment period, the Board will consider whether to vote to approve the final report and recommendations.

All staff presentations are preliminary and are intended solely to allow the Board to consider in a public forum the issues and factors involved in this case. No factual analyses, conclusions or findings should be considered final. Only after the Board has considered the staff presentation and approved the staff report will there be an approved final record of this incident.

The meeting will be open to the public. Please notify CSB if a translator or interpreter is needed, at least 5 business days prior to the public meeting. For more information, please contact the Chemical Safety and Hazard Investigation Board at (202) 261–7600, or visit our Web site at: *http://www.csb.gov.*

Christopher W. Warner,

General Counsel.

[FR Doc. 05–1700 Filed 1–26–05; 12:02 pm]

BILLING CODE 6350–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Deletions from Procurement List.

SUMMARY: The Committee is proposing to delete from the Procurement List services previously furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

Comments Must Be Received on or Before: February 27, 2005.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Sheryl D. Kennerly, Telephone: (703) 603–7740, Fax: (703) 603–0655, or e-mail *SKennerly@jwod.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C 47(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Deletions

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action may result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. If approved, the action may result in authorizing small entities to furnish the services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the services proposed for deletion from the Procurement List.

End of Certification

The following services are proposed for deletion from the Procurement List:

Services

Service Type/Location: Commissary Shelf Stocking & Custodial; Fort Bragg and Malonee Village, Fayetteville, North Carolina.
NPA: None currently authorized.
Contracting Activity: Defense Commissary Agency, Fort Lee, Virginia.

Service Type/Location: Food Service; Pueblo Chemical Depot, Pueblo, Colorado.
NPA: Pueblo Diversified Industries, Inc., Pueblo, Colorado.
Contracting Activity: U.S. Army, Rocky Mountain Arsenal, Commerce City, Colorado.

Service Type/Location: Janitorial/Custodial; U.S. Federal Building and Courthouse, Fresno, California.
NPA: None currently authorized.
Contracting Activity: GSA, Public Buildings Service.

Sheryl D. Kennerly,

Director, Information Management.

[FR Doc. 05–1645 Filed 1–27–05; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to and deletions from Procurement List.

SUMMARY: This action adds to the Procurement List products and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes from the Procurement List products previously furnished by such agencies.

EFFECTIVE DATE: February 27, 2005.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Sheryl D. Kennerly, Telephone: (703) 603–7740, fax: (703) 603–0655, or e-mail *SKennerly@jwod.gov*.

SUPPLEMENTARY INFORMATION:

Additions

On October 29, December 3, and December 17, 2004, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (69 FR 63139, 70222/23, and 75507) of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the products and services and impact of the additions on the current or most recent contractors, the Committee has determined that the products and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and services to the Government.

2. The action will result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products and services proposed for addition to the Procurement List.

End of Certification

Accordingly, the following products and services are added to the Procurement List:

Products

Product/NSN: Folder, File, Classification, 7530–01–011–9454.
NPA: Georgia Industries for the Blind, Bainbridge, Georgia.
Contracting Activity: Office Supplies & Paper Products Acquisition Center New York, New York.

Product/NSN: Mass Casualty First Aid Kit, USAF, 6545–01–525–9821—Mass Casualty Bag, 6545–01–525–9847—Trauma Module, 6545–01–525–9849—Minor Module, 6545–01–526–0062—Splint Module, 6545–01–526–0065—CPR Module, 6545–01–526–0423—Mass Casualty First Aid Kit.
NPA: Chautauqua County Chapter, NYSARC, Jamestown, New York.
Contracting Activity: U.S. Air Force—AFMLO/USAF, Frederick, Maryland.
Contracting Activity: Defense Supply Center Philadelphia, Philadelphia, Pennsylvania.

Services

Service Type/Location: Custodial & Grounds Maintenance, South Eastern Regional Archives, 5780 Jonesboro Road, Morrow, Georgia.
NPA: Goodwill Industries of North Georgia, Inc., Atlanta, Georgia.
Contracting Activity: National Archives & Records Administration, College Park, Maryland.

Service Type/Location: Document Destruction, Internal Revenue Service, NISH, Vienna, Virginia (Prime Contractor). Performance to be allocated to the Nonprofit Agencies identified at the following locations: 101 Park Deville Drive, Columbia, Missouri; 919 Jackson Street, Chillicothe, Missouri; 3702 W. Truman Blvd, Jefferson City, Missouri.
NPA: Independence and Blue Springs Industries, Inc., Independence, Missouri; 137 S. Broadview, Cape Girardeau, Missouri; 2725 N. Westwood Blvd, Poplar Bluff, Missouri.
NPA: Cape Girardeau Community Sheltered Workshop, Inc., Cape Girardeau, Missouri; 12941 I–45 North, Houston, Texas; 8876 Gulf Freeway, Houston, Texas; 8701 South Gessner (Alliance Tower), Houston, Texas; 1919 Smith Street (G. T. ''Mickey'' Leland Federal Building) Houston, Texas; 350 Pine Street (Petroleum Tower), Beaumont, Texas.
NPA: Austin Task, Inc., Austin, Texas, 4050 Alpha Road, Farmers Branch, Texas; 1801 N. Hampton Road (DeSoto State Bank Building), DeSoto, Texas; 1100/1114 Commerce Street (Earle Cabell Federal Building Complex) Dallas, Texas; 2601 Meacham Blvd (FAA Building), Fort Worth, Texas; 819 Taylor Street (U.S. Federal Courthouse), Fort Worth, Texas.
NPA: Expanco, Inc., Fort Worth, Texas; 1800 NW Loop 821 (Bank Building Office Center), Longview, Texas; 909 ESE Loop 323 (Commerce Square III), Tyler, Texas.
NPA: Goodwill Industries—Opportunities in Tyler, Tyler, Texas.
Contract Activity: IRS—Western Area Procurement Branch—APFW, San Francisco, California.

Service Type/Location: Laundry Service, U.S. Mint, 155 Hermann Street, San Francisco, California.
NPA: Toolworks, Inc., San Francisco, California.
Contracting Activity: U.S. Mint, San Francisco, California.

Deletions

On December 3, 2004, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (69 FR 70223) of proposed deletions to the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the products listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action may result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the products to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products deleted from the Procurement List.

End of Certification

Accordingly, the following products are deleted from the Procurement List:

Products

Product/NSN: Power Duster, 7045–00–NIB–0164, 7045–00–NIB–0165, 7045–00–NIB–0166.
NPA: Lighthouse for the Blind, St. Louis, Missouri.
Contracting Activity: Office Supplies & Paper Products Acquisition Center, New York, New York.

Product/NSN: Tape, Electronic Data Processing, 7045–00–377–9235.
NPA: North Central Sight Services, Inc., Williamsport, Pennsylvania.
Contracting Activity: Defense Supply Center Columbus, Columbus, Ohio.

Sheryl D. Kennerly,

Director, Information Management.

[FR Doc. 05–1646 Filed 1–27–05; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Five-Year (''Sunset'') Reviews; Correction

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

In accordance with section 751(c) of the Tariff Act of 1930, as amended (''the Act''), the Department of Commerce (''the Department'') published its notice of five-year (''sunset'') reviews of certain antidumping and countervailing duty orders on January 3, 2005. *See Initiation of Five-Year (''Sunset'') Reviews*, 70 FR 75 (January 3, 2005). In that notice, the published case number of the antidumping duty order on certain carbon cut-to-length quality steel plate from Japan was incorrect. The correct case number is A–588–847.

FOR FURTHER INFORMATION CONTACT: Martha Douthit, Office of Policy, Import Administration, International Trade Administration, U.S. Department of Commerce at (202) 482–5050.

Dated: January 24, 2005.

Gary Taverman,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. E5–338 Filed 1–27–05; 8:45 am]

BILLING CODE: 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–801]

Certain Frozen Fish Fillets From the Socialist Republic of Vietnam: Rescission, in Part, of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, U.S. Department of Commerce.

SUMMARY: The Department of Commerce (''the Department'') is rescinding its administrative review of four companies under the antidumping duty order on certain frozen fish fillets from the Socialist Republic of Vietnam for the period January 1, 2003, through July 31, 2004. This rescission, in part, is based on the timely withdrawal of the request for review by the respective interested party that requested a review. A complete list of the companies for which the administrative review is being rescinded is provided in the *Rescission, in Part, of Administrative Review* section below. The Department is not rescinding its review of Can Tho Agricultural and Animal Products Import-Export Company (CATACO); Phan Quan Company, Ltd.; Phu Thanh Company, Co.; or Vinh Hoan Company, Ltd.

EFFECTIVE DATE: January 28, 2005.

FOR FURTHER INFORMATION CONTACT: Javier Barrientos or Alex Villanueva at (202) 482–2243 and (202) 482–3208, respectively, AD/CVD Operations, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

The Department published in the **Federal Register** an antidumping duty order on certain frozen fish fillets from the Socialist Republic of Vietnam on August 12, 2003 (68 FR 47909). Pursuant to its *Notice of Opportunity to Request an Administrative Review,* 69 FR 46496 (August 3, 2004), and in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended, and section 351.213(b) of the Department's regulations, the Department received timely requests for review from eight exporters: An Giang Fisheries Import and Export Joint Stock Company; An Giang Agriculture and Foods Import-Export Company (AFIEX); Can Tho Agricultural and Animal Products Import-Export Company (CATACO); Mekong Fisheries Joint Stock Company (MEKONIMEX); Phan Quan Company, Ltd.; Phu Thanh Company, Co.; QVD Food Co., Ltd.; and Vinh Hoan Company, Ltd. No other interested party requested a review.

On September 22, 2004, the Department published its *Notice of Initiation of Antidumping and Countervailing Duty Administrative Reviews, Requests for Revocation in Part and Deferral of Administrative Review,* 69 FR 56745 (September 22, 2004), initiating on all eight companies for which an administrative review was requested. The Department subsequently received timely withdrawal requests from four of the eight exporters that requested a review: An Giang Fisheries Import and Export Joint Stock Company (October 26, 2004); AFIEX (October 19, 2004); MEKONIMEX (November 5, 2004); and QVD Food Co., Ltd. (September 29, 2004).

Rescission, in Part, of Administrative Review

Pursuant to section 351.213(d)(1) of the Department's regulations, the Department may rescind an administrative review, ''if a party that requested the review withdraws the request within 90 days of the date of publication of notice of initiation of the requested review.'' Because four exporters have timely withdrawn their requests for an administrative review within the ninety-day period, and no other party requested a review of these companies, we are rescinding this administrative review, in part, for the period January 1, 2003, through July 31, 2004, for the following companies: An Giang Fisheries Import and Export Joint Stock Company; AFIEX; MEKONIMEX; and QVD Food Co., Ltd. However, we will continue the administrative review with respect to: CATACO; Phan Quan Company, Ltd.; Phu Thanh Company, Co.; and Vinh Hoan Company, Ltd., as these exporters individually submitted a request for review.

The Department will issue appropriate assessment instructions directly to the U.S. Customs and Border Protection (''CBP'') within 15 days of the publication of this notice. The Department will direct CBP to assess antidumping duties for these companies at the cash deposit rate in effect on the date of entry for entries during the period January 1, 2003, through July 31, 2004.

Notification to Parties

This notice serves as a reminder to importers of their responsibility under section 351.402(f) of the Department's regulations to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this period of time. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and subsequent assessment of double antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with section 351.305(a)(3) of the Department's regulations. Timely written notification of the return or destruction of APO materials or

conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

This notice is issued and published in accordance with section 351.213(d)(4) of the Department's regulations and sections 751(a)(2)(C) and 777(i)(1) of the Tariff Act of 1930, as amended.

Dated: January 18, 2005.

Gary Taverman,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. E5–339 Filed 1–27–05; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

North American Free-Trade Agreement, Article 1904 NAFTA Panel Reviews; Request for Panel Review

AGENCY: NAFTA Secretariat, United States Section, International Trade Administration, Department of Commerce.

ACTION: Notice of first request for panel review.

SUMMARY: On January 18, 2005, the Canadian Lumber Remanufacturer's Alliance (''CLRA'') and its individual members filed a First Request for Panel Review with the United States Section of the NAFTA Secretariat pursuant to Article 1904 of the North American Free Trade Agreement. A second, third, fourth and fifth Request for Panel Review was filed on January 19, 2005 on behalf of the Canfor Corporation and its affiliates Lakeland Mills Ltd. and the Pas Lumber Company Ltd. (collectively ''Canfor''); Terminal Forest Products Ltd. (''Terminal''); and on behalf of the Government of Canada, the Governments of the Provinces of Alberta, British Columbia, Manitoba, Ontario, and Saskatchewan, the Gouvernement du Quebec, the Governments of the Northwest Territories and the Yukon Territory, the British Columbia Lumber Trade Council and its constituent associations (the Coast Forest & Lumber Association and the Council of Forest Industries), the Ontario Forest Industries Association, the Ontario Lumber Manufacturers Association, Quebec Lumber Manufacturers Association; Apex Forest Products Inc., Aspen Planers Ltd., Buchanan Lumber Sales, Inc. and the Buchanan affiliated mills, exporters and importers (including Atikokan Forest Products Ltd., Buchanan Forest Products Ltd., Buchanan Northern Hardwoods Inc., Dubreuil Forest Products Limited, Great West Timber Limited, Long Lake Forest Products Inc., McKenzie Forest Products Inc., Nakina Forest Products Limited, Northern Sawmills Inc., Northern Wood, and Solid Wood Products Inc.), Devlin Timber (1992) Ltd., Downie Timber Ltd., Federated Co-operative Limited, Gorman Bros. Lumber Ltd., Haida Forest Products Ltd., Kenora Forest Products Ltd., Lecours Lumber Co. Limited, Liskeard Lumber Limited, Manitou Forest Products Ltd., Manning Diversified Forest Products Ltd., Midway Lumber Mills Ltd., Mill & Timber Products Ltd., Nickel Lake Lumber, North Enderby Timber Ltd., Olav Haavaldsrud Timber Company Limited, Pastway Planing Limited, R. Fryer Forest Products Limited, Selkirk Specialty Wood Ltd., Tembec Inc., Tyee Timber Products Ltd., and West Hastings Lumber Products (hereafter, ''the Parties''), respectively. Panel review was requested of the final results of countervailing duty administrative review and rescission of certain company-specific reviews made by the United States Department of Commerce, International Trade Administration, respecting Certain Softwood Lumber Products from Canada. This determination was published in the **Federal Register**, (69 FR 75917) on December 20, 2004. The determination was amended by Notice of Correction to Final Results on December 27, 2004 , 69 **Federal Register** 77220. The NAFTA Secretariat has assigned Case Number USA–CDA–2005–1904–01 to this request.

FOR FURTHER INFORMATION CONTACT: Caratina L. Alston, United States Secretary, NAFTA Secretariat, Suite 2061, 14th and Constitution Avenue, Washington, DC 20230, (202) 482–5438.

SUPPLEMENTARY INFORMATION: Chapter 19 of the North American Free-Trade Agreement (''Agreement'') establishes a mechanism to replace domestic judicial review of final determinations in antidumping and countervailing duty cases involving imports from a NAFTA country with review by independent binational panels. When a Request for Panel Review is filed, a panel is established to act in place of national courts to review expeditiously the final determination to determine whether it conforms with the antidumping or countervailing duty law of the country that made the determination.

Under Article 1904 of the Agreement, which came into force on January 1, 1994, the Government of the United States, the Government of Canada and the Government of Mexico established *Rules of Procedure for Article 1904 Binational Panel Reviews* (''Rules''). These Rules were published in the **Federal Register** on February 23, 1994 (59 FR 8686).

A first Request for Panel Review was filed with the United States Section of the NAFTA Secretariat, pursuant to Article 1904 of the Agreement, on January 18, 2005, requesting panel review of the final determination described above.

The Rules provide that:

(a) A Party or interested person may challenge the final determination in whole or in part by filing a Complaint in accordance with Rule 39 within 30 days after the filing of the first Request for Panel Review (the deadline for filing a Complaint is February 17, 2005);

(b) A Party, investigating authority or interested person that does not file a Complaint but that intends to appear in support of any reviewable portion of the final determination may participate in the panel review by filing a Notice of Appearance in accordance with Rule 40 within 45 days after the filing of the first Request for Panel Review (the deadline for filing a Notice of Appearance is March 4, 2005); and

(c) The panel review shall be limited to the allegations of error of fact or law, including the jurisdiction of the investigating authority, that are set out in the Complaints filed in the panel review and the procedural and substantive defenses raised in the panel review.

Dated: January 25, 2005.

Caratina L. Alston,

United States Secretary, NAFTA Secretariat.

[FR Doc. 05–1617 Filed 1–27–05; 8:45 am]

BILLING CODE 3510–GT–P

DEPARTMENT OF COMMERCE

International Trade Administration

North American Free-Trade Agreement, Article 1904 NAFTA Panel Reviews; Request for Panel Review

AGENCY: NAFTA Secretariat, United States Section, International Trade Administration, Department of Commerce.

ACTION: Notice of first request for panel review.

SUMMARY: On January 18, 2005, the Ontario Forest Industries Association, the Ontario Lumber Manufacturers Association and Tembec, Inc. filed a First Request for Panel Review with the United States Section of the NAFTA Secretariat pursuant to Article 1904 of the North American Free Trade Agreement. Panel review was requested

of the final notice of Implementation of Uruguay Round Agreement, Section 129 Determination by the United States Department of Commerce, International Trade Administration, respecting Certain Softwood Lumber Products from Canada. This determination was published in the **Federal Register,** (69 FR 75305) on December 16, 2004. The NAFTA Secretariat has assigned Case Number USA–CDA–2005–1904–02 to this request.

FOR FURTHER INFORMATION CONTACT: Caratina L. Alston, United States Secretary, NAFTA Secretariat, Suite 2061, 14th and Constitution Avenue, Washington, DC 20230, (202) 482–5438.

SUPPLEMENTARY INFORMATION: Chapter 19 of the North American Free-Trade Agreement (''Agreement'') establishes a mechanism to replace domestic judicial review of final determinations in antidumping and countervailing duty cases involving imports from a NAFTA country with review by independent binational panels. When a Request for Panel Review is filed, a panel is established to act in place of national courts to review expeditiously the final determination to determine whether it conforms with the antidumping or countervailing duty law of the country that made the determination.

Under Article 1904 of the Agreement, which came into force on January 1, 1994, the Government of the United States, the Government of Canada and the Government of Mexico established *Rules of Procedure for Article 1904 Binational Panel Reviews* (''Rules''). These Rules were published in the **Federal Register** on February 23, 1994 (59 FR 8686).

A first Request for Panel Review was filed with the United States Section of the NAFTA Secretariat, pursuant to Article 1904 of the Agreement, on January 18, 2005, requesting panel review of the final determination described above.

The Rules provide that:

(a) A Party or interested person may challenge the final determination in whole or in part by filing a Complaint in accordance with Rule 39 within 30 days after the filing of the first Request for Panel Review (the deadline for filing a Complaint is February 17, 2005);

(b) A Party, investigating authority or interested person that does not file a Complaint but that intends to appear in support of any reviewable portion of the final determination may participate in the panel review by filing a Notice of Appearance in accordance with Rule 40 within 45 days after the filing of the first Request for Panel Review (the deadline for filing a Notice of Appearance is March 4, 2005); and

(c) The panel review shall be limited to the allegations of error of fact or law, including the jurisdiction of the investigating authority, that are set out in the Complaints filed in the panel review and the procedural and substantive defenses raised in the panel review.

Dated: January 25, 2005.

Caratina L. Alston,

United States Secretary, NAFTA Secretariat.

[FR Doc. 05–1618 Filed 1–27–05; 8:45 am]

BILLING CODE 3510–GT–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Proposed Information Collection; Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (hereinafter the ''Corporation''), as part of its continuing effort to reduce paperwork and respondent burden, will submit the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Public Law 104–13, (44 U.S.C. Chapter 35)). The Corporation is soliciting from members of the public and affected agencies comments concerning the proposed collection of information.

Currently, the Corporation is soliciting comments concerning a new information collection for the annual *State Profiles and Performance Report.* The Corporation proposes to conduct an annual data collection request from State Service Commissions to gather information on AmeriCorps member service activity not available in current agency data systems.

Copies of the information collection request can be obtained by contacting the office listed below in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section by March 29, 2005.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) By mail sent to: Corporation for National and Community Service, Attn: Kelly Arey, Department of Research and Policy Development, Rm 8100, 1201 New York Avenue, NW., Washington, DC, 20525.

(2) By hand delivery or by courier to the Corporation's mailroom, Room 6010, at the mail address given in paragraph (1) above, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

(3) By fax to: 202–565–2785, Attn: Kelly Arey.

(4) Electronically through the Corporation's e-mail address system: *karey@cns.gov.*

(5) Individuals who use a telecommunications device for the deaf (TTY–TDD) may call (202) 565–2799 between 8:30 a.m. and 5 p.m. Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The Corporation is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Corporation, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility and clarity of the information to be collected; and
- Minimize the burden of the collection of information to those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g. permitting electronic submissions of responses.

Background: The Corporation is strongly committed to evaluating the effectiveness of its programs. The *State Profiles and Performance Report* presents performance results achieved by the Corporation for National and Community Service programs. The Corporation presents performance data on its programs annually; however, the *State Profiles and Performance Report* is the Corporation's first comprehensive effort at presenting disaggregated performance data by state and program. This data collection effort will use e-mail and telephone correspondence to solicit information annually from State Service Commissions about the programs in their portfolio, including competitive, formula, and commission Education Award Only Programs.

Type of Review: New collection.

Agency: Corporation for National and Community Service.

Title: State Profiles and Performance Report.

OMB Number: None.

Agency Number: None.

Affected Public: State government and not-for-profit institutions.

Total Respondents: 52.

Frequency: Annually.

Average Time Per Response: 20 hours.

Estimated Total Burden Hours: 1,040 hours.

Total Burden Cost (Capital/Startup): None.

Total Burden Cost (Operating/Maintenance): None.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: January 14, 2005.

Robert Grimm,

Director, Department of Research and Policy Development.

[FR Doc. 05–1563 Filed 1–27–05; 8:45 am]

BILLING CODE 6050–$$–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Submission for OMB Emergency Review

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (hereinafter the ''Corporation''), submitted the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, (PRA 95) (44 U.S.C. Chapter 35). The Corporation has requested OMB to review and approve its emergency request by February 1, 2005, for a period of six months. A copy of this ICR, with applicable supporting documentation, may be obtained by contacting the Corporation for National and Community Service, Office of Grants Policy and Operations, Marci Hunn, (202) 606–5000, Ext. 432, or by e-mail at *mhunn@cns.gov*. Individuals who use a telecommunications device for the deaf (TTY–TDD) may call (202) 565–2799 between 8:30 a.m. and 5 p.m. eastern time, Monday through Friday.

ADDRESSES: Comments may be submitted, identified by the title of the information collection activity, by any of the following two methods:

(1) By fax to: (202) 395–6974, Attention: Ms. Katherine Astrich, OMB Desk Officer for the Corporation for National and Community Service; and

(2) Electronically by e-mail to: *Katherine_T._Astrich@omb.eop.gov*.

SUPPLEMENTARY INFORMATION: The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Corporation, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Propose ways to enhance the quality, utility, and clarity of the information to be collected; and
- Propose ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.

Description: The purpose of this grant competition is to engage persons with disabilities in national and community service programs. Through Congressional appropriations, this competition was established to fund innovative national or regional (operating in three or more states) partnership models in which persons with disabilities are engaged in service that results in a measurable impact on the community served. The Corporation encourages all eligible public and private non-profit organizations, including faith-based and other community-based organizations, to apply. This information collection contains application instructions to apply for funding under the Engaging Persons with Disabilities in National and Community Service competition.

Type of Review: Emergency request.

Agency: Corporation for National and Community Service.

Title: Engaging Persons with Disabilities in National and Community Service Application Instructions.

OMB Number: None.

Agency Number: None.

Affected Public: Eligible applicants to the Corporation for funding for disability programs.

Total Respondents: 40.

Frequency: On occasion.

Average Time Per Response: Ten (10) hours.

Estimated Total Burden Hours: 400 hours.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Dated: January 19, 2005.

Amy Mack,

Chief of Staff, Office of Chief Executive Officer.

[FR Doc. 05–1653 Filed 1–27–05; 8:45 am]

BILLING CODE 6050–$$–P

DEPARTMENT OF DEFENSE

Department of the Army

Final Environmental Impact Statement for the Proposed Leasing of Lands at Fort Bliss, TX for the Proposed Siting, Construction, and Operation by the City of El Paso of a Brackish Water Desalination Plant and Support Facilities

AGENCY: Department of the Army, DoD.

ACTION: Notice of availability.

SUMMARY: The Department of the Army announces the availability of the Final Environmental Impact Statement (FEIS) evaluating the potential environmental impacts that could result from granting an easement to the City of El Paso, El Paso Water Utilities (EPWU), to use land in the South Training Areas of Fort Bliss for construction and operation of a desalination plant and support facilities, including wells, pipelines, and disposal sites for the residual brine resulting from the desalination process. The purpose of the proposed plant is to treat brackish (salty) water pumped from the Hueco Bolson Aquifer to provide an additional reliable source of potable water for use by the City of El Paso and Fort Bliss. Pumping of fresh water by EPWU, Fort Bliss, Ciudad Juárez, and others has resulted in declining groundwater levels in the aquifer. In addition, brackish water is intruding into the aquifer's freshwater layer and has the potential to affect water wells on Fort Bliss and in other areas of El Paso.

A sizable volume of brackish water exists adjacent to the freshwater zone of the Hueco Bolson Aquifer. Desalination of the brackish water offers a way to extend the life of the freshwater aquifer as a source of potable water that is to the mutual benefit of Fort Bliss and the City of El Paso. The proposed desalination plant would reduce withdrawals of fresh water from the aquifer, extending its useful life and intercepting the flow of brackish water to wells that are operated by Fort Bliss. Both Fort Bliss and the City of El Paso have considered constructing desalination facilities to tap into this potential water source. The Army and EPWU believe that building a single desalination plant to provide potable water for both the installation and the city would be more efficient and

cost effective than constructing separate desalination plants.

ADDRESSES: To obtain copies of the FEIS, contact John F. Barrera (915) 568–3908 or write to: Fort Bliss Directorate of the Environment, ATTN: AZC–DOE–C, Building 624, Pleasanton Road, Fort Bliss, TX 79916–6812.

FOR FURTHER INFORMATION CONTACT: John F. Barrera, (915) 568–3908.

SUPPLEMENTARY INFORMATION: The proposed desalination plant would treat brackish water drawn from the Hueco Bolson Aquifer using a technology called reverse osmosis (RO). RO uses semipermeable membranes to remove dissolved solids (primarily salts) from brackish water, producing fresh water. Water for the desalination process would be drawn from existing EPWU wells on the east side of El Paso International Airport and from proposed new wells to be installed on Fort Bliss land north of Biggs Army Airfield. The plant is being designed to produce approximately 27.5 million gallons per day (MGD) of drinking water and 3.0 MGD of a brine called concentrate. To implement the proposed desalination project, EPWU is applying for an easement for land in the South Training Areas of Fort Bliss for a desalination plant site, 16 new water wells, concentrate disposal sites, and various connecting pipelines.

The FEIS considers seven alternatives, six action alternatives and the No Action Alternative. The six action alternatives include various combinations of three potential sites for the proposed desalination plant and two methods of disposal on the concentrate. The three alternative desalination plant sites are located in Training Area 1B of the South Training Areas of Fort Bliss, adjacent to El Paso International Airport, north of Montana Avenue, and west of Loop 375. The two concentrate disposal methods under consideration include (1) injecting the concentrate underground into a confined zone where it would be isolated from potable water sources, or (2) piping the concentrate to evaporation ponds, where the liquid would evaporate leaving a solid salt residue that would be trucked to a landfill for final disposal.

Under the No Action Alternative, the Army would not provide land on Fort Bliss for construction and operation of the proposed desalination plant. None of the proposed facilities would be constructed on Army land at Fort Bliss. This alternative could, however, include one or more of the following actions without Army action or participation: construction and operation of a desalination plant on non-Army land, increase in water conservation measures, development of other water sources in the El Paso region, and/or importation of water from sources outside El Paso. Without the proposed desalination project, EPWU would continue to pump from the freshwater layer of the Hueco Bolson Aquifer until it no longer met drinking water standards.

The Army has selected Alternative 3—Constructing the facility north of Montana Avenue and using deep well injection for the disposal of concentrate—as the Preferred Alternative.

The FEIS analyzes the environmental consequences each alternative could have on geology and soils; water resources; utilities and services; hazardous materials, hazardous waste, and safety; air quality; biological resources; land use and aesthetics; transportation; cultural resources; and socioeconomics and environmental justice. In addition, it includes comments received on the Draft EIS, published August 6, 2004, during the public review period that ended September 27, 2004, as well as responses to those comments.

Copies of the FEIS are available for review at the following libraries in El Paso, Texas: El Paso Public Library, 501 N. Oregon Street; Richard Burgess Branch, 9600 Dyer; Irving Schwartz Public Library, 1865 Dean Martin Drive; and Westside Branch Library, 125 Belvedere Street.

Hugh M. Exton, Jr.,

Director, SWRO, Installation Management Agency.

[FR Doc. 05–689 Filed 1–27–05; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0035]

Federal Acquisition Regulation; Information Collection; Claims and Appeals

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning claims and appeals. The clearance currently expires on April 30, 2005.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

DATES: Submit comments on or before March 29, 2005.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the General Services Administration, FAR Secretariat (VIR), 1800 F Street, NW, Room 4035, Washington, DC 20405. Please cite OMB Control No. 9000–0035, Claims and Appeals, in all correspondence.

FOR FURTHER INFORMATION CONTACT: Rhonda Cundiff, Contract Policy Division, GSA (202) 501–0044.

SUPPLEMENTARY INFORMATION:

A. Purpose

It is the Government's policy to try to resolve all contractual issues by mutual agreement at the contracting officer's level without litigation. Contractor's claims must be submitted in writing to the contracting officer for a decision. Claims exceeding $100,000 must be accompanied by a certification that (1) the claim is made in good faith; (2) supporting data are accurate and complete; and (3) the amount requested accurately reflects the contract adjustment for which the contractor believes the Government is liable. Contractors may appeal the contracting officer's decision by submitting written appeals to the appropriate officials.

B. Annual Reporting Burden

Respondents: 4,500.

Responses Per Respondent: 3.

Annual Responses: 13,500.
Hours Per Response: 1.
Total Burden Hours: 13,500.
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, FAR Secretariat (VIR), Room 4035, 1800 F Street, NW, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0035, Claims and Appeals, in all correspondence.

Dated: January 19, 2005.

Laura Auletta

Director, Contract Policy Division.

[FR Doc. 05–1576 Filed 1–27–05; 8:45 am]

BILLING CODE 6820–EP–S

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0060]

Federal Acquisition Regulation; Information Collection; Accident Prevention Plans and Recordkeeping

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning accident prevention plans and recordkeeping. The clearance currently expires May 31, 2005.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

DATES: Submit comments on or before March 29, 2005.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the General Services Administration, FAR Secretariat (VIR), 1800 F Street, NW, Room 4035, Washington, DC 20405. Please cite OMB Control No.9000–0060, accident prevention plans and recordkeeping, in all correspondence.

FOR FURTHER INFORMATION CONTACT Cecelia Davis, Contract Policy Division, GSA (202) 219–0202.

SUPPLEMENTARY INFORMATION:

A. Purpose

The FAR clause at 48 CFR 52.236–13 Accident Prevention requires Federal construction contractors to keep records of accidents incident to work performed under the contract that result in death, traumatic injury, occupational disease or damage to property, materials, supplies or equipment. Records of personal inquiries are required by OSHA (OMB Control No. 1220–0029). The FAR requires records of damage to property, materials, supplies or equipment to provide background information when claims are brought against the Government.

If the contract involves work of a long duration, the contractor must submit a written proposal for implementation of the clause. The Accident Prevention Plan, for projects that are hazardous or of long duration, is analyzed by the contracting officer along with the agency safety representatives to determine if the proposed plan will meet the requirement of the safety regulations and applicable statutes. The records maintained by the contractor are used to evaluate compliance and may be used in workmen's compensation cases. The Accident Prevention Plan is placed in the contract file for reference.

B. Annual Reporting Burden

Respondents: 2,106.
Responses Per Respondent: 2.
Annual Responses: 4,212.
Hours Per Response: 2.
Total Burden Hours: 8,424.
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, FAR Secretariat (VIR), Room 4035, 1800 F Street, NW, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0060, Accident Prevention Plans and Recordkeeping, in all correspondence.

Dated: January 19, 2005.

Julia B. Wise

Acting Director, Contract Policy Division.

[FR Doc. 05–1577 Filed 1–27–05; 8:45 am]

BILLING CODE 6820–EP–S

DEPARTMENT OF EDUCATION

Office of Elementary and Secondary Education; Overview Information; Improving Literacy Through School Libraries Program; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2005

Catalog of Federal Domestic Assistance (CFDA) Number: 84.364A.

Dates:
Applications Available: January 28, 2005.
Deadline for Transmittal of Applications: March 14, 2005.
Deadline for Intergovernmental Review: May 13, 2005.
Eligible Applicants: Local Educational Agencies (LEAs) in which at least 20 percent of the students served by the LEA are from families with incomes below the poverty line based on the most recent satisfactory data available from the U.S. Census Bureau at the time this notice is published. This data is Small Area Income and Poverty Estimates for school districts for income year 2002. A list of LEAs with their family poverty rates (based on this Census Bureau data) is posted on our Web site at: *http://www.ed.gov/programs/lsl/eligibility.html.*
Estimated Available Funds: $19,683,264. Of that amount, $19,092,766 will be awarded competitively. Contingent upon the availability of funds and quality of applications, the Secretary may make additional awards in FY 2006 from the list of unfunded applicants from this competition.
Estimated Range of Awards: $30,000 to $350,000.

Note: Actual award amounts will be based on the number of schools and students served by the project.

Estimated Average Size of Awards: $190,000.
Estimated Number of Awards: 100.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 12 months.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of this program is to improve student reading skills and academic achievement by providing students with

increased access to up-to-date school library materials; well-equipped, technologically advanced school library media centers; and well-trained, professionally certified school library media specialists.

Priority: Under this competition we are particularly interested in applications that address the following priority.

Invitational Priority: For FY 2005 this priority is an invitational priority. Under 34 CFR 75.105(c)(1) we do not give an application that meets this invitational priority a competitive or absolute preference over other applications.

Under this priority the Secretary strongly encourages applicants to focus their efforts on elementary schools to maximize the impact of the project on improving reading achievement.

Program Authority: 20 U.S.C. 6383.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75, 77, 79, 80, 81, 82, 84, 85, 97, 98 and 99. (b) The notice of final clarification of eligible local activities, published April 5, 2004 in the **Federal Register**, 69 FR 17894.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $19,683,264. Of that amount, $19,092,766 will be awarded competitively. Contingent upon the availability of funds and quality of applications, the Secretary may make additional awards in FY 2006 from the list of unfunded applicants from this competition.

Note: Actual award amounts will be based on the number of schools and students served by the project.

Estimated Range of Awards: $30,000 to $350,000.

Estimated Average Size of Awards: $190,000.

Estimated Number of Awards: 100.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 12 months.

III. Eligibility Information

1. *Eligible Applicants:* LEAs in which at least 20 percent of the students served by the LEA are from families with incomes below the poverty line based on the most recent satisfactory data available from the U.S. Census Bureau at the time this notice is published. This data is Small Area Income and Poverty Estimates for school districts for income year 2002. A list of LEAs with their family poverty rates (based on this Census Bureau data) is posted on our Web site at: *http://www.ed.gov/programs/lsl/eligibility.html.*

2. *Cost Sharing or Matching:* This program does not involve cost sharing or matching, but does involve supplement-not-supplant funding provisions. Funds made available under this program must be used to supplement, and not supplant, other Federal, State, and local funds expended to carry out activities relating to library, technology, or professional development activities (20 U.S.C. 6383(i)).

IV. Application and Submission Information

1. *Address to Request Application Package:* You may obtain an application package via the Internet or from the Education Publications Center (ED Pubs). To obtain a copy via the Internet use the following address: *www.ed.gov/programs/lsl/applicant.html.* To obtain a copy from ED Pubs, write or call the following: ED Pubs, P.O. Box 1398, Jessup, MD 20794–1398. Telephone (toll free): 1–877–433–7827. Fax: (301) 470–1244. If you use a telecommunications device for the deaf (TDD), you may call (toll free): 1–877–576–7734.

You may also contact ED Pubs at its Web site: *www.ed.gov/pubs/edpubs.html* or you may contact ED Pubs at its e-mail address: *edpubs@inet.ed.gov.*

If you request an application from ED Pubs, be sure to identify this competition as follows: CFDA number 84.364A.

Individuals with disabilities may obtain a copy of the application package in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) by contacting the program contact person listed under Section VII of this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this program. An Eligibility Form is included in the application package. You must fill out the Eligibility Form, following the instructions provided in the application package.

Page Limit: The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. You must limit the narrative to the equivalent of no more than 15 pages, using the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger.

The page limit does not apply to the forms, budget section, budget justification, assurances and certifications, one-page abstract, endnotes, or resumes. However, you must include all of the application narrative in the narrative section. Charter Schools and State Administered Schools must include some form of documentation from their State Educational Agency (SEA) confirming eligibility for this program. This documentation is not counted toward the page limit.

Our reviewers will not read any pages of your application that—

- Exceed the page limit if you apply these standards; or
- Exceed the equivalent of the page limit if you apply other standards.

Appendices to the narrative are not permitted, with the exception of resumes and endnotes. None of the material sent as appendices to the narrative, with the exception of resumes and endnotes, will be sent to the reviewers.

3. *Submission Dates and Times:*

Applications Available: January 28, 2005.

Deadline for Transmittal of Applications: March 14, 2005.

Applications for grants under this program must be submitted electronically using the Electronic Grant Application System (e-Application) available through the Department's e-Grants system. For information (including dates and times) about how to submit your application electronically or by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to section IV.6. *Other Submission Requirements* in this notice.

We do not consider an application that does not comply with the deadline requirements.

Deadline for Intergovernmental Review: May 13, 2005.

4. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this program.

5. *Funding Restrictions:* We reference regulations outlining funding

restrictions in the *Applicable Regulations* section of this notice.

6. *Other Submission Requirements:* Applications for grants under this competition must be submitted electronically, unless you qualify for an exception to requirement in accordance with the instructions in this section.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement and submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

a. *Electronic Submission of Applications.*

Applications for grants under the Improving Literacy Through School Libraries program—CFDA Number 364A must be submitted electronically using e-Application available through the Department's e-Grants system, accessible through the e-Grants portal page at: *http://e-grants.ed.gov.*

While completing your electronic application, you will be entering data online that will be saved into a database. You may not e-mail an electronic copy of a grant application to us.

Please note the following:

- You must complete the electronic submission of your grant application by 4:30 p.m., Washington, DC time, on the application deadline date. The e-Application system will not accept an application for this competition after 4:30 p.m., Washington, DC time, on the application deadline date. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the application process.
- The regular hours of operation of the e-Grants Web site are 6 a.m. Monday until 7 p.m. Wednesday; and 6 a.m. Thursday until midnight Saturday, Washington, DC time. Please note that the system is unavailable on Sundays, and between 7 p.m. on Wednesdays and 6 a.m. on Thursdays, Washington, DC time, for maintenance. Any modifications to these hours are posted on the e-Grants Web site.
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.
- You must submit all documents electronically, including the Application for Federal Education Assistance (ED 424), Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- Any narrative sections of your application should be attached as files in a .DOC (document), .RTF (rich text), or .PDF (Portable Document) format.
- Your electronic application must comply with any page limit requirements described in this notice.
- Prior to submitting your electronic application, you may wish to print a copy of it for your records.
- After you electronically submit your application, you will receive an automatic acknowledgement that will include a PR/Award number (an identifying number unique to your application).
- Within three working days after submitting your electronic application, fax a signed copy of the ED 424 after following these steps:

(1) Print ED 424 from e-Application.

(2) The applicant's Authorizing Representative must sign this form.

(3) Place the PR/Award number in the upper right hand corner of the hard-copy signature page of the ED 424.

(4) Fax the signed ED 424 to (202) 742–5418.

- We may request that you provide us original signatures on other forms at a later date.

Application Deadline Date Extension in Case of e-Application System Unavailability: If you are prevented from electronically submitting your application on the application deadline date because the e-Application system is unavailable, we will grant you an extension of one business day in order to transmit your application electronically, by mail, or by hand delivery. We will grant this extension if—

(1) You are a registered user of e-Application and you have initiated an electronic application for this competition; and

(2) (a) The e-Application system is unavailable for 60 minutes or more between the hours of 8:30 a.m. and 3:30 p.m., Washington, DC time, on the application deadline date; or

(b) The e-Application system is unavailable for any period of time between 3:30 p.m. and 4:30 p.m., Washington, DC time, on the application deadline date.

We must acknowledge and confirm these periods of unavailability before granting you an extension. To request this extension or to confirm our acknowledgement of any system unavailability, you may contact either (1) the person listed elsewhere in this notice under **FOR FURTHER INFORMATION CONTACT** (*see* VII. Agency Contact) or (2) the e-Grants help desk at 1–888–336–8930. If the system is down and therefore the application deadline is extended, an e-mail will be sent to all registered users who have initiated an e-Application. Extensions referred to in this section apply only to the unavailability of the Department's e-Application system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the e-Application system because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to the Department's e-Application system; and
- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevent you from using the Internet to submit your application. If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Irene Harwarth, U.S. Department of Education, Room 3W227, 400 Maryland Avenue, SW., Washington, DC 20202. Fax: (202) 260–8969.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. *Submission of Paper Applications by Mail.*

If you qualify for any exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the applicable following address:

By mail through the U.S. Postal Service: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.364A) 400 Maryland Avenue, SW., Washington, DC 20202–4260; or

By mail through a commercial carrier: U.S. Department of Education, Application Control Center—Stop 4260, Attention: (CFDA Number 84.364A) 7100 Old Landover Road, Landover, MD 20785–1506.

Regardless of which address you use, you must show proof of mailing consisting of one of the following:

1. A legibly dated U.S. Postal Service postmark,
2. A legible mail receipt with the date of mailing stamped by the U.S. Postal Service,
3. A dated shipping label, invoice, or receipt from a commercial carrier, or
4. Any other proof of mailing acceptable to the Secretary of the U.S. Secretary of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

1. A private metered postmark, or
2. A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. *Submission of Paper Applications by Hand Delivery.* If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention 84.364A, 550 12th Street, SW., Room 7041 Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8 a.m. and 4:30 p.m., Washington, DC time, except Saturdays, Sundays and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department:

1. You must indicate on the envelope and—if not provided by the Department—in Item 4 of the ED424 the CFDA number—and suffix letter, if any—of the competition under which you are submitting your application.

2. The Application Control Center will mail a Grant Application Receipt Acknowledgment to you. If you do not receive the notification of application receipt within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* We use the following selection criteria to evaluate applications for new grants under this competition. The maximum score for all of these criteria is 100 points. The maximum score for each criterion is indicated in parentheses.

We evaluate an application by determining how well the proposed project meets the following criteria:

(a) *Meeting the purpose of the statute (10 points).* How well the proposed project addresses the intended outcome of the statute to improve student reading skills and academic achievement by providing students with increased access to up-to-date school library materials; a well-equipped, technologically advanced school library media center; and well-trained, professionally certified school library media specialists.

(b) *Need for school library resources (10 points).* How well the applicant demonstrates the need for school library media improvement, based on the age and condition of school library media resources, including: Book collections; access of school library media centers to advanced technology; and the availability of well-trained, professionally certified school library media specialists, in schools served by the applicant.

(c) *Use of funds (50 points).* How well the applicant will use the funds made available through the grant to carry out one or more of the following activities that meet its demonstrated needs:

(1) Acquiring up-to-date school library media resources, including books.

(2) Acquiring and using advanced technology, incorporated into the curricula of the school, to develop and enhance the information literacy, information retrieval, and critical thinking skills of students.

(3) Facilitating Internet links and other resource-sharing networks among schools and school library media centers, and public and academic libraries, where possible.

(4) Providing professional development for school library media specialists, that improves literacy in grades K–3 as well as professional development for school library media specialists as described in section 1222(d)(2) of the ESEA (as described in the clarification of eligible local activities as published in the notice of final clarification of eligible local activities published April 5, 2004, in the **Federal Register**, 69 FR 17894) and providing activities that foster increased collaboration between school library media specialists, teachers, and administrators.

(5) Providing students with access to school libraries during non-school hours, including the hours before and after school, during weekends, and during summer vacation periods.

(d) *Use of scientifically based research (10 points).* How well the applicant will use programs and materials that are grounded in scientifically based research, as defined in section 9101(37) of the ESEA, in carrying out one or more of the activities described under criterion (c).

(e) *Broad-based involvement and coordination (10 points).* How well the applicant will extensively involve school library media specialists, teachers, administrators, and parents in the proposed project activities and effectively coordinate the funds and activities provided under this program with other literacy, library, technology, and professional development funds and activities.

(f) *Evaluation of quality and impact (10 points).* How well the applicant will collect and analyze data on the quality and impact of the proposed project activities, including the extent to which the availability of, the access to, and the use of up-to-date school library media resources in the elementary schools and secondary schools served by the applicant were increased; and the impact on improving the reading skills of students.

2. *Review and Selection Process:* An additional factor we consider in selecting an application for an award is the equitable distribution of grants across geographic regions and among LEAs serving urban and rural areas.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may also notify you informally.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other

requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary.

4. *Performance Measures:* In response to the Government Performance and Results Act (GPRA), the Department developed two measures for evaluating the overall effectiveness of the Improving Literacy Through School Libraries program. These measures gauge improvement in student achievement and resources in the schools and districts served by the Improving Literacy Through School Libraries program by assessing increases in: (1) The percentage of participating schools and districts that exceed State Adequate Yearly Progress targets for reading achievement for all students; and (2) the school library media collections at participating schools, compared to schools not participating in the program.

The Department will collect data for these measures from grantees' annual performance reports and other existing data sources.

VII. Agency Contact

For Further Information Contact: Irene Harwarth, U.S. Department of Education, 400 Maryland Avenue, SW., room 3W227, Washington, DC 20202–6200. Telephone: (202) 401–3751 or by e-mail: *Irene.Harwarth@ed.gov.*

If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the program contact person listed in this section.

VIII. Other Information

Electronic Access to This Document: You may view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *www.ed.gov/news/fedregister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *www.gpoaccess.gov/nara/index.html.*

Dated: January 25, 2005.

Raymond Simon,

Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 05–1652 Filed 1–27–05; 8:45 am]

BILLING CODE 4000–01–U

DEPARTMENT OF EDUCATION

Office of Innovation and Improvement Overview Information, Charter Schools Program (CSP); Notice Inviting Applications For New Awards For Fiscal Year (FY) 2005

Catalog of Federal Domestic Assistance (CFDA) Number: 84.282A, 84.282B, and 84.282C.

DATES: *Applications Available:* January 28, 2005.

Deadline for Transmittal of Applications: March 14, 2005.

Deadline for Intergovernmental Review: May 13, 2005.

Eligible Applicants:

(a) State educational agencies (SEAs) in States with a State statute specifically authorizing the establishment of charter schools may apply for funding.

(b) Non-SEA eligible applicants may apply for funding directly from the U.S. Department of Education (Department) if the SEA in the State elects not to participate in the CSP or does not have an application approved under the program.

Additional information concerning eligibility requirements is in Section III, 1. in this notice.

Estimated Available Funds: $91,000,000.

Estimated Range of Awards: SEAs: $500,000–$20,000,000 per year. Other eligible applicants: $10,000–$150,000 per year.

Estimated Average Size of Awards: SEAs: $4,000,000 per year. Other eligible applicants: $130,000 per year.

Estimated Number of Awards: SEAs: 18–23. Other eligible applicants: 25–50.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 36 months.

Note: Planning and implementation grants or subgrants awarded by the Secretary or an SEA to non-SEA eligible applicants will be awarded for a period of up to 36 months, no more than 18 months of which may be used for planning and program design and no more than two years of which may be used for the initial implementation of a charter school. Dissemination grants and subgrants are awarded for a period of up to two years.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of the CSP is to increase national understanding of the charter school model and to expand the number of high-quality charter schools available to students across the Nation by providing financial assistance for the planning, program design, and initial implementation of charter schools, and evaluating the effects of charter schools, including the effects on students, student academic achievement, staff, and parents.

The Department will hold three (3) separate competitions under this program. All SEA applicants must apply for grant funds under CFDA No. 84.282A. Non-SEA eligible applicants that propose to use grant funds for planning, program design, and implementation must apply under CFDA No. 84.282B. Non-SEA eligible applicants that are requesting funds for dissemination activities must submit their applications under CFDA No. 84.282C.

Priorities: In accordance with 34 CFR 75.105(b)(2)(iv), these priorities are from section 5202(e) of the Elementary and Secondary Education Act of 1965, as amended (ESEA), 20 U.S.C. 7221a(e).

Competitive Preference Priorities: For FY 2005 these priorities are competitive preference priorities. Under 34 CFR 75.105(c)(2)(i) we award up to an additional 40 points to an applicant, depending on how well the application meets these priorities.

In awarding grants to SEAs under CFDA No. 84.282A, the Secretary gives priority to States to the extent that the State meets the statutory criterion described in paragraph (a) of this section, and one or more of the statutory criteria described in paragraphs (b) through (d) of this section.

An SEA that meets priority (a) but does not meet one or more of the other priorities will not receive any priority points.

An SEA that does not meet priority (a) but meets one or more of the other priorities will not receive any priority points.

In order to receive preference, an applicant must identify the priorities that it believes it meets and provide documentation supporting its claims.

These priorities are:

(a) *Periodic Review and Evaluation* (10 points). The State provides for periodic review and evaluation by the authorized public chartering agency of each charter school at least once every 5 years, unless required more frequently by State law, to determine whether the charter school is meeting the terms of the school's charter, and is meeting or exceeding the academic achievement requirements and goals for charter schools as provided under State law or the school's charter.

(b) *Number of High-Quality Charter Schools* (10 points). The State has demonstrated progress in increasing the number of high-quality charter schools that are held accountable in the terms of the schools' charters for meeting clear and measurable objectives for the educational progress of the students attending the schools, in the period prior to the period for which an SEA applies for a grant under this competition.

(c) *One Authorized Public Chartering Agency Other than a Local Educational Agency (LEA), or an Appeals Process* (10 points). The State—

(1) Provides for one authorized public chartering agency that is not an LEA, such as a State chartering board, for each individual or entity seeking to operate a charter school pursuant to State law; or

(2) In the case of a State in which LEAs are the only authorized public chartering agencies, allows for an appeals process for the denial of an application for a charter school.

(d) *High Degree of Autonomy* (10 points). The State ensures that each charter school has a high degree of autonomy over the charter school's budgets and expenditures.

Note: The Secretary encourages applicants to provide citations and examples from their State charter law in responding to each of the competitive preference priorities.

Invitational Priority: Under these competitions we are particularly interested in applications that address the following priority. For FY 2005 this priority is an invitational priority. Under 34 CFR 75.105(c)(1), we do not give an applicant that meets this invitational priority a competitive or absolute preference over other applications.

The priority is:

The applicant proposes to plan, design, and implement one or more high-quality charter schools in geographic areas, including urban and rural areas, in which a large proportion or number of public schools has been identified for improvement, corrective action, or restructuring under Title I, part A of the ESEA.

Program Authority: 20 U.S.C. 7221–7221j.

Applicable Regulations: The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75, 76, 77, 79, 80, 81, 82, 84, 85, 86, 97, 98, and 99.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $91,000,000.

Estimated Range of Awards: SEAs: $500,000–$20,000,000 per year. Other eligible applicants: $10,000–$150,000 per year.

Estimated Average Size of Awards: SEAs: $4,000,000 per year. Other eligible applicants: $130,000 per year.

Estimated Number of Awards: SEAs: 18–23. Other eligible applicants: 25–50.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 36 months.

Note: Planning and implementation grants or subgrants awarded by the Secretary or an SEA to non-SEA eligible applicants will be awarded for a period of up to 36 months, no more than 18 months of which may be used for planning and program design and no more than two years of which may be used for the initial implementation of a charter school. Dissemination grants and subgrants are awarded for a period of up to two years.

III. Eligibility Information

1. *Eligible Applicants:* (a) SEAs in States with a State statute specifically authorizing the establishment of charter schools may apply for funding.

Note: The Secretary awards grants to SEAs to enable them to conduct charter school programs in their States. SEAs use their CSP funds to award subgrants to non-SEA eligible applicants for planning, program design, and initial implementation of a charter school and to support the dissemination of information about, including successful practices in, charter schools.

(b) Non-SEA eligible applicants may apply for funding directly from the Department if the SEA in the State elects not to participate in the CSP or does not have an application approved under the program.

Note: A non-SEA *eligible applicant* is defined in the authorizing statute as a developer that has applied to an authorized public chartering authority to operate a charter school and has provided to that authority adequate and timely notice, and a copy, of its CSP application, except that the Secretary or the SEA may waive these requirements in the case of a pre-charter planning grant. Non-SEA eligible applicants, like SEAs, must be in States that have statutes specifically authorizing charter schools. If an SEA's application is approved in this competition, the Department will return applications from non-SEA eligible applicants in that State to the applicants. In such a case, the non-SEA eligible applicant should contact the SEA for information related to the State's subgrant competition.

The following States currently have approved applications under this program: Alaska, California, Colorado, Georgia, Indiana, Iowa, Kansas, Maryland, Massachusetts, Michigan, Missouri, New Hampshire, New Mexico, Ohio, Pennsylvania, South Carolina, and Texas. In these States, only the SEA is eligible to receive an award under this competition. Non-SEA eligible applicants in States that are not listed must apply directly to the Department on or before the deadline for transmittal of applications in order to be considered for funding in this competition.

(c) *Dissemination Grants.* A charter school may apply to an SEA for funds to carry out dissemination activities, whether or not the charter school has applied for or received funds under the CSP for planning or implementation, if the charter school has been in operation for at least three consecutive years and has demonstrated overall success, including—

(1) Substantial progress in improving student academic achievement;

(2) High levels of parent satisfaction; and

(3) The management and leadership necessary to overcome initial start-up problems and establish a thriving, financially viable charter school.

2. *Cost Sharing or Matching:* These competitions do not involve cost sharing or matching.

3. *Other:* All applications must meet the definitions of *charter school, developer, eligible applicant,* and *authorized public chartering agency,* as defined in the authorizing statute. These definitions are in the application package.

IV. Application and Submission Information

1. *Address to Request Application Package:* Dean Kern, U.S. Department of Education, 400 Maryland Avenue, SW., room 4W227, FB6, Washington, DC 20202–5961. Telephone: (202) 260–1882 or by e-mail: *dean.kern@ed.gov.*

If you use a telecommunications device for the deaf (TDD), you may call the Federal Relay Service (FRS) at 1–800–877–8339.

Individuals with disabilities may obtain a copy of the application package in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) by contacting the program contact person listed in this section.

2. *Content and Form of Application Submission:* Requirements concerning

the content of an application, together with the forms you must submit, are in the application package for this competition.

Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. The Secretary strongly encourages applicants to limit Part III to the equivalent of no more than 50 pages, using the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).

The suggested page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, you must include all of the application narrative in Part III.

3. *Submission Dates and Times:*

Applications Available: January 28, 2005.

Deadline for Transmittal of Applications: March 14, 2005.

Applications for grants under this competition must be submitted electronically using the Electronic Grant Application System (e-Application) available through the Department's e-Grants system. For information (including dates and times) about how to submit your application electronically or by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to section IV.6. *Other Submission Requirements* in this notice.

We do not consider an application that does not comply with the deadline requirements.

Deadline for Intergovernmental Review: May 13, 2005.

4. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. *Funding Restrictions: Use of Funds for Dissemination Activities.* An SEA may reserve not more than 10 percent of the grant funds to support dissemination activities. A charter school may use those funds to assist other schools in adapting the charter school's program (or certain aspects of the charter school's program), or to disseminate information about the charter school through such activities as—

(a) Assisting other individuals with the planning and start-up of one or more new public schools, including charter schools, that are independent of the assisting charter school and the assisting charter school's developers and that agree to be held to at least as high a level of accountability as the assisting charter school;

(b) Developing partnerships with other public schools, including charter schools, designed to improve student performance in each of the schools participating in the partnership;

(c) Developing curriculum materials, assessments, and other materials that promote increased student achievement and are based on successful practices within the assisting charter school; and

(d) Conducting evaluations and developing materials that document the successful practices of the assisting charter school and that are designed to improve student achievement.

We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Other Submission Requirements:* Applications for grants under this competition must be submitted electronically, unless you qualify for an exception to this requirement in accordance with the instructions in this section.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement *and* submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

a. *Electronic Submission of Applications.*

Applications for grants under the Charter Schools Program—CFDA Number 84.282A, 84.282B, and 84.282C—must be submitted electronically using e-Application available through the Department's e-Grants system, accessible through the e-Grants portal page at: *http://e-grants.ed.gov.*

While completing your electronic application, you will be entering data online that will be saved into a database. You may not e-mail an electronic copy of a grant application to us.

Please note the following:

- You must complete the electronic submission of your grant application by 4:30 p.m., Washington, DC time, on the application deadline date. The e-Application system will not accept an application for this program [competition] after 4:30 p.m., Washington, DC time, on the application deadline date. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the application process.
- The regular hours of operation of the e-Grants Web site are 6 a.m. Monday until 7 p.m. Wednesday; and 6 a.m. Thursday until midnight Saturday, Washington, DC time. Please note that the system is unavailable on Sundays, and between 7 p.m. on Wednesdays and 6 a.m. on Thursdays, Washington, DC time, for maintenance. Any modifications to these hours are posted on the e-Grants Web site.
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.
- You must submit all documents electronically, including the Application for Federal Education Assistance (ED 424), Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- Any narrative sections of your application should be attached as files in a .DOC (document), .RTF (rich text), or .PDF (Portable Document) format.
- Your electronic application must comply with any page limit requirements described in this notice.
- Prior to submitting your electronic application, you may wish to print a copy of it for your records.
- After you electronically submit your application, you will receive an automatic acknowledgement that will include a PR/Award number (an identifying number unique to your application).
- Within three working days after submitting your electronic application, fax a signed copy of the ED 424 to the Application Control Center after following these steps:

(1) Print ED 424 from e-Application.

(2) The applicant's Authorizing Representative must sign this form.

(3) Place the PR/Award number in the upper right hand corner of the hard-copy signature page of the ED 424.

(4) Fax the signed ED 424 to the Application Control Center at (202) 245–6272.

• We may request that you provide us original signatures on other forms at a later date.

Application Deadline Date Extension in Case of e-Application System Unavailability: If you are prevented from electronically submitting your application on the application deadline date because the e-Application system is unavailable, we will grant you an extension of one business day in order to transmit your application electronically, by mail, or by hand delivery. We will grant this extension if—

(1) You are a registered user of e-Application and you have initiated an electronic application for this competition; and

(2) (a) The e-Application system is unavailable for 60 minutes or more between the hours of 8:30 a.m. and 3:30 p.m., Washington, DC time, on the application deadline date; or

(b) The e-Application system is unavailable for any period of time between 3:30 p.m. and 4:30 p.m., Washington, DC time, on the application deadline date.

We must acknowledge and confirm these periods of unavailability before granting you an extension. To request this extension or to confirm our acknowledgement of any system unavailability, you may contact either (1) the person listed elsewhere in this notice under **FOR FURTHER INFORMATION CONTACT** (*see* VII. Agency Contact) or (2) the e-Grants help desk at 1–888–336–8930. If the system is down and therefore the application deadline is extended, an e-mail will be sent to all registered users who have initiated an e-Application. Extensions referred to in this section apply only to the unavailability of the Department's e-Application system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the e-Application system because—

• You do not have access to the Internet; or

• You do not have the capacity to upload large documents to the Department's e-Application system; and

• No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevent you from using the Internet to submit your application. If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Dean Kern, U.S. Department of Education, 400 Maryland Avenue, SW., room 4W227, Washington, DC 20202–5961. Fax: (202) 205–5630.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. *Submission of Paper Applications by Mail.*

If you qualify for any exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the applicable following address:

By mail through the U.S. Postal Service: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.282A, 84.282B, or 84.282C), 400 Maryland Avenue, SW., Washington, DC 20202–4260; or

By mail through a commercial carrier: U.S. Department of Education, Application Control Center—Stop 4260, Attention: (CFDA Number 84.282A, 84.282B, or 84.282C), 7100 Old Landover Road, Landover, MD 20785–1506.

Regardless of which address you use, you must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark,

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service,

(3) A dated shipping label, invoice, or receipt from a commercial carrier, or

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark, or

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. *Submission of Paper Applications by Hand Delivery.*

If you qualify for an exception to electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application, by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.282A, 84.282B, or 84.282C), 550 12th Street, SW., Room 7041, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8 a.m. and 4:30 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department:

(1) You must indicate on the envelope and—if not provided by the Department—in Item 4 of the ED 424 the CFDA number—and suffix letter, if any—of the competition under which you are submitting your application.

(2) The Application Control Center will mail a grant application receipt acknowledgment to you. If you do not receive the grant application receipt acknowledgment within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* All SEA and non-SEA applicants applying for CSP grant funds must address both the application requirements and the selection criteria. Each SEA and non-SEA applicant applying for CSP grant funds may choose to respond to the application requirements in the context of the applicant's responses to the selection criteria.

(a) *SEAs (CFDA No. 84.282A).*

(i) *Application Requirements (CFDA No. 84.282A).*

(A) Describe the objectives of the SEA's charter school grant program and describe how these objectives will be fulfilled, including steps taken by the

SEA to inform teachers, parents, and communities of the SEA's charter school grant program;

(B) Describe how the SEA will inform each charter school in the State about Federal funds that the charter school is eligible to receive and Federal programs in which the charter school may participate;

(C) Describe how the SEA will ensure that each charter school in the State receives the school's commensurate share of Federal education funds that are allocated by formula each year, including during the first year of operation of the school;

(D) Describe how the SEA will disseminate best or promising practices of charter schools to each LEA in the State;

(E) If an SEA elects to reserve part of its grant funds (no more than 10 percent) for the establishment of a revolving loan fund, describe how the revolving loan fund would operate;

(F) If an SEA desires the Secretary to consider waivers under the authority of the CSP, include a request and justification for any waiver of statutory or regulatory provisions that the SEA believes is necessary for the successful operation of charter schools in the State; and

(G) Describe how charter schools that are considered to be LEAs under State law, and LEAs in which charter schools are located, will comply with sections 613(a)(5) and 613(e)(1)(B) of the Individuals with Disabilities Education Act.

(ii) *Selection Criteria (CFDA No. 84.282A)*. SEAs that propose to use a portion of their grant funds for dissemination activities must address each selection criterion (A) through (E) individually and title each accordingly. SEAs that do not propose to use a portion of their grant funds for dissemination activities must address selection criteria (A) through (D) only, and need not address selection criterion (E).

The maximum possible score is 120 points for SEAs that do not propose to use grant funds to support dissemination activities and 150 points for SEAs that propose to use grant funds to support dissemination activities.

The maximum possible score for each criterion is indicated in parentheses following the criterion.

To ensure fairness, if an SEA is not proposing to use grant funds to support dissemination activities, the Secretary will not consider points awarded under criterion (E) in determining whether to approve an application for funding.

In evaluating an application from an SEA, the Secretary considers the following criteria:

(A) The contribution the charter schools grant program will make in assisting educationally disadvantaged and other students to achieve State academic content standards and State student academic achievement standards (30 points).

Note: The Secretary encourages applicants to provide a description of the objectives for the SEA's charter school grant program and how these objectives will be fulfilled, including steps taken by the SEA to inform teachers, parents, and communities of the SEA's charter school grant program and how the SEA will disseminate best or promising practices of charter schools to each LEA in the State.

(B) The degree of flexibility afforded by the SEA to charter schools under the State's charter school law (30 points).

Note: The Secretary encourages the applicant to include a description of how the State's law establishes an administrative relationship between the charter school and the authorized public chartering agency, and exempts charter schools from significant State or local rules that inhibit the flexible operation and management of public schools.

The Secretary also encourages the applicant to include a description of the degree of autonomy charter schools have achieved over such matters as the charter school's budget, expenditures, daily operation, and personnel in accordance with their State's law.

(C) The number of high-quality charter schools to be created in the State (30 points).

Note: The Secretary considers the SEA's estimate of the number of new charter schools to be authorized and opened in the State during the 36-month period of this grant.

Because research has identified the lack of adequate resources as a major impediment to the creation of high-quality charter schools, the Secretary encourages the applicant to describe how the SEA will inform each charter school in the State about Federal funds that the charter school is eligible to receive and about the Federal programs in which the charter school may participate.

The Secretary also considers how the SEA will ensure that each charter school in the State receives the school's commensurate share of Federal education funds that are allocated by formula each year, including during the first year of operation of the school and during a year in which the school's enrollment expands significantly.

(D) The quality of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks (30 points).

Note: In addition to describing the proposed objectives of the SEA charter school grant program and how these objectives will be fulfilled, the Secretary encourages applicants to provide descriptions of the steps that the SEA will take to award subgrant funds to eligible applicants desiring to receive these funds, including descriptions of the peer review process to review applications for assistance, the timelines for awarding such funds, and how the SEA will assess the quality of the applications.

(E) In the case of SEAs that propose to use grant funds to support dissemination activities under section 5204(f)(6) of the ESEA, the quality of the dissemination activities (15 points) and the likelihood that those activities will improve student achievement (15 points).

Note: The Secretary encourages applicants to provide a description of the steps that the SEA will take to award these funds to eligible applicants, including descriptions of the peer review process to review applications for dissemination, the timelines for awarding such funds, and how the SEA will assess the quality of the applications.

(b) *Non-SEA Applicants (CFDA No. 84.282B and 84.282C)*. The application requirements for all non-SEA applicants are listed in paragraph (i) in this section.

The selection criteria for non-SEA applicants for *Planning, Program Design, and Implementation Grants (CFDA No. 82.282B)* are listed in paragraph (ii) in this section.

The selection criteria for non-SEA applicants for *Dissemination Grants (CFDA No. 84.282C)* are listed in paragraph (iii) in this section.

(i) *Application Requirements (CFDA Nos. 84.282B and 84.282C)*. (A) Describe the educational program to be implemented by the proposed charter school, including how the program will enable all students to meet challenging State student academic achievement standards, the grade levels or ages of students to be served, and the curriculum and instructional practices to be used;

(B) Describe how the charter school will be managed;

(C) Describe the objectives of the charter school and the methods by which the charter school will determine its progress toward achieving those objectives;

(D) Describe the administrative relationship between the charter school and the authorized public chartering agency;

(E) Describe how parents and other members of the community will be

involved in the planning, program design, and implementation of the charter school;

(F) Describe how the authorized public chartering agency will provide for continued operation of the charter school once the Federal grant has expired, if that agency determines that the charter school has met its objectives;

(G) If the charter school desires the Secretary to consider waivers under the authority of the CSP, include a request and justification for waivers of any Federal statutory or regulatory provisions that the applicant believes are necessary for the successful operation of the charter school and a description of any State or local rules, generally applicable to public schools, that will be waived for, or otherwise not apply to, the school;

(H) Describe how the grant funds will be used, including how these funds will be used in conjunction with other Federal programs administered by the Secretary;

(I) Describe how students in the community will be informed about the charter school and be given an equal opportunity to attend the charter school;

(J) Describe how a charter school that is considered an LEA under State law, or an LEA in which a charter school is located, will comply with sections 613(a)(5) and 613(e)(1)(B) of the Individuals with Disabilities Education Act; and

(K) If the eligible applicant desires to use grant funds for dissemination activities under section 5202(c)(2)(C), describe those activities and how those activities will involve charter schools and other public schools, LEAs, developers, and potential developers.

(ii) *Selection Criteria (CFDA No. 84.282B).* Non-SEA Planning, Program Design, and Initial Implementation Grant applicants must address each selection criterion (A) through (I) individually and title each accordingly.

The maximum possible score for all of the criteria in this section is 145 points.

The maximum possible score for each criterion is indicated in parentheses following the criterion.

In evaluating an application from a non-SEA eligible applicant for Planning, Program Design, and Implementation, the Secretary considers the following criteria:

(A) The quality of the proposed curriculum and instructional practices (25 points).

(B) The degree of flexibility afforded by the SEA and, if applicable, the LEA to the charter school (10 points).

(C) The extent of community support for the application (10 points).

(D) The ambitiousness of the objectives for the charter school (15 points).

(E) The quality of the strategy for assessing achievement of those objectives (10 points).

(F) The likelihood that the charter school will meet those objectives and improve educational results for students during and after the period of Federal financial assistance (20 points).

(G) The extent to which the proposed project encourages parental involvement (20 points).

(H) The qualifications, including relevant training and experience, of the project director; and the extent to which the applicant encourages applications for employment from persons who are members of groups that traditionally have been underrepresented based on race, color, national origin, gender, age, or disability (10 points).

(I) The contribution the charter school will make in assisting educationally disadvantaged and other students to achieve to State academic content standards and State student academic achievement standards (25 points).

(iii) *Selection Criteria (CFDA No. 84.282C).* Non-SEA applicants for Dissemination Grants must address each selection criterion (A) through (E) individually and title each accordingly.

The maximum possible score for all of the criteria in this section is 125 points.

The maximum possible score for each criterion is indicated in parentheses following the criterion.

In evaluating an application from a non-SEA eligible applicant for a dissemination grant, the Secretary considers the following criteria:

(A) The quality of the proposed dissemination activities and the likelihood that those activities will improve student achievement (30 points).

(B) The extent to which the school has demonstrated overall success, including—

(1) Substantial progress in improving student achievement (15 points);

(2) High levels of parent satisfaction (15 points); and

(3) The management and leadership necessary to overcome initial start-up problems and establish a thriving, financially viable charter school (15 points).

(C) The extent to which the results of the proposed project will be disseminated in a manner that will enable others to use the information or strategies (20 points).

(D) The qualifications, including relevant training and experience, of the project director and the extent to which the applicant encourages applications for employment from persons who are members of groups that traditionally have been underrepresented based on race, color, national origin, gender, age, or disability (10 points).

(E) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks (20 points).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we will notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may also notify you informally.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as specified by the Secretary in 34 CFR 75.118.

4. *Performance Measures:* Under the Government Performance and Results Act (GPRA), one measure has been developed for evaluating the overall effectiveness of the CSP: To support the creation of a large number of high-quality charter schools. The objective of this goal is to encourage the development of a large number of high-quality charter schools that are free from State or local rules that inhibit flexible operation, are held accountable for enabling students to reach challenging State performance standards, and are open to all students. The Secretary has set an overall performance target that calls for an increase in both the number of States with charter school legislation and the number of charter schools in operation around the Nation.

All grantees will be expected to submit an annual performance report

documenting their contribution in assisting the Department in meeting this performance measure by creating or supporting the creation of one or more high-quality charter schools that are free from State or local rules that inhibit flexible operation, are held accountable for enabling students to reach challenging state performance standards, and are open to all students.

VII. Agency Contact

For Further Information Contact: Dean Kern, U.S. Department of Education, 400 Maryland Avenue, SW., room 4W227, FB6, Washington, DC 20202–5961. Telephone: (202) 260–1882 or by e-mail: *dean.kern@ed.gov.*

If you use a telecommunications device for the deaf (TDD), you may call the Federal Relay Service (FRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the program contact person listed in this section.

VIII. Other Information

Electronic Access to This Document: You may view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Dated: January 25, 2005.

Nina Shokraii Rees,

Assistant Deputy Secretary for Innovation and Improvement.

[FR Doc. 05–1639 Filed 1–27–05; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Office of Innovation and Improvement; Overview Information; Excellence in Economic Education Program; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2005

Catalog of Federal Domestic Assistance (CFDA) Number: 84.215B.

DATES: *Applications Available:* January 31, 2005.

Deadline for Transmittal of Applications: March 23, 2005.

Deadline for Intergovernmental Review: May 24, 2005.

Eligible Applicants: Any national nonprofit educational organization that has as its primary purpose the improvement of the quality of student understanding of personal finance and economics through effective teaching of economics in grades kindergarten through grade 12 in the Nation's classrooms.

Applicants are required to submit evidence of their organization's eligibility.

Estimated Available Funds: $1,478,000 for budget period one, and $1,500,000 for budget periods two through five.

Number of Awards: 1.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

Budget Period: 12 months.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: This program promotes economic and financial literacy among all students in kindergarten through grade 12 through the award of one grant to a national nonprofit educational organization that has as its primary purpose the improvement of the quality of student understanding of personal finance and economics.

Priorities: This competition includes two absolute priorities and two invitational priorities that are explained in the following paragraphs.

In accordance with 34 CFR 75.105(b)(2)(iv), these priorities are from sections 5533(b), 5534(b), and 5535(b) of the Elementary and Secondary Education Act of 1965, as amended (ESEA) (20 U.S.C. 7267b–7267e).

Absolute Priorities: For FY 2005 these priorities are absolute priorities. Under 34 CFR 75.105(c)(3) we consider only applications that meet both of these priorities.

These priorities are:

Absolute Priority 1—Direct Activities

A project must indicate how it would use 25 percent of the funds available each year to do all of the following activities:

(a) Strengthen and expand the grantee's relationships with State and local personal finance, entrepreneurial, and economic education organizations.

(b) Support and promote training of teachers who teach a grade from kindergarten through grade 12 regarding economics, including the dissemination of information on effective practices and research findings regarding the teaching of economics.

(c) Support research on effective teaching practices and the development of assessment instruments to document student understanding of personal finance and economics.

(d) Develop and disseminate appropriate materials to foster economic literacy.

Absolute Priority 2—Subgrant Activities

A project must indicate how it would use 75 percent of the funds available each year to award subgrants both to (a) State educational agencies (SEAs) or local educational agencies (LEAs), and (b) State or local economic, personal finance, or entrepreneurial education organizations. (Definitions of SEAs and LEAs are found in section 9101(26) and (41) of the ESEA, as amended by NCLB (20 U.S.C. 7801(26) and (41)).

(a) *Allowable Subgrantee Activities.* Applications must indicate that these subgrants are to be used to pay for the Federal share of the cost of enabling the subgrantees to work in partnership with *one or more* eligible partners as described elsewhere in this notice, for *one or more* of the following purposes:

(1) Collaboratively establishing and conducting teacher training programs that use effective and innovative approaches to the teaching of economics, personal finance, and entrepreneurship. The teacher training programs must—(i) train teachers who teach a grade from kindergarten through grade 12; and (ii) encourage teachers from disciplines other than economics and financial literacy to participate in such teacher training programs, if the training will promote the economic and financial literacy of those teachers' students.

(2) Providing resources to school districts that desire to incorporate economics and personal finance into the curricula of the schools in those districts.

(3) Conducting evaluations of the impact of economic and financial literacy education on students.

(4) Conducting economic and financial literacy education research.

(5) Creating and conducting school-based student activities to promote consumer, economic, and personal finance education (such as saving, investing, and entrepreneurial education) and to encourage awareness and student academic achievement in economics.

(6) Encouraging replication of best practices to promote economic and financial literacy.

(b) *Eligible partners for subgrantees under Absolute Priority 2.* Applications must indicate that subgrants will be made to an eligible subgrantee to work in partnership with one or more of the following entities:

(1) A private-sector entity.

(2) An SEA.

(3) An LEA.

(4) An institution of higher education.

(5) An organization promoting economic development.

(6) An organization promoting educational excellence.

(7) An organization promoting personal finance or entrepreneurial education.

(c) *Subgrant application process under Absolute Priority 2.* (1) Applications must describe the subgrant process the grantee will conduct prior to awarding subgrants.

(2) Applications must provide that the grantee will invite the following types of individuals to review all applications for subgrants and to make recommendations to the grantee on the approval of the applications:

(A) Leaders in the fields of economics and education.

(B) Other individuals as the grantee determines to be necessary, especially members of the State and local business, banking, and finance communities.

In addition to the two absolute priorities, we are particularly interested in applications that address the following invitational priorities.

Invitational Priorities: For FY 2005 these priorities are invitational priorities. Under 34 CFR 75.105(c)(1) we do not give an application that meets one or both of these invitational priorities a competitive or absolute preference over other applications.

These priorities are:

Invitational Priority 1—Involvement of Business Community

The grantee and subgrantees are strongly encouraged to—

(a) Include interactions with the local business community to the fullest extent possible to reinforce the connection between economic and financial literacy and economic development; and

(b) Work with private businesses to obtain matching contributions for Federal funds and assist subgrantees in working toward self-sufficiency.

Invitational Priority 2—Scientifically Based Evaluation

The grantee and subgrantees are strongly encouraged to use scientifically based research as defined by the No Child Left Behind Act (20 U.S.C. 7801(37)) for the research and evaluation activities listed below that are required under the Absolute Priorities in this notice. Using scientifically based research for these activities will allow the grantee to provide the most trustworthy type of information necessary to meet the Performance Measures requirement for this program listed later in this notice. The activities are:

(a) For research on effective teaching practices and the development of assessment instruments to document student understanding of personal finance and economics;

(b) To conduct economic and financial literacy education research; and

(c) To conduct evaluations of the impact of economic and financial literacy education on students.

Program Authority: 20 U.S.C. 7267.

Applicable Regulations: The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 84, 85, 86, 97, 98, and 99.

II. Award Information

Type of Award: Discretionary grant.

Estimated Available Funds: $1,478,000 for budget period one, and $1,500,000 for budget periods two through five.

Number of Awards: 1.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

Budget Period: 12 months.

III. Eligibility Information

1. *Eligible Applicants:* Any national nonprofit educational organization that has as its primary purpose the improvement of the quality of student understanding of personal finance and economics through effective teaching of economics in grades Kindergarten through grade 12 in the Nation's classrooms.

Applicants are required to submit evidence of their organization's eligibility.

2. *Cost Sharing or Matching: Subgrant Activities.* The recipients of each subgrant are required to match the Federal grant funds with an equal amount of non-Federal funding. The Federal share of each subgrant will be fifty (50) percent of the cost of the funded activities. The recipient of the subgrant must pay the other fifty percent in cash or in kind. In kind payment, including plant, equipment, or services, must be fairly evaluated. (20 U.S.C. 7267e(a) and (b)).

Supplement not supplant. Funds provided through this grant must be used to supplement, and not supplant, other Federal, State, and local funds expended to support activities that fulfill the purpose of this program. (20 U.S.C. 7267f).

IV. Application and Submission Information

1. *Address to Request Application Package:* Carolyn J. Warren, U.S. Department of Education, 400 Maryland Avenue, SW., room 4W209, Washington, DC 20202–5900. Telephone: (202) 205–5443 or by e-mail: *carolyn.warren@ed.gov*.

If you use a telecommunications device for the deaf (TDD), you may call the Federal Relay Service (FRS) at 1–800–877–8339.

Individuals with disabilities may obtain a copy of the application package in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) by contacting the program contact person listed in this section.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition.

Page Limit: The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. *All of the information addressing the selection criteria and the priorities must be included in the narrative section of the application.* It is strongly suggested that you limit the narrative of your application to the equivalent of no more than 25 pages, using the following standards:

- A ''page'' is 8.5″ × 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).

The suggested page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the one-page abstract, the resumes, the bibliography, the evidence of eligibility, or the letters of support.

3. *Submission Dates and Times: Applications Available:* January 31, 2005.

Deadline for Transmittal of Applications: March 23, 2005.

Applications for grants under this competition must be submitted electronically using the Grants.gov Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically or by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to section IV.6. *Other Submission Requirements* in this notice.

We do not consider an application that does not comply with the deadline requirements.

Deadline for Intergovernmental Review: May 24, 2005.

4. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. *Funding Restrictions:* Twenty-five (25) percent of the grant funds must be used for *Direct Activities* as described in Absolute Priority 1. (20 U.S.C. 7267b(b)(1)).

Seventy-five (75) percent of the grant funds must be used for *Subgrant Activities* as described in Absolute Priority 2. (20 U.S.C. 7267b(b)(2)).

The grantee and each subgrantee may use not more than five (5) percent of their grant funds for administrative costs. (20 U.S.C. 7267d(a)).

We reference regulations outlining other funding restrictions in the *Applicable Regulations* section of this notice.

6. *Other Submission Requirements:* Applications for grants under this competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. *Electronic Submission of Applications.* Applications for grants under the Excellence in Economic Education Program—CFDA Number 84.215B must be submitted electronically using the Grants.gov Apply site. Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not e-mail an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement *and* submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

You may access the electronic grant application for Excellence in Economic Education Program at: *http://www.grants.gov*. You must search for the downloadable application package for this program by the CFDA number. Do not include the CFDA number's alpha suffix in your search.

Please note the following:

- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by Grants.gov are time and date stamped. Your application must be fully uploaded and submitted with a date/time received by the Grants.gov system no later than 4:30 p.m., Washington, DC time, on the application deadline date. We will not consider your application if it was received by the Grants.gov system later than 4:30 p.m. on the application deadline date. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was submitted after 4:30 p.m. on the application deadline date.
- The amount of time it can take to upload an application will vary depending on a variety of factors including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the application process through Grants.gov.
- You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this program [competition] to ensure that your application is submitted timely to the Grants.gov system.
- To use Grants.gov, you, as the applicant, must have a D–U–N–S Number and register in the Central Contractor Registry (CCR). You should allow a minimum of five business days to complete the CCR registration.
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.
- You must submit all documents electronically, including all information typically included on the Application for Federal Education Assistance (ED 424), Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications. Any narrative sections of your application should be attached as files in a .DOC (document), .RTF (rich text), or .PDF (Portable Document) format.
- Your electronic application must comply with any page limit requirements described in this notice.
- After you electronically submit your application, you will receive an automatic acknowledgement from Grants.gov that contains a Grants.gov tracking number. The Department will retrieve your application from Grants.gov and send you a second confirmation by e-mail that will include a PR/Award number (an ED-specified identifying number unique to your application).
- We may request that you provide us original signatures on forms at a later date.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the Grants.gov system because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to the Grants.gov system; *and*
- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevent you from using the Internet to submit your application. If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax

your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Carolyn J. Warren, U.S. Department of Education, 400 Maryland Avenue, SW., room 4W209, Washington, DC 20202–5900. FAX: (202) 205–5631.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. *Submission of Paper Applications by Mail.* If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier), your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the applicable following address:

By mail through the U.S. Postal Service: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.215B), 400 Maryland Avenue, SW., Washington, DC 20202–4260; or

By mail through a commercial carrier: U.S. Department of Education, Application Control Center—Stop 4260, Attention: (CFDA Number 84.215B), 7100 Old Landover Road, Landover, MD 20785–1506.

Regardless of which address you use, you must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark,

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service,

(3) A dated shipping label, invoice, or receipt from a commercial carrier, or

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark, or

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. *Submission of Paper Applications by Hand Delivery.* If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.215B), 550 12th Street, SW., Room 7041, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8 a.m. and 4:30 p.m., Washington, DC time, except Saturdays, Sundays and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department:

(1) You must indicate on the envelope and—if not provided by the Department—in Item 4 of the Application for Federal Education Assistance (ED 424) the CFDA number—and suffix letter, if any—of the competition under which you are submitting your application.

(2) The Application Control Center will mail a grant application receipt acknowledgment to you. If you do not receive the grant application receipt acknowledgment within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

Selection Criteria: The selection criteria for this competition are from EDGAR, 34 CFR 75.210, as follows:

1. *Quality of the Project Design—20 points.* In determining the quality of the design of the proposed project, the Secretary considers the extent to which the proposed project represents an exceptional approach to the priorities established for the competition.

2. *Quality of Project Services—30 points.* (a) In determining the quality of the services to be provided by the proposed project, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(b) In addition, the Secretary considers the following factors:

(i) The extent to which the training or professional development services to be provided by the proposed project are of sufficient quality, intensity, and duration to lead to improvements in practice among the recipients of those services.

(ii) The likelihood that the services to be provided by the proposed project will lead to improvements in the achievement of students as measured against rigorous academic standards.

(iii) The extent to which the services to be provided by the proposed project involve the collaboration of appropriate partners for maximizing the effectiveness of project services.

3. *Quality of the Management Plan—20 points.* In determining the quality of the management plan for the proposed project, the Secretary considers the adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

4. *Quality of Project Personnel—10 points.* (a) In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(b) In addition, the Secretary considers the following factors:

(i) The qualifications, including relevant training and experience, of the project director.

(ii) The qualifications, including relevant training and experience, of key project personnel.

5. *Quality of Project Evaluation—20 points.* In determining the quality of the evaluation, the Secretary considers the following factors:

(a) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible.

(b) The extent to which the evaluation will provide guidance about effective strategies suitable for replication or testing in other settings.

Note: The Department notes that the grantee can, as authorized by section 5533(b)(2)(C) of the ESEA, award subgrants to conduct evaluations and to collect the information needed for implementation of the performance measure discussed elsewhere in this notice.

Factors Applicants May Wish to Consider in Developing an Evaluation Plan. A strong evaluation plan should be included in the application narrative and should be used, as appropriate, to shape the development of the project

from the beginning of the grant period. The plan should include benchmarks to monitor progress toward specific project objectives and also outcome measures to assess the impact on teaching and learning or other important outcomes for project participants. More specifically, the plan should, where possible, identify the individual and/or organization that has agreed to serve as evaluator for the project and describe the qualifications of that evaluator. The plan should describe the evaluation design, indicating:

(1) What types of data will be collected.

(2) When various types of data will be collected.

(3) What methods will be used.

(4) What instruments will be developed and when.

(5) How the data will be analyzed.

(6) When reports of results and outcomes will be available.

(7) How the applicant will use the information collected through the evaluation to monitor progress of the funded project and to provide accountability information both about success at the initial site and effective strategies for replication in other settings. Applicants are encouraged to devote an appropriate level of resources to project evaluation.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may also notify you informally.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements*: We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting*: At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as specified by the Secretary in 34 CFR 75.118.

4. *Performance Measures*: The percentage of students of teachers trained under the grant project that demonstrate an improved understanding of personal finance and economics as compared to similar students whose teachers have not had the training provided by this project. The grantee under this program will be expected to collect and report these data to the Department, and applicants are strongly encouraged to design their proposed project evaluations around this performance measure.

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Carolyn J. Warren, U.S. Department of Education, 400 Maryland Avenue, SW., room 4W209, Washington, DC 20202–5900. Telephone: (202) 205–5443 or by e-mail: *carolyn.warren@ed.gov*.

If you use a telecommunications device for the deaf (TDD), you may call the Federal Relay Service (FRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the program contact person listed in this section.

VIII. Other Information

Electronic Access to This Document: You may view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *www.ed.gov/news/fedregister*.

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *www.gpoaccess.gov/nara/index.html*.

Dated: January 25, 2005.

Nina Shokraii Rees,

Assistant Deputy Secretary for Innovation and Improvement.

[FR Doc. 05–1650 Filed 1–27–05; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Office of Special Education and Rehabilitative Services, Individuals With Disabilities Education Act, as Amended by the Individuals With Disabilities Education Improvement Act of 2004

ACTION: Notice of Public Meeting to seek comments and suggestions on regulatory issues under the Individuals with Disabilities Education Act (IDEA), as amended by the Individuals with Disabilities Education Improvement Act of 2004.

SUMMARY: The Secretary announces plans to hold the sixth of a series of public meetings to seek comments and suggestions from the public prior to developing and publishing proposed regulations to implement programs under the recently revised Individuals with Disabilities Education Act.

Date and Time of Public Meeting: Friday, February 18, 2005 from 3:30 p.m. to 5:30 p.m. and from 6:30 p.m. to 8:30 p.m.

ADDRESSES: University of Wyoming, Wyoming Union, 2nd Floor, Laramie, WY 82071.

FOR FURTHER INFORMATION CONTACT: Troy R. Justesen. Telephone: (202) 245–7468.

SUPPLEMENTARY INFORMATION:

Background

On December 3, 2004, the President signed into law Public Law 108–446, the Individuals with Disabilities Education Improvement Act of 2004, amending the Individuals with Disabilities Education Act (IDEA). Copies of the new law may be obtained at the following Web site: *http://edworkforce.house.gov/issues/108th/education/idea/conferencereport/confrept.htm.*

Enactment of the new law provides an opportunity to consider improvements in the regulations implementing the IDEA (including both formula and discretionary grant programs) that would strengthen the Federal effort to ensure every child with a disability has available a free appropriate public education that—(1) is of high quality, and (2) is designed to achieve the high standards reflected in the No Child Left Behind Act and regulations.

The Office of Special Education and Rehabilitative Services will be holding a series of public meetings during the first few months of calendar year 2005 to seek input and suggestions for developing regulations, as needed, based on the Individuals with Disabilities Education Improvement Act of 2004.

This notice provides specific information about the sixth of these meetings, scheduled for Laramie, WY (see Date and Time of Public Meeting earlier in this Notice). The final meeting will be conducted in the following location:

- Washington, DC.

In a subsequent **Federal Register** notice, we will notify you of the specific date and location of this meeting, as well as other relevant information.

Individuals who need accommodations for a disability in order to attend the meeting (*i.e.,* interpreting services, assistive listening devices, and material in alternative format) should notify the contact person listed under **FOR FURTHER INFORMATION CONTACT**. The meeting location is accessible to individuals with disabilities.

Dated: January 24, 2005.

John H. Hager,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 05–1648 Filed 1–27–05; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Office of Special Education and Rehabilitative Services, Individuals With Disabilities Education Act, as Amended by the Individuals With Disabilities Education Improvement Act of 2004

ACTION: Notice of Public Meeting to seek comments and suggestions on regulatory issues under the Individuals with Disabilities Education Act (IDEA), as amended by the Individuals with Disabilities Education Improvement Act of 2004; Correction.

SUMMARY: On January 21, 2005, we published in the **Federal Register** (70 FR 3194) a notice announcing plans to hold the third of a series of public meetings to seek comments and suggestions from the public prior to developing and publishing proposed regulations to implement programs under the recently revised IDEA.

On page 3195, first column, under Date and Time of Public Meeting, the times listed for the Boston, MA public meeting are corrected to read ''10 a.m. to 2 p.m. and 6:30 p.m. to 8:30 p.m.''

FOR FURTHER INFORMATION CONTACT: Troy R. Justesen, U.S. Department of Education, 400 Maryland Avenue, SW., room 5138, Potomac Center Plaza, Washington, DC 20202–2700. Telephone: (202) 245–7468 or by e-mail: *troy.justesen@ed.gov.*

If you use a telecommunications device for the deaf (TDD), you may call the Federal Relay Service (FRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the program contact person listed in this section.

Electronic Access to This Document: You may view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Dated: January 25, 2005.

John H. Hager,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 05–1649 Filed 1–27–05; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Privacy Act of 1974; System of Records

AGENCY: Federal Student Aid, U.S. Department of Education.

ACTION: Notice of an altered system of records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended (Privacy Act), 5 United States Code (U.S.C.) 552a, the Department of Education (Department) publishes this notice of an altered system of records entitled ''Student Aid Internet Gateway (SAIG), Participation Management System'' for the purpose of providing telecommunications support for the delivery and administration of Federal student aid programs authorized under Title IV of the Higher Education Act of 1965, as amended (HEA). This system stores personally identifiable data from individuals who elect to participate in the transfer of electronic data via the SAIG, or enroll in the Financial Aid Administration (FAA) Online Access system for access to either the Central Processing System (CPS) Online or eCampus Online. (The eCampus-Based Web site allows users to submit FISAP information, access Campus-Based account data, and view reports.) The Department is revising this system of records as a result of a system application change and other technical changes to the Title IV Wide Area Network (Title IV WAN 18–11–10) system notice. This altered system of records notice also changes the name of the system from Title IV WAN to Student Aid Internet Gateway (SAIG), Participation Management System; adds two new routine use disclosures; deletes number two under the ''Purposes'' statement, which refers to billing for customer service calls and ISIR data requests; and revises the safeguards and record retention and disposal sections to reflect the current safeguards and record retentions for the paper and electronic (Web-based) records and information.

DATES: The Department seeks comments on the altered system of records described in this notice, in accordance with the requirements of the Privacy Act. We must receive your comments on the proposed routine uses for this system of records on or before February 28, 2005.

The Department has filed a report describing the altered system of records with the Chair of the Senate Committee on Governmental Affairs, the Chair of the House Committee on Government Reform, and the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), on January 24, 2005. This altered system of records will become effective at the later date of: (1) The expiration of the 40-day period for OMB review on March 7, 2005 or (2) February 28, 2005, unless the system of records needs to be changed as a result of public comment or OMB review.

ADDRESSES: Address all comments on the proposed routine uses of this system, and requests for information about this system, to Gregory James, Application Processing, Students Channel, Federal Student Aid, U.S. Department of Education, Union Center Plaza, 830 First Street, NE., Room 31C4, Washington, DC 20202.

If you prefer to send your comments through the Internet, use the following address: *Comments@ed.gov.* You must include the term ''SAIG comments'' in the subject line of your electronic message.

During and after the comment period, you may inspect all comments about this notice at Federal Student Aid (FSA), U.S. Department of Education, Union Center Plaza, 830 First Street, NE., Room 31C4, Washington, DC 20202

between the hours of 8:30 a.m. and 4 p.m., eastern time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record

On request, we will supply an appropriate aid, such as a reader or print magnifier, to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice.

If you want to schedule an appointment for this type of aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Gregory James, Telephone: (202) 377–3386. If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Introduction

The Privacy Act (5 U.S.C. 552a(e)(4)) requires the Department to publish in the **Federal Register** a notice of altered systems of records managed by the Department. The Department's regulations implementing the Privacy Act are contained in the Code of Federal Regulations (CFR) in 34 CFR part 5b.

The Privacy Act applies to a record about an individual that is maintained in a system of records from which information is retrieved by a unique identifier associated with each individual, such as a name or social security number. The information about each individual is called a ''record,'' and the system, whether manual or computer-driven, is called a ''system of records.'' The Privacy Act requires each agency to publish a systems of records notice in the **Federal Register** and to prepare reports to OMB and Congressional Committees whenever the agency publishes a new or ''altered'' system of records.

Electronic Access to This Document

You may view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister*.

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Dated: January 24, 2005.

Theresa S. Shaw,

Chief Operating Officer, Federal Student Aid.

For the reasons discussed in the preamble, the Chief Operating Officer, Federal Student Aid, U.S. Department of Education, publishes a notice of an altered system of records to read as follows:

18–11–10

SYSTEM NAME:

Student Aid Internet Gateway (SAIG), Participant Management System.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Pearson Government Solutions, 2450 Oakdale Boulavard, Coralville, Iowa 52241.

Virtual Data Center (VDC), c/o Computer Science Corporation, 71 Deerfield Lane, Meriden, CT 06450–7151.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system contains records on those individuals who elect to participate in the electronic exchange of data with the Department of Education via the SAIG, or enroll in the Financial Aid Administration system for access to either the Central Processing System (CPS) Online or eCampus Online. Those eligible to participate include: financial aid administrators, authorized employees or representatives of postsecondary institutions, authorized employees or representatives of third-party servicers, authorized employees or representatives of lenders, authorized employees or representatives of guaranty agencies, and authorized employees or representatives of state scholarship programs.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system consists of demographic contact information that individuals affiliated with an authorized entity provide to request electronic access to Title IV Student Aid Systems.

Demographic information includes the individual's name, address, and authentication information (mother's maiden name, Social Security Number, and date of birth).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

20 U.S.C. 1082, 1085, 1094, 1099C, Executive Order 9937.

PURPOSE(S):

The SAIG, Participant Management System performs the following: processes stored data from the SAIG Enrollment Forms (Web and paper versions); maintains the SAIG Enrollment Web site (named FSAWebEnrollment.ed.gov); manages the assignment of individual ID numbers (TG Numbers); and authenticate user's of the CPS Online and e-Campus Online systems.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The Department may disclose information contained in a record in this system of records under the routine uses listed in this system of records without the consent of the individual if the disclosure is compatible with the purposes for which the record was collected.

These disclosures may be made on a case-by-case basis or, if the Department has complied with the computer matching requirements of the Privacy Act, under a computer matching agreement.

(1) *Program disclosures.* The Department may disclose records for the following program purposes:

(a) *Federal Direct Loan Program*—For participation in the Direct Loan Program including the submission of origination records and the reporting of disbursement records that require the transmission of data over the SAIG.

(b) *Central Processing System (CPS)*—Student application data including corrections can be entered and obtained over the SAIG.

(c) *Federal Pell Grant*—Program origination and disbursement records must be reported electronically via the SAIG.

(d) *Fiscal Operations Report and Application to Participate in the Federal Campus-Based Programs (FISAP)*—Participating institutions are required to submit their annual Fiscal Operations and Application to Participate to the Department via the SAIG.

(e) *National Student Loan Data Service (NSLDS)*—Institutions must be provided access to NSLDS to perform online Enrollment Reporting (formerly Student Status Confirmation Reporting

(SSCR)) for updating student enrollment data, and overpayment updates. Additionally, institutions will be able to receive their cohort default rate (CDR) notification (which includes eligibility letters and loan record detail reports) via the SAIG.

(f) *Lender Reporting System (LaRS)*—Lender institutions or their servicers have the option to send financial reporting information to Federal Student Aid's Financial Management System via SAIG.

(2) *Freedom of Information Act (FOIA) advice disclosure.* The Department may disclose records to the Department of Justice (DOJ) and the Office of Management and Budget if the Department seeks advice regarding whether records maintained in the system of records are required to be released under the FOIA and the Privacy Act of 1974.

(3) *Disclosure to the DOJ.* The Department May disclose records to the DOJ to the extent necessary for obtaining DOJ advice on any matter relevant to an audit, inspection, or other inquiry related to the programs covered by this system.

(4) **Contract Disclosure**. If the Department contracts with an entity for the purposes of performing any function that requires disclosure of records in this system to employees of the contractor, the Department may disclose the records to those employees. Before entering into such a contract, the Department shall require the contractor to maintain Privacy Act safeguards as required under 5 U.S.C. 552a(m) with respect to the records in the system.

(5) *Litigation and Alternative Dispute Resolution (ADR) disclosures.*

(a) *Introduction.* In the event that one of the parties listed below is involved in litigation or ADR, or has an interest in litigation or ADR, the Department may disclose certain records to the parties described in paragraphs (b), (c), and (d) of this routine use under the conditions specified in those paragraphs:

(i) The Department of Education, or any component of the Department; or

(ii) Any Department employee in his or her official capacity; or

(iii) Any Department employee in his or her individual capacity if the Department of Justice (DOJ) has agreed to provide or arrange for representation for the employee;

(iv) Any Department employee in his or her individual capacity where the agency has agreed to represent the employee; or

(v) The United States where the Department determines that the litigation is likely to affect the Department or any of its components.

(b) *Disclosure to the Department of Justice (DOJ).* If the Department determines that disclosure of certain records to the DOJ, or attorneys engaged by DOJ, is relevant and necessary to litigation or ADR, and is compatible with the purpose for which the records were collected, the Department may disclose those records as a routine use to the DOJ.

(c) *Adjudicative disclosures.* If the Department determines that disclosure of certain records to an adjudicative body before which the Department is authorized to appear, an individual or entity designated by the Department or otherwise empowered to resolve or mediate disputes is relevant and necessary to the litigation or ADR, the Department may disclose those records as a routine use to the adjudicative body, individual, or entity.

(d) *Parties, counsels, representatives and witnesses.* If the Department determines that disclosure of certain records to a party, counsel, representative or witness in an administrative proceeding is relevant and necessary to the litigation, the Department may disclose those records as a routine use to the party, counsel, representative or witness.

(6) *Research disclosure.* The Department may disclose records to a researcher if an appropriate official of the Department determines that the individual or organization to which the disclosure would be made is qualified to carry out specific research related to functions or purposes of this system of records. The official may disclose records from this system of records to that researcher solely for the purpose of carrying out that research related to the functions or purposes of this system of records. The researcher shall be required to maintain Privacy Act safeguards with respect to the disclosed records.

(7) *Congressional Member disclosure.* The Department may disclose records to a member of Congress from the record of an individual in response to an inquiry from the member made at the written request of that individual. The Member's right to the information is no greater than the right of the individual who requested it.

(8) *Disclosure for use by law enforcement agencies.* The Department may disclose information to any Federal, State, local or other agencies responsible for enforcing, investigating, or prosecuting violations of administrative, civil, or criminal law or regulation if that information is relevant to any enforcement, regulatory, investigative or prosecutorial responsibility within the entity's jurisdiction.

(9) *Enforcement disclosure.* In the event that information in this system of records indicates, either on its face or in connection with other information, a violation or potential violation of any applicable statute, regulation, or order of a competent authority, the Department may disclose the relevant records to the appropriate agency, whether foreign, Federal, State, tribal, or local, charged with the responsibility of investigating or prosecuting that violation or charged with enforcing or implementing the statute, Executive Order, rule, regulation, or order issued pursuant thereto.

(10) *Employment, benefit, and contracting disclosure.* (a) *Decisions by the Department.* The Department may disclose a record to a Federal, State, or local agency maintaining civil, criminal, or other relevant enforcement or other pertinent records, or to another public authority or professional organization, if necessary to obtain information relevant to a decision concerning the hiring or retention of an employee or other personnel action, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit.

(b) *Decisions by Other Public Agencies and Professional Organizations.* The Department may disclose a record to a Federal, State, local, or foreign agency or other public authority or professional organization, in connection with the hiring or retention of an employee or other personnel action, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit, to the extent that the record is relevant and necessary to the receiving entity's decision on the matter.

(11) *Employee grievance, complaint or conduct disclosure.* The Department may disclose a record in this system of records to another agency of the Federal Government if the record is relevant to one of the following proceedings regarding a present or former employee of the Department: Complaint, grievance, discipline or competence determination proceedings. The disclosure may only be made during the course of the proceeding.

(12) *Labor organization disclosure.* The Department may disclose records from this system of records to an arbitrator to resolve disputes under a negotiated grievance procedure or to officials of labor organizations recognized under 5 U.S.C. chapter 71

when relevant and necessary to their duties of exclusive representation.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Disclosure pursuant to 5 U.S.C. 552a(b)(12): The Department may disclose to a consumer reporting agency information regarding a claim, which is determined to be valid and overdue as follows: (1) The name, address, and other information necessary to establish the identity of the individual responsible for the claim; and (2) the program under which the claim arose. The Department may disclose the information specified in this paragraph under 5 U.S.C. 552a(b)(12) and the procedures contained in subsection 31 U.S.C. 3711(e).

A consumer-reporting agency to which these disclosures may be made is defined at 31 U.S.C. 3701(a)(3).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on a computer database as well as in hard copy. All hard copy forms are loaded into an imaging system accessible through internal systems only. Paper is stored in file cabinets at the Pearson Government Solutions facility in Coralville, Iowa.

RETRIEVABILITY:

The records are retrieved by the names of the individual user and/or unique system User ID.

SAFEGUARDS:

All users of this system will have a unique user ID with a personal identifier.

This system does not use persistent cookies (data that a Web server causes to be placed on a user's hard drive) to implement personalization. It is the policy of the Department to prohibit the use of persistent cookies on Department Web sites except when: there is a compelling need; there are appropriate safeguards in place; the use is personally approved by the Secretary of Education; and there is clear and conspicuous notice to the public.

All physical access to the Department site, and the sites of Department contractors where this system of records is maintained, is controlled and monitored by security personnel who check each individual entering the building for his or her employee or visitor badge.

The computer system employed by the Department offers a high degree of resistance to tampering and circumvention. This security system limits data access to Department and contract staff on a ''need-to-know'' basis, and controls individual users'' ability to access and alter records within the system.

All users of this system of records are given a unique user ID with personal identifiers.

All interactions by individual users with the system are recorded.

RETENTION AND DISPOSAL:

SAIG, Participation Management enrollment forms will be retained by the manager of the SAIG Participation Management System (Pearson Government Solutions) for 6 years after the expiration of the contract.

SYSTEM MANAGER(S) AND ADDRESS:

Sue O'Flaherty, Deputy Director, Application Processing, U.S. Department of Education, Students Channel, Federal Student Aid, Union Center Plaza, 830 First Street NE., Room 32E2, Washington, DC 20202.

NOTIFICATION PROCEDURE:

If you wish to determine whether a record exists regarding you in the system of records, contact the system manager. Your request must meet the requirements of the Department's Privacy Act regulations at 34 CFR 5b.5, including proof of identity.

RECORD ACCESS PROCEDURES:

If you wish to gain access to a record regarding you in the system of records, contact the system manager. Your request must meet the requirements of the Department's Privacy Act regulations at 34 CFR 5b.5, including proof of identity.

CONTESTING RECORD PROCEDURES:

If you wish to contest the content of a record regarding you in the system of records, contact the system manager. Your request must meet the requirements of the Department's Privacy Act regulations at 34 CFR 5b.7.

RECORD SOURCE CATEGORIES:

Information in this system is obtained from the following entities: financial aid administrators, postsecondary institutions, third-party servicers, lenders, guaranty agencies, and state scholarship programs.

SYSTEM EXEMPTED FROM CERTAIN PROVISION OF THE PRIVACY ACT:

None.

[FR Doc. 05–1651 Filed 1–27–05; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EC01–66–000, et al.]

Nevada Power Company, et al.; Electric Rate and Corporate Filings

January 19, 2005.

The following filings have been made with the Commission. The filings are listed in ascending order within each docket classification.

1. Nevada Power Company, Reid Gardner Power LLC and Clark Power LLC; Nevada Power Company and Reliant Energy Sunrise LLC

[Docket Nos. EC01–66–000 and EC01–73–000]

Take notice that on September 25, 2003, Nevada Power Company (Nevada Power) filed a motion to terminate the proceedings in the above-referenced docket numbers.

Comment Date: 5 p.m. Eastern Time on February 9, 2005.

2. Liberty Electric Power, LLC

[Docket Nos. EC05–37–000 and ER01–2398–009]

Take notice that on January 13, 2005, Liberty Electric Power, LLC (Applicant) submitted an application pursuant to section 203 of the Federal Power Act for authorization for disposition of jurisdictional facilities relating to the transfer of membership interests in Liberty's indirect upstream owner, LEP Holdings, LLC (LEP Holdings) to several financial institutions and other financial investors or their special purpose affiliates (collectively, New Investors) and the transfer of a managing membership interest in LEP Holdings to Tyr Energy, Inc. (Tyr) or one of its affiliates or another entity which will meet the criteria set forth in the Application.

Applicant states that it owns an approximately 567.7 MW combined cycle gas-fueled electric generating plant located in the Borough of Eddystone, Delaware County, Pennsylvania. Applicant also filed a notice of change in status in the above-captioned rate docket with respect to the proposed transfers of interests in LEP Holdings.

Comment Date: 5 p.m. Eastern Time on February 3, 2005.

3. Rainy River Energy Corporation and Constellation Energy Commodities Group, Inc.

[Docket No. EC05–39–000]

Take notice that on January 14, 2005, Rainy River Energy Corporation (Rainy

River) and Constellation Energy Commodities Group, Inc. (CCG) filed an application pursuant to section 203 of the Federal Power Act seeking authorization for Rainy River to transfer to CCG two power sales agreements. Rainy River and CCG state that they are power marketers with market-based rate tariffs on file with the Commission.

Comment Date: 5 p.m. Eastern Time on February 4, 2005.

4. River Hill Power Company, LLC

[Docket No. EG05–30–000]

Take notice that on January 12, 2005, River Hill Power Company, LLC (RHPC), with a principal place of business at 335 Madison Avenue, 28th Floor, New York, NY 10017, filed with the Commission an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's regulations.

RHPC states that it is a wholly owned subsidiary of RCG River Hill, LLC and that it intends to construct, own, and operate a nominal 290 MW waste coal-fired electricity and steam generating plant at a site in Karthaus Township, Clearfield County, Pennsylvania.

Comment Date: 5 p.m. Eastern Time on February 2, 2005.

5. The Empire District Electric Company

[Docket No. ER99–1757–007]

Take notice that on January 12, 2005, The Empire District Electric Company (Empire District), submitted additional responses and data pursuant to the Commission's deficiency letter order dated November 24, 2004 in Docket No. ER99–1757–005, as an amendment to the September 27, 2004 filing of Empire District's generation market power study.

Comment Date: 5 p.m. Eastern Time on February 2, 2005.

6. Split Rock Energy LLC

[Docket No. ER00–1857–005]

Take notice that on January 12, 2005, Split Rock Energy LLC (Split Rock) supplemented its triennial review originally submitted on November 9, 2004 in Docket No. ER00–1857–004 pursuant to the Commission's order issued May 13, 2004 in Docket No. ER02–1406–001, *et al.*, 107 FERC ¶ 61,168 (2004).

Comment Date: 5 p.m. Eastern Time on February 2, 2005.

7. Ameren Energy Development Company

[Docket Nos. ER01–294–003); Ameren Energy Generating Company (Docket No. ER00–3412–004); Ameren Energy Marketing Company (Docket No. ER00–816–002); AmerenEnergy Medina Valley Cogen, LLC (Docket No. ER04–8–003); AmerenEnergy Resources Generating Company (Docket No. ER04–53–004); Central Illinois Light Company (Docket No. ER98–2440–004); Central Illinois Public Service Company (Docket No. ER98–3285–001); Union Electric Company (Docket No. ER00–2687–003]

Take notice that on December 27, 2004, Ameren Services Company, on behalf of the above-listed affiliates and subsidiaries of Ameren Corporation, submitted an updated market power analysis in compliance with Commission orders in *AEP Power Marketing, Inc., et al.*, 107 FERC ¶ 61,018 (2004), *order on reh'g,* 108 FERC ¶ 61,026 (2004).

Comment Date: 5 p.m. Eastern Time on January 26, 2005.

8. Ameren Energy Development Company

[Docket Nos. ER01–294–004); Ameren Energy Generating Company (Docket No. ER00–3412–005); Ameren Energy Marketing Company (Docket No. ER00–816–003); AmerenEnergy Medina Valley Cogen, LLC (Docket No. ER04–8–004); Central Illinois Light Company (Docket No. ER98–2440–005); Central Illinois Public Service Company (Docket No. ER98–3285–002); Union Electric Company (Docket No. ER00–2687–004]

Take notice that on December 27, 2004, Ameren Services Company, on behalf of the above-listed affiliates and subsidiaries of Ameren Corporation, submitted updated and revised market-based rate tariffs and rate schedules in compliance with the Commission's orders in *Investigation of Terms and Conditions of Public Utility Market-Based Rate Authorizations, 105 FERC ¶ 61,218 (2003), order on reh'g,* 107 FERC ¶ 61,175 (2004).

Comment Date: 5 p.m. Eastern Time on January 26, 2005.

9. Williams Power Company, Inc.

[Docket No. ER05–44–001]

Take notice that on January 12, 2005, Williams Power Company, Inc. (Williams) filed amended pages to the reliability must-run agreements between Williams and the California Independent System Operator Corporation for the Alamitos and Huntington Beach Generation Units.

Comment Date: 5 p.m. Eastern Time on February 2, 2005.

10. Virginia Electric and Power Company

[Docket No. ER05–74–001]

Take notice that on January 12, 2005, Virginia Electric and Power Company (Dominion Virginia Power) tendered for filing an executed Standard Large Generator Interconnection Agreement (LGIA) with Five Forks Energy Associates, LLC (Five Forks) and its response to the Commission's deficiency letter issued December 15, 2004 in Docket No. ER05–74–000. Dominion Virginia Power states that the executed LGIA replaces the unexecuted LGIA that was filed in these proceedings on October 26, 2004. Dominion Virginia Power requests an effective date of January 13, 2005.

Dominion Virginia Power states that copies of the filing were served on the parties on the Commission's official service list in these proceedings, Five Forks and the Virginia State Corporation Commission.

Comment Date: 5 p.m. Eastern Time on February 2, 2005.

11. Northeast Energy Associates, a Limited Partnership

[Docket No. ER05–236–002]

Take notice that on January 14, 2005, Northeast Energy Associates, a Limited Partnership submitted a supplement to the application for market-based rate authority filed on November 18, 2004, which clarifies that it does not intend to retain its qualifying facility status.

Northeast Energy Associates states that copies of the filing were served upon the Florida Public Service Commission.

Comment Date: 5 p.m. Eastern Time on January 24, 2005.

12. Westbank Energy Capital LLC

[Docket No. ER05–294–001]

Take notice that on January 13, 2005, Westbank Energy Capital, LLC (Westbank) submitted an amendment to its petition filed December 6, 2004 in Docket No. ER05–294–000 for acceptance of Westbank's Rate Schedule FERC No. 1; the granting of certain blanket approvals, including the authority to sell electricity at market-based rates; and the waiver of certain Commission regulations.

Comment Date: 5 p.m. Eastern Time on February 3, 2005.

13. Spokane Energy, LLC

[Docket No. ER05–310–001]

Take notice that on January 12, 2005, Spokane Energy, LLC (Spokane Energy) filed with the Commission proposed revisions to its First Revised Rate Schedule FERC No. 1, which was

originally filed on December 7, 2004 in Docket No. ER05–310–000.

Comment Date: 5 p.m. Eastern Time on February 2, 2005.

14. Avista Turbine Power, Inc.

[Docket No. ER05–311–001]

Take notice that on January 12, 2005, Avista Turbine Power, Inc. (Avista Turbine) filed with the Commission proposed revisions to its First Revised Rate Schedule No. 1, which was originally filed on December 7, 2005 in Docket No. ER05–311–000.

Comment Date: 5 p.m. Eastern Time on February 2, 2005.

15. San Diego Gas & Electric Company

[Docket No. ER05–354–001]

Take notice that on December 28, 2004, San Diego Gas & Electric Company (SDG&E) tendered for filing an amendment to its December 17, 2004 filing of changes to its Transmission Owner Tariff Reliability Services Rates.

SDG&E states that copies of the filing have been served on the California Public Utilities Commission and the California Independent System Operator.

Comment Date: 5 p.m. Eastern Time on January 31 , 2005.

16. Sempra Generation

[Docket No. ER05–440–000]

Take notice that on January 12, 2005, Sempra Generation submitted a notice of succession pursuant to section 35.16 of the Commission's Regulations to reflect a corporate name change from Sempra Energy Resources to Sempra Generation, effective January 1, 2005.

Comment Date: 5 p.m. Eastern Time on February 2, 2005.

17. American Electric Power Service Corporation

[Docket No. ER05–441–000]

Take notice that on January 12, 2005, the American Electric Power Service Corporation (AEPSC), tendered for filing notices of cancellation of Service Agreement Nos. 317 and 318 under the Operating Companies of the American Electric Power System's FERC Electric Tariff, Third Revised Volume No. 6, for firm and non-firm point-to-point transmission service agreements for Entergy-Koch Trading, LP. AEPSC requests an effective date of January 1, 2005.

AEPSC states that a copy of the filing was served on the Parties and the state utility regulatory commissions of Arkansas, Indiana, Kentucky, Louisiana, Michigan, Ohio, Oklahoma, Tennessee, Texas, Virginia and West Virginia.

Comment Date: 5 p.m. Eastern Time on February 2, 2005.

18. Condon Wind Power, LLC

[Docket Nos. ER05–442–000 and ER02–305–003); AES Alamitos, LLC (Docket No. ER98–2185–008); AEE 2, LLC (Docket No. ER99–2284–004); AES Creative Resources, LP and AES Eastern Energy, LP (Docket No. ER99–1773–004); Indianapolis Power & Light Company (Docket No. ER00–1026–009); AES Ironwood, LLC (Docket No. ER04–1010–002); AES Red Oak, LLC (Docket No. ER01–2401–003); AES Huntington Beach, LLC (Docket No. ER98–2184–008); AES Redondo Beach, LLC (Docket No. ER98–2186–008); AES Placerita, Inc. (Docket No. ER00–33–006); AES Delano, Inc. (Docket No. ER03–1207–002]

Take notice that on January 12, 2005, the above-captioned entities (collectively, Applicants) tendered for filing an amendment to the tariff of Condon Wind Power, LLC (Condon), and a notice of change in status. Applicants state that the amendment to the Condon's tariff and the notice of change in status are intended to reflect a transaction in which SeaWest Holdings, Inc., which owns a 38.9 percent managing interest in Condon, will be acquired by a subsidiary of AES Corporation, the parent of the other Applicants.

Comment Date: 5 p.m. Eastern Time on February 2, 2005.

19. Transmission Owners of the Midwest Independent Transmission System Operator, Inc.

[Docket No. ER05–447–000]

Take notice that on January 13, 2005, the Transmission Owners of the Midwest Independent Transmission System Operator (Midwest ISO Transmission Owners) submitted for filing a rate schedule change concerning the direct recovery of Midwest ISO Schedule 10 and 17 costs assessed to Carved-Out Grandfathered Agreements by the Midwest ISO to the transmission owners.

The Midwest ISO Transmission Owners state that this filing will be served on all affected customers and on all applicable state commissions and that the filing will be posted on the Midwest ISO's home page.

Comment Date: 5 p.m. Eastern Time on February 3, 2005.

20. Arizona Public Service Company

[Docket No. ER05–448–000]

Take notice that on January 13, 2005, Arizona Public Service Company (APS) tendered for filing revisions to its open access transmission tariff in order to comply with Order 2003–B issued December 20, 2004 in Docket No. RM02–1–005.

APS states that a copy of the transmittal letter has been served on all parties listed on the Service List and that copies of the complete filing can be found on APS' OASIS at *http://www.oatioasos.com\azps\index.*

Comment Date: 5 p.m. Eastern Time on February 3, 2005.

Standard Paragraph

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant and all parties to this proceeding.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible online at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Linda Mitry,

Deputy Secretary.

[FR Doc. E5–315 Filed 1–27–05; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[OW–2004–0038, FRL–7865–3]

Agency Information Collection Activities: Proposed Collection; Comment Request; Survey of Airport Deicing Operations, EPA ICR Number 2171.01

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit a proposed Information Collection Request (ICR) to the Office of Management and Budget (OMB). This is a request for a new collection. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before March 29, 2005.

ADDRESSES: Submit your comments, referencing docket ID number OW–2004–0038, to EPA online using EDocket (our preferred method), by e-mail to *ow-docket@epa.gov,* or by mail to: Water Docket, 4101T, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Eric Strassler, EPA Office of Water, telephone 202–566–1026, email *strassler.eric@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has established a public docket for this ICR under Docket ID number OW–2004–0038, which is available for public viewing at the Water Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is 202–566–1744, and the telephone number for the Water Docket is 202–566–2422. An electronic version of the public docket is available through EPA Dockets (EDocket) at *http://www.epa.gov/edocket.* Use EDocket to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''Search,'' then key in the docket ID number identified above.

Any comments related to this ICR should be submitted to EPA within 60 days of this notice. EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDocket as EPA receives them and without change, unless the comment contains copyrighted material, confidential business information (CBI), or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDocket. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDocket. For further information about the electronic docket, see EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *http://www.epa.gov/edocket.*

Affected entities: Entities potentially affected by this action are airport owners/operators.

Title: Survey of Airport Deicing Operations (Airport Questionnaire)

Abstract: EPA is developing wastewater discharge standards, called ''effluent guidelines,'' for airports pursuant to the Agency's 2004 Effluent Guidelines Plan (69 FR 53719, September 2, 2004). The focus of the rulemaking is on wastewater discharges from aircraft and runway deicing operations. EPA will send survey questionnaires to a sample of airport owners/operators to help the Agency compile a national assessment of deicing operations. The survey will include questions on the deicing technologies employed, amount of deicing chemicals used, wastewater collection and treatment systems used, pollution prevention techniques, and economic and financial information. Completion of this one-time survey will be mandatory pursuant to sec. 308 of the Clean Water Act. (EPA is preparing a separate questionnaire for airlines. This questionnaire will be announced in a separate **Federal Register** notice.)

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

EPA would like to solicit comments to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(ii) Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Burden Statement. The estimated burden for this survey is 30 hours per airport respondent. The total number of airport respondents is 157, producing an approximate total burden of 4,710 hours. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Dated: January 13, 2005.

Geoffrey H. Grubbs,

Director, Office of Science and Technology.

[FR Doc. 05–1625 Filed 1–27–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[Docket No. R10–OAR–2005–WA–001; FRL–7864–9]

Adequacy Status of the Spokane, WA Carbon Monoxide Maintenance Plan and Redesignation Request for Transportation Conformity Purposes

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of adequacy.

SUMMARY: In this notice, EPA is notifying the public that we have found that the motor vehicle emissions budget contained in the submitted Spokane Carbon Monoxide Maintenance Plan and Redesignation Request is adequate for transportation conformity purposes. On March 2, 1999, the D.C. Circuit Court ruled that submitted State Implementation Plans (SIPs) cannot be used for conformity determinations

until EPA has found them adequate. This affects future transportation conformity determinations prepared, reviewed and approved by the Spokane Regional Transportation Council, Washington State Department of Transportation, Federal Highway Administration and the Federal Transit Administration.

DATES: This finding is effective February 14, 2005.

FOR FURTHER INFORMATION CONTACT: The finding is available at EPA's conformity Web site: *http://www.epa.gov/otaq/transp.htm*, (once there, click on the ''Transportation Conformity'' button, then look for ''Adequacy Review of SIP Submissions''). You may also contact Wayne Elson, U.S. EPA, Region 10, Office of Air, Waste, and Toxics (AWT–107), 1200 Sixth Ave, Seattle WA 98101; (206) 553–1463 or *elson.wayne@epa.gov*.

SUPPLEMENTARY INFORMATION:

Background

Today's notice is simply an announcement of a finding that we have already made. EPA Region 10 sent a letter to the Washington Department of Ecology January 13, 2005, stating that the SIP is adequate for transportation conformity purposes.

Transportation conformity is required by section 176(c) of the Clean Air Act. EPA's conformity rule requires that transportation plans, programs, and projects conform to SIPs. Conformity to a SIP means that transportation activities will not produce new air quality violations, worsen existing violations, or delay timely attainment of the national ambient air quality standards.

The criteria by which we determine whether a SIP is adequate for conformity purposes are outlined in 40 CFR 93.118(e)(4). Please note that an adequacy review is separate from EPA's completeness review and it also should not be used to prejudge our ultimate approval of the SIP. Even if we find a SIP adequate for conformity, the SIP could later be disapproved. For the reader's ease, the 2002 motor vehicle emission budget excerpted from the Maintenance Plan is 279 tons per winter time day of carbon monoxide.

We have described our process for determining adequacy in SIPs in guidance dated May 14, 1999. This guidance is now reflected in the amended transportation conformity rule, July 1, 2004 (69 FR 40004). We followed this process in making our adequacy determination.

Authority: 42 U.S.C. 7401–7671q.

Dated: January 20, 2005.

Julie M. Hagensen,

Acting Regional Administrator, Region 10.

[FR Doc. 05–1632 Filed 1–27–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6659–9]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7167 or *http://www.epa.gov/compliance/nepa/*.

Weekly receipt of Environmental Impact Statements

Filed January 17, 2005 through January 21, 2005

Pursuant to 40 CFR 1506.9.

EIS No. 050017, Final EIS, NOA, ME, MA, RI, NH, CT, Atlantic Herring Fishery Management Plan, Minimizing Impacts on Essential Fish Habitat of Any Species, Gulf of Maine—Georges Bank, ME, NH, MA, CT and RI, Wait Period Ends: February 22, 2005, Contact: Peter D. Colosi (978) 281–3332.

The above NOA EIS should have appeared in the 01/21/2005 **Federal Register**. The 30 day Wait Period is Calculated from 01/21/2005.

EIS No. 050018, Draft EIS, FAA, IL, O'Hare Modernization Program, Proposes Major Development, Chicago O'Hare International Airport, Airport Layout Plan (ALP), Federal Funding, US Army COE Section 404 Permit, City of Chicago, IL, Comment Period Ends: March 23, 2005, Contact: Michael W. MacMullen (847) 294–8339.

The above FAA EIS should have appeared in the 01–21–2005 **Federal Register**.

EIS No. 050019, Final EIS, AFS, AK, Shoreline Outfitter/Guide Plan, Commercial Permits Issuance for Shoreline-Based Activities on National Forest System Lands, Admiralty Island National Monument, Hoonah, Sitka and Juneau Ranger Districts, Tongass National Forest, AK, Wait Period Ends: February 28, 2005, Contact: Bill Tremblay (907) 772–5877.

EIS No. 050020, Draft EIS, USN, FL, Navy Air-To-Ground Training at Avon Park Air Force Range, To Conduct Air-to-Ground Ordnance Delivery and Training, Fleet Forces Command's Fleet Readiness Training Program (FRTP), Polk and Highlands Counties, FL, Comments Period Ends: March 14, 2005, Contact: Will Sloger (843) 820–5797.

EIS No. 050021, Draft EIS, NRC, WI, Generic-License Renewal for Point Beach Nuclear Plant, Units 1 and 2, Supplement 23, to NUREG–1437 (TAC Nos. MC2049 and MC2050), Lake Michigan, Manitowoc County, WI, Comment Period Ends: April 13, 2005, Contact: Stacey Imboden (301) 415–2462.

EIS No. 050022, Draft EIS, AFS, WA, Methow Transmission Project, Construction of New Transmission Line or Reconstruction an Existing Line, Okanogan and Wenatchee National Forests, Methow Valley Ranger District, Okanogan County, WA, Comment Period Ends: March 15, 2005, Contact: Jan Flatten (509) 826–3277.

EIS No. 050023, Final EIS, DOE, SC, Savannah River Site Construction and Operation of a Mixed Oxide (MOX) Fuel Fabrication Facility, NUREG–1767, Aiken, Barnwell and Allendale Counties, SC, Wait Period Ends: February 28, 2005, Contact: Matthew Blevins (301) 415–7684.

EIS No. 050024, Draft EIS, AFS, CO, Gold Camp Road Plan, Develop a Feasible Plan to Manage the Operation of Tunnel #3 and the 8.5 mile Road Segment, Pike National Forest, Pikes Peak Ranger District, Colorado Springs, El Paso County, CO, Comment Period Ends: March 29, 2005, Contact: Frank Landis (719) 477–4203.

EIS No. 050025, Final EIS, UAF, TX, Relocation of the C–5 Formal Training Unit from Altus Air Force Base, Oklahoma to Lackland Air Force Base, Bexar County, TX, Wait Period Ends: February 28, 2005, Contact: Lt.Col. Dee Anderson (210) 671–2907.

EIS No. 050026, Draft EIS, BIA, WI, Beloit Casino Project, To Expand to Tribal Governmental Revenue Base, St. Croix Chippewa Indians of Wisconsin and Bad River Band of the Lake Superior Tribe of Chippewa Indians, Rock County, WI, Comment Period Ends: March 14, 2005, Contact: Herb Nelson (612) 713–4400.

EIS No. 050027, Final EIS, BLM, AK, Northeast National Petroleum Reserve Alaska Amended Integrated Activity Plan, To Amend 1998 Northeast Petroleum Reserve, To Consider Opening Portions of the BLM-Administrated Lands, North Slope Borough, AK, Wait Period Ends: February 28, 2005, Contact: Susan Childs (907) 271–1985.

EIS No. 050028, Draft Supplement EIS, FHW, AK, Juneau Access Transportation Project, Improvements in the Lynn Canal/Taiya Inlet

Corridor between Juneau and Haines/Skagway, Updated Information, Special-Use-Permit and COE Section 10 and 404 Permits, Tongass National Forest, Klondike Gold Rush National Historic Park, Haines States Forest, City and Borough of Juneau, Haines Borough, Cities Haines and Skagway, AK, Comment Period Ends: 03/21/2005, Contact: Tim Haugh (907) 586–7430.

Amended Notices

EIS No. 050014, Final EIS, FAA, CA, Los Angeles International Aiport Proposed Master Plan Improvements, Alternative D Selected, Enhanced Safety and Security Plan, Los Angeles County, CA, Wait Period Ends: February 22, 2005, Contact: David B. Kessler (310) 725–3615.

Revision of FR Notice Published on 01/21/2004: Correction to EIS Status from Draft to Final.

EIS No. 040544, Draft Supplemental EIS, FHW, UT, Legacy Parkway Project, Construction from I–215 at 2100 North in Salt Lake City to I–15 and US 89 near Farmington, Updated Information, Funding and US Army COE Section 404 Permit, Salt Lake and Davis Counties, UT, Comment Period Ends: March 4, 2005, Contact: Gregory Punske (801) 963–0182.

Revision of FR Notice Published on 12/03/2004: CEQ Comment Period Ending 02/01/2005 has been Extended to 03/04/2005.

Dated: January 25, 2005.

Robert W. Hargrove,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 05–1635 Filed 1–27–05; 8:45 am]

BILLING CODE 6560–50–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7864–7]

Meeting of the Local Government Advisory Committee

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The Local Government Advisory Committee will meet on February 9–11, 2005 in Half Moon Bay, CA. The Committee will be discussing environmental indicators, water infrastructure needs and small community issues.

The Committee will hear comments from the public between 10 a.m.–10:15 a.m. on Thursday, February 10th. Each individual or organization wishing to address the LGAC meeting will be allowed a maximum of five minutes to present their point of view. Please contact the Designated Federal Officer (DFO) at the number listed below to schedule agenda time. Time will be allotted on a first come, first serve basis, and the total period for comments may be extended, if the number of requests for appearances require it.

This is an open meeting and all interested persons are invited to attend. LGAC meeting minutes and Subcommittee summary notes will be available after the meeting and can be obtained by written request from the DFO. Members of the public are requested to call the DFO at the number listed below if planning to attend so that arrangements can be made to comfortably accommodate attendees as much as possible. Seating will be on a first come, first serve basis.

DATES: The Local Government Advisory Committee plenary session will begin at 8:30 a.m. Thursday, February 10th and conclude at 12 p.m. on Friday, February 11th.

ADDRESSES: The meeting will be held in Half Moon Bay, CA at the Half Moon Bay Lodge, located at 2400 S. Cabrillo Highway in the Club Conference Room.

Additional information can be obtained by writing the DFO at 1200 Pennsylvania Avenue, NW., (1301A), Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: The DFO for the Local Government Advisory Committee (LGAC) is Pamela Luttner (202) 564–3107.

Information on Services for the Handicapped: For information on facilities or services for the handicapped or to request special assistance at the meetings, contact the Designated Federal Officer at (202) 564–3107 as soon as possible.

Dated: January 12, 2005.

Pamela A. Luttner,

Designated Federal Officer, Local Government Advisory Committee.

[FR Doc. 05–1647 Filed 1–27–05; 8:45 am]

BILLING CODE 6560–80–P

ENVIRONMENTAL PROTECTION AGENCY

[Docket No. ORD–2005–0002]

[FRL–7864–8]

Board of Scientific Counselors, Human Health Subcommittee Meetings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of meetings.

SUMMARY: Pursuant to the Federal Advisory Committee Act, Public Law 92–463, the Environmental Protection Agency, Office of Research and Development (ORD), announces three meetings of the Board of Scientific Counselors (BOSC) Human Health Subcommittee.

DATES: Two teleconference call meetings will be held, the first on Tuesday, February 15, 2005, from 12 noon to 2 p.m., and the second on Thursday, February 24, 2005, from 12 noon to 2 p.m. A face-to-face meeting will be held beginning Monday, February 28, 2005 (8:30 a.m. to 5 p.m.), continuing on Tuesday, March 1, 2005 (8:30 a.m. to 5 p.m.), and concluding on Wednesday, March 2, 2005 (8:30 a.m. to 2 p.m.). All times noted are Eastern Standard Time. Meetings may adjourn early if all business is completed.

ADDRESSES: *Conference calls:* Participation in the conference calls will be by teleconference only—meeting rooms will not be used. Members of the public may obtain the call-in number and access code for the teleconference meeting from Virginia Houk, whose contact information is listed under the **FOR FURTHER INFORMATION CONTACT** section of this notice. Face-to-Face Meeting: The face-to-face meeting will be held at the U.S. EPA Research Triangle Park (RTP) Campus (Room C–111A/B/C), located at 109 T.W. Alexander Drive, Research Triangle Park, NC 27711.

Document Availability

Draft agendas for the meetings are available from Virginia Houk, whose contact information is listed under the **FOR FURTHER INFORMATION CONTACT** section of this notice. Requests for the draft agendas will be accepted up to 2 business days prior to each conference call/meeting date. The draft agendas also can be viewed through EDOCKET, as provided in Unit I.A. of the **SUPPLEMENTARY INFORMATION** section.

Any member of the public interested in making an oral presentation at one of the conference calls or at the face-to-face meeting may contact Virginia Houk, whose contact information is listed under the **FOR FURTHER INFORMATION CONTACT** section of this notice. Requests for making oral presentations will be accepted up to 2 business days prior to each conference call/meeting date. In general, each individual making an oral presentation will be limited to a total of three minutes.

Submitting Comments

Written comments may be submitted electronically, by mail, or through hand

delivery/courier. Follow the detailed instructions as provided in Unit I.B. of this section. Written comments will be accepted up to 2 business days prior to each conference call/meeting date.

FOR FURTHER INFORMATION CONTACT: Virginia Houk, Designated Federal Officer, Environmental Protection Agency, Office of Research and Development, Mail Code B305–02, Research Triangle Park, NC, 27711; telephone (919) 541–2815; fax (919) 685–3250; e-mail *houk.virginia@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

This notice announces three meetings of the BOSC Human Health Subcommittee. The purpose of the meetings are to evaluate EPA's Human Health Research Program. Proposed agenda items for the conference calls include, but are not limited to: charge questions, objective of program reviews, background on the U.S. EPA's Human Health Research Program, writing assignments, and planning for the face-to-face meeting. Proposed agenda items for the face-to-face meeting include, but are not limited to: presentations by key EPA staff involved in the Human Health Research Program, poster sessions on ORD's Human Health research, and preparation of the draft report. The conference calls and the face-to-face meeting are open to the public.

Information on Services for the Handicapped: Individuals requiring special accommodations at this meeting should contact Virginia Houk, Designated Federal Officer, at (919) 541–2815 at least five business days prior to the meeting so that appropriate arrangements can be made to facilitate their participation.

A. How Can I Get Copies of Related Information ?

1. *Docket*. EPA has established an official public docket for this action under Docket ID No. ORD–2005–0002. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Documents in the official public docket are listed in the index in EPA's electronic public docket and comment system, EDOCKET. Documents are available either electronically or in hard copy. Electronic documents may be viewed through EDOCKET. Hard copies of the draft agendas may be viewed at the Board of Scientific Counselors, Human Health Meetings Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the ORD Docket is (202) 566–1752.

2. *Electronic Access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EDOCKET. You may use EDOCKET at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket identification number (ORD–2005–0002).

For those wishing to make public comments, it is important to note that EPA's policy is that comments, whether submitted electronically or on paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, confidential business information (CBI), or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks mailed or delivered to the docket will be transferred to EPA's electronic public docket. Written public comments mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket.

B. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket identification number (ORD–2005–0002) in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period.

1. *Electronically*. If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment, and it allows EPA to contact you if further information on the substance of the comment is needed or if your comment cannot be read due to technical difficulties. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment placed in the official public docket and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EDOCKET*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EDOCKET at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. To access EPA's electronic public docket from the EPA Internet Home Page, *http://www.epa.gov*, select ''Information Sources,'' ''Dockets,'' and ''EDOCKET.'' Once in the system, select ''search,'' and then key in Docket ID No. ORD–2005–0002. The system is an anonymous access system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by electronic mail (e-mail) to *ORD.Docket@epa.gov*, Attention Docket ID No. ORD–2005–0002. In contrast to EPA's electronic public docket, EPA's e-mail system is not an anonymous access system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM mailed to the mailing address identified in Unit I.B.2. These electronic submissions will be accepted in Word, WordPerfect or rich text files. Avoid the use of special characters and any form of encryption.

2. *By Mail.* Send your comments to: U.S. Environmental Protection Agency, ORD Docket, EPA Docket Center (EPA/DC), Mailcode: 28221T, 1200 Pennsylvania Ave., NW, Washington, DC, 20460, Attention Docket ID No. ORD–2005–0002.

3. *By Hand Delivery or Courier.* Deliver your comments to: EPA Docket Center (EPA/DC), Room B102, EPA West Building, 1301 Constitution Avenue, NW., Washington, DC, Attention Docket ID No. ORD–2005–0002 (**note:** this is not a mailing address). Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.A.1.

Dated: January 24, 2005.

Kevin Y. Teichman,

Director, Office of Science Policy.

[FR Doc. 05–1631 Filed 1–27–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPPT–2005–0002; FRL–7697–2]

Certain New Chemicals; Receipt and Status Information

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5 of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture (defined by statute to include import) a new chemical (i.e., a chemical not on the TSCA Inventory) to notify EPA and comply with the statutory provisions pertaining to the manufacture of new chemicals. Under sections 5(d)(2) and 5(d)(3) of TSCA, EPA is required to publish a notice of receipt of a premanufacture notice (PMN) or an application for a test marketing exemption (TME), and to publish periodic status reports on the chemicals under review and the receipt of notices of commencement to manufacture those chemicals. This status report, which covers the period from December 1, 2004 to December 14, 2004, consists of the PMNs pending or expired, and the notices of commencement to manufacture a new chemical that the Agency has received under TSCA section 5 during this time period.

DATES: Comments identified by the docket ID number OPPT–2005–0002 and the specific PMN number or TME number, must be received on or before February 28, 2005.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Colby Lintner, Regulatory Coordinator, Environmental Assistance Division, Office of Pollution Prevention and Toxics (7408M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. As such, the Agency has not attempted to describe the specific entities that this action may apply to. Although others may be affected, this action applies directly to the submitter of the premanufacture notices addressed in the action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPPT–2005–0002. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the EPA Docket Center, Rm. B102-Reading Room, EPA West, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566–1744 and the telephone number for the OPPT Docket, which is located in EPA Docket Center, is (202) 566–0280.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical

objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number and specific PMN number or TME number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPPT–2005–0002. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to *oppt.ncic@epa.gov*, Attention: Docket ID Number OPPT–2005–0002 and PMN Number or TME Number. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *By hand delivery or courier*. Deliver your comments to: OPPT Document Control Office (DCO) in EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number OPPT–2005–0002 and PMN Number or TME Number. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the notice or collection activity.
7. Make sure to submit your comments by the deadline in this document.
8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action and the specific PMN number you are commenting on in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Why is EPA Taking this Action?

Section 5 of TSCA requires any person who intends to manufacture (defined by statute to include import) a new chemical (i.e., a chemical not on the TSCA Inventory to notify EPA and comply with the statutory provisions pertaining to the manufacture of new chemicals. Under sections 5(d)(2) and 5(d)(3) of TSCA, EPA is required to publish a notice of receipt of a PMN or an application for a TME and to publish periodic status reports on the chemicals under review and the receipt of notices of commencement to manufacture those chemicals. This status report, which covers the period from December 1, 2005 to December 14, 2005, consists of the PMNs pending or expired, and the notices of commencement to manufacture a new chemical that the Agency has received under TSCA section 5 during this time period.

III. Receipt and Status Report for PMNs

This status report identifies the PMNs pending or expired, and the notices of

commencement to manufacture a new chemical that the Agency has received under TSCA section 5 during this time period. If you are interested in information that is not included in the following tables, you may contact EPA as described in Unit II. to access additional non-CBI information that may be available.

In Table I of this unit, EPA provides the following information (to the extent that such information is not claimed as CBI) on the PMNs received by EPA during this period: the EPA case number assigned to the PMN; the date the PMN was received by EPA; the projected end date for EPA's review of the PMN; the submitting manufacturer; the potential uses identified by the manufacturer in the PMN; and the chemical identity.

I. 34 PREMANUFACTURE NOTICES RECEIVED FROM: 12/01/04 TO 12/14/04

Case No.	Received Date	Projected Notice End Date	Manufacturer/Importer	Use	Chemical
P–05–0159	12/01/04	02/28/05	CBI	(S) Resin for wood coatings	(G) Copolymer of acrylic and methacrylic esters
P–05–0160	12/01/04	02/28/05	CBI	(G) Metalworking fluid additive	(G) Polyethylene glycol esters of fatty acids
P–05–0161	12/01/04	02/28/05	CBI	(G) Metalworking fluid additive	(G) Polyethylene glycol esters of fatty acids
P–05–0162	12/01/04	02/28/05	Ashland Inc., Environmental Health and Safety	(G) Adhesive, coating, ink	(G) Aliphatic urethane diacrylate monomer
P–05–0163	12/01/04	02/28/05	Ashland Inc., Environmental Health and Safety	(G) Adhesive, coating, ink	(G) Aliphatic urethane diacrylate monomer
P–05–0164	12/01/04	02/28/05	Ashland Inc., Environmental Health and Safety	(G) Adhesive, coating, ink	(G) Aliphatic urethane diacrylate monomer
P–05–0165	12/01/04	02/28/05	Ashland Inc., Environmental Health and Safety	(G) Adhesive, coating, ink	(G) Aliphatic urethane diacrylate monomer
P–05–0166	12/01/04	02/28/05	Ashland Inc., Environmental Health and Safety	(G) Adhesive, coating, ink	(G) Aliphatic urethane diacrylate monomer
P–05–0167	12/01/04	02/28/05	Ashland Inc., Environmental Health and Safety	(G) Adhesive, coating, ink	(G) Aliphatic urethane polyacrylate monomer
P–05–0168	12/03/04	03/02/05	CBI	(G) Open, non-dispersive use.	(G) Polyester amidoamine
P–05–0169	12/03/04	03/02/05	CBI	(G) Adhesion promoter	(G) Maleic anhydride and acrylics modified polyolefin
P–05–0170	12/07/04	03/06/05	CBI	(G) Thickening compound for aqueous systems	(G) Acrylic emulsion polymer
P–05–0171	12/07/04	03/06/05	CBI	(G) Thickening compound for aqueous systems	(G) Acrylic emulsion polymer
P–05–0172	12/07/04	03/06/05	CBI	(G) Thickening compound for aqueous systems	(G) Acrylic emulsion polymer
P–05–0173	12/07/04	03/06/05	CBI	(G) Thickening compound for aqueous systems	(G) Acrylic emulsion polymer
P–05–0174	12/07/04	03/06/05	CBI	(G) Thickening compound for aqueous systems	(G) Acrylic emulsion polymer
P–05–0175	12/07/04	03/06/05	CBI	(G) Thickening compound for aqueous systems	(G) Acrylic emulsion polymer
P–05–0176	12/06/04	03/05/05	CBI	(G) Resin for coatings	(G) 2-propenoic acid, 2-methyl-, oxiranylalkyl ester, polymer with alkyl 2-propenoate, ethenylbenzene, and trialkylcycloaklyl 2-methyl-2-propenoate, dialkyl peroxide and trialkylhexaneperoxoate-initiated.
P–05–0177	12/07/04	03/06/05	CBI	(S) Base resin for utra violet/electron beam curable formulations; base resin for peroxide curable formulations	(G) Alcohol reaction products with hexakis(methoxymethyl)melamine
P–05–0178	12/09/04	03/08/05	Ashland Inc., Environmental Health and Safety	(G) Adhesive, coating, ink	(G) Multifunctional acrylate oligomer resin
P–05–0179	12/09/04	03/08/05	Ashland Inc., Environmental Health and Safety	(G) Adhesive, coating, ink	(G) Multifunctional acrylate oligomer resin
P–05–0180	12/09/04	03/08/05	Ashland Inc., Environmental Health and Safety	(G) Adhesive, coating, ink	(G) Multifunctional acrylate oligomer resin

I. 34 PREMANUFACTURE NOTICES RECEIVED FROM: 12/01/04 TO 12/14/04—Continued

Case No.	Received Date	Projected Notice End Date	Manufacturer/Importer	Use	Chemical
P–05–0181	12/09/04	03/08/05	Ashland Inc., Environmental Health and Safety	(G) Adhesive, coating, ink	(G) Multifunctional acrylate oligomer resin
P–05–0182	12/09/04	03/08/05	Ashland Inc., Environmental Health and Safety	(G) Adhesive, coating, ink	(G) Multifunctional acrylate oligomer resin
P–05–0183	12/09/04	03/08/05	Ashland Inc., Environmental Health and Safety	(G) Adhesive, coating, ink	(G) Multifunctional acrylate oligomer resin
P–05–0184	12/09/04	03/08/05	CBI	(S) Organic synthesis intermediate	(G) Heteropolycyclic, 9-(2-carboxyphenyl)-3,6-bis[(2-methylphenyl)amino]-, chloride
P–05–0185	12/09/04	03/08/05	Genencor international, Inc.	(G) Contained use	(S) 2-o-beta-d-glucopyranosyl-d-glucose
P–05–0186	12/09/04	03/08/05	CBI	(S) Curing agent for epoxy coating systems	(G) There are 5 chemical substances in this pmn of which 3 are Class I substances and the rest 2 are Class II substances. The generic name for each of the 5 chemical susbstances are given below. Class I substances: (1) Reaction product of polyether amine and methyl isobutyl ketone. (2) Reaction product of aminopropyl morpholine and methyl isobutyl ketone. (3) Reaction product of fatty acids, ethylene amine and methyl isobutyl ketone. Class II substances: (1) Reaction product of formaldehyde, 1,3-benzenedimethanamine, phenol, and methyl isobutyl ketone. (2) Reaction product of fatty acids, butoxymethyl oxirane, formaldehyde-phenol polymer glycidyl ether, aminopropyl morpholine, polyether amine, ethylene amine and methyl isobutyl ketone
P–05–0187	12/09/04	03/08/05	CBI	(G) Precursor to polymers used as structural components	(G) Polycarbonate
P–05–0188	12/10/04	03/09/05	CBI	(S) Paint or coating component	(G) Fluoroethylene-vinyl copolymer
P–05–0189	12/13/04	03/12/05	CBI	(G) Inhibition of gas hydrates	(G) Methacrylamide copolymer
P–05–0190	12/13/04	03/12/05	CBI	(G) Fiberglass film former	(G) Allylether functional unsaturated polyester
P–05–0191	12/14/04	03/13/05	Toho Carbon Fibers, Inc.	(G) Sizing agent for coating the surface of carbon multifilament yarn.	(S) 2-propenoic acid, 2-methyl-, 1,3-phenylenebis[methylenenitrilobis(2-hydroxy-3,1-propanediyl)] ester
P–05–0192	12/14/04	03/13/05	CBI	(G) Binder resin for ink	(S) 2-propenoic acid, 2-methyl-, polymer with butyl 2-propenoate, ethenylbenzene, .alpha.-(2-methyl-1-oxo-2-propenyl)-.omega.-[(2-methyl-1-oxo-2-propenyl)oxy]poly(oxy-1,2-ethanediyl) and 2-propenamide

In Table II of this unit, EPA provides the following information (to the extent that such information is not claimed as CBI) on the Notices of Commencement to manufacture received:

II. 15 NOTICES OF COMMENCEMENT FROM: 12/01/04 TO 12/14/04

Case No.	Received Date	Commencement Notice End Date	Chemical
P–00–0907	12/02/04	11/15/04	(G) Hydroxy functional acrylic polymer
P–04–0467	12/09/04	11/02/04	(G) Alkanedioic acid, polymer with amino-alkanes
P–04–0470	12/10/04	11/20/04	(G) Acrylate esters
P–04–0518	11/30/04	11/24/04	(G) Substituted benzenesulfonic acid substituted pyrazol azo phenyl amino triazin amino substituted phenyl compound

II. 15 NOTICES OF COMMENCEMENT FROM: 12/01/04 TO 12/14/04—Continued

Case No.	Received Date	Commencement Notice End Date	Chemical
P–04–0519	11/30/04	11/24/04	(G) Substituted benzenesulfonic acid substituted pyrazol azo phenyl amino triazin amino substituted phenyl compound
P–04–0611	12/07/04	11/03/04	(S) (1r,4s)-4-methoxy-2,2,7,7-tetramethyltricyclo[6.2.1.01,6]undec-5-ene
P–04–0626	12/08/04	11/09/04	(G) Substituted phenol, polymer with polyalkylene polyether polyol and epichlorohydrin
P–04–0659	12/14/04	11/16/04	(G) N-sulfoalkyl-aminocarbonylalkenyl, polymer modified with n,n-dialkyl-aminocarbonylalkenyl, calcium salt
P–04–0683	12/06/04	11/23/04	(G) Substituted pyridinecarbonitrile pigment
P–04–0710	12/06/04	11/15/04	(G) Alkyl methacrylate copolymer
P–04–0752	11/30/04	11/12/04	(G) Organomodified siloxane and silicone
P–04–0793	12/06/04	11/20/04	(G) Essential oil
P–04–0815	12/06/04	11/16/04	(G) Styrene acrylic copolymer
P–04–0891	12/01/04	11/02/04	(G) Dynacoll 7250, dynacoll 7140
P–93–1704	12/13/04	11/29/04	(G) Polyester polyol isocyanate polymer reaction products

List of Subjects

Environmental protection, Chemicals, Premanufacturer notices.

Dated: January 13, 2005.

Vicki A. Simons,

Acting Director, Information Management Division, Office of Pollution Prevention and Toxics.

[FR Doc. 05–1637 Filed 1–27–05; 8:45 am]

BILLING CODE 6560–50–S

EXPORT–IMPORT BANK OF THE UNITED STATES

Sunshine Act Meeting

ACTION: Notice of a partially open meeting of the Board of Directors of the Export-Import Bank of the United States.

TIME AND PLACE: Thursday, February 3, 2005 at 9:30 a.m. The meeting will be held at Ex-Im Bank in Room 1143, 811 Vermont Avenue, NW., Washington, DC 20571.

OPEN AGENDA ITEM: Ex-Im Bank Sub-Saharan Africa Advisory Committee for 2005.

PUBLIC PARTICIPATION: The meeting will be open to public participation for Item No. 1 only.

FURTHER INFORMATION: For further information, contact: Office of the Secretary, 811 Vermont Avenue, NW., Washington, DC 20571 (Tel. No. (202) 565–3957).

James K. Hess,

Senior Vice President and Chief Financial Officer.

[FR Doc. 05–1727 Filed 1–26–05; 12:39 pm]

BILLING CODE 6690–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Standards and Security (SSS).

Time and Date: February 1st, 2005 9 a.m.–5 p.m., February 2nd, 2005 9 a.m.–1 p.m.

Place: Hubert H. Humphrey Building, 200 Independence Avenue, SW., Room 505A, Washington, DC 20201.

Status: Open.

Purpose: The Subcommittee will continue to focus on potential e-prescribing standards, including a discussion on the use of RxNorm in the e-prescribing context and an update from the industry on the progress of related workgroups (e.g., codified SIG). The development of a draft recommendation letter to the HHS Secretary will be discussed.

Contact Person For More Information: Substantive program information as well as summaries of meetings and a roster of Committee members may be obtained from Maria Friedman, Health Insurance Specialist, Security and Standards Group, Centers for Medicare and Medicaid Services, MS: C5–24–04, 7500 Security Boulevard, Baltimore, MD 21244–1850, telephone: 410–786–6333 or Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, Room 1100, Presidential Building, 3311 Toledo Road, Hyattsville, Maryland 20782, telephone: (301) 458–4245. Information also is available on the NCVHS home page of the HHS Web site: *http://www.ncvhs.hhs.gov/* where an agenda for the meeting will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458–4EEO (4336) as soon as possible.

Dated: January 14, 2005.

James Scanlon,

Acting Deputy Assistant Secretary for Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 05–1619 Filed 1–27–05; 8:45 am]

BILLING CODE 4151–05–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–05–0263]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call (404) 371–5976 or send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information

on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Requirement for a Special Permit to Import Cynomolgus, African Green, or Rhesus Monkeys into the United States (0920–0263)—Revision—National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC).

A registered importer must request a special permit to import Cynomolgus, African Green, or Rhesus Monkeys. To receive a special permit to import nonhuman primates the importer must submit to the Director of CDC, a written plan which specifies the steps that will be taken to prevent exposure of persons and animals during the entire importation and quarantine process for the arriving nonhuman primates.

Under the special permit arrangement, registered importers must submit a plan to CDC for the importation and quarantine if they wish to import the specific monkeys covered. The plan must address disease prevention procedures to be carried out in every step of the chain of custody of such monkeys, from embarkation in the country of origin to release from quarantine. Information such as species, origin and intended use for monkeys, transit information, isolation and quarantine procedures, and procedures for testing of quarantined animals is necessary for CDC to make public health decisions. This information enables CDC to evaluate compliance with the standards and to determine whether the measures being taken to prevent exposure of persons and animals during importation are adequate. Once CDC is assured, through the monitoring of shipments (normally no more than 2), that the provisions of a special permit plan are being followed by a new permit holder and that the use of adequate disease control practices is being demonstrated, the special permit is extended to cover the receipt of additional shipments under the same plan for a period of 180 days, and may be renewed upon request. This eliminates the burden on importers to repeatedly report identical information, requiring only that specific shipment itineraries and information on changes to the plan which require approval be submitted.

Respondents are commercial or not-for-profit importers of nonhuman primates. The burden represents full submission of information and itinerary/change information respectively. There are no costs to respondents except for their time to complete the requisition process.

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Business (limited permit)	5	2	30/60	5
Businesses (extended permit)	1	3	10/60	.5
Organizations (limited permit)	3	2	30/60	3
Organizations (extended permit)	12	2	10/60	4
Total				12.5

Dated: January 21, 2005.

Betsey Dunaway,

Acting Reports Clearance Officer, Office of the Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. 05–1589 Filed 1–27–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–50 and CMS–10054]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medical Records Review under Inpatient PPS and Supporting Regulations in 42 CFR, Sections 412.40–412.52; *Form No:* CMS–R–50 (OMB# 0938–0359); *Use:* The Quality Improvement Organizations (QIOs) are authorized to conduct medical review activities under the Prospective Payment System (PPS). In order to conduct these review activities, CMS depends upon hospitals to make available specific records regarding care provided to Medicare beneficiaries. The Clinical Data Abstraction Centers (CDACs) obtain copies of medical records from which they abstract data to analyze patterns of care and outcomes for heart failure/myocardial infarction, pneumonia, diabetes and surgical infection; *Frequency:* When records are reviewed; *Affected Public:* Business or other for-profit, Not-for-profit institutions, Federal Government, and State, Local or Tribal Government; *Number of Respondents:* 6,100; *Total Annual Responses:* 397,500; *Total Annual Hours:* 11,925.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Recognition of Payment for New Technology Services for Ambulatory Payment Classifications (APCs) Under the Outpatient Prospective Payment System and Supporting Regulations in 42 CFR, Sections 413.65 and 419.42; *Form Number:* CMS–10054 (OMB# 0938–0860); *Use:* Information is necessary to determine eligibility of medical devices for establishment of additional device categories for payment under transitional pass-through payment

provisions as required by section 1833(t)(6) of the Social Security Act. Transitional pass-through payments have been made to hospitals for certain drugs, biologicals, and medical devices; *Frequency:* On occasion; *Affected Public:* Business or other for-profit; *Number of Respondents:* 15; *Total Annual Responses:* 15; *Total Annual Hours:* 180.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/regulations/pra/,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Christopher Martin, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: January 19, 2005.

John P. Burke, III,

CMS Paperwork Reduction Act Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group.

[FR Doc. 05–1481 Filed 1–27–05; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–1771, CMS–R–71 and CMS–222]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Attending Physicians Statement and Documentation of Medicare Emergency and Supporting Regulations in 42 CFR, Section 424.103; *Use:* Payment may be made for certain part A inpatient hospital services and part B outpatient provided in a nonparticipating U.S. or foreign hospital when services are necessary to prevent the death or serious impairment of the health of the individual. This collection is used to document the attending physician's statement that the hospitalization was required due to an emergency and give clinical support for the claim.; *Form Number:* CMS–1771 (OMB#: 0938–0023); *Frequency:* On Occasion; *Affected Public:* Business or other for-profit; *Number of Respondents:* 200; *Total Annual Responses:* 200; *Total Annual Hours:* 50.

2. *Type of Information Collection Request:* Extension of a Currently Approved Collection; *Title of Information Collection:* Quality Improvement Organization (QIO) Assumption of Responsibilities and Supporting Regulations in 42 CFR Sections 412.44, 412.46, 431.630, 476.71, 476.73, 476.74, 476.78; *Form No.:* CMS–R–71 (OMB# 0938–0445); *Use:* This collection describes the review functions to be performed by the QIO. It outlines relationships among QIOs, providers, practitioners, beneficiaries, intermediaries, and carriers. QIOs assure that covered care provided to Medicare patients is reasonable, medically necessary, appropriate, and of a quality that meets professionally recognized standards of care, and that inpatient services could not be more appropriately provided on an outpatient basis or in a different type of facility.; *Frequency:* As Needed; *Affected Public:* Business or other for-profit; *Number of Respondents:* 6,036; *Total Annual Responses:* 6,036; Total Annual Hours: 81,818.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Independent Rural Health Center/Freestanding Federally Qualified Health Center Cost Report and Supporting Regulations in 42 CFR, Section 413.20 and 413.24; *Form No.:* CMS–222 (OMB#0938–0107); *Use:* The independent rural health clinic/freestanding federally qualified health center cost report is the cost report to be used by the mentioned clinics/centers to submit annual information. This information is used to achieve a settlement of costs for health care services rendered to Medicare beneficiaries. *Frequency:* Annually; *Affected Public:* Not-for-Profit institutions, Business or other for-profit, and State, local or tribal government; *Number of Respondents:* 3,000; *Total Annual Responses:* 3,000; *Total Annual Hours Requested:* 150,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS'' Web site address at *http://www.cms.hhs.gov/regulations/pra/,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Reduction Act Reports Clearance Officer designated at the address below: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Melissa Musotto, Room C5–14–03, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: January 19, 2005.

John P. Burke, III,

CMS Paperwork Reduction Act Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group.

[FR Doc. 05–1482 Filed 1–27–05; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–10132]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

Agency: Center for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid services (CMS), Department of Health

and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. This is necessary to ensure compliance with an initiative of section 641 of the Medicare Modernization Act of 2003. We cannot reasonably comply with the normal clearance procedures because the normal procedures are likely to cause a statutory deadline to be missed.

Section 641 of the MMA provides for the implementation of a demonstration in which Medicare would pay for selected self-administered drugs or biologicals that replace currently-covered Part B drugs. Apart from under this demonstration, Medicare outpatient drug coverage is limited to drugs that are provided incident to a physician's service or are oral cancer drugs with the same chemical composition as physician-administered agents. This demonstration project offers temporary, early coverage for selected prescription drugs before the new prescription drug benefit (Medicare Part D) begins in January 2006. The evaluation is required to address the effects of the program on beneficiary access, outcomes, and costs. Survey results are necessary for CMS to complete its mandated Report to Congress. The survey also represents a unique opportunity to inform CMS on the magnitude of effects on access and health status that result from expanding coverage of a select set of drugs to a well-defined group or seriously ill beneficiaries, and to provide CMS information on how enrollees learned about the demonstration.

CMS is requesting OMB review and approval of this collection by March 1, 2005, with a 180-day approval period. Written comments and recommendations will be considered from the public if received by the individuals designated below by January 31, 2005.

Type of Information Collection Request: New collection; *Title of Information Collection:* Beneficiary Survey on the Medicare Replacement Drug Demonstration; *Use:* The statute authorizing the Medicare Replacement Drug Demonstration mandates a report to Congress on the effects of the demonstration, to be submitted not later than July 2006. This report is to include an evaluation of patient access to care and patient outcomes under the project. The Medicare Replacement Drug Demonstration Evaluation is necessary to collect information on the demonstration's effects on access and outcomes for this report; *Form Number:* CMS–10132 (OMB#: 0938–NEW); *Frequency:* Other—once per beneficiary; *Affected Public:* Individuals or Households; *Number of Respondents:* 3200; *Total Annual Responses:* 3200; *Total Annual Hours:* 800. We have submitted a copy of this notice to OMB for its review of these information collections. A notice will be published in the **Federal Register** when approval is obtained.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/regulations/pra* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below by January 31, 2005:

Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Room C5–13–27, 7500 Security Boulevard, Baltimore, MD 21244–1850, Fax Number: (410) 786–0262, Attn: William N. Parham, III, CMS–10056.

and,

OMB Human Resources and Housing Branch, Attention: Christopher Martin, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: January 13, 2005.

Dawn Willinghan,

Acting, CMS Paperwork Reduction Act Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group.

[FR Doc. 05–1555 Filed 1–27–05; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4079–N]

Medicare Program: Re-Chartering of the Advisory Panel on Medicare Education (APME) and Notice of the APME Meeting—February 24, 2005

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the renewal of the charter of the Advisory Panel on Medicare Education (the Panel). The Panel advises and makes recommendations to the Secretary of the Department of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services on opportunities to enhance the effectiveness of consumer education strategies concerning the Medicare program. The charter renewal was signed by the Secretary on January 14, 2005. The charter will terminate on January 14, 2007, unless renewed by the Secretary.

In accordance with the Federal Advisory Committee Act, 5 U.S.C. Appendix 2, section 10(a) (Pub. L. 92–463), this notice also announces a meeting of the Panel on February 24, 2005. This meeting is open to the public.

DATES: The meeting is scheduled for February 24, 2005 from 9 a.m. to 4 p.m., e.s.t.

Deadline for Presentations and Comments: February 17, 2005, 12 noon, e.s.t.

ADDRESSES: The meeting will be held at the Loews L'Enfant Plaza Hotel, 480 L'Enfant Plaza, Washington, DC 20024, (202) 484–1000.

FOR FURTHER INFORMATION CONTACT: Lynne Johnson, Health Insurance Specialist, Division of Partnership Development, Center for Beneficiary

Choices, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail stop S2–23–05, Baltimore, MD 21244–1850, (410) 786–0090. Please refer to the CMS Advisory Committees' Information Line (1–877–449–5659 toll free)/(410–786–9379 local) or the Internet (*http://www.cms.hhs.gov/faca/apme/default.asp*) for additional information and updates on committee activities, or contact Ms. Johnson via e-mail at ljohnson3@cms.hhs.gov.

Press inquiries are handled through the CMS Press Office at (202) 690–6145.

SUPPLEMENTARY INFORMATION: Section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended, grants to the Secretary of the Department of Health and Human Services (the Secretary) the authority to establish an advisory panel if the Secretary finds the panel necessary and in the public interest. The Secretary signed the charter establishing the Advisory Panel on Medicare Education (the Panel) on January 21, 1999 and approved the renewal of the charter on January 14, 2005. The Panel advises and makes recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on opportunities to enhance the effectiveness of consumer education strategies concerning the Medicare program.

The goals of the Panel are as follows:

- To develop and implement a national Medicare education program that describes the options for selecting a health plan under Medicare.
- To enhance the Federal government's effectiveness in informing the Medicare consumer, including the appropriate use of public-private partnerships.
- To expand outreach to vulnerable and underserved communities, including racial and ethnic minorities, in the context of a national Medicare education program.
- To assemble an information base of best practices for helping consumers evaluate health plan options and build a community infrastructure for information, counseling, and assistance.

The current members of the Panel are: Dr. Drew E. Altman, President and Chief Executive Officer, Henry J. Kaiser Family Foundation; James L. Bildner, Chairman and Chief Executive Officer, New Horizons Partners, LLC; Dr. Jane Delgado, Chief Executive Officer, National Alliance For Hispanic Health; Clayton Fong, President and Chief Executive Officer, National Asian Pacific Center on Aging; Thomas Hall, Chairman and Chief Executive Officer, Cardio-Kinetics, Inc.; Bobby Jindal; David Knutson, Director, Health System Studies, Park Nicollet Institute for Research and Education; Dr. David Lansky, Director, Health Program, Markle Foundation; Donald J. Lott, Executive Director, Indian Family Health Clinic; Dr. Frank I. Luntz, President and Chief Executive Officer, Luntz Research Companies; Dr. Daniel Lyons, Senior Vice President, Government Programs, Independence Blue Cross; Katherine Metzger, Director, Medicare and Medicaid Programs, Fallon Community Health Plan; Dr. Keith Mueller, Professor and Section Head, Health Services Research and Rural Health Policy, University of Nebraska; David Null, Financial Advisor, Merrill Lynch; Lee Partridge, Senior Health Policy Advisor, National Partnership for Women and Families; Dr. Marlon Priest, Professor of Emergency Medicine, University of Alabama at Birmingham; Susan O. Raetzman, Associate Director, Public Policy Institute, AARP; Catherine Valenti, Chairperson and Chief Executive Officer, Caring Voice Coalition; and Grant Wedner, Senior Director, New Services Department, WebMD.

The agenda for the February 24, 2005 meeting will include the following:

- Recap of the previous (November 30, 2004) meeting.
- Centers for Medicare & Medicaid Services update.
- Medicare Modernization Act: education and outreach strategies.
- Public comment.
- Listening session with CMS leadership.
- Next steps.

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic should submit a written copy of the oral presentation to Lynne Johnson, Health Insurance Specialist, Division of Partnership Development, Center for Beneficiary Choices, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail stop S2–23–05, Baltimore, MD 21244–1850 or by e-mail at *ljohnson3@cms.hhs.gov* no later than 12 noon, e.s.t., February 17, 2005. The number of oral presentations may be limited by the time available. Individuals not wishing to make a presentation may submit written comments to Ms. Johnson by 12 noon, e.s.t., February 17, 2005. The meeting is open to the public, but attendance is limited to the space available.

Special Accommodation: Individuals requiring sign language interpretation or other special accommodations should contact Ms. Johnson at least 15 days before the meeting.

Authority: Sec. 222 of the Public Health Service Act (42 U.S.C. 217a) and sec. 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, sec. 10(a) and 41 CFR 102–3).

(Catalog of Federal Domestic Assistance Program No. 93.733, Medicare—Hospital Insurance Program; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 19, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–1504 Filed 1–27–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–5037–N]

Medicare Program; Demonstration of Coverage of Chiropractic Services Under Medicare

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the implementation of a demonstration mandated under Section 651 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), which will expand coverage of chiropractic services under Medicare beyond the current coverage for manipulation to correct a neuromusculoskeletal condition. Chiropractors will be permitted to bill Medicare for diagnostic and other services that a chiropractor is legally authorized to perform by the State or jurisdiction in which such treatment is provided. The demonstration will be conducted in four sites, two urban and two rural; one site in each area type must be a health professional shortage area (HPSA).

Any chiropractor that provides services in these geographic areas will be able to participate in the demonstration. Any beneficiary enrolled under Medicare Part B, and served by chiropractors practicing in these sites would be eligible to receive services. Physician approval would not be required for these services. The statute requires that the demonstration be budget neutral. We anticipate that the demonstration will begin in April 2005 and operate for two years.

ADDRESSES:

1. *By Mail:* Written inquiries regarding this demonstration must be submitted by mail to the following address:

Centers for Medicare & Medicaid Services, Attn: Sidney Trieger, Division of Health Promotion and Disease Prevention Demonstrations, Office of Research, Development, and Information, Centers for Medicare & Medicaid Services, S3–02–01, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Please allow sufficient time for mailed information to be received in a timely manner in the event of delivery delays.

2. *E-mail:* Inquiries may be sent to the following e-mail address: *MMA_section_651@cms.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Julie Jones, (410) 786–3039 or Sidney Trieger, (410) 786–6613.

SUPPLEMENTARY INFORMATION:

I. Background

Section 651 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173) provides for a two-year demonstration to evaluate the feasibility and advisability of covering chiropractic services under Medicare. These services extend beyond the current coverage for manipulation to correct neuromusculoskeletal conditions typical among eligible beneficiaries, and would cover diagnostic and other services that a chiropractor is legally authorized to perform by the State or jurisdiction in which the treatment is provided. Physician approval would not be required for these services. The demonstration must be budget neutral and will be conducted in four sites, two rural and two urban; one site of each area type must be a health professional shortage area (HPSA).

Current Medicare coverage for chiropractic care is limited to manual manipulation of the spine to correct a subluxation, which chiropractors define as a malfunction of the spine. The three currently covered CPT codes are 98940 (manipulative treatment, 1–2 regions of the spine), 98941 (manipulative treatment, 3–4 regions of the spine), and 98942 (manipulative treatment, 5 regions of the spine).

Treatment must be provided for an active subluxation and not for prevention or maintenance. Treatment of the subluxation must be related to a neuromusculoskeletal condition where there is a reasonable expectation of recovery or functional improvement. Chiropractors are required to document the patient's complaint and establish a treatment plan, which includes the expected duration and frequency of treatment, specific goals and measures of effectiveness. This information must be maintained in the medical record and made available to Medicare upon request. Patients do not need a medical physician referral for treatment by a chiropractor under fee-for-service; some Medicare Advantage (MA) plans may require an enrollee to obtain a referral before seeing a chiropractor. In addition, some MA plans do not have chiropractors in their networks and allow osteopaths to provide manipulative services.

II. Provisions of the Notice

A. Covered Services

To determine which services will be covered, we conducted a literature review of the evidence of the effectiveness of chiropractor services. We held discussions with the American Chiropractic Association (ACA) and also reviewed the current coverage of chiropractor services with the Department of Defense and the Veterans Administration. In addition, we convened an Open Door Forum in November 2004 to invite comments on our proposed design for the demonstration. Based on these discussions, the evidence for effectiveness of chiropractic care, and current Medicare policy, the following guidelines for the demonstration were developed:

1. Services must be related to active treatment, not maintenance or prevention. This follows current Medicare coverage for similar services, such as physical therapy. Medicare does not authorize payment for maintenance therapies for other providers. We will require that all claims under the demonstration will have the active therapy (AT) modifier.

2. The demonstration will expand the services chiropractors are allowed to provide in the demonstration only to treatment of neuromusculoskeletal conditions, but not to other conditions. We have found no literature that provides conclusive evidence that chiropractic services are effective for treatment of other diagnoses.

3. Under the demonstration chiropractors can provide plain x-rays, electromyography (EMG) tests and nerve conduction studies; order magnetic resonance imaging (MRI) scans and computed tomography (CT) scans; as well as order or provide laboratory tests (where the applicable State practice act permits chiropractors to provide these services). These diagnostic services are related to the diagnosis and treatment of neuromusculoskeletal conditions. No limits will be imposed on chiropractors for providing diagnostic services, unless limits exist for other providers delivering these services.

4. The demonstration will cover CPT code 98943 for extraspinal manipulation, as it is a recognized procedure for treating neuromusculoskeletal conditions. It will also expand coverage to include other services chiropractors are legally allowed to provide and Medicare currently covers. These procedures include electrotherapy, ultrasound, transcutaneous electrical nerve stimulation (TENS) therapy, and other services that are medically necessary for the treatment of neuromusculoskeletal conditions. Chiropractors delivering these services will be subject to the same payment policies as other Medicare clinicians currently delivering these services. These requirements can be found in the Medicare Benefit Policy Manual 100–2 in Chapter 15, Sections 220 and 230 and the Medicare Claims Processing Manual 100–4 in Chapter 4, Section 20 and other manual sections. For example, physical and occupational therapy services must be identified through the use of modifiers GP and GO respectively. Chiropractors will also be allowed to make referrals for these therapy services.

5. Chiropractors would also be reimbursed for evaluation and management (E&M) services delivered for neuromusculoskeletal conditions.

Under the demonstration, chiropractors would be allowed to bill Medicare for treatment in addition to an E&M visit on the same day the first time they assess a patient, and thereafter only when they assess a patient for a new, separate problem not currently being treated. The current E&M CPT codes will apply.

We will require chiropractors to submit claims for demonstration services separately from claims for currently covered services (CPT codes 98940, 98941, and 98942). Chiropractors will have to add demonstration code 45 to all demonstration claims in order to be reimbursed for demonstration services.

B. Managed Care Plans

The legislation requires that the same demonstration benefits be offered under MA plans as for Medicare fee for service beneficiaries. Because participation of managed care plans is voluntary, we cannot require plans to participate in the demonstration. We therefore plan to approach MA plans in the demonstration site areas to determine if they would offer demonstration services to beneficiaries, but we will not change the MA plan rates since the demonstration is required to be budget neutral.

C. Payment Rates

The payment rates for demonstration services will be the same as under the physician fee schedule.

D. Budget Neutrality

The statute requires the Secretary to ensure that the aggregate payments made under the Medicare program do not exceed the amount that would have been paid under the Medicare program in the absence of this demonstration.

Ensuring budget neutrality requires that the Secretary develop a strategy for recouping funds should the demonstration result in costs higher than would occur in the absence of the demonstration. We will first determine over the two-year demonstration whether the demonstration was budget neutral. If the demonstration is not budget neutral, we plan to meet the legislative requirements by making adjustments in the national chiropractor fee schedule to recover the costs of the demonstration in excess of the amount estimated to yield budget neutrality. We will assess budget neutrality by determining the change in costs based on a pre-post comparison of costs and the rate of change for specific diagnoses that are treated by chiropractors and physicians in the demonstration sites and control sites. We will not limit our analysis to reviewing only chiropractor claims because the costs of the expanded chiropractor services may have an impact on other Medicare costs.

A CMS evaluation contractor will conduct the analysis of claims and budget neutrality. Since it will take approximately two years to complete the claims analysis, we anticipate that any necessary reduction will be made in the 2010 and 2011 fee schedules. If we determine that the adjustment for budget neutrality would be greater than two percent of the chiropractor fee schedule, we will implement the adjustment over a two-year period. However, if the adjustment is less than two percent of the chiropractor fee schedule, we will implement the adjustment over a one-year period. We will include the detailed analysis of budget neutrality and the proposed offset in the 2009 **Federal Register** publication of the physician fee schedule.

We invite comments regarding the appropriate methodology for determining budget neutrality. Written materials may be submitted by mail or e-mail to the addresses listed in the **ADDRESSES** section of this notice.

E. Site Selection

The statute requires that this demonstration be conducted in four sites—two rural and two urban; one site in each type of area must be a health professional shortage area (HPSA). We have selected:

- 26 northern counties in Illinois which includes Cook, Dekalb, DuPage, Grundy, Kane, Kendall, McHenry, Will, Boone, Bureau, Carroll, Henry, JoDaviess, Kankakee, Lake, LaSalle, Lee, Marshall, Mercer, Ogle, Putnam, Rock Island, Stark, Stephenson, Whiteside, and Winnebago, and Scott county in Iowa (urban);
- 17 central HPSA counties in Richmond, Charlottesville, Lynchburg, and Danville MSAs in Virginia (urban HPSA)—the Virginia counties include Pittsylvania, Campbell, Appomattox, Nelson, Buckingham, Fluvanna, Louisa, Caroline, Hanover, New Kent, Henrico, Richmond City, Goochland, Cumberland, Powhatan, Amelia and Danville City;
- New Mexico (rural HPSA); and
- Maine (rural).

We first grouped States by Medicare carriers, because we determined it was important that control and experimental sites should have the same carriers (since some carriers impose limits on chiropractor claims they approve). We then determined appropriate sites based on the following criteria:

- Exclude States with restrictive practice regulations.
- Exclude States that will not have transitioned to the MCS system in time for the demonstration.
- Exclude States that are ranked in the top or bottom 5 values for two or more of the following six statistics:

—Medicare per capita claims costs
—Medicare per capita chiropractic costs
—Per user (patient) chiropractic costs based on carrier data
—Chiropractic service users as a percentage of Part B beneficiaries
—Chiropractors per 10,000 State population
—Chiropractors per 1,000 Part B beneficiaries

- Exclude States among those remaining that are served by a unique carrier and, thus, would lack a potential comparison site.
- Each carrier group was assessed to determine its ability to support treatment and comparison groups for one or more types of sites.
- Data was then used to estimate the number of beneficiaries residing in Urban/Rural and HPSA/non HPSA areas and determine which of the remaining States could support a demonstration site or sites.

Few States had enough beneficiaries residing in HPSAs to be considered for one of the HPSA demonstration sites.

III. Collection of Information Requirements

This document does not impose information collection and record-keeping requirements. Consequently, it does not need to be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

Authority: Section 651 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (Pub. L. 108–173).

(Catalog of Federal Domestic Assistance Program No. 93.778 and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 17, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–1505 Filed 1–27–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–5033–N2]

Medicare Program; Meeting of the Advisory Board on the Demonstration of a Bundled Case-Mix Adjusted Payment System for End-Stage Renal Disease Services

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the first public meeting of the Advisory Board on the Demonstration of a Bundled Case-Mix Adjusted Payment System for End-Stage Renal Disease (ESRD) Services. Notice of this meeting is required by the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). The Advisory Board will provide advice and recommendations with respect to the establishment and operation of the demonstration mandated by section 623(e) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. This notice also announces the appointment of eleven individuals to serve as members of the Advisory Board, including one individual to serve as co-chairperson, and one additional co-chairperson, who is employed by CMS.

DATES: The meeting is on February 16, 2005 from 9 a.m. to 5 p.m., eastern standard time.

Special Accomodations: Persons attending the meeting, who are hearing

or visually impaired, or have a condition that requires special assistance or accommodations, are asked to notify Pamela Kelly by February 8, 2005 by e-mail at *ESRDAdvisoryBoard@cms.hhs.gov* or by telephone at (410) 786–2461.

ADDRESSES: The meeting will be held at the Hyatt Regency, 300 Light Street, Baltimore, MD 21202.

Attendance is limited to the space available, so seating will be on a first come, first served basis.

Web site: Up-to-date information on this meeting is located at *http://www.cms.hhs.gov/faca/esrd.*

Hotline: Up-to-date information on this meeting is located on the CMS Advisory Committee Hotline at 1 (877) 449–5659 (toll free) or in the Baltimore area at (410) 786–9379.

FOR FURTHER INFORMATION CONTACT: Pamela Kelly by e-mail at *ESRDAdvisoryBoard@cms.hhs.gov* or telephone at (410) 786–2461. The CMS Press Office at (202) 690–6145.

SUPPLEMENTARY INFORMATION: On June 2, 2004, we published a **Federal Register** notice requesting nominations for individuals to serve on the Advisory Board on the Demonstration of a Bundled Case-Mix Adjusted Payment System for End-Stage Renal Disease (ESRD) Services. The June 2, 2004 notice also announced the establishment of the Advisory Board and the signing by the Secretary on May 11, 2004 of the charter establishing the Advisory Board. This notice announces the first public meeting of this Advisory Board and the appointment of eleven individuals to serve as members of the Advisory Board on the Demonstration of a Bundled Case-Mix Adjusted Payment System for ESRD Services, including one individual to serve as co-chairperson, and one additional co-chairperson, who is employed by CMS.

I. Members of the Advisory Board

The Advisory Board on the Demonstration of a Bundled Case-Mix Adjusted Payment System for ESRD Services members are: Dr. Robert Rubin (Co-Chairperson), Clinical Professor of Medicine at Georgetown University School of Medicine; Dr. John Burkart, Professor of Internal Medicine/Nephrology at Wake Forest University; Tom Cantor, Owner of Scantibodies Laboratory; Paula Cuellar, RN, Dialysis Care Center Director for the University of Chicago Hospitals; Paul Eggers, Program Director for Kidney and Urology Epidemiology, National Institute for Diabetes and Digestive and Kidney Diseases, National Institute of Health; Bonnie Greenspan, Health Care Consultant; Dr. Michael J. Lazarus, Chief Medical Officer and Senior Vice President of Clinical Quality, Fresenius Medical Care NA; Dr. William Owen, Adjunct Professor of Medicine, Duke University School of Medicine, and Senior Scholar, Fuqua School of Business; Nancy Ray, Research Director for the Medicare Payment Advisory Commission; Kris Robinson, Executive Director of the American Association of Kidney Patients; and Dr. Jay Wish, President of ESRD Networks 9 and 10. The Advisory Board will also be co-chaired by Brady Augustine, a CMS employee.

II. Topics of the Advisory Board Meeting

The Advisory Board on the Demonstration of a Bundled Case-Mix Adjusted Payment System for ESRD Services will study and make recommendations on the following issues:

- The drugs, biologicals, and clinical laboratory tests to be bundled into the demonstration payment rates.
- The method and approach to be used for the patient characteristics to be included in the fully case-mix adjusted demonstration payment system.
- The manner in which payment for bundled services provided by non-demonstration providers should be handled for beneficiaries participating in the demonstration.
- The feasibility of providing financial incentives and penalties to organizations operating under the demonstration that meet or fail to meet applicable quality standards.
- The specific quality standards to be used.
- The feasibility of using disease management techniques to improve quality and patient satisfaction and reduce costs of care for the beneficiaries participating in the demonstration.
- The selection criteria for demonstration organizations.

III. Procedure and Agenda of the Advisory Board Meeting

This meeting is open to the public. First, the appointees will be sworn in by a Federal Official. Each Advisory Board member will then be given the opportunity to make a self-introduction. The Advisory Board will hear background presentations from CMS. The Advisory Board will then deliberate openly on the general topic and will make recommendations on specific topics for future meetings. The Advisory Board will also allow a 30-minute open public session. Interested parties may speak or ask questions during the public comment period. Comments may be limited by the time available. Written questions should be submitted by February 8, 2005 to *ESRDAdvisoryBoard@cms.hhs,gov.* Parties may also submit written comments following the meeting to the contact listed under the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Authority: 5 U.S.C. App. 2, section 10(a).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 26, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–1743 Filed 1–27–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3150–N]

Medicare Program; Meeting of the Medicare Coverage Advisory Committee—March 29, 2005

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces a public meeting of the Medicare Coverage Advisory Committee (MCAC). The Committee provides advice and recommendations about whether scientific evidence is adequate to determine whether certain medical items and services are reasonable and necessary under the Medicare statute. This meeting concerns usual care of chronic wounds. Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)).

DATES: The public meeting will be held on Tuesday, March 29, 2005 from 7:30 a.m. until 4:30 p.m. e.s.t.

Deadline for Presentations and Comments: Written comments and presentations must be received by February 3, 2005, 5 p.m., e.s.t.

Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to notify the Executive Secretary by February 3, 2005 (*see* **FOR FURTHER INFORMATION CONTACT**).

ADDRESSES: The meeting will be held in the auditorium at the Centers for

Medicare & Medicaid Services, 7500 Security Blvd, Baltimore, MD 21244.

Presentations and Comments: Interested persons may present data, information, or views orally or in writing on issues pending before the Committee. Please submit written comments to Kimberly Long, by e-mail at *klong@cms.hhs.gov* or by mail to the Executive Secretary for MCAC, Coverage and Analysis Group, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C1–09–06, Baltimore, MD 21244.

Web site: You may access up-to-date information on this meeting at *www.cms.hhs.gov/mcac/default.asp#meetings.*

Hotline: You may access up-to-date information on this meeting on the CMS Advisory Committee Information Hotline, 1–877–449–5659 (toll free) or in the Baltimore area (410) 786–9379.

FOR FURTHER INFORMATION CONTACT: Kimberly Long, Executive Secretary, by telephone at 410–786–5702 or by e-mail at *klong@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION: On December 14, 1998, we published a notice in the **Federal Register** (63 FR 68780) to describe the Medicare Coverage Advisory Committee (MCAC), which provides advice and recommendations to us about clinical issues. This notice announces a public meeting of the Committee.

Meeting Topic: The Committee will discuss evidence, hear presentations and public comment and make recommendations regarding the standard treatment of chronic wounds. Discussion will address such usual care treatment as cleansing, debridement, dressings, compression, off-loading and antibiotics. Members will also review factors necessary for quality clinical trials that address other wound healing technologies. The Committee will not discuss other treatments that may be used when wounds do not heal.

Background information about this topic, including panel materials, is available on the Internet at *http://www.cms.hhs.gov/coverage/.*

Procedure: This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. The Committee may limit the number and duration of oral presentations to the time available. If you wish to make formal presentations, you must notify the Executive Secretary named in the **FOR FURTHER INFORMATION CONTACT** section and submit the following by the *Deadline for Presentations and Comments* date listed in the **DATES** section of this notice: a brief statement of the general nature of the evidence or arguments you wish to present, and the names and addresses of proposed participants. A written copy of your presentation must be provided to each Committee member before offering your public comments. Your presentation must address the questions asked by CMS to the Committee. The questions will be available on our Web site at *http://www.cms.hhs.gov/mcac/default.asp* meetings. If the specific questions are not addressed, your presentation will not be accepted. We request that you declare at the meeting whether or not you have any financial involvement with manufacturers of any items or services being discussed (or with their competitors).

After the public and CMS presentations, the Committee will deliberate openly on the topic. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topic. At the conclusion of the day, the members will vote and the Committee will make its recommendation.

Registration Instructions

The Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register by contacting Maria Ellis at 410–786–0309, mailing address: Coverage and Analysis Group, OCSQ; Centers for Medicare & Medicaid Services; 7500 Security Blvd, Mailstop: C1–09–06; Baltimore, MD 21244, or by e-mail at *Mellis@cms.hhs.gov.* Please provide your name, address, organization, telephone and fax number, and e-mail address.

You will receive a registration confirmation with instructions for your arrival at the CMS complex. You will be notified if the seating capacity has been reached.

Because the meeting is located on Federal property, for security reasons, any persons wishing to attend this meeting must register by close of business on January 17, 2005. In order to gain access to the building and grounds, participants must show to the Federal Protective Service or guard service personnel, government-issued photo identification and a copy of their registration confirmation. Individuals who have not registered in advance will not be allowed to enter the building to attend the meeting.

Authority: 5 U.S.C. App. 2, section 10(a).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 21, 2005.

Sean R. Tunis,

Director, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services.

[FR Doc. 05–1503 Filed 1–27–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0010]

High Chemical Co. et al.; Proposal to Withdraw Approval of 13 New Drug Applications; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for a hearing on the agency's proposal to withdraw approval of 13 new drug applications (NDAs) from multiple sponsors. The basis for the proposal is that the sponsors have repeatedly failed to file required annual reports for these applications.

DATES: Submit written requests for a hearing by February 28, 2005; submit data and information in support of the hearing request by March 29, 2005.

ADDRESSES: Requests for a hearing, supporting data, and other comments are to be identified with Docket No. 2005N–0010 and submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The holders of approved applications to market new drugs for human use are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 314.81 (21 CFR 314.81). The holders of the approved applications listed in the following table have failed to submit the required annual reports and have not responded to the agency's request by certified mail for submission of the reports.

Application No.	Drug	Applicant
NDA 0–763	Sterile Solution Procaine Injection 2% (Procaine Hydrochloride (HCl))	High Chemical Co., 1760 N. Howard St., Philadelphia, PA 19122
NDA 2–959	Nicotinic Acid (Niacin) Tablets	The Blue Line Chemical Co., 302 South Broadway, St. Louis, MO 63102
NDA 4–236	Sherman (thiamine HCl) Elixir	Do.
NDA 4–368	Ascorbic Acid Tablets	Do.
NDA 5–159	D.S.D. (diethylstilbestrol dipropionate)	Do.
NDA 9–452	Multifuge (piperazine citrate) Syrup	Do.
NDA 10–055	Fire Gard Three-Alarm Burn Relief (Methylcellulose)	Gard Products, Inc., 2560 Tara Lane, Brunswick, GA 31520
NDA 10–337	Fling Antiperspirant Foot Powder	Bauer & Black, A Division of The Kendall Co., One Federal St., Boston, MA 02110
NDA 10–541	BY–NA–MID (Butylphenamide or B and Zinc Oxide or Stearate) Tincture, Ointment, Lotion, and Powder	Miles Inc., Cutter Biological, P.O. Box 1986, Berkeley, CA 94701
NDA 10–823	BIKE Foot and Body Powder	Bauer & Black, A Division of The Kendall Co.
NDA 10–824	BIKE Anti-Fungal Aerosol Spray	Do.
NDA 11–233	TKO with Entrin Roll-On Liquid	Modern-Labs, Inc., Maple Rd., Gambrills, MD 21504
NDA 19–432	Spectamine (Iofetamine Hydrochloride I–123) Injection	IMP Inc., 8050 El Rio, Houston, TX 77054

Therefore, notice is given to the holders of the approved applications listed in the table and to all other interested persons that the Director of the Center for Drug Evaluation and Research proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) withdrawing approval of the applications and all amendments and supplements thereto on the ground that the applicants have failed to submit reports required under § 314.81.

In accordance with section 505 of the act and 21 CFR part 314, the applicants are hereby provided an opportunity for a hearing to show why the applications listed previously should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by these applications.

An applicant who decides to seek a hearing shall file: (1) A written notice of participation and request for a hearing (see **DATES**) and (2) the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing (see **DATES**). Any other interested person may also submit comments on this document. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation and request for a hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 and 21 CFR part 12.

The failure of an applicant to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that applicant not to avail itself of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the applications and the drug products may not thereafter lawfully be marketed, and FDA will begin appropriate regulatory action to remove the products from the market. Any new drug product marketed without an approved NDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. Reports submitted to remedy the deficiencies must be complete in all respects in accordance with § 314.81. If the submission is not complete or if a request for a hearing is not made in the required format or with the required reports, the Commissioner of Food and Drugs (the Commissioner) will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing must be filed in four copies. Except for data and information prohibited from public disclosure under section 301 of the act (21 U.S.C. 331(j)) or 18 U.S.C. 1905, the submissions may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the act (section 505 (21 U.S.C. 355)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner.

Dated: January 19, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–1656 Filed 1–27–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Antiviral Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Antiviral Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 11, 2005, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A and B, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Anuja Patel, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *patela@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512531. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug applications 21–797 and 21–798, entecavir tablets and entecavir oral solution, respectively, Bristol-Myers Squibb Co., proposed for the treatment of patients with chronic hepatitis B infection (HBV).

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 25, 2005. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 25, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Angie Whitacre at 301–827–7001, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 23, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–1578 Filed 1–27–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Access to Recovery (ATR) Program—New

In preparation for implementing Performance Partnership Grants, SAMHSA has developed a set of performance outcome measures for substance abuse treatment that cover seven domains. The domains are: Abstinence from drug use and alcohol abuse, or decreased mental illness symptomatology; increased or retained employment and school enrollment; decreased involvement with the criminal justice system; increased stability in family and living conditions; increased access to services; increased retention in services for substance abuse treatment or decreased utilization of psychiatric inpatient beds for mental health treatment; and increased social connectedness to family, friends, co-workers and classmates.

SAMHSA's Center for Substance Abuse Treatment (CSAT), is responsible for implementing the new Access to Recovery (ATR) grant program. States funded in the ATR program will use these outcome measures to meet the reporting requirements of the Government Performance and Results Act (GPRA) by quantifying the effects and accomplishments of the funded programs. The ATR Program is part of a Presidential initiative to: (1) Provide client choice among substance abuse clinical treatment and recovery support service providers, (2) expand access to a comprehensive array of clinical treatment and recovery support options (including faith-based programmatic options), and (3) increase substance abuse treatment capacity. Monitoring outcomes, tracking costs, and preventing waste, fraud and abuse to ensure accountability and effectiveness in the use of Federal funds are also important elements of the ATR program. Grantees, as a contingency of their award, are responsible for collecting data from their clients at intake, discharge, at 30 days after intake, and every two months during an episode of care. An episode of care is defined as a client's entry to and exit from the ATR.

The following tables summarize the annual response burden for the ATR activities using the performance outcome measures.

Data collection point	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden (proportion of added burden)*
Client Interviews:					
ATR Intake	42,095	1	42,095	0.33	7,640
Discharge/30 day interview**	42,095	1	42,095	0.33	13,891
3 months	28,625	1	28,625	0.33	9,446
5 months	22,732	1	22,732	0.33	7,502
7 months	18,101	1	18,101	0.33	5,973
9 months	15,155	1	15,155	0.33	5,001

Data collection point	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden (proportion of added burden)*
11 months	11,787	1	11,787	0.33	3,890
12 months***	7,999	1	7,999	0.33	2,640
Total	188,589		188,589		55,983
Record Management by Provider Staff:					
Sections A and G per client at each data collection point after intake	[1] 146,494	1	146,494	.16	23,439
Voucher information and transaction	42,095	1.5	63,143	.03	1,894
Provider staff total per client	188,589		209,637		25,333
Grantees (14 States and 1 Tribal Organization):					
Grantee extract and upload	15	4	60	.03	2
Total	377,193		398,226		81,318

*This estimate is an added burden proportion which is an adjustment reflecting the extent to which programs typically already collect the data items. The formula for calculating the proportion of added burden is: total number of items in the standard instrument, minus the number of core items currently included, divided by the total number of items in the standard instrument. Thus, 13,891 times .55 proportion of added burden = 7,640. This only applies to the intake interview.

**The ATR interview will be administered every 2 months beginning at 30 days. It is assumed that those who are discharged at 30 days or less will receive an intake and discharge interview only and are included in the number in the first two rows. The number of respondents who are still in treatment by month is based on experience with CSAT's GPRA services data.

***Based on experience with CSAT's GPRA services data, it is expected that few clients will still be in treatment longer than 12 months.

\1\ Clients.

Written comments and recommendations concerning the proposed information collection should be sent by February 28, 2005 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: (202) –395–6974.

Dated: January 24, 2005.

Anna Marsh,

Executive Officer, SAMHSA.

[FR Doc. 05–1583 Filed 1–27–05; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, U.S. Department of Homeland Security.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted the following information collection to the Office of Management and Budget (OMB) for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The submission describes the nature of the information collection, the categories of respondents, the estimated burden (*i.e.*, the time, effort and resources used by respondents to respond) and cost, and includes the actual data collection instruments FEMA will use.

Title: Emergency Management Institute Follow-up Evaluation Survey.

OMB Number: 1660–0044.

Abstract: FEMA Form 95–56 is a continuous self-assessment qualitative tool used to identify trainees' knowledge and skills gained through emergency management-related courses and the extent to which they have been beneficial and applicable in the conduct of their official positions. The information collected is primarily used to review course content and offerings for program planning and management purposes. Results are combined with other program metrics to document performance per GPRA mandates.

Affected Public: Individuals or households; State, local or tribal governments.

Number of Respondents: 2,300.

Estimated Time Per Respondent: FEMA Form 95–56, 15 minutes; Students participating in pilot testing for electronic version of FEMA Form 95–56, 30 minutes.

Estimated Total Annual Burden Hours: 600.

Frequency of Response: One per course.

COMMENTS: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs at OMB, Attention: Desk Officer for the Department of Homeland Security/FEMA, Docket Library, Room 10102, 725 17th Street, NW., Washington, DC 20503, or facsimile number (202) 395–7285. Comments must be submitted on or before February 28, 2005.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Muriel B. Anderson, Section Chief, Records Management, FEMA at 500 C Street, SW., Room 316, Washington, DC 20472, facsimile number (202) 646–3347, or e-mail address *FEMA-Information-Collections@dhs.gov.*

Dated: January 21, 2005.

Edward W. Kernan,

Branch Chief, Information Resources Management Branch, Information Technology Services Division.

[FR Doc. 05–1571 Filed 1–27–05; 8:45 am]

BILLING CODE 9110–17–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–3197–EM]

Indiana; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of Indiana (FEMA–3197–EM), dated January 11, 2005, and related determinations.

EFFECTIVE DATE: January 11, 2005.

ADDRESSES:

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated January 11, 2005, the President declared an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act), as follows:

I have determined that the impact in certain areas of the State of Indiana, resulting from the record/near record snow on December 21–23, 2004, is of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act). Therefore, I declare that such an emergency exists in the State of Indiana.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide emergency protective measures under the Public Assistance program to save lives, protect public health and safety, and property. Other forms of assistance under Title V of the Stafford Act may be added at a later date, as you deem appropriate. You are further authorized to provide this emergency assistance in the affected areas for a period of 48 hours. You may extend the period of assistance, as warranted. This assistance excludes regular time costs for sub-grantees' regular employees. Assistance under this emergency is authorized at 75 percent Federal funding for eligible costs.

Further, you are authorized to make changes to this declaration to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Under Secretary for Emergency Preparedness and Response, Department of Homeland Security, under Executive Order 12148, as amended, Ron Sherman, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

I do hereby determine the following areas of the State of Indiana to have been affected adversely by this declared emergency:

The counties of Bartholomew, Blackford, Brown, Clark, Crawford, Daviess, Dearborn, Decatur, Delaware, Dubois, Fayette, Floyd, Franklin, Gibson, Greene, Hamilton, Hancock, Harrison, Henry, Jackson, Jay, Jefferson, Jennings, Johnson, Knox, Lawrence, Madison, Marion, Martin, Monroe, Morgan, Ohio, Orange, Owen, Perry, Pike, Posey, Randolph, Ripley, Rush, Scott, Shelby, Sullivan, Switzerland, Union, Vanderburgh, Warrick, Washington, and Wayne for emergency protective measures (Category B) under the Public Assistance program for a period of 48 hours.

(Catalog of Federal Domestic Assistance No. 97.036, Disaster Assistance.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–1568 Filed 1–27–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–3197–EM]

Indiana; Amendment No. 1 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the State of Indiana (FEMA–3197–EM), dated January 11, 2005, and related determinations.

EFFECTIVE DATE: January 19, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: The notice of an emergency declaration for the State of Indiana is hereby amended to include the following area among those areas determined to have been adversely affected by the catastrophe declared an emergency by the President in his declaration of January 11, 2005:

Spencer County for emergency protective measures (Category B) under the Public Assistance program for a period of 48 hours.

(Catalog of Federal Domestic Assistance No. 97.036, Disaster Assistance.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–1569 Filed 1–27–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–3198–EM]

Ohio; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of Ohio (FEMA–3198–EM), dated January 11, 2005, and related determinations.

EFFECTIVE DATE: January 11, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated January 11, 2005, the President declared an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act), as follows:

I have determined that the impact in certain areas of the State of Ohio, resulting from the record snow on December 22–24, 2004, is of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act). Therefore, I declare that such an emergency exists in the State of Ohio.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide emergency protective measures under the Public Assistance program to save lives, protect public health and safety, and property. Other forms of assistance under Title V of the Stafford Act may be added at a later date, as you deem appropriate. You are further authorized to provide this emergency

assistance in the affected areas for a period of 48 hours. You may extend the period of assistance, as warranted. This assistance excludes regular time costs for sub-grantees' regular employees. Assistance under this emergency is authorized at 75 percent Federal funding for eligible costs.

Further, you are authorized to make changes to this declaration to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Under Secretary for Emergency Preparedness and Response, Department of Homeland Security, under Executive Order 12148, as amended, Lee Champagne, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

I do hereby determine the following areas of the State of Ohio to have been affected adversely by this declared emergency:

The counties of Butler, Champaign, Clark, Darke, Delaware, Franklin, Greene, Hamilton, Hardin, Logan, Madison, Miami, Montgomery, Preble, Shelby, Union, and Warren for emergency protective measures (Category B) under the Public Assistance program for a period of 48 hours.

(Catalog of Federal Domestic Assistance No. 97.036, Disaster Assistance.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–1570 Filed 1–27–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4980–N–04]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal Property reviewed by HUD for suitability for possible use to assist the homeless.

EFFECTIVE DATE: January 28, 2005.

FOR FURTHER INFORMATION CONTACT: Kathy Ezzell, Department of Housing and Urban Development, Room 7262, 451 Seventh Street, SW., Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: January 19, 2005.

Mark R. Johnston,

Director, Office of Special Needs Assistance Programs.

[FR Doc. 05–1453 Filed 1–27–05; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA 180–1150 BS]

Notice of Emergency Closure of Public Lands in Amador County, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Notice is hereby given that certain access roads and certain areas are temporarily closed to all public entry that could result in the spread of *Phytophthora cinnamomi*, a fungus related to the one responsible for sudden oak death, to uninfected stands of Ione and whiteleaf manzanita as well as to other susceptible plants including natives and ornamentals. These activities include motor vehicle operation and foot traffic.

DATES: The closure will take effect on October 27, 2004 and continue until further notice.

FOR FURTHER INFORMATION CONTACT: Deane Swickard, Folsom Field Office Manager, 63 Natoma Street, Folsom, California 95630, telephone (916) 985–4474.

SUPPLEMENTARY INFORMATION: *Phytophthora cinnamomi* is a root and crown fungus that attacks Ione manzanita (*Archtostaphylos myrtifolia*) and whiteleaf manzanita (*Archtostaphylos viscida*). The Ione manzanita is listed as threatened under the Endangered Species Act, and occurs in Amador and Calaveras Counties, California. Infected stands of these species experience rapid desiccation and mortality at the onset of hot weather. *Phytophthora cinnamomi* is primarily spread by humans driving or walking through infested areas, and then into non-infested areas.

The closed area is the Ione Manzanita Area of Critical Environmental Concern (ACEC), and portions of nearby public lands portions in which the Ione manzanita occurs, a total of about 240 acres. Legal descriptions of the closed areas are:

T.5 N, R.10 E, M.D.B. & M.;
Sec. 32, NE ¼ SE ¼, SW ¼ SE ¼, E ½ SE ¼;
Sec. 33, SW ¼ NW ¼, NW ¼ SW ¼.
T.7 N, R.9 E, M.D.B. & M.;
Sec. 28, S ½ SE ¼ SW ¼;
Sec. 33, NW ¼ NE ¼.

Closure signs will be posted at main entry points to this area. Maps of the closure area may be obtained from the Folsom Field Office, 63 Natoma Street, Folsom, California, 95630. Phone: (916) 985–4474.

Under the authority of 43 CFR 8364.1(a), the Bureau of Land Management will enforce the closure of the infested lands to prevent the spread of the fungus to uninfested stands of the federally threatened Ione manzanita and other susceptible vegetation. Official vehicles, including fire or law enforcement, are exempt from the emergency order. Currently, there is no legal public access to the subject lands. The only people affected by the emergency closure order are adjacent property owners.

The authority for this closure is found under section 303(a) of the Federal Land Policy and Management Act of 1976 (43 CFR 8360.0–7). Any person who violates this closure may be tried before a United States Magistrate and fined no more than $1,000 or imprisoned for no more that 12 months, or both. Such violations may also be subject to the enhanced fines provided for by 18 U.S.C. 8571.

(Authority: 43 CFR 8364.1(a))

Dated: October 27, 2004.

D.K. Swickard,

Folsom Field Office Manager.

[FR Doc. 05–1594 Filed 1–27–05; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–027–1020–PI–020H; G5–0035]

Steens Mountain Advisory Council; Call for Nominations

AGENCY: Bureau of Land Management (BLM), Burns District.

ACTION: Call for nominations for the Steens Mountain Advisory Council (SMAC).

SUMMARY: BLM is publishing this notice under Section 9(a)(2) of the Federal Advisory Committee Act. Pursuant to the Steens Mountain Cooperative Management and Protection Act of 2000 (Public Law 106–399), BLM gives notice that the Secretary of the Interior intends to call for nominations for terms expiring on the SMAC. This notice requests the public to submit nominations for membership on the SMAC. Any individual or organization may nominate one or more persons to serve on the SMAC. Individuals may nominate themselves for SMAC membership. Nomination forms may be obtained from the Burns District Office, Bureau of Land Management (see address below). To make a nomination, submit a completed nomination form, letters of reference from the represented interests or organizations, and any other information that speaks to the nominee's qualifications, to the Burns District Office. Nominations may be made for the following categories of interest:

- One person who is a grazing permittee on Federal land in the Steens Mountain Cooperative Management and Protection Area (CMPA) (appointed from nominees submitted by the County Court of Harney County);
- One person who is a recognized environmental representative from the local area (appointed from nominees submitted by the Governor of Oregon);
- A person who participates in what is commonly called dispersed recreation, such as hiking, camping, nature viewing, nature photography, bird watching, horseback riding, or trail walking (appointed from nominees submitted by the Oregon State Director of the BLM); and
- A person with expertise and interest in wild horse management on Steens Mountain (appointed from nominees submitted by the Oregon State Director for BLM).

The specific category the nominee will represent should be identified in the letter of nomination. The Burns District will collect the nomination forms and letters of reference and distribute them to the officials responsible for submitting nominations (County Court of Harney County, the Governor of Oregon, and BLM). BLM will then forward recommended nominations to the Secretary of the Interior, who has responsibility for making the appointments.

DATES: Nominations should be submitted to the address listed below no later than 30 days after publication of this notice.

FOR FURTHER INFORMATION CONTACT: Rhonda Karges, Management Support Specialist, Burns District Office, 28910 Hwy 20 West, Hines, Oregon 97738, (541) 573–4433, or *Rhonda_Karges@or.blm.gov* or from the following Web site *http://www.or.blm.gov/steens* (Public Law 106–399 in its entirety can be found on the Steens Web site as previously cited.)

SUPPLEMENTARY INFORMATION: The purpose of the SMAC is to advise BLM on the management of the CMPA as described in Title 1 of Public Law 106–399. Each member will be a person who, as a result of training and experience, has knowledge or special expertise which qualifies him or her to provide advice for one or more of the interest categories listed above.

Members of the SMAC are appointed for terms of 3 years. The Grazing Permittee, Environmental Representative, Dispersed Recreation, and Wild Horse Management position terms will expire August 2005. These four positions will begin no earlier than August 2005 and will end August 2008.

Members will serve without monetary compensation, but will be reimbursed for travel and per diem expenses at current rates for Government employees. The SMAC shall meet only at the call of the Designated Federal Official, but not less than once per year.

Dated: December 21, 2004.

Karla Bird,

Andrews Resource Area Field Manager, Bureau of Land Management, Burns, Oregon.

[FR Doc. 05–1596 Filed 1–27–05; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AK–931–1310–DT–NPRA]

Notice of Availability of the Amendment to the Northeast National Petroleum Reserve-Alaska Final Integrated Activity Plan/Environmental Impact Statement

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: The Amendment to the Northeast National Petroleum Reserve-Alaska (NPR-A) Final Integrated Activity Plan/ Environmental Impact Statement (IAP/EIS) will be made available to the public for a 30-day period beginning on the date the Environmental Protection Agency (EPA) files a Notice of Availability of the Final IAP/EIS in the **Federal Register**. The EPA notice is expected to occur on or about January 28, 2005. A Record of Decision (ROD) will be issued after the 30-day availability period. The ROD will identify the selected alternative as well as mitigation measures.

The Final IAP/EIS addresses two primary objectives for the amendment of the Northeast National Petroleum Reserve-Alaska IAP/EIS.

1. Consider making available all or portions of lands currently closed to oil and gas leasing in the Planning Area; and,

2.Consider developing performance-based lease stipulations and ROPs to provide the BLM greater flexibility in protecting important surface resources from the impacts of oil and gas activities, similar to those developed for the Northwest National Petroleum Reserve—Alaska.

Location of the Document: The Final IAP/EIS will be available in either hard copy or on compact disk at the Alaska State Office, Public Information Center at 222 West 7th Avenue, Anchorage, Alaska 99513–7599. Copies of the Final IAP/EIS will also be available at the following locations: Tuzzy Public Library, Barrow, Alaska; City of Nuiqsut, Nuiqsut, Alaska; City of Atqasuk, Atqasuk, Alaska; City of Anaktuvuk Pass, Anaktuvuk Pass, Alaska; City of Bethel, Bethel, Alaska, Z. J. Loussac Public Library, Anchorage, AK; Noel Wien Public Library, Fairbanks, AK.

The final IAP/EIS will also be available on the project Web site at *http://nenpra.ensr.com/nenpra/default.html.*

FOR FURTHER INFORMATION CONTACT: Susan Childs, BLM Alaska State office (907) 271–1985.

SUPPLEMENTARY INFORMATION: The Northeast Planning Area (Planning Area) boundary encompasses approximately 4.6 million acres located in the northeastern portion of the National Petroleum Reserve-Alaska. The Planning Area is roughly bounded by the Beaufort Sea to the North, the Ikpikpuk River to the west and the Colville River to the east and south of the planning area. The 1998 Record of Decision (ROD) for the Northeast Planning area provided 87% of the area for oil and gas leasing; however, approximately 840,000 acres, much of the area surrounding the Teshekpuk Lake, including the lake, was made unavailable for leasing under the 1998 ROD. In 2002, the President's National Energy Policy Development Group recommended that the President direct

the Secretary of the Interior to consider additional environmentally responsible oil and gas development, based on sound science and the best available technology, through further lease sales in the National Petroleum Reserve-Alaska and that such consideration should include areas not currently leased within the northeast corner of the National Petroleum Reserve-Alaska. In addition, Public Law 96–514 of December 12, 1980, amended the NPRPA authorizing oil and gas leasing in the reserve and as codified in 42 U.S.C. 6508 stated, ''There shall be conducted, not withstanding any other provision of law and pursuant to such rules and regulations as the Secretary may prescribe, an expeditious program of competitive leasing of oil and gas in the National Petroleum Reserve in Alaska; provided, that: (1) Activities undertaken pursuant to this section shall include or provide for such conditions, restrictions, and prohibitions as the Secretary deems necessary or appropriate to mitigate reasonably foreseeable and significantly adverse effects on the surface resources of the National Petroleum Reserve in Alaska * * *.'' In exercising this authority a revised Preferred Alternative which incorporates additional surface protection measures has been developed to safeguard important resources and subsistence activities. This Final IAP/EIS amendment contains four alternatives for a land management plan for the 4.6 million-acre planning area and assessments of each plan's impacts on the surface resources present there, as well as the cumulative effects of each alternative.

A Draft Amended IAP/EIS was made available for a 76-day comment period on June 9, 2004. Scoping and comment meetings on the Draft IAP/EIS were held in Bethel, Nuiqsut, Atqasuk, Barrow, Anaktuvuk Pass, Fairbanks, Anchorage, and Washington, DC. The Northeast Planning Area provides particularly important habitat for caribou, waterfowl, subsistence species, and other waterfowl. Many of the local residents of the area rely on harvesting these resources for subsistence purposes. Ensuring adequate protection of these resources has been one of the main focuses of public comment. The BLM held public hearings on subsistence as well as public hearings on the Draft IAP/EIS. The first set of subsistence hearings was held in conjunction with the public hearings on the Draft IAP/EIS during the weeks of June 28, August 9 and 16 in Bethel, Nuiqsut, Atqasuk, Barrow, Anaktuvuk Pass, Fairbanks, Anchorage (all in Alaska) and Washington, DC. An additional set of subsistence hearings was held in the effected Alaska North Slope communities of Nuiqsut, Ataqasuk, Barrow and Anaktuvuk Pass, Alaska, as well as the community of Bethel, Alaska, in the Yukon Delta, during the weeks of October 25 and November 29. Under the final Preferred Alternative, approximately 4,389,000 acres of BLM administered subsurface estate within the Planning Area would be available for oil and gas leasing. Teshekpuk Lake would be deferred from oil and gas leasing under this alternative. In addition, there would be no recommended Wilderness Study Areas or Wild and Scenic Rivers. Lease stipulations and required operating procedures under the final Preferred Alternative, would establish setbacks prohibiting permanent facilities within ¼ to 1 mile along major rivers and 1 to 3 miles along Fish Creek; ¼ mile shoreward from deep water lakes and ¾ mile along coastal areas, to protect subsistence resources/activities and other important surface resources. No Surface Occupancy for permanent oil and gas development stipulations were included which would protect goose molting areas, caribou movement corridors, and the southern caribou calving grounds. Multi-year studies would be required prior to development to protect spectacled and Steller's eiders, yellow-billed loons, and caribou. Other stipulations and required operating procedures would establish restrictions and guidance that apply to waste prevention and spills, water use, winter overland moves and seismic activity, exploratory drilling, aircraft use and subsistence consultation.

The no action alternative calls for continuation of current management, which does provide for continued leasing in the area previously made available for oil and gas leasing through the 1998 Northeast National Petroleum Reserve-Alaska IAP/EIS and Record of Decision. Alternatives A through C make progressively more land, available for oil and gas leasing. The final Proposed Action, Altnerative D, would make a more land available Alternatives A, but less land available than Alternatives B or C. Alternative A, makes available 87% of the planning area available for oil and gas leasing; Alternative B makes 96% percent of the planning area available for oil and gas leasing; Alternative C makes 100% of the planning area available for oil and gas leasing; and the final Proposed Action, Alternative D, makes approximately 95% available for oil and gas leasing. Performance-based stipulations and (ROPs) would provide protection for natural and cultural resources under all alternatives: B, C, and D, but their nature, number and scope varies between the alternatives. Alternative A, the No Action Alternative, would continue to protect the planning area with stipulations implemented throughout the 1998 Northeast Record of Decision.

Dated: December 6, 2004.

Henri R. Bisson,

State Director, Alaska.

[FR Doc. 05–1730 Filed 1–27–05; 8:45 am]

BILLING CODE 4310–JA–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[UTU76532]

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease, Utah

December 22, 2004.

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: In accordance with Title IV of the Federal Oil and Gas Royalty Management Act (Public Law 97–451), a petition for reinstatement of oil and gas lease UTU76532 for lands in San Juan County, Utah, was timely filed and required rentals accruing from July 1, 2004, the date of termination, have been paid.

FOR FURTHER INFORMATION CONTACT: Teresa Catlin, Acting Chief, Branch of Fluid Minerals at (801) 539–4122.

SUPPLEMENTARY INFORMATION: The lessee has agreed to new lease terms for rentals and royalties at rates of $5 per acre and 16–⅔ percent, respectively. The $500 administrative fee for the lease has been paid and the lessee has reimbursed the Bureau of Land Management for the cost of publishing this notice.

Having met all the requirements for reinstatement of the lease as set out in Section 31(d) and (e) of the Mineral Leasing Act of 1920 (30 U.S.C. 188), the Bureau of Land Management is proposing to reinstate lease UTU76532, effective July 1, 2004, subject to the original terms and conditions of the lease and the increased rental and royalty rates cited above.

Robert Henricks,

Acting Chief, Branch of Fluid Minerals.

[FR Doc. 05–1593 Filed 1–27–05; 8:45 am]

BILLING CODE 4310–$$–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–920–1310–01; WYW145952]

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of proposed reinstatement of terminated oil and gas lease.

SUMMARY: Under the provisions of 30 U.S.C. 188(d) and (e), and 43 CFR 3108.2–3(a) and (b)(1), the Bureau of Land Management (BLM) received a petition for reinstatement of oil and gas lease WYW145952 for lands in Lincoln County, Wyoming. The petition was filed on time and was accompanied by all the rentals due since the date the lease terminated under the law.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, Theresa M. Stevens, Land Law Examiner, at (307) 775–6167.

SUPPLEMENTARY INFORMATION: The lessee has agreed to the amended lease terms for rentals and royalties at rates of $5.00 per acre or fraction thereof, per year and 16⅔ percent, respectively. The lessee has paid the required $500 administrative fee and $166 to reimburse the Department for the cost of this **Federal Register** notice. The lessee has met all the requirements for reinstatement of the lease as set out in Section 31(d) and (e) of the Mineral Lands Leasing Act of 1920 (30 U.S.C. 188), and the Bureau of Land Management is proposing to reinstate lease WYW145952 effective August 1, 2003, under the original terms and conditions of the lease and the increased rental and royalty rates cited above. BLM has not issued a valid lease affecting the lands.

Theresa M. Stevens,

Land Law Examiner.

[FR Doc. 05–1597 Filed 1–27–05; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–920–1310–01; WYW145953]

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Proposed Reinstatement of Terminated Oil and Gas Lease.

SUMMARY: Under the provisions of 30 U.S.C. 188(d) and (e), and 43 CFR 3108.2–3(a) and (b)(1), the Bureau of Land Management (BLM) received a petition for reinstatement of oil and gas lease WYW145953 for lands in Lincoln County, Wyoming. The petition was filed on time and was accompanied by all the rentals due since the date the lease terminated under the law.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, Theresa M. Stevens, Land Law Examiner, at (307) 775–6167.

SUPPLEMENTARY INFORMATION: The lessee has agreed to the amended lease terms for rentals and royalties at rates of $5.00 per acre or fraction thereof, per year and 16–⅔ percent, respectively. The lessee has paid the required $500 administrative fee and $166 to reimburse the Department for the cost of this **Federal Register** notice. The lessee has met all the requirements for reinstatement of the lease as set out in Section 31(d) and (e) of the Mineral Lands Leasing Act of 1920 (30 U.S.C. 188), and the Bureau of Land Management is proposing to reinstate lease WYW145953 effective August 1, 2003, under the original terms and conditions of the lease and the increased rental and royalty rates cited above. BLM has not issued a valid lease affecting the lands.

Theresa M. Stevens,

Land Law Examiner.

[FR Doc. 05–1598 Filed 1–27–05; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT–070–05–1220–AL]

Notice to Rescind Seasonal Area Closure of Public Lands Along Hauser Lake, MT

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The purpose of this notice is to rescind the annual October 15 to December 31 closure of all public lands lying in the 2.5 mile stretch from Canyon Ferry Dam downstream to Brown's Gulch Road and between the east shore of Hauser Lake and Johnny's Gulch Road. The public lands affected by this notice are all lands administered by the Bureau of Land Management in Sections 5 and 6, T. 10 N., R.1 W., and Section 32, T. 11N., R. 1 W. Principle Meridian, Montana. The closure area that we are rescinding totals 769 acres.

DATES: This Notice will take affect upon publication in the **Federal Register**.

ADDRESSES: Copies of this rescindment and a map are available from the Butte Field Office, 106 N. Parkmont, Butte, Montana 59701.

FOR FURTHER INFORMATION CONTACT: Steve Hartmann, Assistant Field Manager, Butte Field Office at (406) 533–7600.

SUPPLEMENTARY INFORMATION: Kokanee Salmon were introduced into Hauser Reservoir in the 1970's to provide a fishery for local anglers. The salmon population thrived and bald eagles migrating from Canada to their wintering grounds in Utah, Colorado, and Wyoming began to congregate around Hauser Reservoir to feed on spawning salmon. When the numbers of eagles began to steadily increase, the Bureau of Reclamation, Bureau of Land Management, Forest Service, and Montana Fish, Wildlife and Parks closed the area to public access to protect bald eagles from human disturbance.

From 1991 to 1996, 100–300 migrating eagles were identified congregating at Hauser Reservoir. By 1997, however, the number of bald eagles had dropped to fewer than 65, the lowest number of bald eagles counted over the seven year period. Declining angler success, reduced captures in Montana Fish, Wildlife and Parks gill nets, and extremely low carcass counts from 1995–1997 showed a decline in the Kokanee salmon population. Migrating bald eagles responded to the reduction in food supply. By 2000, fewer than 20 bald eagles were identified at Hauser Reservoir and the closure is no longer necessary.

Dated: December 1, 2004.

Richard M. Hotaling,

Field Manager.

[FR Doc. 05–1603 Filed 1–27–05; 8:45 am]

BILLING CODE 4310–$$–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–958–1430–ET; HAG05–0004; OR 52171]

Termination of Classification and Order Providing for Opening of Land, OR 52171

AGENCY: Bureau of Land Management (BLM), Interior.

ACTION: Notice.

SUMMARY: This notice terminates the existing classification in its entirety for public lands that were classified as suitable for lease/disposal pursuant to the Recreation and Public Purposes Act

of June 14, 1926, as amended (43 U.S.C. 869 *et seq.*), and opens 3.00 acres of land to surface entry and mining, subject to the existing laws, rules, and regulations applicable to public lands administered by the Bureau of Land Management.

EFFECTIVE DATE: February 28, 2005.

FOR FURTHER INFORMATION CONTACT: Lakisha Sloan, Land Law Examiner, Oregon State Office, PO Box 2965, Portland, OR 97208, 503–808–6595, or Stuart Hirsh, Realty Specialist, Salem District Office, 1717 Fabry Road SE., Salem, OR 97306, (503) 375–5623.

SUPPLEMENTARY INFORMATION: On July 19, 1995, 3.00 acres of public land under the jurisdiction of the Bureau of Land Management were classified as suitable for lease pursuant to the Recreation and Public Purposes Act of June 14, 1926, as amended, (43 U.S.C. 869 *et seq.*), and the regulations at 43 CFR 2400. Upon classification the land was leased to the Pacific City water district for the construction, operation, and maintenance of an administration/maintenance facility for the term of 25 years under Bureau of Land Management Serial Number OR 52171. On May 20, 2004, this lease was relinquished.

The formerly leased land is described as follows:

Willamette Meridian, Oregon

T. 4 S., R. 10 W.,
Sec. 19, Lot 18

The area described contains 3.00 acres in Tillamook County, Oregon.

At 8:30 a.m., on February 28, 2005, the land will be opened to operation of the public land laws generally, but not to location or entry, subject to valid existing rights, the provisions of existing withdrawals, and the requirements of applicable law. All valid existing applications received at or prior to 8:30 a.m., on February 28, 2005, will be considered as simultaneously filed at that time. Those received thereafter will be considered in the order of filing.

At 8:30 a.m., on February 28, 2005, the land will be opened to location and entry under the United States mining laws. Appropriation under the general mining laws prior to the date and time of restoration is unauthorized. Any such attempted appropriation, including attempted adverse possession under 30 U.S.C. Sec. 38, shall vest no rights against the United States. Acts required to establish a location and to initiate a right of possession are governed by State law where not in conflict with Federal law. The Bureau of Land Management will not intervene in disputes between rival locators over possessory rights since Congress has provided for such determination in local courts.

(Authority: 43 CFR 2461.5(c)(2)).

Ralph R. Kuhns, Jr.,
Acting, Chief, Branch of Realty and Records Services.

[FR Doc. 05–1595 Filed 1–27–05; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

Limitation on Use of Credit and Debit Cards for Payments to the Bureau of Land Management

Authority: 31 U.S.C. 3720, 31 CFR 206.4, 43 CFR 3103.1–1.

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management has established a $99,999.99 limit on payments made by credit and debit cards. Under U.S. Department of the Treasury regulations, federal agencies are required to use electronic fund transfers for collections and payments, as long as it is cost effective to do so. Fees for large dollar debit and credit card transactions are prohibitive. Cardholders cannot be required to pay any part of the fees which financial institutions charge, directly or indirectly, through any increase in price or otherwise. Customers who need to tender payments larger than the cap are encouraged to make electronic payments using the Automated Clearing House or Federal Wire Transfer procedures.

EFFECTIVE DATE: February 1, 2005.

ADDRESSES: Bureau of Land Management, National Business Center, Attention: Alice Sonne (BC–621), PO Box 25047, Denver, CO 80225–0047.

FOR FURTHER INFORMATION CONTACT: Jay Douglas, BLM (202) 452–0336 or Alice Sonne, BLM (303) 236–6332.

SUPPLEMENTARY INFORMATION: Effective February 1, 2005, the Bureau of Land Management will not accept credit or debit card payments for any amount greater than $99,999.99 for any purpose. Multiple same-day transactions of smaller amounts, which in their total exceed the cap, cannot be used to bypass this requirement. Detailed guidance about how to make electronic payments is available from each Bureau State Office. A list of State offices is available at the Bureau's external Web site (*http://www.blm.gov/nhp/directory/index.htm*) and at Title 43 Code of Federal Regulations Subpart 1821.10. Personal and corporate checks are acceptable forms of payment.

Thomas F. Boyd,
Director, National Business Center.

[FR Doc. 05–1592 Filed 1–27–05; 8:45 am]

BILLING CODE 4310–AG–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV–050–5853–ES; N–59514, N–77790]

Notice of Realty Action: Segregation Terminated, Lease/Conveyance for Recreation and Public Purposes (R&PP)

AGENCY: Bureau of Land Management, Interior.

ACTION: Segregation terminated, Recreation and Public Purposes lease/conveyance.

SUMMARY: Clark County, Nevada has relinquished an R&PP lease (N–59514) for a fire station site on 2.5 acres of public land in Las Vegas, Nevada. The fire station site is proposed to be relocated on nearby public land (N–77790), located in Clark County, Nevada, which BLM has determined is suitable for classification for lease/conveyance to Clark County.

FOR FURTHER INFORMATION CONTACT: Beth Domowicz, BLM Realty Specialist, (702) 515–5147.

SUPPLEMENTARY INFORMATION: Clark County, Nevada has relinquished an R&PP lease (N–59514) for a fire station on public lands due to development in the area that made the land unsuitable for the proposed use. These lands in Las Vegas, Clark County, Nevada are described as follows:

N–59514

Mount Diablo Meridian, Nevada

T. 22 S., R. 60 E., Sec. 24,
NW¼NW¼SW¼NW¼.
Consisting of 2.5 acres.

The segregation of the subject land for R&PP (N–59514) under the Notice published in the **Federal Register** volume 61, page 1944, dated January 24, 1996, will be terminated upon publication of this notice.

The following described public land in Las Vegas, Clark County, Nevada has been examined and found suitable for lease/conveyance for recreational or public purposes under provisions of the Recreation and Public Purposes (R&PP) Act, as amended (43 U.S.C. 869 *et seq.*). Clark County proposes to use the land for a fire station.

N–77790

Mount Diablo Meridian, Nevada

T. 22 S., R. 60 E.,
Sec. 24, NE¼NE¼SW¼NW¼.
Consisting of 2.5 acres

The public land is not required for any Federal purpose. Lease/conveyance is consistent with current Bureau planning for this area and would be in the public interest. The lease/conveyance, when issued, will be subject to the provisions of the Recreation and Public Purposes Act and applicable regulations of the Secretary of the Interior and will contain the following reservations to the United States:

1. A right-of-way thereon for ditches and canals constructed by the authority of the United States, Act of August 30, 1890 (43 U.S.C. 945).

2. All minerals shall be reserved to the United States, together with the right to prospect for, mine and remove such deposits from the same under applicable law and such regulations as the Secretary of the Interior may prescribe.

And will be subject to:

1. All valid and existing rights.

Detailed information concerning this action is available for review at the office of the Bureau of Land Management, Las Vegas Field Office, 4701 N. Torrey Pines Drive, Las Vegas, Nevada 89130.

Upon publication of this notice in the **Federal Register**, the public lands described in N–77790 will be segregated from all other forms of appropriation under the public land laws, including the general mining laws, except for lease/conveyance under the Recreation and Public Purposes Act, leasing under the mineral leasing laws and disposal under the mineral material disposal laws.

Interested parties may submit comments regarding the proposed classification for lease/conveyance of the public lands to the Field Manager, Las Vegas Field Office, 4701 N. Torrey Pines Drive, Las Vegas, Nevada 89130 until March 14, 2005.

Classification Comments: Interested parties may submit comments involving the suitability of the public land for the proposed facilities. Comments on the classification are restricted to whether the land is physically suited for the proposal, whether the use will maximize the future use or uses of the land, whether the use is consistent with local planning and zoning or if the use is consistent with State and Federal programs.

Application Comments: Interested parties may submit comments regarding the specific use proposed in the application and plan of development, whether the BLM followed proper administrative procedures in reaching the decision or any other factor not related to the suitability of the land for the proposed church facilities. Any adverse comments will be reviewed by the State Director who may sustain, vacate, or modify this Realty action. In the absence of any adverse comments, the classification of the land described in the Notice will become effective on March 29, 2005. The lands will not be offered for lease/conveyance until after the classification becomes effective.

Dated: December 28, 2004.

Sharon DiPinto,

Assistant Field Manager, Division of Lands.

[FR Doc. 05–1600 Filed 1–27–05; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV–050–5853–ES; N–65825]

Notice of Realty Action: Change of Use for Recreation and Public Purposes Lease/Conveyance

AGENCY: Bureau of Land Management, Interior.

ACTION: Recreation and Public Purposes lease/conveyance change of use.

SUMMARY: Clark County, Nevada proposes to change the use on 40.87 acres of public land in Las Vegas, Nevada from a fire station and training facility to a fire station, Regional Park and Clark County Family Services building.

FOR FURTHER INFORMATION CONTACT: Beth Domowicz, BLM Realty Specialist, SCEP, (702) 515–5147.

SUPPLEMENTARY INFORMATION: The following described public land in Las Vegas, Clark County, Nevada was segregated on October 20, 1999 for lease/conveyance under provisions of the Recreation and Public Purposes (R&PP) Act, as amended (43 U.S.C. 869 *et seq.*).

N–65825—Clark County proposes a change of use on the following public lands:

Mount Diablo Meridian, Nevada

T. 21 S., R. 62 E., Sec. 2: Lot 15.
Consisting of 40.87 acres

This public land was previously classified and segregated for Recreation and Public Purposes under FR, Volume 64, No. 212, page 59789, on Wednesday, November 3, 1999. The change of use from a fire station and fire training facility to a fire station, Regional Park and Clark County Family Services building is consistent with the uses authorized under the Recreation and Public Purposes Act. The change of use is consistent with current Bureau planning for this area and would be in the public interest.

Interested parties may submit comments regarding the proposed change of use for the public lands to the Field Manager, Las Vegas Field Office, 4701 N. Torrey Pines Drive, Las Vegas, Nevada 89130 until March 14, 2005.

Classification Comments: Given that the public lands were previously classified for Recreation and Public Purposes, comments pertaining to classification will not be accepted.

Application Comments: Interested parties may submit comments regarding the specific use proposed in the application and plan of development, whether the BLM followed proper administrative procedures in reaching the decision or any other factor not related to the suitability of the public land for the proposed facilities. Any adverse comments will be reviewed by the State Director who may sustain, vacate, or modify this Realty action. In the absence of any adverse comments, the classification of the public land described in the Notice will become effective on March 29, 2005. The lands will not be offered for lease/conveyance until after the classification becomes effective.

Dated: December 27, 2005.

Sharon DiPinto,

Assistant Field Manager, Division of Lands.

[FR Doc. 05–1601 Filed 1–27–05; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV–050–5853–ES; N–78565]

Notice of Realty Action: Change of Use for Recreation and Public Purposes Lease/Conveyance

AGENCY: Bureau of Land Management, Interior.

ACTION: Recreation and Public Purposes lease/conveyance change of use.

SUMMARY: Clark County, Nevada proposes a park site on 10 acres of public land in Las Vegas, Nevada previously classified for a school site.

FOR FURTHER INFORMATION CONTACT: Beth Domowicz, BLM Realty Specialist, (702) 515–5147.

SUPPLEMENTARY INFORMATION: The following described public land in Las

Vegas, Clark County, Nevada was segregated on February 16, 1996 for lease/conveyance under provisions of the Recreation and Public Purposes (R&PP) Act, as amended (43 U.S.C. 869 *et seq.*).

N–78565—Clark County proposes a change of use on the following public lands:

Mount Diablo Meridian, Nevada

T. 21 S., R. 60 E., Sec. 9: NW¼SW¼NE¼.
Consisting of 10.00 acres.

This public land was previously classified and segregated for Recreation and Public Purposes under **Federal Register**, Volume 61, No. 33, page 6258, on February 16, 1996. The change of use from a school site to a park site is consistent with the uses authorized under the Recreation and Public Purposes Act. The change of use is consistent with current Bureau planning for this area and would be in the public interest.

Interested parties may submit comments regarding the proposed change of use for the public lands to the Field Manager, BLM Las Vegas Field Office, 4701 N. Torrey Pines Drive, Las Vegas, Nevada 89130 until March 14, 2005.

Classification Comments: Given that the public lands were previously classified for Recreation and Public Purposes, comments pertaining to classification will not be accepted.

Application Comments: Interested parties may submit comments regarding the specific use proposed in the application and plan of development, whether the BLM followed proper administrative procedures in reaching the decision or any other factor not related to the suitability of the public land for the proposed facilities. Any adverse comments will be reviewed by the State Director who may sustain, vacate, or modify this Realty action. In the absence of any adverse comments, the classification of the public land described in the Notice will become effective on March 29, 2005. The lands will not be offered for lease/conveyance until after the classification becomes effective.

Dated: December 27, 2004.

Sharon DiPinto,

Assistant Field Manager, Division of Lands.

[FR Doc. 05–1602 Filed 1–27–05; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–958–04–1430–EU; GP–05–0011]

Receipt of Application for Conveyance of Mineral Interests, Josephine County, OR [OR 60700]

AGENCY: Bureau of Land Management (BLM), Interior.

ACTION: Notice of mineral conveyance application.

SUMMARY: This action informs the public of the receipt of an application from Stephen E. Evensen of Murphy, Oregon for conveyance of 20 acres of federal mineral estate from lands administered by the BLM in the Medford District.

EFFECTIVE DATE: January 28, 2005.

FOR FURTHER INFORMATION CONTACT: Phyllis Gregory, BLM Oregon/Washington State Office, P.O. Box 2965, Portland, Oregon 97208, 503–808–6188.

SUPPLEMENTARY INFORMATION: Notice is hereby given that pursuant to Section 209 of the Act of October 21, 1976 (90 Stat. 2757), Stephen E. Evensen has filed an application to purchase the Federally-owned mineral estate in the land described below:

Willamette Meridian,

T. 37 S., R. 05 W.,
Sec. 09, W½NW¼SE¼.

The area described contains 20 acres, more or less, in Josephine County, Oregon. On May 19, 2004, the surface estate was offered to the Evensen family following the processing of a class 1 application for Color-of-Title (OR–57154). Mr. Evensen desires to acquire the mineral estate beneath the 20 acres of BLM administered lands included in the color-of-title application to effectively acquire fee title to the land. The mineral interests being offered for conveyance have no known mineral value.

Upon publication of this notice in the **Federal Register**, the mineral interest described above will be segregated to the extent that it will not be subject to appropriation under the public land laws including the mineral laws. The segregative effect of the application shall terminate either upon issuance of a patent or other document of conveyance to such mineral interests, upon final rejection of the application, or two years from the date of filing of the application, June 30, 2004, whichever comes first.

(Authority: 43 CFR 2720.1–1(b)).

Dated: October 25, 2004.

Robert D. DeViney, Jr.,

Chief, Branch of Realty and Records Services.

[FR Doc. 05–1590 Filed 1–27–05; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CO–100–1610–DU]

Notice of Intent To Amend the Little Snake Resource Management Plan for Acquisition and Management of Emerald Mountain

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: This document provides notice that the Bureau of Land Management (BLM) will initiate a plan amendment to address acquisition and management of lands in Routt County, Colorado. The lands would be acquired in a proposed land exchange between the State of Colorado (Colorado State Land Board) and the United States (Little Snake Field Office, BLM).

DATES: All relevant public meetings will be announced through the local news media, newsletters, and the BLM Web site at: *http://www.co.blm.gov/lsra/lsraindex.htm*, at least 15 days prior to the event. The minutes and list of attendees from each meeting will be available in the Field Office and at the Web site, and will be open for 30 days after a meeting to any participant who wishes to clarify the views they expressed.

ADDRESSES: Please send written comments to the Bureau of Land Management, Little Snake Field Office, Attn: Emerald Mountain Land Use Amendment, 455 Emerson Street, Craig, CO 81625–1129; FAX: (970) 826–5002. Email comments may be sent to *Duane_Johnson@co.blm.gov*.

FOR FURTHER INFORMATION CONTACT: For further information and/or to have your name added to the mailing list, contact Duane Johnson, Team Leader, at the Little Snake Field Office (LSFO) address listed below or by calling (970) 826–5001.

SUPPLEMENTARY INFORMATION: The proposed land exchange involves 129 public land parcels totaling approximately 15,621 acres and one 6,347 acre parcel of State land called Emerald Mountain. The proposed land exchange would result in BLM acquiring new Federal land and disposing of scattered Federal lands.

The parcel to be acquired is currently not under BLM management, and an amendment of the current Resource Management Plan (RMP) is required to address acquisition and future management of the parcel by BLM. As part of the RMP amendment, an Environmental Assessment (EA) will be prepared to analyze and compare the impacts of the management alternatives for the acquired lands. As provided by 43 CFR 1610.5–5, the BLM will prepare the plan amendment and associated EA simultaneously with the processing of the Notice of Exchange Proposal (NOEP). The plan will be amended in conformity with the National Environmental Policy Act (NEPA), the Federal Land Policy and Management Act (FLPMA), and BLM management policies. The BLM will ask state and local governments to be cooperators on the plan amendment. BLM will work with interested parties to identify the management decisions that are best suited to local, regional, and national needs. The public scoping process will identify planning issues and planning criteria. The BLM will prepare the land management amendment through coordination with other federal, state and local agencies, and affected users of BLM managed lands. The BLM will hold public meetings during the plan scoping period. Early participation is encouraged and will help determine the future management decisions of the BLM-administered lands involved in this amendment. Comments on issues and concerns can be submitted in writing to the address listed above and will be accepted throughout the creation of the Draft RMP amendment/EA. In addition to the ongoing public participation process, the BLM will provide formal opportunities for public participation by conducting scheduled public meetings and requesting comments upon BLM's publication of the draft RMP amendment/EA. The BLM will notify the Governor of Colorado, the Routt County Commissioners, adjacent landowners, and potentially affected members of the public of the proposed management decisions. The Emerald Mountain Partnership has promoted the exchange. The Emerald Mountain Partnership is a non-profit group dedicated to the conservation of the natural resources of Emerald Mountain and surrounding lands and to the creation of a multi-use model of land use to ensure the compatibility of agriculture, wildlife, recreation, and education. A notice of exchange proposal (NEOP) will be prepared, published in local news media, and mailed to interested parties. Anyone wishing to obtain a copy of the NOEP may request one from the LSFO contact listed above.

Documents pertinent to this proposal may be examined at the LSFO and Web site at: *http://www.co.blm.gov/lsra/emerald_mtn/em.html*. Comments, including names and street addresses of respondents, will be available for public review at the LSFO during regular business hours (7:45 a.m. to 4:30 p.m.) Monday through Friday, except holidays; and may be published as part of the EA. Individual respondents may request confidentiality. If you wish to withhold your name or street address from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your written comment. Such requests will be honored to the extent allowed by law. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be available for public inspection in their entirety.

Preliminary issues and management concerns have been identified by BLM personnel, other agencies, and in meetings with the Emerald Mountain Partnership, the Routt County Commissioners, and user groups. They represent the BLM's knowledge to date on the existing issues and concerns with current management. The preliminary issues include: impacts to users of BLM-administered lands and adjacent private landowners; impacts to wildlife habitat; and impacts to water quality, vegetation, including riparian and wetland areas, soils, and recreation opportunities on Emerald Mountain. These issues, along with others that may be identified through public participation, will be considered in the planning process. After gathering public comments on what issues the plan amendment should address, the suggested issues will be placed in one of the three categories:

1. Issues to be resolved in the plan amendment;
2. Issues resolved through policy or administrative action; or
3. Issues beyond the scope of the plan amendment.

Rationale will be provided in the plan for each issue placed in category two or three. In addition to these major issues, a number of management questions and concerns will be addressed in the plan amendment. The public is encouraged to help identify these questions and concerns during the scoping phase.

An interdisciplinary approach will be used to develop the plan amendment in order to consider the variety of resource issues and concerns identified. Disciplines involved in the planning process will include specialists with expertise in rangeland management, minerals and geology, forestry, outdoor recreation, law enforcement, cultural resources, wildlife and fisheries, lands and realty, hydrology, soils, vegetation, and fire.

(Authority: 43 CFR 1610.2(c) and (f)).

John E. Husband,
Field Manager.

[FR Doc. 05–1591 Filed 1–27–05; 8:45 am]
BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NM–030–1610–DO]

Notice of Intent To Prepare a Resource Management Plan (RMP) Revision, a Resource Management Plan Amendment (RMPA), and Associated Environmental Impact Statement (EIS); and Notice of Public Scoping Meetings.

AGENCY: Bureau of Land Management (BLM), Interior.

ACTION: Notice of Intent to Revise the White Sands RMP, New Mexico and Notice of Intent to Amend the Mimbres RMP, New Mexico, and Notice of Public Scoping Meetings.

SUMMARY: The BLM proposes to revise the White Sands RMP and to amend the Mimbres RMP. The revision and amendment and associated environmental analysis will update planning level decisions for public lands in Sierra, Otero, and Dona Ana Counties, which are managed by the Las Cruces Field Office (LCFO), New Mexico. The proposed RMP revision and amendment are intended to address issues that have developed since the previous RMPs were prepared in 1986 and 1994 respectively. This notice initiates the public scoping process to identify specific issues related to the proposed revision and amendment and the NEPA process.

DATES: The public scoping period for the proposal will commence with publication of this Notice. Comments about the proposal must be submitted on or before 60 calendar days from the date the Environmental Protection Agency (EPA) publishes its NOI in the **Federal Register**. The BLM can best utilize your participation, comments and resource information submissions during the 60 day comment period and scheduled public meetings. Public meetings will be held in Truth or

Consequences, Alamogordo, and Las Cruces, New Mexico to ensure the opportunity for local community participation and input. All public meetings will be announced through the local news media and will be posted on the New Mexico BLM Web site (*http://www.nm.blm.gov*) at least 15 days in advance.

ADDRESSES: Existing planning documents and information are available at the Las Cruces Field Office, 1800 Marquess St., Las Cruces, New Mexico 88005. Written comments regarding the proposed plan revision and amendment should be sent to the BLM at the above address, Attention: RMP Team Leader. Written comments may also be faxed to 505–525–4412 or e-mailed to *LCFO_RMP@nm.blm.gov.* Comments that are faxed or e-mailed must include ''Scoping Comments for LCFO–RMP'' in the subject line. Public comments, including names and street addresses of respondents, will be available for public review at the LCFO during regular business hours 7:30 a.m. to 4:30 p.m., Monday through Friday, except holidays, and may be published as part of the EIS. Individual respondents may request confidentiality. If you wish to withhold your name or street address from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your written comment. Such requests will be honored to the extent allowed by law. All submissions from organizations and businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be available for public inspection in their entirety.

FOR FURTHER INFORMATION CONTACT: Tom Phillips, RMP Team Leader, at (505) 525–4377. To have your name added to our mailing list, contact Rena Gutierrez at (505) 525–4338 or via e-mail at: *Rena_Gutierrez@nm.blm.gov.*

SUPPLEMENTARY INFORMATION: The area encompassed by this planning effort includes Sierra, Otero, and Dona Ana Counties, New Mexico. Public lands in Sierra and Otero County are administered under the White Sands RMP, while public lands in Dona Ana County are administered under the Mimbres RMP. This entire Planning Area is about 6.65 million acres with approximately 2.88 million surface acres of public land and 5.01 million acres of federal minerals. BLM managed lands comprise about 43 percent of the three-county area.

The planning process will comply with the Federal Land Policy and Management Act of 1976 (FLPMA), the National Environmental Policy Act of 1969 (NEPA) and associated Federal regulations. The BLM will work collaboratively with interested parties to identify the management decisions that are best suited to local and regional needs as well as national needs and concerns.

There are several preliminary issues that BLM is seeking public input on through scoping. These issues were identified from evaluation of decisions in the current RMPs that BLM believes require updating and include: recreation; off highway vehicle management; threatened and endangered species management; renewable energy development potential (solar, wind, etc.); Areas of Critical Environmental Concern (ACECs); naturalness, solitude, and primitive recreation; special status species habitat management; access; travel management; rights-of-way; and land tenure (acquisition or disposal). The preliminary planning criteria, which have been identified to guide the development of the RMP Revision-Amendment/EIS, are:

A. Actions must comply with laws, regulations, executive orders, and BLM Manuals (*i.e.*, supplemental program guidance).

B. Actions must be reasonable and achievable and allow for flexibility where appropriate (*i.e.*, adaptive management).

C. The Economic Profile System (EPS) developed by the Sonoran Institute will be used as a community involvement technique and a source of demographic and economic data for the planning process.

D. Actions will be considered through an interdisciplinary approach.

E. The White Sands RMP Revision and the Mimbres RMP Amendment planning team will work cooperatively with county and municipal governments, other Federal, State and local agencies, and interested groups and individuals. Collaborative public involvement and participation will be emphasized throughout this process.

F. The revision and amendment will establish the guidance upon which the LCFO will manage public lands within the three counties.

G. The planning process will include an EIS that complies with NEPA standards.

H. The revision and amendment will provide for the maintenance and enhancement of habitats for special status species within the Planning Area, while allowing the public the opportunity for access to public lands in a productive and meaningful way.

I. The revision and amendment will recognize valid existing rights related to the use of public lands. The revision and amendment will define the process that the LCFO will use to address applications or notices filed after the completion of the revision and amendment on existing land use authorizations.

J. The RMP revision and amendment process will involve Native American tribal governments and will provide strategies for protection of cultural resources on public lands.

K. Decisions in the revision and amendment will strive to be compatible with existing plans and policies of adjacent local, State, and Federal governments and agencies, as long as the decisions are in conformance with BLM management policies.

Public participation will be encouraged through the three public meetings described above. Early participation is encouraged. In addition to the public meetings, opportunities for public participation will be available during the development of alternatives and upon publication of the Draft EIS. Notification of the publications and updates will be sent to various State and local government agencies, interest groups, Native American Tribes, permittees, and other interested public, as well as to the local news media. Federal, State and county governments have been asked to participate in the process and will be offered an opportunity to be cooperating agencies to assure their active participation.

Dated: November 5, 2004.

Linda S. C. Rundell,

New Mexico State Director.

[FR Doc. 05–1567 Filed 1–27–05; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Extension of the Public Review Period for the Draft Environmental Impact Statement for the Oil and Gas Management Plan, Big Thicket National Preserve

AGENCY: National Park Service, Department of the Interior.

SUMMARY: This notice informs the public that the comment period is extended.

DATES: The comment period is extended 30 days, to March 10, 2005.

ADDRESSES: The OGMP/DEIS will be available for public review and comment at the following locations: Office of the Superintendent, Art Hutchinson, Big Thicket National Preserve, 3785 Milam Street, Beaumont,

Texas 77701–4724, Telephone: (409) 951–6802; Office of Minerals/Oil and Gas Support, Intermountain Region, National Park Service, 1100 Old Santa Fe Trail, Santa Fe, New Mexico 87501, Telephone: (505) 988–6095; Planning and Environmental Quality, Intermountain Region, National Park Service, 12795 W. Alameda Parkway, Lakewood, Colorado 80228, Telephone: (303) 969–2377; Office of Public Affairs, Department of the Interior, 18th and C Streets NW., Washington, DC 20240, Telephone: 202–208–6843. The OGMP/DEIS can also be downloaded at *http://www.nps.gov/bith/pphtml/documents.html*. A printed copy or CD is also available, upon request, from Linda Dansby, EIS Project Manager, while supplies last.

FOR FURTHER INFORMATION CONTACT: Linda Dansby, EIS Project Manager, Office of Minerals/Oil and Gas Support, Intermountain Region, P.O. Box 728, Santa Fe, New Mexico 87504–0728, telephone (505) 988–6095.

SUPPLEMENTARY INFORMATION: Notices of availability of the Draft Environmental Impact Statement for the Oil and Gas Management Plan, Big Thicket National Preserve, Texas, were published in the **Federal Register** by the National Park Service on December 13, 2004, (69 FR 72214–72215) and by the U.S. Environmental Protection Agency on December 10, 2004. (EIS No. 040555) (69 FR 71811). The 60-day public review period began on the day of the EPA's publication and would have ended on February 8, 2005.

Dated: January 7, 2005.

John A. Wessels,

Acting Director, Intermountain Region, National Park Service.

[FR Doc. 05–1573 Filed 1–27–05; 8:45 am]

BILLING CODE 4312–CB–P

DEPARTMENT OF THE INTERIOR

National Park Service

Mississippi National River and Recreation Area, Environmental Impact Statement Concerning the Disposition of the Bureau of Mines, Twin Cities Research Center Main Campus, Hennepin County, MN

AGENCY: National Park Service, Department of the Interior.

ACTION: Notice of Intent to prepare an Environmental Impact Statement concerning disposition of the former Bureau of Mines, Twin Cities Research Center Main Campus, Hennepin County, Minnesota.

SUMMARY: Pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4332(2)(C), the National Park Service (NPS) will prepare an environmental impact statement (EIS) in partnership with the U.S. Fish and Wildlife Service, Region 3, concerning disposition of the former Bureau of Mines, Twin Cities Research Center Main Campus (Center), Hennepin County, near Minneapolis, Minnesota, and within the Mississippi National River and Recreation Area (MNRRA), a unit of the National Park System. The EIS will consider a range of alternatives for disposition of the Center and will be part of a planning process that will span three to four years, ending with a record of decision. There has been considerable public interest in the disposition of the Center. Some of the issues identified to date concern preservation and protection of cultural and natural resources, including protection of the groundwater associated with Coldwater Spring, and continued public access to the site.

The NPS anticipates starting the public scoping process for the EIS in February 2005. The NPS will prepare a scoping newsletter in the coming months that will identify issues and inform the public of the schedule for the EIS process and dates for upcoming meetings. To receive a copy of the newsletter, telephone or e-mail the NPS at the address listed below. Public scoping will occur through open public meetings and newsletters to State and Federal Agencies; federally recognized Indian Tribes, neighborhood community groups, county commissioners, local organizations, the congressional delegation, local elected officials, and other interested members of the public. All interested persons, organizations, and agencies are encouraged to submit comments and suggestions on issues, concerns and future uses of the Center that should be addressed in the EIS. Public meetings and site visits of the Center will be held throughout the spring and summer of 2005.

In addition to attending the upcoming scoping meetings, interested parties may provide comments on this initial phase of developing alternatives for the EIS. Send or e-mail comments to the NPS address listed below.

DATES: Specific dates, times, and locations of upcoming public meetings will be announced in the St. Paul Pioneer Press and the Minneapolis Star Tribune newspapers, on the Internet at *http://www.nps.gov/miss/bom,* and will also be available by contacting the NPS office listed in the contact information below.

ADDRESSES: The National Park Service, Mississippi National River and Recreation Area, 111 Kellogg Blvd East, St. Paul, Minnesota, telephone: 651–290–3030. E-mail: *miss_bomcomments@nps.gov.*

FOR FURTHER INFORMATION CONTACT: General information about MNRRA is available on the Internet at: *http://www.nps.gov/miss;* information specific to the proposed action is available at: *http://www.nps.gov/miss/bom.*

SUPPLEMENTARY INFORMATION: If you wish to comment on any issues associated with the EIS, you may submit your comments by any one of several methods. You may mail or hand deliver comments to the address listed in the contact information section of this notice or via the Internet at *miss_bomcomments@nps.gov.* Due to concerns regarding computer viruses, comments will not be accepted as attachments. All comments you provide must be within the body of the e-mail. Be sure to include your name and return street address in your Internet message. Our practice is to make comments, including the names, home addresses, and other personal identifying information of commenters, available for public review during regular business hours. Individual commenters may request that we withhold specified personal identifying information from the public record, which we will honor to the extent allowable by law. There, also, may be circumstances in which, on our own initiative, we would withhold from the public record a commenter's identity, as allowable by law. If you wish us to withhold any of your personal identifying information from the public record you must state this prominently at the beginning of your comment and identify the specific information you wish us to withhold. We cannot withhold an entire comment from the public record. We will make all commenter's submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for inspection in the public record.

Dated: October 27, 2004.

Ernest Quintana,

Regional Director, Midwest Region.

[FR Doc. 05–1572 Filed 1–27–05; 8:45 am]

BILLING CODE 4312–98–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[DES 05–06]

Humboldt Project Conveyance, Pershing, Churchill and Lander Counties, Nevada

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of Availability of the Draft Environmental Impact Statement (DEIS) and notice of public hearing.

SUMMARY: Pursuant to the National Environmental Policy Act (NEPA) of 1969, as amended, the Bureau of Reclamation (Reclamation) has prepared a DEIS to evaluate the potential effects of conveying title of the Humboldt Project (Project) and associated lands to the Pershing County Water Conservation District (PCWCD), State of Nevada, Lander County and Pershing County. The action is needed to comply with Title VIII of Public Law 107–282 which directs Reclamation to transfer title of the Project to the entities listed above.

DATES: Submit written comments on the Draft EIS on or before March 28, 2005, at the address provided below.

Public hearings will be held to accept oral and written comments on the DEIS:

- Monday, March 14, 2005, 12:30 p.m. to 2:30 p.m., Lovelock, Nevada;
- Monday, March 14, 2005, 7 p.m. to 9 p.m., Battle Mountain, Nevada;
- Tuesday, March 15, 2005 6:30 p.m. to 8:30 p.m., Reno, Nevada.

ADDRESSES: The public hearings will be held at the following locations:

- Lovelock, Nevada—Lovelock Community Center, 820 Sixth Street;
- Battle Mountain, Nevada—Battle Mountain Civic Center, 625 South Broad Street;
- Reno, Nevada—Washoe County Dept. of Water Resources, 4930 Energy Way.

Comments should be sent to Caryn Huntt DeCarlo, Bureau of Reclamation, Lahontan Basin Area Office, 705 N Plaza, Room 320, Carson City, NV 89701; or faxed to (775) 882–7592; or e-mail to *chunttdecarlo@mp.usbr.gov*.

A copy of the document may be obtained by writing to Greystone Environmental Consultants, 401 West Baseline Road, Ste. 204, Tempe, AZ 85283, or by calling (480) 775–6330. The DEIS is accessible from the following Web site: *http://www.usbr.gov/mp/nepa/nepa_projdetails.cfm?Project_ID=550*.

FOR FURTHER INFORMATION CONTACT: Caryn Huntt DeCarlo, Bureau of Reclamation, Lahontan Basin Area Office, 705 N Plaza, Room 320, Carson City, NV 89701, telephone (775) 884–8352.

SUPPLEMENTARY INFORMATION: The Project is located along the Humboldt River in northwestern Nevada. Reclamation began Project construction in 1935 and in 1941 the first water was delivered to agricultural lands in the Lovelock Valley from storage in Rye Patch Reservoir. PCWCD assumed operation of the Project in 1941. PCWCD has had several Project repayment contracts with Reclamation that have all been repaid. Project features include Battle Mountain Community Pasture, Rye Patch Dam and Reservoir, and the Humboldt Sink. Battle Mountain Community Pasture, located near Battle Mountain, is approximately 30,000 acres and is managed for grazing by the PCWCD under a lease agreement with Reclamation. Rye Patch Reservoir is located 26 miles upstream from Lovelock, is 21 miles in length, and has a capacity of 190,000 acre-feet. The State of Nevada manages the recreation at the reservoir under a management agreement with Reclamation and the PCWCD. The Humboldt Sink is also part of the Project and is managed by the State of Nevada under a management agreement with Reclamation.

Copies of the DEIS are available for public inspection and review at the following locations:

- Bureau of Reclamation, Lahontan Basin Area Office, 705 N Plaza, Room 320, Carson City, Nevada, (775) 884–8352.
- Pershing County Water Conservation District Office, Lovelock, Nevada, (775) 273–2293.
- Nevada Division of State Parks, 1300 South Curry Street, Carson City, Nevada (775) 687–4384.
- Nevada Division of Wildlife, 1100 Valley Road, Reno, Nevada, (775) 688–1500.
- Lander County Court House, 315 South Humboldt, Battle Mountain, Nevada, (775) 635–5195.
- Pershing County Court House, 400 Main Street, Lovelock, Nevada, (775) 273–2613.
- Humboldt County Court House, 25 West 5th Street, Winnemucca, Nevada, (775) 623–6369.

Libraries:

- Reno Public Library, 301 South Center Street, Reno, Nevada, (775) 328–2586.
- Pershing County Library, 1125 Central Avenue, Lovelock, Nevada, (775) 273–2216.
- Humboldt County Library, 85 East 5th Street, Winnemucca, Nevada, (775) 623–6388.
- Battle Mountain County Library, 625 South Broad Street, Battle Mountain, Nevada, (775) 635–2534.
- Elko County Library, 720 Court Street, Elko, Nevada, (775) 738–3066.

Hearing Process Information. The purpose of the public hearing is to provide the public with an opportunity to comment on environmental issues addressed in the DEIS. Written comments will also be accepted. Persons needing reasonable accommodations in order to attend and participate in the public meeting should contact Sandra Fairchild by telephone at (480) 775–6330; or fax (480) 775–6253 for accessibility accommodations, including sign language interpreters or other auxiliary aids. Requests should be made within 10 business days of the hearing, to allow sufficient time to arrange for accommodation. Requests to make oral comments at the public hearings may be made at each hearing. Comments will be recorded by a court reporter. Speakers will be called in the order of their requests. In the interest of available time, each speaker will be asked to limit oral comments to 5 minutes. Longer comments should be summarized at the public hearing and submitted in writing either at the public hearing or identified as hearing comments and mailed to be received by Caryn Huntt DeCarlo no later than close of business on April 1, 2005.

Our practice is to make comments, including names and home addresses of respondents, available for public review. Individual respondents may request that we withhold their home address from public disclosure, which we will honor to the extent allowable by law. There may also be circumstances in which we would withhold a respondent's identity from public disclosure, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public disclosure in their entirety.

Dated: January 18, 2005.

Kirk C. Rodgers,

Regional Director, Mid-Pacific Region.

[FR Doc. 05–1636 Filed 1–27–05; 8:45 am]

BILLING CODE 4310–MN–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–653 (Second Review)]

Sebacic Acid From China

AGENCY: United States International Trade Commission.

ACTION: Revised schedule for the subject review.

EFFECTIVE DATES: January 25, 2005.

FOR FURTHER INFORMATION CONTACT: Jai Motwane (202–205–3176), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*). The public record for this review may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*.

SUPPLEMENTARY INFORMATION: On July 28, 2004 (69 FR 45075), the Commission published a notice in the **Federal Register** scheduling a full five-year review concerning the antidumping duty order on sebacic acid from China. Pursuant to 19 U.S.C. 1675 (c)(5)(B),[1] the Commission has extended the review period by up to 90 days.

The record in this review will be reopened and parties may submit final comments on any new information on or before April 21, 2005. Such final comments must comply with section 207.68 of the Commission's rules.

For further information concerning this review, see the Commission's notice cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and F (19 CFR part 207).

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to sections 201.35 and 207.62 of the Commission's rules.

By order of the Commission.

Issued: January 25, 2005.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 05–1655 Filed 1–27–05; 8:45 am]

BILLING CODE 7020–02–P

[1] As a transition order five-year review, the subject review is extraordinarily complicated pursuant to section 751(c)(5)(C) of the Tariff Act of 1930.

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 60-day notice of information collection under review: Firearms Transaction Record Part II—Intrastate Non-Over-the-Counter.

The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for ''sixty days'' until March 29, 2005. This process is conducted in accordance with 5 CFR 1320.10.

If you have comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Cherie Knoblock, Firearms Enforcement Branch, Room 7202, 650 Massachusetts Avenue NW., Washington, DC 20226.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Firearms Transaction Record Part II—Intrastate Non-Over-the-Counter.

(3) *Agency Form Number, if Any, and the Applicable Component of the Department of Justice Sponsoring the Collection:* Form Number: ATF F 4473 Part II (5300.9). Bureau of Alcohol, Tobacco, Firearms and Explosives.

(4) *Affected Public Who Will be Asked or Required to Respond, as Well as a Brief Abstract:* Primary: Individuals or households. Other: Business or other for-profit. The form is used to determine the eligibility of a person to receive a firearm from a Federal firearms licensee and to establish the identity of the buyer. The form is also used in law enforcement investigations to trace firearms or to confirm criminal activity.

(5) *An Estimate of the Total Number of Respondents and the Amount of Time Estimated for an Average Respondent to Respond:* It is estimated that 500 respondents will complete a 20 minute form.

(6) *An Estimate of the Total Public Burden (in Hours) Associated With the Collection:* There are an estimated 167 annual total burden hours associated with this collection.

If additional information is required contact: Brenda E. Dyer, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street NW., Washington, DC 20530.

Dated: January 25, 2005.

Brenda E. Dyer,

Department Clearance Officer, Department of Justice.

[FR Doc. 05–1582 Filed 1–27–05; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 60-day notice of information collection under review: 2005 National Survey of Prosecutors.

The Department of Justice (DOJ), Office of Justice Programs (OJP), has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for ''sixty days'' until March 29, 2005. This process is conducted in accordance with 5 CFR 1320.10.

If you have comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Steven W. Perry, Bureau of Justice Statistics, Office of Justice Programs, Department of Justice, 810 Seventh Street, NW., Washington, DC 20531.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Reinstatement, with change, of previously approved collection for which approval has expired.

(2) *Title of the Form/Collection:* 2005 National Survey of Prosecutors.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: NSP–05. Bureau of Justice Statistics, Office of Justice Programs, Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* The NSP–05 is the only collection effort that provides basic information on prosecutorial office staffing and operations, use of innovative prosecution techniques, felony and misdemeanor caseloads, prosecution of computer related crimes, juvenile offenses, and use of DNA evidence.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: It is estimated that 310 surveys, requiring approximately 30 minutes to complete, will be submitted to the State Prosecutor Offices in each selected district.

(6) An estimate of the total public burden (in hours) associated with the collection: The estimated public burden associated with this collection is 155 hours.

If additional information is required contact: Brenda E. Dyer, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street NW., Washington, DC 20530.

Dated: January 25, 2005.

Brenda E. Dyer,

Department Clearance Officer, Department of Justice.

[FR Doc. 05–1581 Filed 1–27–05; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Employment Standards Administration; Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR Part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR Part 1, Appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedes decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR Part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under the Davis-Bacon and Related Acts,'' shall be the minimum paid by

contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, NW., Room S–3014, Washington, DC 20210.

Modification to General Wage Determination Decisions

The number of the decisions listed to the Government Printing Office document entitled ''General Wage Determinations Issued Under the Davis-Bacon and related Acts'' being modified are listed by Volume and State. Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I

Connecticut
CT030001 (Jun. 13, 2003)
CT030002 (Jun. 13, 2003)
CT030004 (June. 13, 2003)
New Jersey
NJ030003 (Jun. 13, 2003)

Volume II

Virginia
VA030005 (Jun. 13, 2003)
VA030023 (Jun. 13, 2003)
VA030031 (Jun. 13, 2003)
VA030033 (Jun. 13, 2003)
VA030067 (Jun. 13, 2003)
VA030087 (Jun. 13, 2003)
VA030088 (Jun. 13, 2003)
West Virginia
WV030001 (Jun. 13, 2003)
WV030002 (Jun. 13, 2003)
WV030003 (Jun. 13, 2003)
WV030006 (Jun. 13, 2003)
WV030009 (Jun. 13, 2003)
WV030010 (Jun. 13, 2003)

Volume III

Florida
FL030001 (Jun. 13, 2003)
FL030009 (Jun. 13, 2003)
FL030032 (Jun. 13, 2003)
Georgia
GA030073 (Jun. 13, 2003)
GA030085 (Jun. 13, 2003)
GA030086 (Jun. 13, 2003)
GA030087 (Jun. 13, 2003)
GA030088 (Jun. 13, 2003)

Volume IV

Minnesota
MN030005 (Jun. 13, 2003)

Volume V

Missouri
MO030001 (Jun. 13, 2003)
MO030003 (Jun. 13, 2003)
MO030006 (Jun. 13, 2003)
MO030007 (Jun. 13, 2003)
MO030008 (Jun. 13, 2003)
MO030010 (Jun. 13, 2003)
MO030014 (Jun. 13, 2003)
MO030016 (Jun. 13, 2003)
MO030019 (Jun. 13, 2003)
MO030041 (Jun. 13, 2003)
MO030043 (Jun. 13, 2003)
MO030045 (Jun. 13, 2003)
MO030046 (Jun. 13, 2003)
MO030047 (Jun. 13, 2003)
MO030051 (Jun. 13, 2003)
MO030052 (Jun. 13, 2003)
MO030053 (Jun. 13, 2003)
MO030055 (Jun. 13, 2003)
MO030056 (Jun. 13, 2003)
MO030057 (Jun. 13, 2003)
MO030059 (Jun. 13, 2003)
MO030060 (Jun. 13, 2003)
MO030061 (Jun. 13, 2003)
Texas
TX030122 (Jun. 13, 2003)
TX030123 (Jun. 13, 2003)
TX030124 (Jun. 13, 2003)

Volume VI

None

Volume VII

California
CA030001 (Jun. 13, 2003)
CA030002 (Jun. 13, 2003)
CA030004 (Jun. 13, 2003)
CA030009 (Jun. 13, 2003)
CA030013 (Jun. 13, 2003)
CA030019 (Jun. 13, 2003)
CA030023 (Jun. 13, 2003)
CA030025 (Jun. 13, 2003)
CA030028 (Jun. 13, 2003)
CA030029 (Jun. 13, 2003)
CA030030 (Jun. 13, 2003)
CA030031 (Jun. 13, 2003)
CA030032 (Jun. 13, 2003)
CA030033 (Jun. 13, 2003)
CA030035 (Jun. 13, 2003)
CA030036 (Jun. 13, 2003)
CA030037 (Jun. 13, 2003)

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled ''General Wage determinations Issued Under the Davis-Bacon And Related Acts''. This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country.

General wage determinations issued under the Davis-Bacon and related Acts are available electronically at no cost on the Government Printing Office site at *www.access.gpo.gov/davisbacon.* They are also available electronically by subscription to the Davis-Bacon Online Service (*http://davisbacon.fedworld.gov*) of the National Technical Information Service (NTIS) of the U.S. Department of Commerce at 1–800–363–2068. This subscription offers value-added features such as electronic delivery of modified wage decisions directly to the user's desktop, the ability to access prior wage decisions issued during the year, extensive Help desk Support, etc.

Hard-copy subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, (202) 512–1800.

When ordering hard-copy subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the six separate Volumes, arranged by State. Subscriptions include an annual edition (issued in January or February) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates will be distributed to subscribers.

Signed at Washington, D.C. this 19 day of January 2005.

John Frank,

Acting Chief, Branch of Construction Wage Determinations.

[FR Doc. 05–1335 Filed 1–27–05; 8:45 am]

BILLING CODE 4510–27–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 05–008]

NASA Nuclear Systems Strategic Roadmap Committee; Meeting

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announces a meeting of the NASA Nuclear Systems Strategic Roadmap Committee.

DATES: Tuesday, February 15, 2005, 8 a.m. to 7:30 p.m., Wednesday, February 16, 2005, 8 a.m. to 7:30 p.m., eastern standard time.

ADDRESSES: University of Maryland University College, The Inn and Conference Center, 3501 University Blvd. E., Adelphi, MD 20783–7998, (301) 985–7303.

FOR FURTHER INFORMATION CONTACT: Ms. Victoria Friedensen, Exploration Systems Directorate, National Aeronautics and Space Administration, Washington, DC 20546, (202) 358–1916.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up

to the seating capacity of the meeting room. Attendees will be requested to sign a register.

The agenda for the meeting is as follows:

—Launch Approval Processes
—Public Engagement
—Radioisotope-based Power Sources
—Fission-based Power Systems
—Nuclear Thermal Propulsion

It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

P. Diane Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 05–1549 Filed 1–27–05; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 05–010]

NASA Space Science Advisory Committee, Solar System Exploration Subcommittee; Meeting

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of meeting.

SUMMARY: The National Aeronautics and Space Administration announces a meeting of the NASA Space Science Advisory Committee (SScAC), Solar System Exploration Subcommittee (SSES).

DATES: Monday, February 14, 2005, 8:30 a.m. to 5:30 p.m., and Tuesday, February 15, 2005, 8:30 a.m. to 5 p.m.

ADDRESSES: Santa Fe Institute, Noyce Conference Room, 1399 Hyde Park Road, Sante Fe, NM 87501.

FOR FURTHER INFORMATION CONTACT: Dr. Michael H. New, Science Mission Directorate, National Aeronautics and Space Administration, Washington, DC 20546, (202) 358–1766, *michael.h.new@nasa.gov*.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. The agenda for the meeting is as follows:

—Status of Solar System Exploration
—Status of Mars Exploration Program
—Update on the Discovery Program
—Kepler Mission Update
—Update on Deep Space Network
—Status of Robotic Lunar Exploration Program
—Update on Jupiter Icy Moons Orbiter

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants. Attendees will be requested to sign a visitor's register.

Dated: January 21, 2005.

P. Diane Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 05–1547 Filed 1–27–05; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 05–009]

NASA Sun-Solar System Connection Strategic Roadmap Committee; Meeting

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announces a meeting of the NASA Sun-Solar System Connection Strategic Roadmap Committee.

DATES: Thursday, February 10, 2005, 8:30 a.m. to 5 p.m., Friday, February 11, 2005, 8:30 a.m. to 5 p.m. eastern standard time.

ADDRESSES: NASA Headquarters, Auditorium (February 10) and room 6H46 (February 10 and 11), 300 E Street, SW., Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Dr. Barbara Giles, 202–358–1762.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the meeting room.

The agenda for the meeting is as follows:

—Sun-Earth Systems Program Overview and Status
—Reports on Sun-Solar System Connection Roadmap foundation work
—Discussion of science objectives and missions under study

Attendees will be requested to sign a register and to comply with NASA security requirements, including the presentation of a valid picture ID, before receiving an access badge. Foreign nationals attending this meeting will be required to provide the following information no less than 3 working days prior to the meeting: Full name; gender; date/place of birth; citizenship; visa/green card information (number, type, expiration date); passport information (number, country, expiration date); employer/affiliation information (name of institution, address, country, phone); title/position of attendee. To expedite admittance, attendees with U.S. citizenship can provide identifying information in advance by contacting Wanda Doyle via e-mail at *wdoyle@hq.nasa.gov* or by telephone at (202) 358–2206.

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants.

Dated: January 21, 2005.

P. Diane Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 05–1548 Filed 1–27–05; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 05–012]

Notice of Prospective Patent License

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of Prospective Patent License.

SUMMARY: NASA hereby gives notice that Bartron Medical Imaging, LLC, of New Haven, Connecticut, has applied for a partially exclusive license to practice the inventions described and claimed in U.S. Patent Application No. 09/839,147, entitled ''Method for Implementation of Recursive Hierarchical Segmentation on Parallel Computers,'' and claimed in U.S. Patent Application No. 10/845,419, entitled ''A Method for Recursive Hierarchical Segmentation which Eliminates Processing Window Artifacts,'' which are assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. Written objections to the prospective grant of a license should be sent to NASA Goddard Space Flight Center. NASA has not yet made a determination to grant the requested license and may deny the requested license even if no objections are submitted within the comment period.

DATES: Responses to this notice must be received by February 14, 2005.

FOR FURTHER INFORMATION CONTACT: Keith Dixon, NASA Goddard Space Flight Center, Code 503, Greenbelt, MD 20771, (301) 286–9279.

Dated: January 18, 2005.

Keith T. Sefton,

Deputy General Counsel (Administration and Management).

[FR Doc. 05–1546 Filed 1–27–05; 8:45 am]

BILLING CODE 7510–13–U

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 05–011]

Notice of Prospective Patent License

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of Prospective Patent License.

SUMMARY: NASA hereby gives notice that Lake Shore Cryotronics, Inc. of Westerville, OH, has applied for a partially exclusive license to practice the inventions described and claimed in U.S. Patent Application No. 10/192,886, entitled ''Passive Gas-Gap Heat Switch for Adiabatic Demagnetization Refrigeration,'' and described in U.S. Provisional Patent Application No. 60/572,663, entitled ''Adiabatic Demagnetization Refrigerator (ADR) Salt Pill Design and Crystal Growth Process for Hydrated Magnetic Salts,'' which are assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. Written objections to the prospective grant of a license should be sent to NASA Goddard Space Flight Center. NASA has not yet made a determination to grant the requested license and may deny the requested license even if no objections are submitted within the comment period.

DATES: Responses to this notice must be received within 15 days from date of publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Christopher Kirkman, NASA Goddard Space Flight Center, Code 503, Greenbelt, MD 20771, (301) 286–0602.

Dated: January 18, 2005.

Keith T. Sefton,

Deputy General Counsel (Administration and Management).

[FR Doc. 05–1545 Filed 1–27–05; 8:45 am]

BILLING CODE 7510–13–U

NATIONAL SCIENCE FOUNDATION

Committee on Equal Opportunities in Science and Engineering; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Committee on Equal Opportunities in Science and Engineering (1173).

Dates and Time: February 15, 2005, 8:30 a.m.–5:30 p.m. and February 16, 2005, 8:30 a.m.–2 p.m.

Place: National Science Foundation, 4201 Wilson Boulevard, Room 1235 S, Arlington, VA 22230.

Type of Meeting: Open.

Contact Person: Dr. Margaret E.M. Tolbert, Senior Advisor and Executive Liaison, CEOSE, Office of Integrative Activities, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230, Telephone: (703) 292–8040.

Minutes: May be obtained from the Executive Liaison at the above address.

Purpose of Meeting: To provide advice and recommendations concerning broadening participation in science and engineering.

Agenda:

Tuesday, February 15, 2005

Welcome by the CEOSE Chair
Introductions
Review of CEOSE Meeting Agenda and Minutes
Discussions/Presentations:
- Broadening Participation in Chemistry—Dr. Arthur B. Ellis, Director of the Chemistry Division/National Science Foundation
- Congressionally Required Decennial and Biennial Reports Prepared by CEOSE Members
- Dialogue with Dr. Arden L. Bement, Jr., Director of the National Science Foundation

Wednesday, February 16, 2005

Opening Statement by the CEOSE Chair
Discussions/Presentations:
- Continuation of Unfinished Discussions of February 15, 2005
- Response to Action Items in the CEOSE Meeting Minutes
- Reports on NSF Advisory Committees
- Plans for the Final Preparation and Distribution of the Single-Volume Decennial and 2004 Biennial Report to Congress
- Information on the Nomination of New Members
- Refinement of Recommendations by CEOSE
- Selection of Dates for Future CEOSE Meetings

Dated: January 25, 2005.

Susanne Bolton,

Committee Management Officer.

[FR Doc. 05–1640 Filed 1–27–05; 8:45 am]

BILLING CODE 7999–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. PAPO–00, ASLBP No. 04–829–01–PAPO NEV–01]

Atomic Safety and Licensing Board; Department of Energy (High Level Waste Repository: Pre-Application Matters); First Case Management Order (Regarding Preparation of Privilege Logs)

January 24, 2005.

Before Administrative Judges: Thomas S. Moore, Chairman, Alex S. Karlin and Alan S. Rosenthal

The purpose of this order is to promote good management and efficiency in the resolution of documentary privilege disputes during the pre-license application phase of the expected application by the United States Department of Energy (DOE) for a license to construct a repository for high-level radioactive waste (HLW) at Yucca Mountain, Nevada. DOE, the NRC Staff, the State of Nevada (State), other potential parties, interested Indian Tribes, and interested units of local government (collectively Potential Participants) are directed to submit their responses to this order within the times specified below.

I. Background

On August 31, 2004, this Board granted the motion of the State to strike DOE certification regarding its production of documentary material on the grounds, *inter alia*, that the gaps in its document production, and the incompleteness of DOE's review of the documents for claims of privilege, showed that DOE had not made all documentary material available as required by 10 CFR 2.1003(a). LBP–04–20, 60 NRC 300 (2004). In that decision, we noted that DOE had claimed approximately one million of its documents were entitled to some form of privilege and yet had not completed its privilege review for several hundred thousand of these documents. 60 NRC at 316, 318. Underscoring the magnitude of the issue, counsel for the State indicated that, given DOE's numerous claims of privilege, ''we're going to be [before the Board] thousands of times asking for documents.'' 60 NRC at 328 n.47. Although our ruling of August 31, 2004 temporarily postponed such privilege disputes, once DOE re-submits and re-certifies its documents, the controversies will begin anew.

Even assuming that DOE's pending document production is of the highest quality, it is now clear that thousands of documents in this proceeding (whether

from DOE or other participants) will be subject to various claims of privilege and that hundreds, if not thousands, of these claims will be disputed. This threatens to delay the proceeding. But, as we noted in August, ''a full and fair 6-month document discovery period, where all of DOE's documents are to be available to the potential parties and the public, is a necessary precondition to the development of well articulated contentions and to the Commission's ability to meet the statutory mandate to issue a final decision within three years.'' 60 NRC at 315. Mindful of the enormous task that looms before us, it is incumbent on this Board to develop procedures to manage and to resolve efficiently a very large number of privilege disputes.

II. Regulatory Structure

Development of an efficient plan for managing the privilege disputes in this proceeding first requires an understanding of the scope of the types of privilege claims that are available, and of the existing regulatory and technical structure.

A. Scope of Available Privilege Claims

As we explained in our August decision, the regulations applicable to the Yucca Mountain proceeding, 10 CFR Part 2, Subpart J, require that DOE and other Potential Participants make ''all documentary material'' available. 10 CFR 2.1003(a)(1); *see generally* 60 NRC at 311. Documents must be produced electronically and will be placed on the NRC Licensing Support Network (LSN). The full text and an ''electronic bibliographic header'' (Header) is required for all documents except for documents ''(i) for which a claim of privilege is asserted; (ii) which constitutes confidential financial or commercial information; or (iii) which constitute safeguards information,'' where only a Header is required. 10 CFR 2.1003(a)(4)(i)–(iii) (collectively ''privileges'' or ''privileged documents'').[1]

The scope of the privileges available under 10 CFR 2.1003(a)(4)(i) is addressed in 10 CFR 2.1006(a), that states:

> [T]he traditional discovery privileges recognized in NRC adjudicatory proceedings and the exceptions from disclosure in § 2.390 may be asserted by potential parties, interested States, local governmental bodies, Federally-recognized Indian Tribes, and parties. In addition to Federal agencies, the deliberative process privilege may also be asserted by States, local governmental bodies and Federally-recognized Indian Tribes.

The regulation specifies that the Board may, in appropriate circumstances, deny claims of privilege, order the document produced, and/or require document production under an appropriate protective order.

The exemptions from disclosure specified in 10 CFR 2.390 are those specified in the Freedom of Information Act (FOIA), 5 U.S.C. 552. The regulation sets forth the general rule that NRC must make all records and documents available to the public, and the nine FOIA exemptions from disclosure. These nine exemptions include documents that (1) are properly classified; (2) relate solely to internal personnel rules and practices; (3) are specifically exempted from disclosure by a statute that leaves no discretion on the issue; (4) are trade secrets or privileged or confidential commercial or financial information; (5) are interagency or intra-agency memoranda that would not be available by law to a party other than in litigation;[2] (6) personnel and medical files, etc.[3]

In sum, the Subpart J regulations establish numerous categories of privileged documents with respect to which the person producing them need only provide a ''Header.'' These categories include:

(1) The traditional discovery privileges recognized in NRC proceedings (e.g., the attorney work product privilege and the attorney-client communication privilege);
(2) Confidential financial or commercial information;
(3) Safeguards information;
(4) The deliberative process privilege information (for governmental entities); and
(5) The nine FOIA exemptions of 10 CFR 2.390(a).

For each of these privileges, there are specific elements or requirements that must be met, and the elements vary substantially depending on the privilege. For example, a person claiming that a document is protected under the attorney-client communication privilege generally must establish that the document was (a) to or from an attorney acting in his or her capacity as an attorney; (b) written primarily for the purpose of seeking or providing legal advice; and (c) not shared or disseminated to persons outside of the attorney-client relationship. On the other hand, in order for a document to qualify under the deliberative process privilege the person claiming the privilege generally needs to show that it is pre-decisional, deliberative, and that an appropriately senior agency official personally reviewed and specifically identified the documents as meeting the requirements of the deliberative process privilege.[4] In order to determine whether a document properly qualifies for a specific privilege, the Board must be provided with the facts showing that the document satisfies all of the elements applicable to the privilege claimed.

B. Content of Electronic Bibliographic Headers

Turning to the prescribed content of the Headers, they do not appear to provide the parties or the Board with the information necessary to determine whether a given document satisfies the elements applicable to the privilege claimed for it. More fundamentally, the regulations do not require that the Header state that a withheld document is claimed to be privileged, much less the type of privilege claimed.[5] Similarly, there is no requirement that the person producing the document provide the essential information that would normally be required in a litigation privilege log, *i.e.*, the facts relating to the document that represent the elements of each privilege. ''Bibliographic header'' is defined as ''the minimum series of descriptive fields that a potential party, interested governmental participant, or party must submit with a document or other material.'' 10 CFR 2.1001. But no regulation lists or mandates this ''minimum series of descriptive fields'' or their contents.

The LSN Administrator and the LSN Advisory Review Panel, neither of which have authority to issue binding regulations, have attempted to fill this gap by issuing guidance. Guidance document ''LSN Baselined Design Requirements'' specifies a ''Recommended Participant

[1] A Header only is also acceptable for a document that is not suitable for image or searchable full text. 10 CFR 2.1003(a)(3).

[2] This FOIA exclusion is related to, but not identical with, the deliberative process privilege.

[3] There is some obvious overlap between the three categories of documents excluded under 10 CFR 2.1003(a)(4)(i)–(iii) and the nine FOIA exclusions. For example, section 2.1003(a)(4)(I) excludes ''confidential financial or commercial information,'' whereas section 2.390(a)(4) (FOIA Exemption 4) excludes ''trade secrets and commercial or financial information obtained from a person and privileged or confidential.'' These are not identical.

[4] The descriptions of the elements of the attorney-client communication privilege and the deliberative process privilege are provided to illustrate their differences, and are not to be construed as this Board's final interpretation of the elements of these privileges.

[5] A person may provide only a Header for a document that (a) is not technically suitable for electronic text display or (b) is claimed to be privileged. *See* 10 CFR 2.1003(a)(3) and (4). But the regulations and guidance do not require the person to state which of the two reasons justify his or her withholding of the document's text.

Bibliographic Header Field Structure,'' that suggests that each Header include fields for items such as: Addressee name, addressee organization, author name, author organization, comments, descriptors, document date, document type, and title.[6] The guidance describes the ''comments'' field basically as a catch-all field that can be used to explain (a) whether the document was claimed to be privileged and (b) if so, why.[7] The guidance document divides the suggested fields into three categories—mandatory, required if available, and optional—and the comments field is listed as ''optional.''

Although the recommended Header fields help identify a document (name of author, date, subject), they do not provide the information necessary to assess whether a document qualifies for any given privilege. For example, although the recommended Header fields include the ''addressee name'' and the ''author name,'' they do not provide the information necessary to determine whether the document qualifies for the attorney-client communication privilege, *i.e.*, (a) whether the addressee or author was an attorney, (b) whether the addressee and author had an attorney-client relationship, (c) whether the document was written for purposes of requesting or providing legal advice, and (d) whether the document was shared or disseminated to persons outside of the attorney-client relationship.[8] Alternatively, the Header fields provide no information about whether the document might qualify for the deliberative process privilege, such as was it pre-decisional and was it deliberative.

In short, even if a person were inclined to follow the optional recommendations of the LSN Administrator's non-binding guidance, the information in the Header fields would be of little assistance in resolving privilege disputes.

C. Privilege Logs

Privilege logs are the tool employed to manage and to resolve privilege claims. For example, Rule 26(b)(1) of the Federal Rules of Civil Procedure states that a party ''may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party'' and further provides:

> When a party withholds information otherwise discoverable under these rules by claiming that it is privileged or subject to protection as trial preparation material, the party shall make the claim expressly and shall describe the nature of the documents, communications, or things not produced or disclosed in a manner that, without revealing information itself privileged or protected, will enable other parties to assess the applicability of the privilege or protection.

Fed. R. Civ. Proc. 26(b)(5). The ''privilege log'' is the mechanism whereby a party claiming the privilege ''describes the nature of the documents * * * in a manner that * * * will enable other parties to assess the applicability of the privilege or protection.'' The log is generally a chart, listing each document for which a privilege applies, and providing, in different columns or fields, the information necessary to assess whether the privilege legitimately applies.

The Commission's general rules of practice for adjudicatory proceedings support the use of privilege logs. The rules governing Subpart G proceedings are virtually identical to the above quoted provisions of Rule 26. *See* 10 CFR 2.705(b)(1) and (4). Even in Subpart L proceedings, where discovery is limited to certain mandatory disclosures, the rules require each party to provide a privilege log—''a list of documents otherwise required to be disclosed for which a claim of privilege or protected status is being made, together with sufficient information for assessing the claim of privilege or protected status of the documents.'' 10 CFR 2.336(a)(3).

Although the regulations for the Yucca Mountain HLW proceeding do not incorporate 10 CFR 2.705 or 2.336 (*see* 10 CFR 2.1001), privilege logs remain an authorized and necessary tool under Subpart J. This Board, as the pre-license application presiding officer, is required and authorized to resolve privilege claims, *see* 10 CFR 2.1006(b) and 2.1010(b), and possesses all the general powers of a presiding officer, including the power to manage the process, rule on offers of proof, and avoid delay. *See* 10 CFR 2.1010(e) and 2.319.

Privilege logs will vary from case to case.[9] In many lawsuits, only a few dozen, or perhaps a hundred documents will be listed on a privilege log. In most cases, only two privileges are asserted—the attorney-client communication privilege and the attorney work product privilege. In these typical cases the privilege logs will be short and relatively simple. In other cases, privilege logs are larger and more complicated. For example, in the tobacco claims litigation involving massive numbers of documents, the court issued a detailed case management plan and procedure for resolving discovery and privilege disputes.[10] Likewise, in FOIA cases, where there are nine FOIA exemptions, rather than the two traditional privileges, the logs may be more complicated because each type of FOIA exemption has its own sub-elements. *See Vaugh* v. *Rosen*, 484 F.2d 820 (DC Cir. 1973). Certainly in any case involving a significant number of privileged documents, it is critical to establish at an early point the information that the privilege log must contain if there is to be any hope that the case is to proceed fairly and expeditiously.[11]

III. Order

Based on the foregoing, the Board hereby orders DOE, the NRC Staff and the State, together with any other Potential Participants who may wish to respond, to meet, either telephonically or in person, within 20 days of the publication of this order in the **Federal Register**, for the purpose of developing and agreeing on (a) a joint proposed format for privilege logs and (b) associated procedures for resolving

[6] LSN Baselined Design Requirements (June 5, 2001), at 17, Table A, 22–23.

[7] The guidance document states that the ''comments'' field should include ''any information not covered in other fields which the submitter or indexer believes would be of help to identify or retrieve the document, or to further explain any field entry for the document * * * This field may include summaries of documents that are privileged.'' *Id.* at 17.

[8] Of course the Board, by inspecting the document, might glean some or all of this information. But this misses the point, which is that it is literally impossible for this Board to review individually 100,000 or a million documents to attempt to determine what privilege, if any, the document provider is claiming and whether the document meets the necessary elements.

[9] *See* Robert J. Nelson, *The Importance of Privilege Logs*, The Practical Litigator, 27, 29 (Mar. 2000). *See also Heavin* v. *Owens-Corning Fiberglass*, No. 02–2572–KHV–DJW, 2004 U.S. Dist. LEXIS 2265 *1, *24 (D. Kan. Feb. 3, 2004) (describing what a privilege log should include ''at a minimum''); *Hill* v. *McHenry*, No. 99–2026–CM, 2002 U.S. Dist. LEXIS 6637 *1, *8 (D. Kan. Apr. 10, 2002) (listing requirements of satisfactory privilege log).

[10] *United States* v. *Phillip Morris, Inc.*, Ninth Case Management Order, 99–CV–2496, 2001 U.S. Dist. LEXIS 12603 *1 (D.D.C. Mar. 27, 2001).

[11] As one commentator has noted that ''it is in the producing party's interest to provide the absolute minimum amount of information about the document on the privilege log; downplay the potential importance of the document, disguise the weaknesses associated with the privilege or work product claim; and ultimately to delay producing or never produce the document.'' Robert J. Nelson, *The Importance of Privilege Logs*, The Practical Litigator, 27, 29 (Mar. 2000). To the contrary, it is in the public interest in this case, as well as the interest of sound judicial management, that the privilege logs contain all necessary information, so that privilege disputes can be minimized and promptly resolved.

privilege disputes. The joint proposed format for the privilege logs shall cover all categories of privilege or protected status claims available under Subpart J and relevant to this proceeding. *See* II.A.(1)–(5) above. For each category of claimed privilege (e.g., attorney-client communication, deliberative, Privacy Act), the joint proposed format for that particular privilege log should specify and define the sub-elements of information that must be provided in order to enable other parties to assess the applicability of the privilege or protection without revealing the privileged or protected information itself.[12]

The jointly agreed procedures associated with privilege claims and disputes shall be based upon the regulatory requirements and procedures of Subpart J and provide any suggested additional measures or procedures that will avoid, or expedite the resolution of, privilege disputes.[13] For example, the procedure may call for additional conferences between the parties, or for a mechanism for the redaction of small amounts of ''privileged information'' from an otherwise unprivileged document, in lieu of the blanket exclusion of a document. To the maximum extent possible, the privilege logs and procedures should encourage the prompt resolution of privilege disputes by the parties themselves. The proposed procedures should distinguish between those privileges that are absolute, and those that are qualified. The proposed procedures shall maximize the effective use of the LSN.

Not later than 40 days after the publication of this order in the **Federal Register**, DOE, the NRC Staff, and the State shall submit a jointly-agreed proposed case management order to the Board that establishes a proposed format for a privilege log and specifies privilege claim related procedures for this proceeding. They shall allow any other Potential Participant the opportunity to negotiate, to endorse and/or to join in the joint submission. In addition, such other Potential Participants may develop and submit their own joint or individual alternative proposed case management orders on the subject of privilege log formats and procedures.

If DOE, the NRC Staff, and the State are unable to agree upon a joint proposed case management order prescribing the format for a privilege log and associated procedures, then, 50 days after the publication of this order in the **Federal Register**, each of them, and any other Potential Participant shall submit separate proposed case management orders on this subject. In such case, 65 days after publication of this order in the **Federal Register,** each person or entity filing a proposed case management order shall file a supplement identifying and explaining the material differences between its proposed order and the other proposed orders.

It is so ordered.

January 24, 2005, Rockville, Maryland.

The Pre-license Application Presiding Officer Board.

Thomas S. Moore,

Chairman, Administrative Judge.

Alan S. Rosenthal,

Administrative Judge.

Alex S. Karlin,

Administrative Judge.

[FR Doc. 05–1575 Filed 1–27–05; 8:45 am]

BILLING CODE 7590–01–U

[12] For example, DOE and its litigation support contractor, CACI Inc., are using computer software to screen documents for potential claims of privilege as well as teams of people reviewing and evaluating documents for privilege. *See* 60 NRC at 318. This software, and DOE's instructions to these individuals, presumably identify the elements of each category of privilege that DOE is claiming. The NRC, which made its documents available on the LSN on September 30, 2004, presumably developed similar criteria and went through a similar process in evaluating which documents qualified for a privilege.

[13] Appointment of a discovery master, authorized under 10 CFR 2.1018(g), merely pushes the discovery disputes to another level and, therefore, would not appear to be a panacea.

OFFICE OF MANAGEMENT AND BUDGET

2004 List of Designated Federal Entities and Federal Entities

AGENCY: Office of Management and Budget.

ACTION: Notice.

SUMMARY: As required by the Inspector General Act of 1978, as amended (IG Act), this notice provides a list of Designated Federal Entities and Federal Entities.

FOR FURTHER INFORMATION CONTACT: Office of Federal Financial Management, Office of Management and Budget, at (202) 395–3993.

SUPPLEMENTARY INFORMATION: This notice provides a copy of the 2004 List of Designated Federal Entities and Federal Entities which, under the IG Act, the Office of Management and Budget (OMB) is required to publish annually. This list is also posted on the OMB Web site at *http//www.whitehouse.gov/omb.html*.

The list is divided into two groups: Designated Federal Entities and Federal Entities. Designated Federal Entities are listed in the IG Act, except for those agencies that have ceased to exist or that have been deleted from the list. The Designated Federal Entities are required to establish and maintain Offices of Inspector General to: (1) Conduct and supervise audits and investigations relating to programs and operations; (2) promote economy, efficiency, and effectiveness of, and to prevent and detect fraud and abuse in such programs and operations; and (3) provide a means of keeping the entity head and the Congress fully and currently informed about problems and deficiencies relating to the administration of such programs and operations and the necessity for, and progress of, corrective actions.

Federal Entities are defined, in section 8G(a)(1) of the Inspector General Act, as any Government corporation (within the meaning of section 103(1) of title 5, United States Code), any Government controlled corporation (within the meaning of section 103(2) of such title), or any other entity in the Executive Branch of the government, or any independent regulatory agency, but does not include:

(1) An establishment (as defined in section 11(2) of the Inspector General Act) or part of an establishment;

(2) A designated Federal entity (as defined in section 8G(a)(2) of the Inspector General Act) or part of a designated Federal entity;

(3) The Executive Office of the President;

(4) The Central Intelligence Agency;

(5) The Government Accountability Office; or

(6) Any entity in the judicial or legislative branches of the Government, including the Administrative Office of the United States Courts and the Architect of the Capitol and any activities under the direction of the Architect of the Capitol.

Federal Entities are required to report annually to each House of the Congress and OMB on audit and investigative activities in their organizations.

For the Designated Federal Entities list for 2004, there is one addition (the Broadcasting Board of Governors succeeded the Board for International Broadcasting) and one amendment (the designated entity head of Amtrak was changed to the Chairperson who is the chief policymaking officer), for a total of two changes to the 2003 list. For the Federal Entities list for 2004, there are four additions (the Court Services and Offender Supervision Agency for the District of Columbia, the Millennium Challenge Corporation, the U.S. Interagency Council on Homelessness, and the White House Commission on the National Moment of Remembrance) and three deletions (the Commission on

Ocean Policy, the Office of Independent Counsels, and the Pacific Charter Commission), for a total of seven changes to the 2003 list.

The 2004 List of Designated Federal Entities and Federal Entities was prepared in consultation with the U.S. Government Accountability Office.

Linda M. Springer,

Controller, Office of Federal Financial Management.

Herein follows the text of the 2004 List of Designated Federal Entities and Federal Entities:

2004 List of Designated Federal Entities and Federal Entities

The Inspector General Act of 1978, as amended, requires OMB to publish a list of ''Designated Federal Entities'' and ''Federal Entities'' and the heads of such entities. Designated Federal Entities are required to establish Offices of Inspector General and to report semiannually to each House of the Congress and the Office of the Management and Budget summarizing the activities of the Office during the immediately preceding six-month periods ending March 31 and September 30. Federal Entities are required to report annually on October 31 to each House of the Congress and the Office of Management and Budget on audit and investigative activities in their organizations.

Designated Federal Entities and Entity Heads

1. Amtrak—Chairperson.
2. Appalachian Regional Commission—Federal Co-Chairperson.
3. The Board of Governors, Federal Reserve System—Chairperson.
4. Broadcasting Board of Governors—Chairperson.
5. Commodity Futures Trading Commission—Chairperson.
6. Consumer Product Safety Commission—Chairperson.
7. Corporation for Public Broadcasting—Board of Directors.
8. Denali Commission—Chairperson.
9. Election Assistance Commission—Chairperson.
10. Equal Employment Opportunity Commission—Chairperson.
11. Farm Credit Administration—Chairperson.
12. Federal Communications Commission—Chairperson.
13. Federal Election Commission—Chairperson.
14. Federal Housing Finance Board—Chairperson.
15. Federal Labor Relations Authority—Chairperson.
16. Federal Maritime Commission—Chairperson.
17. Federal Trade Commission—Chairperson.
18. Legal Services Corporation—Board of Directors.
19. National Archives and Records Administration—Archivist of the United States.
20. National Credit Union Administration—Chairperson.
21. National Endowment for the Arts—Chairperson.
22. National Endowment for the Humanities—Chairperson.
23. National Labor Relations Board—Chairperson.
24. National Science Foundation—National Science Board.
25. Peace Corps—Director.
26. Pension Benefit Guaranty Corporation—Chairperson.
27. Securities and Exchange Commission—Chairperson.
27. Smithsonian Institution—Secretary.
28. United States International Trade Commission—Chairperson.
29. United States Postal Service—Governors of the Postal Service.

Federal Entities and Entity Heads

1. Advisory Council on Historic Preservation—Chairperson.
2. African Development Foundation—Chairperson.
3. American Battle Monuments Commission—Chairperson.
4. Architectural and Transportation Barriers Compliance Board—Chairperson.
5. Armed Forces Retirement Home—Board of Directors.
6. Barry Goldwater Scholarship and Excellence in Education Foundation—Chairperson.
7. Chemical Safety and Hazard Investigation Board—Chairperson.
8. Christopher Columbus Fellowship Foundation—Chairperson.
9. Commission for the Preservation of America's Heritage Abroad—Chairperson.
10. Commission of Fine Arts—Chairperson.
11. Commission on Civil Rights—Chairperson.
12. Committee for Purchase From People Who Are Blind or Severely Disabled—Chairperson.
13. Court of Appeals for Veterans Claims—Chief Judge.
14. Court Services and Offender Supervision Agency for DC—Director.
15. Defense Nuclear Facilities Safety Board—Chairperson.
16. Delta Regional Authority—Federal Co-Chairperson.
17. Farm Credit System Financial Assistance Corporation—Chairperson.
18. Farm Credit System Insurance Corporation—Chairperson.
19. Federal Financial Institutions Examination Council—Chairperson.
20. Federal Mediation and Conciliation Service—Director.
21. Federal Mine Safety and Health Review Commission—Chairperson.
22. Federal Retirement Thrift Investment Board—Executive Director.
23. Harry S. Truman Scholarship Foundation—Chairperson.
24. Institute of American Indian and Alaska Native Culture and Arts Development—Chairperson.
25. Institute of Museum and Library Services—Director.
26. Inter-American Foundation—Chairperson.
27. James Madison Memorial Fellowship Foundation—Chairperson.
28. Japan-U.S. Friendship Commission—Chairperson.
29. Marine Mammal Commission—Chairperson.
30. Merit Systems Protection Board—Chairperson.
31. Millennium Challenge Corporation—Chief Executive Officer.
32. Morris K. Udall Scholarship and Excellence in National Environmental Policy Foundation—Chairperson.
33. National Capital Planning Commission—Chairperson.
34. National Commission on Libraries and Information Science—Chairperson.
35. National Council on Disability—Chairperson.
36. National Mediation Board—Chairperson.
37. National Transportation Safety Board—Chairperson.
38. National Veterans Business Development Corporation—Chairperson.
39. Neighborhood Reinvestment Corporation—Chairperson.
40. Nuclear Waste Technical Review Board—Chairperson.
41. Occupational Safety and Health Review Commission—Chairperson.
42. Office of Government Ethics—Director.
43. Office of Navajo and Hopi Indian Relocation—Chairperson.
44. Office of Special Counsel—Special Counsel.
45. Overseas Private Investment Corporation—Board of Directors.
46. Presidio Trust—Chairperson.
47. Selective Service System—Director.
48. Smithsonian Institution/John F. Kennedy Center for the Performing Arts—Chairperson.
49. Smithsonian Institution/National Gallery of Art—President.
50. Smithsonian Institution/Woodrow Wilson International Center for Scholars—Director.
51. Trade and Development Agency—Director.
52. U.S. Holocaust Memorial Museum—Chairperson.
53. U.S. Interagency Council on Homelessness—Chairperson.
54. U.S. Institute of Peace—Chairperson.
55. Vietnam Educational Foundation—Chairperson.
56. White House Commission on the National Moment of Remembrance—Chairperson.

[FR Doc. 05–1641 Filed 1–27–05; 8:45 am]

BILLING CODE 3110–01–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

OFFICE OF MANAGEMENT AND BUDGET

Office of Federal Financial Management; Proposed Policy on Research and Research-Related Grant Terms and Conditions

AGENCY: Executive Office of the President, Office of Science and Technology Policy (OSTP) and Office of Management and Budget (OMB), Office of Federal Financial Management (OFFM).

ACTION: Notice of proposed issuance of policy on terms and conditions for grants under Federal research and research-related programs.

SUMMARY: The Federal Demonstration Partnership (FDP), a streamlining initiative of ten Federal awarding offices and 92 academic and nonprofit research institutions, developed a core set of FDP terms and conditions that it has been using for several years for the implementation of OMB Circular A–110, ''Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations,'' (2 CFR part 215). The OSTP and OFFM request comment on making the FDP terms and conditions a government-wide standard, and broadening their use to all academic and nonprofit grantees, under Federal research and research-related programs.

The proposed policy directive also instructs Federal agencies to minimize the degree to which they supplement the core set with agency-specific, program-specific, or award-specific terms and conditions. The directive should therefore result in the near term in the use of more uniform terms and conditions for Federal research and research-related grants. In parallel with the establishment of this standard for research and research-related grants, an interagency group helping to implement the Federal Financial Assistance Management Improvement Act of 1999 (Public Law 106–107) will continue working toward the longer-term objective of standard award format and content for all Federal grants and cooperative agreements, including government-wide standard terms and conditions.

DATES: Comments must be received by February 28, 2005.

ADDRESSES: Comments should be addressed to Beth Phillips, Office of Federal Financial Management, 725 17th Street, NW., Washington, DC 20503; telephone (202) 395–3993; FAX (202) 395–3952; e-mail *ephillip@omb.eop.gov.* Due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, we encourage respondents to submit comments electronically to ensure timely receipt. We cannot guarantee that comments mailed will be received before the comment closing date.

FOR FURTHER INFORMATION CONTACT: For information on OMB Circular A–110 requirements, contact Beth Phillips at the addresses noted above. For information on the Research Business Models (RBM) Subcommittee see the RBM Web site at *http://rbm.nih.gov,* or contact Geoff Grant at the Office of Science and Technology Policy at 725 17th Street, NW., Washington, DC 20503; e-mail *ggrant@ostp.eop.gov;* telephone (202) 456–6131; FAX (202) 456–6027.

SUPPLEMENTARY INFORMATION

I. Background

This proposal is an initiative of the Research Business Models (RBM) Subcommittee of the Committee on Science (CoS), a committee of the National Science and Technology Council (NSTC). The RBM Subcommittee's objectives include:

- Facilitating a coordinated effort across Federal agencies to address policy implications arising from the changing nature of scientific research, and
- Examining the effects of these changes on business models for the conduct of scientific research sponsored by the Federal government.

The Subcommittee used public comments, agency perspectives, and input from a series of regional public meetings to identify priority areas in which it would focus its initial efforts. In each priority area, the Subcommittee is pursuing initiatives to promote, as appropriate, either common policy, the streamlining of current procedures, or the identification of agencies' and institutions' ''effective practices.'' As information about the initiatives becomes available, it is posted at the Subcommittee's Internet site *http://rbm.nih.gov.*

The objective of one RBM priority area is greater consistency in the format and content of Federal agencies' research grant and cooperative agreement awards. Federal agency awarding offices currently include different requirements in their awards, use different language to state the same requirements, and organize the award content differently. The variation in format and content increases both administrative effort and costs for recipients of Federal awards. More uniformity is possible because most requirements flow from common sources in the OMB circulars and in government-wide statutes and regulations.

Within the priority area on award uniformity, the Subcommittee identified two initiatives—one that could be achieved in the near term and a second that would be a longer-term effort. The proposal in this **Federal Register** notice is the result of the near-term initiative, which is to broaden use of the core set of terms and conditions developed by the FDP for research and research-related grants. The longer-term initiative relies on work being carried out by the Pre-Award Work Group under Public Law 106–107 to develop standard award format and content for all Federal grants and cooperative agreements.

This near-term initiative will broaden use of the core set of terms and conditions developed by the FDP:

- From Federal agencies that participate in the FDP to all Federal agencies that make research and research-related awards (each Federal agency must determine which of its programs are ''research-related'' for purposes of using the terms and conditions).
- From the ten awarding offices in agencies that currently participate in the FDP to all awarding offices in those agencies.
- From research and research-related awards received by universities and nonprofit organizations that participate in the FDP to research and related awards received by all such institutions.

II. Terms and Conditions—General Approaches

While Federal agencies organize their grant and cooperative agreement awards differently, there are three elements that they include in some form. One element is what some agencies call the award notice, which includes basic information such as the name of the recipient organization, the amount of Federal funding under the award, any required cost sharing, the beginning and end dates for Federal support, and the title of the project. Because this information is specific to a particular award, an awarding agency transmits it to the recipient each time an award is made.

The other two elements of the award are the administrative requirements and the national policy requirements with which recipients must comply, which together comprise the award terms and conditions. Examples of administrative

requirements are: Standards that a recipient's financial management, property management, and procurement systems must meet; performance reporting requirements; and rules for use and disposition of supplies and equipment. OMB Circular A–110 (2 CFR part 215) is the government-wide source of administrative requirements for an academic or other nonprofit research institution. An award's administrative terms and conditions therefore must implement that circular. In some cases, awards under a particular program may impose additional administrative requirements due to the nature of the program or its authorizing statute. In a relatively few instances, there also may be award-specific administrative requirements due to the nature of a particular project.

National policy requirements arise from Federal statutes, Presidential executive orders, or regulations with government-wide effect, such as prohibitions against discrimination. Most apply broadly to many or all Federal programs, though some apply only to specific agencies or programs. National policy requirements are included in award terms and conditions to help ensure post-award compliance, notwithstanding any pre-award assurances of compliance an agency requires applicants to submit.

Usually, an awarding office has a set of general terms and conditions that apply to a broad class of awards, which may be all of the awards that office makes or, in some cases, all of the awards the office makes under a particular program. An awarding office's general terms and conditions include the government-wide, as well as agency-specific, administrative requirements and national policy requirements described above, and also may include program-specific requirements. Agencies often do not transmit the general terms and conditions with each award, instead incorporating them by reference in the award notice (*e.g.*, by reference to an Internet site where the agency or office maintains its general terms and conditions). In that case, the agency only needs to transmit with the award notice any award-specific terms and conditions that are required to supplement the general terms and conditions.

III. The Proposed Core Set of Terms and Conditions—The FDP Approach

The core terms and conditions developed by the FDP work differently from the general approach described in the previous section, in that there is a core set that all of the FDP participating agencies use along with a separate set of agency-specific terms and conditions for each agency. The core set includes both uniform administrative requirements and national policy requirements.

The administrative requirements are designed as a model implementation of OMB Circular A–110 (2 CFR part 215), and they:

- Provide a standard organization of the administrative requirements that parallels the order of presentation in the circular.
- Provide standard language for administrative requirements for which the circular sets a single government-wide approach, rather than alternative approaches among which an agency may select.
- Include default provisions, with standard language, for administrative requirements for which there are agency options. For example, OMB Circular A–110 (2 CFR part 215) provides multiple options for disposition of program income a recipient might earn—an agency can specify that a recipient is to use: (1) An additive method, using the income to increase the total funding for the project supported by the award; (2) a deductive method, keeping the amount of support the same and reducing the amount of Federal funding to be used; or (3) a method that uses the income to help meet the recipient's cost sharing requirement. The administrative requirements in the FDP core terms and conditions include language in the program income article to specify use of the additive method. An agency that needs to override that default can do so by specifying a different option in its agency-specific or award-specific terms and conditions.

The administrative requirements may be viewed in one of two ways on the Internet at *http://rbm.nih.gov.* One of the posted documents shows the core set's administrative terms and conditions. The other document shows each article of the administrative requirements in a side-by-side presentation with the section of OMB Circular A–110 (2 CFR part 215) that is the basis for that article. The second document is designed to assist users who are not familiar with the language of the circular.

The national policy requirements in the core set of terms and conditions also may be viewed at *http://rbm.nih.gov.* They are presented within a table that includes information on the types of awards, types of recipient organizations, and specific situations to which each requirement applies. Each award term, in the left-hand column of the table, includes citations for the agencies' regulations pertinent to the particular national policy requirement.

In the future, OMB in conjunction with OSTP plans to maintain—or designate a Federal agency or interagency group to maintain—the core set of administrative and national policy requirements in an RBM Tool Kit at *http://rbm.nih.gov,* perhaps with links to additional sites such as OMB, OSTP, and the NSTC. When the terms and conditions are amended, previous versions would be maintained in the archives at the RBM site for access by recipients with awards pre-dating the amendment. Each version would bear a version date for clarity.

At the same Internet site, OSTP plans to maintain a list of the research or research-related programs that obtained approval, under Section 5.b of the proposed policy directive, for an exception from the requirement to use the government-wide core set of terms and conditions. With a centrally maintained list, an academic or nonprofit research institution can verify whether an award that does not include the standard terms and conditions falls within an approved exception. To enable OMB to maintain the list, Section 5.c of the proposed policy directive would require agencies to notify OMB when they approve exceptions.

As we expand the use of the core set of terms and conditions to more agencies, awarding offices, and programs, it is possible that some offices may need to augment the core set with program-specific or award-specific terms and conditions, in addition to any agency-wide supplement. A particular program, for example, may not need the article in the terms and conditions that specifies procedures a recipient must follow when research results unexpectedly raise questions about a need to classify the results for national security reasons. A program office that did not need that article could include an agency-specific or program-specific term to override the requirement. The proposed policy directive would allow that flexibility, which is essential to some programs; however, to maintain maximum uniformity Section 4.b of the proposed directive includes language that would instruct agencies to minimize supplementation of the core set.

IV. Invitation To Comment

We welcome your input on any aspect of the proposed policy provided below, and the core set of terms and conditions posted on the Internet at *http://rbm.nih.gov.* (Please note the final policy will include the core set of terms and conditions as an attachment, as stated in the ''Background'' section. However, those are not included in this

notice, but rather are available at the Web site noted above.) Questions that you may wish to address include:

- Are the terms and conditions easy to use and understand?
- With the general terms and conditions posted on the Internet, would you be able to readily determine which terms and conditions apply to a specific award?
- Where OMB Circular A–110 (2 CFR part 215) gives agencies options for addressing particular administrative requirements, does the core set of terms and conditions include default provisions appropriate for research and research-related grants?
- Are there other national policy requirements that should be included in the core set of terms and conditions?
- Is the proposed policy directive clear and unambiguous, or does it need further detail?

Dated: January 25, 2005.

Linda M. Springer,

Controller, Office of Management and Budget.

Kathie L. Olsen,

Associate Director for Science, Office of Science and Technology Policy.

To the Heads of Executive Departments and Establishments

Subject: Interim Standard Terms and Conditions for Research Grants.

1. *Purpose.* This policy letter establishes a core set of terms and conditions as the government-wide standard for research grants. The standard is for use by Executive Branch departments and agencies on an interim basis, pending completion of an ongoing effort to develop a standard for all Federal grant and cooperative agreement awards.

2. *Authority.* This policy letter is a result of the regular review of the Government-university research partnership under Executive Order 13185. It also is a part of the implementation of the Federal Financial Assistance Management Improvement Act of 1999 (Public Law 106–107).

3. *Background.* Begun as the Florida Demonstration Project in the 1980's, the Federal Demonstration Partnership (FDP) is a cooperative initiative among ten Federal awarding offices and 92 academic and nonprofit institutions that receive Federal research awards. The FDP's purpose is to streamline administrative procedures associated with the award and administration of research funding. In the late 1990's, the FDP developed terms and conditions that are a model implementation, specifically for research grants, of the 1993 issuance of OMB Circular A–110, ''Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations.'' (OMB Circular A–110 is now located in Title 2 Code of Federal Regulations, Part 215.) The ten Federal awarding offices have been using the FDP terms and conditions for research grants to the non-Federal institutions participating in the FDP.

Another effort to develop standard terms and conditions began after the enactment of Pub. L. 106–107. That Act requires the Office of Management and Budget (OMB) to direct, coordinate, and assist Executive Branch departments and agencies in establishing an interagency process to streamline and simplify Federal financial assistance procedures for non-Federal entities. Twenty-six Executive Branch agencies currently participate in interagency initiatives to implement Pub. L. 106–107. One of the initiatives is to develop standard terms and conditions, to the extent practicable, for all Federal awards of grants and cooperative agreements to governmental and nonprofit organizations, including research awards.

Pending the completion of the Pub. L. 106–107 initiative, which is a long-term endeavor, some near-term benefits can be obtained on an interim basis by expanding the use of the FDP's grant terms and conditions to more Federal awarding offices and more research recipients. To enable that expanded use, the Research Business Models (RBM) Subcommittee of the National Science and Technology Council's Committee on Science made minor modifications to the terms and conditions developed originally for FDP participants. The result—the terms and conditions attached to this policy letter—are appropriate for all Federal agencies' research grants to academic and nonprofit institutions.

4. *Policy.* a. The standard terms and conditions maintained by OMB and the Office of Science and Technology Policy (OSTP) under paragraph 5.b.i of this directive are the government-wide core set to be used by agencies for grants awarded to institutions of higher education, hospitals, and other non-profit organizations under basic and applied research and research-related programs.

b. Agencies may supplement the core set of terms and conditions with agency-specific, program-specific, or award-specific terms and conditions. Agencies are to minimize supplements, limiting these to terms and conditions that are required by a statute or:

i. Consistent with OMB Circular A–110; and

ii. Necessary for programmatic purposes or good stewardship of Federal funds.

c. Agencies are encouraged to extend the use of the attached grant terms and conditions to cooperative agreements and other forms of financial assistance, to the extent practicable.

5. *Responsibilities.* a. Each Executive Branch department and agency must:

i. Issue any needed direction to offices that award research grants, in order to establish the attached terms and conditions as the core set for those offices' awards.

ii. Designate policy level officials, (1) authorized to grant exceptions from the requirement to use the attached core set if a departmental or agency office, or program, can demonstrate the need for an exception; and (2) responsible for notifying the OMB in writing about the scope of exceptions approved by the department or agency and the reasons for them.

b. OMB and OSTP will maintain—or designate a Federal agency or interagency group to maintain—at a government-wide Internet site (either the RBM Web site, currently at *http://rbm.nih.gov,* or a site to be named) and with additional links to OMB, OSTP, and the National Science and Technology Council:

i. The core set of terms and conditions, including uniform administrative requirements and national policy requirements.

ii. A list of agency programs and offices that have been granted exceptions, under paragraph 5.a.ii of this directive, from the requirement to use the core set of terms and conditions.

6. *Information Contact.* Direct any questions regarding this policy letter to Elizabeth Phillips, Office of Federal Financial Management, (202) 395–3993.

7. *Effective Date.* The policy letter is effective 30 days after issuance. All implementing actions other than regulatory revisions must be completed by the Executive departments and agencies within 6 months of the effective date; any regulatory revisions must be completed within 18 months.

[FR Doc. 05–1643 Filed 1–27–05; 8:45 am]

BILLING CODE 3110–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copy Available From: Securities and Exchange Commission, Office of Filings and

Information Services, Washington, DC 20549.

Extension:

Form N–14, SEC File No. 270–297, OMB Control No. 3235–0336.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget requests for extension of the previously approved collection of information discussed below.

Form N–14—Registration Statement Under the Securities Act of 1933 for Securities Issued in Business Combination Transactions by Investment Companies and Business Development Companies. Form N–14 is used by investment companies registered under the Investment Company Act of 1940 [15 U.S.C. 80a–1 *et seq.*] (''Investment Company Act'') and business development companies as defined by section 2(a)(48) of the Investment Company Act to register securities under the Securities Act of 1933 [15 U.S.C. 77a *et seq.*] to be issued in business combination transactions specified in Rule 145(a) (17 CFR 230.145(a)) and exchange offers. The securities are registered under the Securities Act to ensure that investors receive the material information necessary to evaluate securities issued in business combination transactions. The Commission staff reviews registration statements on Form N–14 for the adequacy and accuracy of the disclosure contained therein. Without Form N–14, the Commission would be unable to verify compliance with securities law requirements. The respondents to the collection of information are investment companies or business development companies issuing securities in business combination transactions. The estimated number of responses is 457 and the collection occurs only when a merger or other business combination is planned. The estimated total annual reporting burden of the collection of information is approximately 620 hours per response for a new registration statement, and approximately 350 hours per response for an amended Form N–14, for a total of 235,010 annual burden hours. Providing the information on Form N–14 is mandatory. Responses will not be kept confidential. Estimates of the burden hours are made solely for the purposes of the Paperwork Reduction Act, and are not derived from a comprehensive or even a representative survey or study of the costs of SEC rules and forms.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

General comments regarding the above information should be directed to the following persons: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503 or e-mail to: *David_Rostker@omb.eop.gov*; and (ii) R. Corey Booth, Director/Chief Information Officer, Office of Information Technology, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Comments must be submitted to OMB within 30 days of this notice.

Dated: January 21, 2005.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–321 Filed 1–27–05; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon written request, copies available from: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension: Rule 7d–1; SEC File No. 270–176; OMB Control No. 3235–0311.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget requests for extension of the previously approved collections of information discussed below.

Section 7(d) of the Investment Company Act of 1940 [15 U.S.C. 80a–7(d)] (the ''Act'' or ''Investment Company Act'') requires an investment company (''fund'') organized outside the United States (''foreign fund'') to obtain an order from the Commission allowing the fund to register under the Act before making a public offering of its securities through the United States mail or any means of interstate commerce. The Commission may issue an order only if it finds that it is both legally and practically feasible effectively to enforce the provisions of the Act against the foreign fund, and that the registration of the fund is consistent with the public interest and protection of investors.

Rule 7d–1 [17 CFR 270.7d–1] under the Act, which was adopted in 1954, specifies the conditions under which a Canadian management investment company (''Canadian fund'') may request an order from the Commission permitting it to register under the Act. Although rule 7d–1 by its terms applies only to Canadian funds, other foreign funds generally have agreed to comply with the requirements of rule 7d–1 as a prerequisite to receiving an order permitting the foreign fund's registration under the Act.

The rule requires a Canadian fund proposing to register under the Act to file an application with the Commission that contains various undertakings and agreements of the fund. Certain of these undertakings and agreements, in turn, impose the following additional information collection requirements:

(1) The fund must file agreements between the fund and its directors, officers, and service providers requiring them to comply with the fund's charter and bylaws, the Act, and certain other obligations relating to the undertakings and agreements in the application;

(2) The fund and each of its directors, officers, and investment advisers that is not a U.S. resident, must file an irrevocable designation of the fund's custodian in the United States as agent for service of process;

(3) The fund's charter and bylaws must provide that (a) the fund will comply with certain provisions of the Act applicable to all funds, (b) the fund will maintain originals or copies of its books and records in the United States, and (c) the fund's contracts with its custodian, investment adviser, and principal underwriter, will contain certain terms, including a requirement that the adviser maintain originals or copies of pertinent records in the United States;

(4) The fund's contracts with service providers will require that the provider perform the contract in accordance with the Act, the Securities Act of 1933 (15 U.S.C. 77a–77z–3), and the Securities Exchange Act of 1934 (15 U.S.C. 78a–78mm), as applicable; and

(5) The fund must file, and periodically revise, a list of persons affiliated with the fund or its adviser or underwriter.

Under section 7(d) of the Act the Commission may issue an order permitting a foreign fund's registration only if the Commission finds that ''by reason of special circumstances or arrangements, it is both legally and practically feasible effectively to enforce the provisions of the [Act].''The

information collection requirements are necessary to assure that the substantive provisions of the Act may be enforced as a matter of contract right in the United States or Canada by the fund's shareholders or by the Commission.

Certain information collection requirements in rule 7d–1 are associated with complying with the Act's provisions. These information collection requirements are reflected in the information collection requirements applicable to those provisions for all registered funds.

The Commission believes that one fund is registered under rule 7d–1 and currently active. Apart from requirements under the Act applicable to all registered funds, rule 7d–1 imposes ongoing burdens to maintain records in the United States, and to update, as necessary, the foreign fund's list of affiliated persons. The Commission staff estimates that the rule requires a total of three responses each year. The staff estimates that a respondent would make two responses each year under the rule, one response to maintain records in the United States and one response to update its list of affiliated persons. The Commission staff further estimates that a respondent's investment adviser would make one response each year under the rule to maintain records in the United States. Commission staff estimates that each recordkeeping response would require 6.25 hours each of secretarial and compliance clerk time at a cost of $21.10 and $21.50 per hour, respectively, and the response to update the list of affiliated persons would require 0.25 hours of secretarial time, for a total annual burden of 25.25 hours at a cost of $537.78. The estimated number of 25.25 burden hours is identical to the current allocation.

If a foreign fund were to file an application under the rule, the Commission estimates that the rule would impose initial information collection burdens (for filing an application, preparing the specified charter, bylaw, and contract provisions, designations of agents for service of process, and an initial list of affiliated persons, and establishing a means of keeping records in the United States) of approximately 90 hours for the fund and its associated persons. The Commission is not including these hours in its calculation of the annual burden because no fund has applied under rule 7d–1 to register under the Act in the last three years.

After registration, a foreign fund may file a supplemental application seeking special relief designed for the fund's particular circumstances. Because rule 7d–1 does not mandate these applications and the fund determines whether to submit an application, the Commission has not allocated any burden hours for these applications.

These estimates of average burden hours are made solely for the purposes of the Paperwork Reduction Act. The estimate is not derived from a comprehensive or even a representative survey or study of Commission rules.

The Commission believes that the active registrant and its associated persons may spend (excluding the cost of burden hours) approximately $540 per year in maintaining records in the United States. These estimated costs include fees for a custodian or other agent to retain records, storage costs, and the costs of transmitting records.

If a Canadian or other foreign fund in the future applied to register under the Act under rule 7d–1, the fund initially might have capital and start-up costs (not including hourly burdens) of an estimated $17,280 to comply with the rule's initial information collection requirements. These costs include legal and processing-related fees for preparing the required documentation (such as the application, charter, bylaw, and contract provisions), designations for service of process, and the list of affiliated persons. Other related costs would include fees for establishing arrangements with a custodian or other agent for maintaining records in the United States, copying and transportation costs for records, and the costs of purchasing or leasing computer equipment, software, or other record storage equipment for records maintained in electronic or photographic form.

The Commission expects that a foreign fund and its sponsors would incur these costs immediately, and that the annualized cost of the expenditures would be $17,280 in the first year. Some expenditures might involve capital improvements, such as computer equipment, having expected useful lives for which annualized figures beyond the first year would be meaningful. These annualized figures are not provided, however, because, in most cases, the expenses would be incurred immediately rather than on an annual basis. The Commission is not including these costs in its calculation of the annualized capital/start-up costs because no investment company has applied under rule 7d–1 to register under the Act pursuant to rule 7d–1 in the last three years.

These estimates of average costs are made solely for the purposes of the Paperwork Reduction Act. The estimate is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

General comments regarding the above information should be directed to the following persons: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503 or e-mail to: *David_Rostker@omb.eop.gov*; and (ii) R. Corey Booth, Director/Chief Information Officer, Office of Information Technology, Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549. Comments must be submitted to OMB within 30 days of this notice.

Dated: January 21, 2005.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–322 Filed 1–27–05; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51062; File No. SR–Amex–00–27]

Self-Regulatory Organizations; Order Approving a Proposed Rule Change and Amendments No. 1, 2, 3, 4, 5, and 6 Thereto, and Notice of Filing and Order Granting Accelerated Approval to Amendments No. 7 and 8 Thereto by the American Stock Exchange LLC To Require the Immediate Display of Customer Options Limit Orders

January 21, 2005.

I. Introduction

On May 10, 2000, the American Stock Exchange LLC (''Amex'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Amex Rules 958A and 958A–ANTE to require the immediate display of customer options limit orders. Amex filed amendments to the proposed rule change on March 13,

[1] 15 U.S.C. 78s(b)(1).

[2] 2 17 CFR 240.19b–4

2002,[3] April 3, 2003,[4] July 15, 2003,[5] August 19, 2003,[6] October 22, 2003,[7] and August 12, 2004.[8] The proposed rule change, as amended by Amendments No. 1 through 6, was published for comment in the **Federal Register** on August 19, 2004.[9] No comments were received regarding the amended proposal. Amex filed amendments to the proposed rule change on December 16, 2004,[10] and January 6, 2005.[11] This order approves the proposed rule change and Amendments No. 1 through 6 and grants accelerated approval to and solicits comment on Amendments No. 7 and 8.

II. Description of Proposed Rule

Amex proposes to amend Amex Rules 958A and 958A–ANTE to require the immediate display of customer options limit orders[12] that better the current market quotation (''Display Obligation''). Under the proposal, Amex specialists would be required to display immediately upon receipt the price and size of each customer options limit order held by the specialist that is at a price or size that would improve the displayed bid or offer in the option that is the subject of the limit order. Amex proposes to define ''immediately upon receipt'' to mean, under normal market conditions, as soon as practicable but no later than 30 seconds after receipt by the specialist.[13]

Amex proposes to exempt, or partially exempt, certain orders from the Display Obligation. Specifically, Amex proposes to exempt orders executed upon receipt as well as any order where the customer who placed it requests that the order not be displayed if, upon receipt of the order, the specialist announces to the trading crowd the information about the order that would be displayed absent the customer's request. Amex further proposes that orders the terms of which are delivered by the specialist to another exchange for execution be exempted from the Display Obligation. Exempt order types would also include all or none orders, at the close orders, fill or kill orders, immediate or cancel orders, stop orders, stop limit orders, and complex orders (*i.e.*, spread, straddle, switch and combination orders), orders received prior to or during the opening trading rotation whether at the beginning of the trading day or after a trading halt (although once the trading rotation ends such orders would then be subject to the Display Obligation), and orders of more than 100 contracts, unless the customer placing such order requests that it be displayed.[14] Amex also proposes to amend Amex Rule 590 to include violations of the Exchange's limit order display rule in the Minor Rule Violation Fine System.

III. Commission Findings and Order Granting Approval

The Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange[15] and, in particular, the requirements of section 6(b)(5) of the Act,[16] which requires, among other things, that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

Specifically, the Commission believes that the display of customer options limit orders that improve the price or size of the best disseminated Amex quote should promote transparency and enhance the quality of executions of customer options limit orders on Amex. The proposed amendments to Amex Rules 958A and 958A–ANTE introduce requirements for customer limit order display that are comparable to the requirements of the Commission's Display Rule, Rule 11Ac1–4 under the Act,[17] which is applicable to customer limit orders received in the equity market. In addition, the Commission believes that the Exchange's proposal to exempt all or none, fill or kill, immediate or cancel, and large sized orders from the Display Obligation is reasonable since these order types are either identical or substantially similar to order types exempt from the Commission's Display Rule.

The Commission also believes that it is consistent with the Act for Amex to exempt stop orders and stop limit orders from the Display Obligation under its rules. These orders are contingent orders that are subject to a particular triggering event and, thus, are not available for execution until the triggering event occurs. A stop order becomes a market order when triggered and thus is not subject to the Display Obligation because such an order would then be immediately executable. A stop limit order becomes a limit order when the triggering event occurs. This limit order would be subject to the Display Obligation.

At the close orders may not be represented, displayed or booked until as near as possible to the close of trading, and, therefore, the Commission believes it is reasonable to exempt such orders from the Display Obligation. Spread, combination, straddle, stock-option, and one-cancels-the-other orders are complex orders with more than one component and, thus, the Commission believes, are not suitable for display.

During a trading rotation, Amex systems attempt to set an opening price for the series. Until that opening price is established, there is no disseminated market. Therefore, the Commission believes it is reasonable to exempt

[3] On March 13, 2002, Amex filed a Form 19b–4, which replaced the original filing in its entirety (''Amendment No. 1'').

[4] On April 3, 2003, Amex filed a Form 19b–4, which replaced the original filing and Amendment No. 1 in their entirety (''Amendment No. 2'').

[5] On July 15, 2003, Amex filed a Form 19b–4, which replaced the original filing and all previous amendments in their entirety (''Amendment No. 3'').

[6] On August 19, 2003, Amex filed a Form 19b–4, which replaced the original filing and all previous amendments in their entirety (''Amendment No. 4'').

[7] *See* letter from Claire P. McGrath, Senior Vice President and Deputy General Counsel, Amex, to Nancy Sanow, Assistant Director, Division of Market Regulation, Commission, dated October 21, 2003 (''Amendment No. 5'').

[8] On August 12, 2004, Amex filed a Form 19b–4, which replaced the original filing and all previous amendments in their entirety (''Amendment No. 6'').

[9] *See* Securities Exchange Act Release No. 50188 (August 12, 2004), 69 FR 51495 (''Notice of the Proposal'').

[10] *See* Amendment No. 7, dated December 16, 2004, submitted by Clare P. McGrath, Senior Vice President and Deputy General Counsel, Amex (''Amendment No. 7''). In Amendment No. 7, Amex proposes a minor modification to the exemptions to the Display Obligation.

[11] *See* Amendment No. 8, dated January 6, 2005, submitted by Clare P. McGrath, Senior Vice President and Deputy General Counsel, Amex (''Amendment No. 8''). In Amendment No. 8, Amex proposes a minor modification to the exemptions to the Display Obligation.

[12] Amex proposes to define the term ''customer options limit order'' as ''an order to buy or sell an option at a specified price and size that is for the account of a customer as defined in paragraph (a)(26) of Rule 11Ac1–1 under the Securities Exchange Act of 1934.'' Proposed Amex Rules 958A(e)(3) and 958A–ANTE(e)(3).

[13] In its filing, Amex states that ''receipt'' means the time the order enters the Amex Order File system (''AOF''), which is consistent with its surveillance standard for other rules, such as the firm quote rule, wherein the Exchange measures compliance with the rule using the time the order enters the AOF. This means that the time of receipt is when the order is received in the AOF, even if the specialist does not happen to see it for several seconds.

[14] For a complete discussion of these exempt order types, see Notice of the Proposal, supra note 3.

[15] In approving this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[16] 15 U.S.C. 78f(b)(5).

[17] 17 CFR 240.11Ac1–4.

orders received during a trading rotation from the Display Obligation. The Commission notes, however, that once the trading rotation ends, any orders not executed would then be subject to the Display Obligation.

Finally, customer orders the terms of which are delivered by the specialist to another exchange for execution are exempt from the Exchange's Display Obligation. The Commission believes it is reasonable to exempt such orders since they are subject to execution upon receipt at the other options exchange. Moreover, the Exchange represents that if the order delivered to the other options exchange were canceled, in whole or in part, by the other exchange, then the original customer order would be subject to the Display Obligation immediately upon receipt of the cancellation notice by the Exchange.

The Commission finds good cause for approving Amendments No. 7 and 8 to the proposed rule change prior to the thirtieth day after their publication in the **Federal Register**, pursuant to section 19(b)(2) of the Act.[18] Amendments No. 7 and 8 made minor modifications to the exemption for customer orders the terms of which are immediately delivered to another exchange for execution. Acceleration of Amendments No. 7 and 8 will permit the Exchange to implement the proposal in an expeditious manner. The Commission, therefore, believes that good cause exists, consistent with section 6(b)(5)[19] and section 19(b)[20] of the Act, to accelerate approval of Amendments No. 7 and 8.

IV. Solicitation of Comments Concerning Amendments No. 7 and 8

Interested persons are invited to submit written data, views, and arguments concerning Amendments No. 7 and 8, including whether they are consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR-Amex-00–27 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR-Amex-00–27. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-Amex-00–27 and should be submitted on or before February 18, 2005.

V. Conclusion

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[21] that the proposed rule change (File No. SR-Amex-00–27), as amended, be approved, and that Amendments No. 7 and 8 thereto be approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[22]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–317 Filed 1–27–05; 8:45 am]

BILLING CODE 8010–01–P

[18] 15 U.S.C. 78s(b)(2).

[19] 15 U.S.C. 78f(b)(5).

[20] 15 U.S.C. 78s(b).

[21] *Id.*

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51063; File No. SR–CBOE–2004–35]

Self-Regulatory Organizations; Order Approving a Proposed Rule Change and Notice of Filing and Order Granting Accelerated Approval to Amendment No. 2 Thereto by the Chicago Board Options Exchange, Inc. To Require the Immediate Display of Customer Limit Orders

January 21, 2005.

I. Introduction

On June 17, 2004, the Chicago Board Options Exchange, Inc. (''CBOE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b-4 thereunder,[2] a proposed rule change to amend CBOE Rule 8.85 to require the immediate display of customer limit orders. The proposed rule change was published for comment in the **Federal Register** on July 2, 2004.[3] No comments were received regarding the proposal. CBOE filed Amendments No. 1 and 2 with the Commission on August 31, 2004,[4] and January 6, 2005,[5] respectively. This order approves the proposed rule change, grants accelerated approval to Amendment No. 2, and solicits comment on Amendment No 2.

II. Description of Proposed Rule

CBOE proposes to amend CBOE Rule 8.85(b)(i) to codify an immediate display requirement with respect to eligible customer limit orders[6] (''Display Obligation''). Under the proposal, each DPM would be required

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 49916 (June 25, 2004), 69 FR 40422 (''Notice of the Proposal'').

[4] *See* letter from Steve Youhn, Assistant Secretary, CBOE, to Nancy Sanow, Assistant Director, Commission, Division of Market Regulation, dated August 30, 2004 (''Amendment No. 1''). In Amendment No. 1, CBOE corrected a typographical error in the proposed rule text. Because Amendment No. 1 is a technical amendment, it is not subject to notice and comment.

[5] *See* Amendment No. 2, dated January 6, 2005, submitted by Steve Youhn, Assistant Secretary, CBOE (''Amendment No. 2''). In Amendment No. 2, CBOE proposes a minor modification to the exemptions to the Display Obligation.

[6] CBOE proposes to define the term ''customer limit order'' as ''an order to buy or sell a listed option at a specified price that is not for the account of either a broker or dealer; provided, however, that the term customer limit order shall include an order transmitted by a broker or dealer on behalf of a customer.'' Proposed CBOE Rule 8.85(b)(i).

to display the price and full size of eligible customer limit orders when such orders represent buying or selling interest that is at a better price than the best disseminated CBOE quote. A DPM also must increase the size of its quote to reflect a limit order priced equal to the CBOE disseminated quote. In proposed CBOE Rule 8.85(b)(i), CBOE proposes to define ''immediately'' to mean, under normal market conditions, as soon as practicable but no later than 30 seconds after receipt by the DPM.[7]

CBOE proposes to exempt, or partially exempt, certain orders from the Display Obligation. Specifically, CBOE proposes to exempt orders executed upon receipt as well as any order where the customer who placed it requests that the order not be displayed, if upon receipt of the order the DPM announces via public outcry the information about the order that would be displayed if the order were subject to display. CBOE further proposes an exemption from the Display Obligation for orders for which, immediately upon receipt, a related order for the principal account of a DPM reflecting the terms of the customer order is routed to another options exchange that is a participant in the intermarket options linkage plan.[8] Exempt order types would also include contingency orders (*i.e.*, market-if-touched, market-on-close, stop (stop-loss), and stop-limit orders), one-cancels-the-other orders, all or none orders, fill or kill orders, immediate or cancel orders, complex orders (*i.e.*, spread, combination, straddle and stock-option orders), orders received during a trading rotation (although once the trading rotation ends such orders would then be subject to the Display Obligation), and orders of more than 100 contracts, unless the customer placing such order requests that it be displayed.[9]

III. Commission Findings and Order Granting Approval

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange[10] and, in particular, the requirements of section 6(b)(5) of the Act,[11] which requires, among other things, that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

Specifically, the Commission believes that the display of customer options limit orders that improve the price or size of the best disseminated CBOE quote should promote transparency and enhance the quality of executions of customer limit orders on CBOE. The proposed amendments to CBOE Rule 8.85 introduce requirements for customer limit order display that are comparable to the requirements of the Commission's Display Rule, Rule 11Ac1–4 under the Act,[12] which is applicable to customer limit orders received in the equity market. In addition, the Commission believes that the Exchange's proposal to exempt all-or-none, fill-or-kill, immediate-or-cancel, and large sized orders from the Display Obligation is reasonable since these order types are either identical or substantially similar to order types exempt from the Commission's Display Rule.

The Commission also believes that it is consistent with the Act for CBOE to exempt from the Display Obligation under its rules market-if-touched, stop-limit, and stop or stop-loss orders. These orders are contingent orders that are subject to a particular triggering event and, thus, are not available for execution until the triggering event occurs. A market-if-touched or stop-loss order becomes a market order when triggered and thus is not subject to the Display Obligation because such an order would then be immediately executable. A stop-limit order becomes a limit order when the triggering event occurs. This limit order would be subject to the Display Obligation.

Market-on-close orders may not be represented, displayed or booked until as near as possible to the close of trading, and, therefore, the Commission believes it is reasonable to exempt such orders from the Display Obligation. Spread, combination, straddle, stock-option, and one-cancels-the-other orders are complex orders with more than one component and, thus, the Commission believes, are not suitable for display.

During a trading rotation, CBOE systems attempt to set an opening price for the series. Until that opening price is established, there is no disseminated market. Therefore, it is reasonable to exempt orders received during a trading rotation from the Display Obligation. The Commission notes, however, that once the trading rotation ends, any orders not executed would then be subject to the Display Obligation.

Finally, the Exchange proposes to exempt from the Display Obligation customer orders for which a related order for the principal account of a DPM reflecting the terms of the customer order is routed to another options exchange. The Commission believes it is reasonable to exempt such orders since they are subject to execution upon receipt at the other options exchange. Moreover, the Exchange represents that if an order routed to another options exchange is cancelled in whole or in part by the other exchange, then the order would be subject to the Display Obligation immediately upon receipt of the cancellation notice by the Exchange.

The Commission finds good cause for approving Amendment No. 2 to the proposed rule change prior to the thirtieth day after their publication in the **Federal Register**, pursuant to section 19(b)(2) of the Act.[13] Amendment No. 2 made a minor modification to the exemption for customer orders for which a related order reflecting the terms of the customer order is immediately delivered to another exchange for execution. Acceleration of Amendment No. 2 will permit the Exchange to implement the proposal in an expeditious manner. The Commission, therefore, believes that good cause exists, consistent with section 6(b)(5)[14] and section 19(b)[15] of the Act, to accelerate approval of Amendment No. 2.

IV. Solicitation of Comments Concerning Amendment No. 2

Interested persons are invited to submit written data, views, and arguments concerning Amendment No. 2, including whether it is consistent with the Act. Comments may be submitted by any of the following methods:

[7] In its filing, CBOE states that ''receipt by the DPM'' means receipt on the PAR terminal in the DPM trading crowd, which is consistent with the firm quote definition of ''time of receipt.'' This means that the time of receipt is when the order is received on PAR, even if the DPM or PAR operator does not happen to see it for several seconds.

[8] *See* Securities Exchange Act Release No. 43086 (July 28, 2000), 65 FR 48023 (August 4, 2000) (order approving the Plan for the Purpose of Creating and Operating an Intermarket Option Linkage).

[9] For a complete discussion of these exempt order types, *see* Notice of the Proposal, *supra* note 3.

[10] In approving this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[11] 15 U.S.C. 78f(b)(5).

[12] 17 CFR 240.11Ac1–4.

[13] 15 U.S.C. 78s(b)(2).

[14] 15 U.S.C. 78f(b)(5).

[15] 15 U.S.C. 78s(b).

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–CBOE–2004–35 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–CBOE–2004–35. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2004–35 and should be submitted on or before February 18, 2005.

V. Conclusion

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[16] that the proposed rule change (File No. SR–CBOE–2004–35) be approved, and that Amendment No. 2 thereto be approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[17]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–318 Filed 1–27–05; 8:45 am]

BILLING CODE 8010–01–P

[16] *Id.*

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51066; File No. SR–FICC–2005–02]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing of Proposed Rule Change To Amend the Application and Continuing Membership Standards of the Government Securities Division and the Mortgage-Backed Securities Division

January 21, 2005.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on January 7, 2005, the Fixed Income Clearing Corporation (''FICC'') filed with the Securities and Exchange Commission (''Commission'') and on January 14, 2005, amended the proposed rule change described in Items I, II, and III below, which items have been prepared primarily by FICC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested parties.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FICC is seeking to amend the rules of the Government Securities Division (''GSD'') and the Mortgage-Backed Securities Division (''MBSD'') to: (1) Provide that when an applicant, member, or participant becomes subject to an order of statutory disqualification or order of similar effect, including an order issued by a non-U.S. regulator or examining authority, the FICC Membership and Risk Management Committee (''Committee'') shall determine whether such order shall be the basis for denial of the membership applicant or termination of membership rather than such denial or termination being automatic; (2) impose a fine on members and participants that fail to notify FICC within two business days of falling out of compliance with specified membership standards, including becoming subject to an order of statutory disqualification or order of similar effect; and (3) require applicants, members, and participants to notify FICC within two business days if they become aware of an investigation or similar proceeding against them that could lead them to violate a FICC membership standard.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FICC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FICC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.[2]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

FICC is seeking to amend the application and continuing membership standards of the GSD and the MBSD to: (1) Provide that when an applicant, member, or participant becomes subject to an order of statutory disqualification or order of similar effect, including an order issued by a non-U.S. regulator or examining authority, the Committee shall determine whether this shall be the basis for denial of the membership applicant or termination of membership, rather than such denial or termination being automatic; (2) impose a fine on members and participants that fail to notify FICC within 2 business days of falling out of compliance with specified membership standards, including becoming subject to an order of statutory disqualification or order of similar effect; and (3) require applicants, members, and participants to notify FICC within two business days if they become aware of an investigation or similar proceeding against them that could lead them to violate a FICC membership standard.

1. Action in Cases of Statutory Disqualification or Orders of Similar Effect

The GSD and MBSD rules currently provide that a membership applicant that is subject to an order of statutory disqualification under Section 3(a)(39) of the Act or an order of similar effect is not eligible for membership.[3]

[1] 15 U.S.C. 78s(b)(1).

[2] The Commission has modified the text of the summaries prepared by FICC.

[3] For example, GSD Rule 3, ''Financial Responsibility and Operational Capability

Continued

Currently, a waiver of this requirement by the Committee is necessary in order for FICC to admit such applicant into membership. The admission requirements also serve as continuance standards for current members and participants. Therefore, if a member or participant becomes subject to a statutory disqualification, a waiver must be sought in order for membership in FICC to continue.

At the time it was organized as a clearing corporation, the Government Securities Clearing Corporation, the predecessor to FICC, modeled its rules provisions regarding statutory disqualifications on those of other clearing agencies which are now subsidiaries of The Depository Trust & Clearing Corporation. The understanding at the time was that instances of statutory disqualification were a rare occurrence and called into question the entity's ability to meet membership requirements or to remain a member in good standing. More recently, firms are increasingly becoming subject to statutory disqualification, but the reasons for a firm's statutory disqualification may have little or no bearing on its ability to become or remain a member in good standing.[4] FICC would retain the ability to deny membership to or terminate as a member or participant a firm whose ability to meet applicable membership requirements is called into question. However, to the extent an order of statutory disqualification does not call this into question, FICC does not believe it appropriate for the Committee to issue a waiver in order to admit or retain the member.

The proposed rule change would eliminate the automatic need to obtain a waiver in cases where an entity is subject to an order of statutory disqualification or order of similar effect but would keep such orders as a criterion to be considered for membership or continued membership. FICC management would continue to present all instances of such orders to the Committee, and the Committee would make all final determinations with respect to these entities. In this manner, FICC management and the Committee would be able to thoroughly evaluate the risks presented by an applicant, member, or participant that becomes subject to an order. The proposed rule change would allow the Committee to permit FICC to admit or retain members or participants that pose no risk to FICC.[5] In instances where waivers are still required under the rules and are granted by the Committee, FICC would promptly notify the Commission.

2. Fines for Failure To Notify FICC for Falling Out of Compliance With Membership Criteria

In addition to the changes above, FICC is proposing to implement a fine for those members and participants that do not promptly notify FICC of their noncompliance with any membership standard.[6] The membership standards are set forth in GSD Rules 2, ''Members,'' and 3, ''Financial Responsibility and Operational Capability Standards,'' which apply to comparison-only and netting members as applicable, and in MBSD clearing rules Article III, ''Participants,'' which apply to MBSD clearing participants. For risk management purposes, it is important that FICC learn of a member or participant's failure to meet a membership standard as soon as possible in order to determine a course of action that will best protect FICC. In addition, in some instances, such as certain cases where a member or participant becomes subject to a statutory disqualification order,[7] FICC is required to promptly notify the Commission. Given the importance of FICC's membership standards and the need for FICC to learn of noncompliance as soon as possible, FICC is proposing to fine members $1,000 per instance of a failure to notify FICC within two business days of the member or participant first having knowledge of its falling out of compliance with the particular membership standard.[8] Members and participants would be afforded the same due process as is currently available under FICC's rules with respect to other types of fines. As with all fines, FICC will notify the Commission of all fines that are imposed pursuant to this rule change.

In addition, members and participants that fail to timely notify FICC of falling out of compliance with any membership standard would automatically be placed on the Watch List and be subject to more frequent and thorough monitoring as provided for in GSD Rule 4, ''Clearing Fund, Watch List, and Loss Allocation,'' Section 3, ''Watch List,'' and MBSD Article IV, ''Participants Fund,'' Rule 6, ''Watch List.''

3. Notification of Pending Investigations

The proposed rule change also requires applicants, members, and participants to notify FICC within two business days of first having knowledge of a pending investigation or similar proceeding or condition that could lead them to violate a membership standard. The proposed rule change would provide an exception to this requirement in cases where disclosure to FICC would cause the applicant, member, or participant to violate an applicable law, rule, or regulation.

4. Definitions

Finally, MBSD is proposing to add two definitions to Article I, ''Definitions and General Provisions.'' The term ''Associated Person'' would be defined to mean, when applied to any ''person,'' any partner, officer, or director of such ''person'' or any ''person'' directly or indirectly controlling or controlled by such ''person,'' including an employee of such ''person.'' The term ''Person'' would mean a partnership, Corporation or other organization, entity or individual.

FICC believes that the proposed rule change is consistent with the requirements of Section 17A of the Act[9] and the rules and regulations thereunder applicable to FICC because it amends FICC's membership criteria in a prudent manner. It imposes fines that will encourage members and participants to notify FICC promptly of falling out of compliance with membership standards, which will

Standards,'' Section 1, ''Admissions Criteria for Comparison-Only Members,'' provides that an applicant may not be subject to an order of statutory disqualification or ''an order of similar effect issued by a Federal or State banking authority, or other examining authority or regulator.'' Section 3(a)(39) of the Act, which sets forth the definition of ''statutory disqualification,'' specifically covers orders issued by foreign financial regulatory authorities that are the equivalent to Commission-issued orders covered by the definition. The statutory definition also includes specific references to entities being barred from the ''foreign equivalent of a self-regulatory organization [or a] foreign or international securities exchange'' under ''any substantially equivalent foreign statute or regulation.''

[4] Of note is that in those situations brought by management before the Committee recently, the Commission has permitted the entity to continue operating as a registered broker-dealer, and the relevant designated examining authority has retained the entity as a member. In addition, Rule 19h–1 promulgated pursuant to the Act, does not require that self-regulatory organizations automatically terminate the membership of entities subject to statutory disqualification.

[5] To the extent the Committee determines to admit or retain a member despite a statutory disqualification, the Committee will still retain all rights it currently has under FICC rules to impose limitations or restrictions on such member or participant.

[6] The rules of FICC currently require members and participants to promptly notify FICC in the event that they are not meeting their membership standards.

[7] Rule 19h–1 of the Act does not require a notification or notice to the Commission in all cases of statutory disqualification.

[8] Once FICC is notified of an applicant or member's statutory disqualification, it will follow the provisions of Rule 19h–1 of the Act.

[9] 15 U.S.C. 78q–1.

enable FICC to act quickly to protect itself and its members and participants and which will better enable FICC to safeguard the securities and funds in its custody or control or for which it is responsible.

(B) Self-Regulatory Organization's Statement on Burden on Competition

FICC does not believe that the proposed rule change will have any impact or impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rule change have not yet been solicited or received. FICC will notify the Commission of any written comments received by FICC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within thirty-five days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to ninety days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*) or
- Send an E-mail to *rule-comments@sec.gov.* Please include File Number SR–FICC–2005–02 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–FICC–2005–02. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of FICC and on FICC's Web site at *http://www.ficc.com.* All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FICC–2005–02 and should be submitted on or before February 18, 2005.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[10]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–316 Filed 1–27–05; 8:45 am]

BILLING CODE 8010–01–P

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51075; File No. SR–NASD–2004–179]

Self Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by National Association of Securities Dealers, Inc. Relating to Amendments to Section 13 of Schedule A to the NASD By-Laws (Review Charge for Advertisement, Sales Literature, and Other Such Material Filed With or Submitted to NASD)

January 24, 2005.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 8, 2004, the National Association of Securities Dealers, Inc. (''NASD'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in items I, II, and III below, which items have been prepared by NASD. NASD has designated the proposed rule change as ''establishing or changing a due, fee or other charge'' under section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

NASD is proposing to amend Section 13 of Schedule A to the NASD By-Laws (''Section 13'') governing the review charges for advertisements, sales literature, and other such material filed with or submitted to NASD's Advertising Regulation Department (the ''Department''). Below is the text of the proposed rule change. Proposed new language is *italicized;* proposed deletions are in [brackets].

* * * * *

SCHEDULE A TO NASD BY-LAWS

* * * * *

Section 13—Review Charge for Advertisement, Sales Literature, and Other Such Material Filed or Submitted

There shall be a review charge for each and every item of advertisement, sales literature, and other such material, whether in printed, video or other form, filed with or submitted to NASD, except for items that are filed or submitted in response to a written request from NASD's Advertising Regulation Department issued pursuant to the spot check procedures set forth in NASD's Rules as follows: (1) For printed material reviewed, [$75.00] *$100.00*, plus $10.00 for each page reviewed in excess of 10 pages; and (2) for video or audio media, [$75.00] *$100.00*, plus $10.00 per minute for each minute of tape reviewed in excess of 10 minutes.

Where a member requests expedited review of material submitted to the Advertising Regulation Department there shall be a review charge of $500.00 per item plus $25 for each page reviewed in excess of 10 pages. Expedited review shall be completed within three business days, not

[1] 15 U.S.C. 78s(b)(3).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

including the date the item is received by the Advertising Regulation Department, unless a shorter or longer period is agreed to by the Advertising Regulation Department. The Advertising Regulation Department may, in its sole discretion, refuse requests for expedited review.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NASD included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in item IV below. NASD has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Department is responsible for ensuring that all NASD member firms' communications with the public are fair, balanced, and not misleading. The mission of the Department, as provided in Rule 2210 and the Interpretations issued thereunder, is to ensure that all member communications with the public, including advertisements, sales literature, and correspondence, are based on principles of fair dealing and good faith, are fair and balanced, and provide a sound basis for evaluating the facts in regard to any particular security or type of security, industry, or service. Among other things, the Department reviews member communications with the public for false, exaggerated, unwarranted, misleading statements or claims, and exaggerated or unwarranted claims, opinions or forecasts.

The purpose of the proposed rule change is to amend Section 13 to raise the fee that may be charged by the Department for reviewing each and every item of advertisement, sales literature, and other such material, whether in printed, video or other form, filed with or submitted to NASD (except for items that are filed or submitted in response to a written request from the Department issued pursuant to the spot check procedures set forth in NASD's Rules).

Despite annual cost increases, NASD has not adjusted the charge to members for submitting advertisements, sales literature, and other such material to the Department since 1999. A recent analysis of the Department's operating and technology costs showed that NASD's costs have increased significantly due to increased responsibilities, economic conditions and the need for enhanced technology. Based on this review, NASD proposes to raise the fee charged for the review of printed material and video or audio media from $75.00 to $100.00 to offset these cost increases.

2. Statutory Basis

NASD believes that the proposed rule change is consistent with the provisions of section 15A of the Act [5] in general and with section 15A(b)(5) of the Act [6] in particular, which requires, among other things, that NASD's rules provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system that NASD operates or controls. NASD believes that the rule change is consistent with section 15A(b)(5) of the Act in that the proposed review charge is reasonable based on NASD's costs and equitably allocated among all members that file or submit advertisements, sales literature, and other such material, whether in printed, video or other form.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASD does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective upon filing with the Commission, pursuant to section 19(b)(3)(A)(ii) of the Act [7] and paragraph (f)(2) of Rule 19b–4 thereunder,[8] because it establishes or changes a due, fee, or other charge imposed by NASD. At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NASD–2004–179 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–NASD–2004–179. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of the filing will also be available for inspection and copying at the principal office of NASD. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to the File Number SR–NASD–2004–179 and should be submitted on or before February 18, 2005.

[5] 15 U.S.C. 78o–3.

[6] 15 U.S.C. 78o–3(b)(5).

[7] 15 U.S.C. 78s(b)(3)(a)(ii).

[8] 17 CFR 240.19b–4(f)(2).

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–320 Filed 1–27–05; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51048; File No. SR–NYSE–2004–70]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change and Amendment No. 1 Thereto by the New York Stock Exchange, Inc. To Amend Exchange Rule 104 to Require Specialists To Yield Orally-Consummated Proprietary Trades to Later-Arriving System Orders

January 18, 2005.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 13, 2004, the New York Stock Exchange, Inc. (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in items I, II, and III below, which items have been prepared by the Exchange. On January 7, 2005, the Exchange filed Amendment No. 1 to the proposed rule change.[3] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend NYSE Rule 104, Dealings by Specialists, to require that in transactions between a specialist and a contra order that have been orally agreed to but not yet reported, the specialist must yield to any system orders that enter the specialist's book and can take the specialist's position in the orally-consummated transaction.

The text of the proposed amendments is set forth below. Italics indicate additions.

Rule 104

Dealings by Specialists

* * * * *

Supplementary Material

Functions of Specialists

.10

* * * * *

(11)(i) Notwithstanding the ability of a specialist to trade for his or her dealer account, dealer transactions by a specialist that have not yet been reported by the specialist must yield to any order or orders received through an Exchange order delivery system after the oral commitment to transact, provided that such order or orders are capable of trading in place of the specialist in the consummated transaction.

(ii) The provisions of subparagraph (i) above shall not apply if the specialist's trade for his or her dealer account:

(a) *Is to correct an error on a previously reported transaction;*

(b) *Is executed in satisfaction of the specialist's obligation to give up a trade to an agency order;*

(c) *Is a non-regular way trade between the specialist and a Crowd broker;*

(d) *Is the result of the election of ''stop'' orders as required in Rule 123A.40;*

(e) *Is in connection with the execution of ''stop'' orders or CAP orders executed as part of the opening of trading;*

(f) *Participates on the closing transaction in a security to offset a market-at-the-close and/or limit-at-the-close order imbalance; or*

(g) *Is a report of principal participation on a commitment sent to another market center through the ITS system.*

(iii) Transactions by a specialist pursuant to subparagraph (ii) above must be documented and reported to the Exchange in such manner and within such time as the Exchange shall designate.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend NYSE Rule 104 to provide that where a specialist has completed, but not yet reported, a transaction as principal with an order in the book or in the crowd, the specialist must yield to any order received through SuperDOT® that could take the specialist's place in the unreported principal transaction.

Exchange rules provide that specialists must always yield to customer orders on the book when trading in the specialist's specialty securities for the dealer account. When no other interest is present on the book, specialists may trade for their own account with interests represented on the book or by a broker in the crowd; in such situations, the specialist may trade either fully or in parity with other contra interests represented in the crowd, as the case may be. The Exchange proposes to amend NYSE Rule 104.10 to include new section (11) to require that, notwithstanding the ability of a specialist to trade as principal with either a system order or a broker in the crowd, if a marketable order arrives on the book before the report of the specialist's trade as principal is completed, the specialist must yield to such order. Where the specialist is required to yield, the customer whose order entered the book would be reported as the contra party for the trade instead of the specialist.

The proposed rule would provide seven limited exceptions, representing situations in which it would continue to be appropriate for the specialist to act as principal, notwithstanding the presence of a new customer order on the book. These exceptions are:

(1) Corrections of bona fide specialist errors;

(2) Trading in satisfaction of the specialist's obligation to give up a trade to an agency order;

(3) Reports of non-regular-way principal-to-crowd transactions;

(4) Principal participation on stop order electing transactions;

(5) Principal participation in connection with opening transactions;

(6) Closing transactions involving market-on-close (''MOC'') imbalances; and

(7) Report of principal participation on a commitment sent to another market

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[9] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Form 19b–4 dated January 7, 2004 (''Amendment No. 1''). In Amendment No. 1, the NYSE changed the basis under which the proposed rule change was filed from section 19(b)(3) of the Act to section 19(b)(2) of the Act.

through the Intermarket Trading System (''ITS'').

These exceptions are discussed in more detail below:

1. Corrections of Bona Fide Specialist Errors: These are cases where a specialist has to issue corrected reports that include dealer participation via the Display Book® to correct a previously executed and reported transaction. Such corrections could involve the price, volume, or names involved in a transaction. If an executable system order is on the same side as the dealer participation necessary to correct the error, this would trigger the Display Book's® ''P'' indicator (preventing the specialist from participating as dealer ahead of executable system orders). In this situation, the specialist would be permitted to use the ''Prin Ahead'' override feature, provided that the specialist placed the notation ''Error'' in the Display Book's® free-form comment field. The specialist would be required to adequately document the error on the firm's books and records.

2. Trading in satisfaction of the specialist's obligation to give up a trade to an agency order: These are cases where Exchange rules require the specialist to give up a trade to an agency order after the initial trade has been reported and the specialist cannot substitute the agency customer's name, such as where a customer requests to participate on a trade previously executed by the specialist as principal on a non-regular way basis. When reporting such substituted trades, the specialist would have to participate as dealer in order to unwind his own participation in the initial transaction. If an executable system order is on the same side as the dealer participation necessary to effect the substitution, this would trigger the Display Book's® ''P'' indicator. In this situation, the specialist would be permitted to use the ''Prin Ahead'' override feature to complete the substitute transaction. The specialist would be required to document the substitution trade in the Display Book's® free-form comment field.

3. Reports of non-regular-way principal-to-crowd transactions: These are cases where a crowd broker represents a non-regular-way settlement order (*e.g.*, cash basis, next day, and sellers option) and the specialist is willing to trade with that order at a price at which there are regular way settlement customer orders on the same side on the Display Book®. The ''Prin Ahead'' override feature may be used by the specialist to effect the non-regular way transaction, provided, however, that the specialist may be required to give up the trade to an agency order if the customer indicates its willingness to participate on the same terms as the specialist.

4. Principal participation on stop order electing transactions: These are cases where the specialist participation in an electing transaction requires the guarantee of the same price to the elected stop order(s), the specialist bases the price on the total volume of both transactions, and the specialist effects both transactions contemporaneously and at the same price. Exchange rules require the specialist to report the transaction that elects the stop orders independently from the transaction that fills the stop orders. Orders may arrive on the Display Book® between the time the specialist reports the electing trade and the fill for the stop transaction, which would trigger the ''P'' indicator. In connection with the transaction filling the stop order, the specialist would be permitted to use the ''Prin Ahead'' override feature. The specialist would be required to document the dealer participation by placing a stop order comment in the Display Book's® free-form comment field.

5. Principal participation in connection with opening transactions: These are cases where the specialist participates as dealer in connection with stop orders and convert-and-parity (''CAP'') orders [4] that are included in the specialist's calculation of the opening price, elected by the opening crossing trade, and executed substantially contemporaneously with the opening transaction at the opening cross price, but that are reported separately from the report of the opening transaction. Orders may arrive on the Display Book® between the time the specialist reports the opening trade and the fill for the elected stop transaction, which would trigger the ''P'' indicator. In connection with the transaction filling the stop order at the opening, the specialist would be permitted to use the ''Prin Ahead'' override feature. The specialist would be required to document the dealer participation by placing a stop order comment in the Display Book's® free-form comment field.

6. Closing transactions involving MOC imbalances: These are cases where the specialist participates on the closing transaction to offset a market-on-close/limit-on-close order imbalance. The situation may arise if unexecuted market orders entered just prior to the close are assigned to the paired-off portion of the closing trades. When the specialist reports dealer participation to offset an imbalance on the first print of the closing (as required by Exchange rules) and there are market orders on the same side assigned to the paired off portion, which is the second print of the close, the ''P'' indicator would be triggered. In this instance, the specialist would be permitted to use the ''Prin Ahead'' override feature. The specialist would be required to document the dealer participation by indicating ''MOC'' in the Display Book's® free-form comment field.

7. Report of principal participation on a commitment sent to another market through the ITS System: These are cases where the specialist has indicated dealer interest to trade on a regional exchange and has sent a commitment to trade. It may take a regional exchange up to 30 seconds to execute and report the transaction. However, before the specialist can report the trade to the position minder system via the Display Book®, customer orders on the same side at the same or a better price may have been received, which would trigger the ''P'' indicator when the specialist attempts to report the ITS trade. In such cases, the specialist would be permitted to use the ''Prin Ahead'' override feature. The specialist would be required to document the situation.

The Exchange believes that the amendment is designed to further ensure that public orders receive executions in the Exchange market against other public orders to the greatest extent possible.

2. Statutory Basis

The Exchange believes that the proposal, as amended, is consistent with section 6(b)(5) of the Act,[5] which requires that an exchange have rules that are designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposal would not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

[4] CAP orders are orders in which the specialist may convert all or part of an unelected portion of a percentage order, and may trade on parity with the elected or converted portions of the order, as long as the specialist is not holding orders at the same price that do not grant parity.

[5] 15 U.S.C. 78f(b)(5).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding, or (ii) as to which the Exchange consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send e-mail to *rule-comments@sec.gov*. Please include File Number SR–NYSE–2004–70 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–NYSE–2004–70. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro/shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NYSE. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2004–70 and should be submitted on or before February 18, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[6]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–319 Filed 1–27–05; 8:45 am]

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[6] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51051; File No. SR–PCX–2004–58]

Self-Regulatory Organizations; the Pacific Exchange, Inc.; Order Approving Proposed Rule Change and Amendment No. 2 Thereto by the Pacific Exchange, Inc., Relating to the Exchange's Rules Under Its Minor Rule Plan and Recommended Fine Schedule

January 18, 2005.

On December 2, 2004, the Pacific Exchange, Inc., (''PCX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend PCX Rule 10.12 to add new provisions (h)(45) and (k)(i)45. These provisions amend the PCX Minor Rule Plan (''MRP'') and Recommended Fine Schedule (''RFS'') to add the failure to maintain adequate procedures and controls to monitor and supervise the entry of electronic orders by Users [3] to prevent the prohibited practices set forth in PCX Rules 6.87(d) and 6.90(e).[4] The proposed rule change was published for comment in the **Federal Register** on December 17, 2004.[5] On January 3, 2005, PCX filed Amendment No. 1 to the proposal. On January 4, 2005, PCX withdrew Amendment No. 1 and filed Amendment No. 2 to the proposal.[6] The Commission received no comments on the proposal. This order approves the proposed rule change, as amended.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange,[7] and, in particular, the requirements of section 6(b)(5) of the Act,[8] in that it is designed to promote just and equitable principles of trade, facilitate transactions in securities, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission also finds that the proposal is consistent with section 6(b)(6) of the Act,[9] which requires that members and persons associated with members be appropriately disciplined for violations of Exchange rules, and section 6(b)(7) of the Act,[10] which requires that members and persons associated with members are provided a fair procedures for disciplinary procedure.

In approving this proposal, the Commission in no way minimizes the importance of compliance with these rules, and all other rules subject to the imposition of fines under the MRP. The Commission believes that the violation of any self-regulatory organization's rules, as well as Commission rules, is a serious matter. However, in an effort to provide the Exchange with greater flexibility in addressing certain violations, the MRP provides a reasonable means to address rule violations that do not rise to the level of requiring formal disciplinary

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Pursuant to PCX Rule 6.87(a)(2), ''User'' means any person or firm that obtains electronic access to Auto-Ex (defined in PCX Rule 6.87(a)(1)) through an Order Entry Firm (defined in PCX Rule 6.87(a)(3)). Pursuant to PCX Rule 6.90(c)(1), ''User'' means any person or broker-dealer that obtains electronic access to PCX Plus (defined in PCX Rule 6.90(a)) through an Order Entry Firm (defined in PCX Rule 6.90(c)(2)).

[4] PCX Rules 6.87(c)(4) and 6.90(d)(3) require Order Entry Firms to maintain such controls and procedures.

[5] *See* Securities Exchange Act Release No. 50830 (December 9, 2004), 69 FR 75581 (December 17, 2004) (''Notice'').

[6] In Amendment No. 2, PCX proposes to correct a typographical error in the proposed rule text by changing footnote 1 to tie to PCX Rule 10.12(k)(i) instead of to PCX Rule 10.12(k). Amendment No. 2 is a technical amendment, and, therefore, not subject to notice and comment.

[7] In approving this proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78f(b)(6).

[10] 15 U.S.C. 78f(b)(7).

proceedings. The Commission notes, however, that after the first failure by an Order Entry Firm to maintain adequate controls and procedures to monitor and supervise the entry of electronic orders pursuant to PCX Rules 6.87(c)(4) and 6.90(d)(3), the Exchange will treat subsequent violations as a formal disciplinary matter.[11] The Commission expects that the Exchange will continue to conduct surveillance with due diligence, and make a determination based on its findings as to whether fines of more or less than the recommended amount are appropriate for violations of rules under the MRP on a case-by-case basis, or if a violation requires formal disciplinary action.

It is therefore ordered, pursuant to section 19(b)(2) of the Act[12], that the proposed rule change, including Amendment No.2 thereto (File No. SR–PCX–2004–58) be, and it hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–325 Filed 1–27–05; 8:45 am]

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[11] *See* proposed PCX Rule 10.12(k)(i)45. *See also* Notice, *supra* note 5.

[12] 15 U.S.C. 78s(b)(2).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51053; File No. SR–PCX–2005–03]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Pacific Exchange, Inc., Relating to Exchange Fees and Charges

January 18, 2005.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 11, 2005, the Pacific Exchange, Inc., (''PCX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the PCX. The PCX has designated this proposal as one establishing or changing a due, fee, or other charge imposed by the PCX under section 19(b)(3)(A)(ii) of the Act,[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The PCX is proposing to amend its Schedule of Fees and Charges For Exchange Services (''Schedule'') in order to add provisions for the handling of options on the Standard and Poor's Depositary Receipts (ticker symbol ''SPY'') under the Exchange's marketing fee program. The text of the proposed rule change is available on the PCX's Web site (*http://www.pacificex.com*), at the PCX's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the PCX included statements concerning the purpose of and basis for its proposal and discussed any comments it had received regarding the proposal. The text of these statements may be examined at the places specified in Item IV below. The PCX has prepared summaries, set forth in Sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The PCX states that the purpose of the proposed filing is to amend the Schedule in order to add provisions for the handling of SPY options under the Exchange's marketing fee program. The Exchange proposes to collect a $1.00 per contract marketing fee for SPY options and assess this fee on all transactions except for Market Maker to Market Maker transactions. In addition, the Exchange is proposing to exclude trades of SPY options from the existing cap on marketing fees. The PCX states that this charge is necessary as a result of the costs associated with trading SPY options. The Exchange believes that capping marketing fees at $200 per trade would put it at a competitive disadvantage to other exchanges that trade SPY options.

The Exchange has also proposed to revise the Schedule to show the change in the symbol of the Nasdaq-100 Tracking Stock Options from QQQ to QQQQ.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act[5] in general, and furthers the objectives of section 6(b)(4) of the Act[6] in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among its members and other persons using its facilities for trading option contracts.[7]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The PCX neither solicited nor received written comments with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing rule change establishes or changes a due, fee, or other charge imposed by the Exchange, it has become effective pursuant to section 19(b)(3)(A)(ii) of the Act[8] and subparagraph (f)(2) of Rule 19b–4 thereunder.[9] Accordingly, the proposal will take effect upon filing with the Commission. At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(4).

[7] Telephone conversation between Steven Matlin, Senior Counsel, PCX, and Davis Liu, Attorney, Division of Market Regulation, Commission, on January 14, 2005.

[8] 15 U.S.C. 78s(b)(3)(A)(ii).

[9] 17 CFR 240.19b–4(f)(2).

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–PCX–2005–03 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–PCX–2005–03. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of the filing also will be available for inspection and copying at the principal office of the PCX. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–PCX–2005–03 and should be submitted on or before February 18, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–326 Filed 1–27–05; 8:45 am]

BILLING CODE 8010–01–P

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51061; File No. SR–PCX–00–15]

Self-Regulatory Organizations; Order Approving a Proposed Rule Change and Amendments No. 1 and 2 Thereto and Notice of Filing and Order Granting Accelerated Approval to Amendments No. 3, 4, 5, 6, and 7 Thereto by the Pacific Exchange, Inc. To Require the Immediate Display of Customer Limit Orders

January 21, 2005.

I. Introduction

On June 14, 2000, the Pacific Exchange, Inc. (''PCX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend PCX Rule 6.55 to require the immediate display of customer limit orders. PCX filed Amendments No. 1 and 2 to the proposed rule change on August 1, 2000,[3] and October 17, 2000,[4] respectively. The proposed rule change, as amended by Amendments No. 1 and 2, was published for comment in the **Federal Register** on November 21, 2000.[5] No comments were received regarding the amended proposal.

PCX filed Amendments No. 3, 4, 5, 6, and 7 with the Commission on October 28, 2004,[6] November 18, 2004,[7] December 10, 2004,[8] December 31, 2004,[9] and January 7, 2005,[10] respectively. This order approves the proposed rule change and Amendments No. 1 and 2 and grants accelerated approval to and solicits comment on Amendments No. 3, 4, 5, 6 and 7.

II. Description of Proposed Rule

PCX proposes to amend PCX Rule 6.55 to codify an immediate display requirement with respect to eligible customer limit orders (''Display Obligation''). The text of the proposed rule change, as amended, follows. Additions are in *italics*. Deletions are in [brackets].

Displaying Bids and Offers in the Book Rule 6.55. The limit orders in the custody of an Order Book Official [shall] constitute *the* [his] book. *Each Order Book Official shall display immediately the full price and size of any customer limit order that improves the price or increases the size of the best disseminated PCX quote.* [So far as practicable, an Order Book Official shall continuously display, in a visible manner, the highest bid and lowest offer along with an indication of the number of option contracts bid for at the highest bid and offered at the lowest offer in his book in each option contract for which

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* letter from Hassan Abedi, Attorney, Regulatory Policy, PCX, to Nancy Sanow, Assistant Director, Division of Market Regulation (''Division''), Commission, dated July 31, 2000 (''Amendment No. 1'').

[4] *See* letter from Hassan Abedi, Attorney, Regulatory Policy, PCX, to Nancy Sanow, Assistant Director, Division, Commission, dated September 29, 2000 (''Amendment No. 2'').

[5] *See* Securities Exchange Act Release No. 43550 (November 13, 2000), 65 FR 69979 (''Notice'').

[6] On October 28, 2004, PCX filed a Form 19b–4, which replaced the original filing and Amendments No. 1 and 2 in their entirety (''Amendment No. 3''). In Amendment No. 3, PCX proposes to revise the proposal to reflect changes to PCX's systems (*i.e.*, the approval and roll-out of PCX Plus) since the Notice was published for comment. Amendment No. 3 also added a number of exemptions to the Display Obligation, discussed in more detail below, which mirror exemptions proposed by the Chicago Board Options Exchange (''CBOE'') and American Stock Exchange (''Amex'') in recently-published proposals. *See* Securities Exchange Act Release Nos. 49916 (June 25, 2004), 69 FR 40422 (July 2, 2004) (SR–CBOE–2004–35) (''CBOE Notice'') and 50188 (August 12, 2004), 69 FR 51495 (August 19, 2004) (SR–Amex–00–27) (''Amex Notice''), which we also approve today, *see* Securities Exchange Act Release Nos. 51063 (January 21, 2005) (''CBOE Approval'') and 51062 (January 21, 2005) (''Amex Approval'').

[7] *See* letter from Tania Blanford, Staff Attorney, Regulatory Policy, PCX, to Nancy Sanow, Assistant Director, Division, Commission, dated November 18, 2004 (''Amendment No. 4''). In Amendment No. 4, PCX proposes a minor modification to the exemptions to the Display Obligation.

[8] *See* Partial Amendment, dated December 10, 2004, submitted by Tania Blanford, Staff Attorney, PCX (''Amendment No. 5''). In Amendment No. 5, PCX proposes a minor modification to the exemptions to the Display Obligation.

[9] *See* Partial Amendment, dated December 31, 2004, submitted by Tania Blanford, Staff Attorney, PCX (''Amendment No. 6''). In Amendment No. 6, PCX proposes a minor modification to the exemptions to the Display Obligation.

[10] *See* Partial Amendment, dated January 7, 2005, submitted by Tania Blanford, Staff Attorney, PCX (''Amendment No. 7''). In Amendment No. 7, PCX proposes a minor modification to the exemptions to the Display Obligation.

he is acting as Order Book Official.] *For the purpose of this rule ''immediately'' means as soon as practicable after receipt, which under normal market conditions means no later than 30 seconds after receipt. The term ''customer limit order'' means an order to buy or sell a listed option at a specified price that is not for the account of either a broker or dealer; provided, however, that the term customer limit order shall include an order transmitted by a broker or dealer on behalf of a customer.* [provided, however, that where the highest bid or lowest offer is for more than twenty-five option contracts, or such other number of option contracts as may be prescribed from time to time by the Options Floor Trading Committee, the Order Book Official may display an indication that the bid or offer is for at least that number of option contracts. When required by market conditions, he may make such quotations available orally rather than by displaying them.] *The following order types are exempt from the display obligation:*

(a) An order executed upon receipt;

(b) An order where the customer who placed it requests that it not be displayed, and upon receipt of the order, the Floor Broker announces in public outcry the information concerning the order that would be displayed if the order were subject to being displayed;

(c) An order the terms of which are delivered immediately upon receipt to another options exchange that is a participant in the Intermarket Options Linkage Plan;

(d) Order types defined in PCX Rule 6.62(c)–(d), (f)–(h) and (j)–(k);

(e) Large-sized orders (orders for more than 100 contracts), unless the customer placing such order requests that the order be displayed;

(f) Orders received before or during a trading rotation (once the trading rotation ends and regular trading begins, orders received before or during the trading rotation will be subject to the display requirement).

Commentary:

[.01 In displaying the highest bid or the lowest offer in his book for a particular option contract, an Order Book Official shall indicate the full size of such bid or offer if it is for 25 or fewer option contracts. If the highest bid or the lowest offer is for more than 25 option contracts, the Order Book Official shall display a size indication of at least 25 units, and may indicate at his discretion, a larger number.]

[.02] *.01* Renumbered.

[.03] *.02* Renumbered.

Currently, PCX Rule 6.55 provides that an Order Book Official (''OBO'') ''shall continuously display, in a visible manner, the highest bid and lowest offer along with an indication of the number of option contracts bid for at the highest bid and offered at the lowest offer in his book in each option contract for which he is acting as Order Book Official.'' The OBO may take custody of limit orders both manually and electronically. An order is entered manually into an OBO's custody when a Floor Broker places a written, time-stamped order ticket into the proper receptacle at the trading post.[11] Alternatively, an order is entered electronically into the OBO's custody when an OTP Holder or OTP Firm sends it to the Pacific Options Exchange Trading System (''POETS'') or PCX Plus [12] via the Exchange's Member Firm Interface and the order, not being marketable, is electronically entered into the Consolidated Book [13] via the Auto-Ex Book [14] function of POETS or via PCX Plus. Orders entered electronically into the Consolidated Book are immediately displayed on the overhead screens on the trading floor and disseminated to the public via the Options Price Reporting Authority (''OPRA''). Orders entered manually must be entered into POETS or PCX Plus before being displayed on the floor or disseminated via OPRA.

Under the proposal, OBOs would be required to display immediately the price and full size of any eligible customer limit order that improves the price or increases the size of the best disseminated PCX quote. PCX proposes to define ''immediately'' to mean, under normal market conditions, as soon as practicable but no later than 30 seconds after receipt by the OBO.[15] PCX proposes to define the term ''customer limit order'' as ''an order to buy or sell a listed option at a specified price that is not for the account of either a broker or dealer; provided, however, that the term customer limit order shall include an order transmitted by a broker or dealer on behalf of a customer.''

PCX proposes to exempt, or partially exempt, certain order types from the Display Obligation. Specifically, PCX proposes to exempt orders executed upon receipt as well as any order where the customer who placed it requests that the order not be displayed, if upon receipt of the order, the Floor Broker announces via public outcry the information about the order that would be displayed if the order were subject to display.[16] PCX further proposes to exempt from the Display Obligation a customer order the terms of which are delivered, immediately upon receipt, to another options exchange that participates in the options intermarket linkage plan.[17]

The Exchange also proposes to exempt, or partially exempt, from the Display Obligation the following types of orders set forth in PCX Rule 6.62(c)–(d), (f)–(h) and (j)–(k):

Contingency orders: Stop-limit orders (PCX Rule 6.62(c)(1)) and stop (stop-loss) orders (PCX Rule 6.62(c)(2))—These orders are not executable until the market reaches a specified ''trigger'' price, at which point a stop-limit order converts to a limit order and a stop order converts to a market order. As such, these orders are not available to trade and have no standing in the quoted markets until the specified price trigger is reached. However, the limit order resulting from a triggered stop-limit order is subject to the Display Obligation.

Complex orders: Spread orders (PCX Rule 6.62(d)); straddle orders (PCX Rule 6.62(g)); combination orders (PCX Rule 6.62(h)); stock/option orders (PCX Rule 6.62(j)(1)); and ratio orders (PCX Rule 6.62(k))—These orders specify instructions to trade more than one options series or product as a package,

[11] *See* PCX Rule 6.52, Commentary .04. A Floor Broker must use due diligence in handling an order that it represents as agent. *See generally* PCX Rule 6.46.

[12] *See* Securities Exchange Act Release No. 49718 (May 17, 2004), 69 FR 29611 (May 24, 2004) (order approving PCX Plus).

[13] *See* PCX Rule 6.1(b)(37).

[14] *See* PCX Rule 6.87(1).

[15] In its filing, PCX states that ''receipt by the OBO'' means receipt on POETS or the PCX Plus system, which is consistent with the firm quote definition of ''time of receipt.'' This means that the time of receipt is when the order is received on POETS or PCX Plus, even if the OBO does not happen to see it for several seconds.

[16] While the Exchange's proposed Display Obligation would be imposed on the OBO, the OBO, who does not hold customer orders, cannot take custody of a limit order that a customer has instructed not to be displayed. Under PCX Rule 6.46(a) and (f) and Commentaries .01 and .05 thereto, the Floor Broker, as the person holding the order, will have the obligation to vocalize the information concerning the order that would be displayed if the order were subject to being displayed. Telephone conversation between Tania Blanford, Staff Attorney, Regulatory Policy, PCX, and Nathan Saunders, Attorney, Division, Commission, November 9, 2004.

[17] *See* Securities Exchange Act Release No. 43086 (July 28, 2000), 65 FR 48023 (August 4, 2000) (order approving the Plan for the Purpose of Creating and Operating an Intermarket Option Linkage). The Exchange represents that if such a related order that is delivered immediately upon receipt to another options exchange that is a particiipant in the intermarket options linkage plan were canceled, in whole or in part, by the other options exchange, then the OBO would be obligated to display immediately upon receipt of the cancellation notice the price and size of the customer order as set forth in proposed PCX Rule 6.55.

typically at a specified net debit or credit as opposed to at a specific limit price for each leg involved. Therefore, there is no specified limit price for each leg of the order to display in the Exchange's disseminated quotes. Moreover, OPRA does not accept complex order quotes at net prices.

One-cancels-the-other orders (PCX Rule 6.62(f))—A one-cancels-the-other order consists of two or more orders treated as a unit. The execution of any one of the orders causes the others to be cancelled. If the Floor Broker cannot execute any of the orders upon receipt, then none can be displayed or booked as doing so could result in the approximately simultaneous execution of more than one component order, in direct contravention of the primary order condition.

Large sized orders—The Commission's Display Rule, Rule 11Ac1–4 under the Act,[18] applicable to customer limit orders received in the equity market, provides a general exclusion for block size orders of at least 10,000 shares.[19] PCX proposes to adopt a similar exemption for large sized orders. Accordingly, there would be no obligation to display orders for more than 100 contracts, unless the customer placing such order requests otherwise.

Orders received during a trading rotation—Orders received before or during a trading rotation (as defined in PCX Rule 6.64) would be exempt from the 30-second standard. During a rotation, the PCX systems attempt to find the opening price and until the opening price is established, there is no disseminated market. Once the trading rotation ends and regular trading begins, orders received before or during the trading rotation would be subject to the Display Obligation.

Finally, PCX proposes to delete language in PCX Rule 6.55, Commentary .01, referring to display obligations where the highest bid or lowest offer is for more than twenty-five option contracts as such language is no longer applicable.

III. Commission Findings and Order Granting Approval

The Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange[20] and, in particular, the requirements of section 6(b)(5) of the Act,[21] which requires, among other things, that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Specifically, the Commission believes that the immediate display of customer limit orders that improve the price or size of the best disseminated PCX quote should promote transparency and enhance the quality of executions of customer limit orders on PCX.

The proposed amendments to PCX Rule 6.55 introduce requirements for customer limit order display that are comparable to the requirements of the Commission's Display Rule, which is applicable to customer limit orders received in the equity market. In addition, the Commission believes that the Exchange's proposal to exempt large sized orders from the Display Obligation is reasonable since a substantially similar exemption is set forth in the Commission's Display Rule.

The Commission also believes that it is consistent with the Act for PCX to exempt from the Display Obligation under its rules stop-limit and stop or stop-loss orders. These orders are contingent orders that are subject to a particular triggering event and, thus, are not available for execution until the triggering event occurs. A stop-loss order becomes a market order when triggered and thus is not subject to the Display Obligation because such an order would then be immediately executable. A stop-limit order becomes a limit order when the triggering event occurs. This limit order would be subject to the Display Obligation. Spread, straddle, combination, stock/option, ratio and one-cancels-the-other orders are complex orders with more than one component and, thus, the Commission believes, are not suitable for display.

During a trading rotation, PCX systems attempt to set an opening price for the series. Until that opening price is established, there is no disseminated market. Therefore, it is reasonable to exempt orders received before or during a trading rotation from the Display Obligation. The Commission notes, however, that once the trading rotation ends, any orders not executed would then be subject to the Display Obligation.

Finally, the Exchange proposes to exempt from the Display Obligation customer orders the terms of which are delivered, immediately upon receipt, to another options exchange. The Commission believes it is reasonable to exempt such orders since they are subject to execution upon receipt at the other options exchange. Moreover, the Exchange represents that if the order delivered to the other options exchange were canceled, in whole or in part, by the other exchange, then the original customer order would be subject to the Display Obligation immediately upon receipt of the cancellation notice by the Exchange.

The Commission finds good cause for approving Amendments No. 3, 4, 5, 6, and 7 to the proposed rule change prior to the thirtieth day after their publication in the **Federal Register,** pursuant to section 19(b)(2) of the Act.[22] Amendment No. 3 would revise the proposal to reflect changes to PCX's systems since the Notice was published for comment. These revisions are necessary given recent changes to PCX's systems, such as the approval and implementation of the PCX Plus electronic trading platform, but do not alter the primary purpose of the proposal: to require immediate display of customer limit orders on the Exchange.

In Amendment No. 3, PCX also proposes several exemptions to the Display Obligation. The Commission notes that these exemptions, discussed in detail in Part II above, are substantially identical to exemptions proposed by CBOE and Amex in their customer limit order display proposals, which were recently noticed for full 21-day comment periods.[23] No comments were received on either the CBOE or Amex proposal. Amendments No. 4, 5, 6, and 7 proposed minor modifications to the proposed rule text, and thus are appropriate for accelerated approval.

Accelerated approval of Amendments No. 3, 4, 5, 6, and 7 will permit the Exchange to implement the proposal in an expeditious manner, *i.e.,* simultaneously with the implementation of similar proposals by CBOE, Amex and the Philadelphia Stock Exchange (''Phlx''), which we also approve today.[24] The Commission,

[18] 17 CFR 240.11Ac1–4.

[19] *See* 17 CFR 240.11Ac1–4(c)(4).

[20] In approving this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[21] 15 U.S.C. 78f(b)(5).

[22] 15 U.S.C. 78s(b)(2).

[23] *See* CBOE Notice and Amex Notice, *supra* note 6.

[24] *See* CBOE Approval, *supra* note 6; Amex Approval, *supra* note 6; and Securities Exchange Act Release No. 51064 (January 21, 2005) (notice of

Continued

therefore, believes that good cause exists, consistent with section 6(b)(5)[25] and section 19(b)[26] of the Act, to accelerate approval of Amendments No. 3, 4, 5, 6, and 7.

IV. Solicitation of Comments Concerning Amendments No. 3, 4, 5, 6, and 7

Interested persons are invited to submit written data, views, and arguments concerning Amendments No. 3, 4, 5, 6, and 7, including whether they are consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–PCX–00–15 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–PCX–00–15. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–PCX–00–15 and should be submitted on or before February 18, 2005.

V. Conclusion

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[27] that the proposed rule change (File No. SR–PCX–00–15), as amended, be approved, and that Amendments No. 3, 4, 5, 6, and 7 thereto be approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[28]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–327 Filed 1–27–05; 8:45 am]

BILLING CODE 8010–01–P

filing and order granting accelerated approval to SR–Phlx–2004–73).

[25] 15 U.S.C. 78f(b)(5).

[26] 15 U.S.C. 78s(b).

[27] *Id.*

[28] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51060; File No. SR–Phlx–2005–01]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Philadelphia Stock Exchange, Inc., Relating To Imposing a New Licensing Fee in Connection With the Firm-Related Equity Option and Index Option Fee Cap

January 19, 2005.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 10, 2005, the Philadelphia Stock Exchange, Inc. (''Exchange'' or ''Phlx'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in items I, II, and III below, which items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Phlx, pursuant to section 19(b)(1) of the Act and Rule 19b–4 thereunder, proposes to amend its schedule of fees to adopt a license fee of $.10 for options traded on the Standard & Poor's Depositary Receipts®, Trust Series 1 (''SPDRs''), traded under the symbol SPY (''SPY'')[3] to be assessed per contract side for equity option ''firm'' transactions (comprised of equity option firm/proprietary comparison transactions, equity option firm/proprietary transactions and firm/proprietary facilitation transactions). This license fee will be imposed only after the Exchange's $60,000 ''firm-related'' equity option and index option comparison and transaction charge cap, described more fully below, is reached.

Currently, the Exchange imposes a cap of $60,000 per member organization[4] on all ''firm-related'' equity option and index option comparison and transaction charges combined.[5] Specifically, ''firm-related'' charges include equity option firm/proprietary comparison charges, equity option firm/proprietary transaction charges, equity option firm/proprietary facilitation transaction charges, index option firm (proprietary and customer executions) comparison charges, index option firm/proprietary transaction charges, and index option firm/proprietary facilitation transaction charges (collectively, ''firm-related charges''). Thus, such firm-related charges for equity options and index options, in the aggregate for one billing month, may not exceed $60,000 per month per member organization.

The Exchange also imposes a license fee of $0.10 per contract side for equity option ''firm'' transactions on options on Nasdaq-100 Index Tracking Stocksm,[6] traded under the symbol

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] ''Standard & Poor's,'' ''S&P®,'' ''S&P 500®,'' ''Standard & Poor's 500®,'' ''Standard & Poor's Depositary Receipts®,'' and ''500'' are trademarks of The McGraw-Hill Companies, Inc., and have been licensed for use by the Philadelphia Stock Exchange, Inc., in connection with the listing and trading of SPDRs, on the Phlx. These products are not sponsored, sold or endorsed by Standard & Poor's, a division of The McGraw-Hill Companies, Inc., and Standard & Poor's makes no representation regarding the advisability of investing SPDRs.

[4] The firm/proprietary comparison or transaction charge applies to member organizations for orders for the proprietary account of any member or non-member broker-dealer that derives more than 35% of its annual, gross revenues from commissions and principal transactions with customers. Member organizations are required to verify this amount to the Exchange by certifying that they have reached this threshold and by submitting a copy of their annual report, which was prepared in accordance with Generally Accepted Accounting Principles (''GAAP''). In the event that a member organization has not been in business for one year, the most recent quarterly reports, prepared in accordance with GAAP, will be accepted. *See* Securities Exchange Act Release No. 43558 (November 14, 2000), 65 FR 69984 (November 21, 2000) (SR–Phlx–00–85).

[5] *See* Securities Exchange Act Release No. 51024 (January 11, 2005), 70 FR 3088 (January 19, 2005) (File No. SR–Phlx–2004–94).

[6] The Nasdaq-100®, Nasdaq-100 Index®, Nasdaq®, The Nasdaq Stock Market®, Nasdaq-100 Shares℠, Nasdaq-100 Trust℠, Nasdaq-100 Index

QQQQ (''QQQ''), and certain other licensed products[7] (collectively, ''licensed product'') after the $60,000 cap, as described above, is reached. Therefore, when a member organization exceeds the $60,000 cap (comprised of combined firm-related charges), the member organization is charged $60,000, plus license fees of $0.10 per contract side for any applicable licensed product trades (if any) over those that were included in reaching the $60,000 cap. In other words, once the cap is reached, the $0.10 license fee is imposed on all subsequent firm-related transactions; these license fees are charged in addition to the $60,000 cap.

The Exchange proposes to adopt a $.10 license fee per contract side for the SPY for equity option firm transactions, which will be imposed after the $60,000 cap is reached in the same way the current licensed product fees are assessed. Thus, when a member organization exceeds the $60,000 cap, the member organization will be charged $60,000 plus any applicable license fees for trades of licensed products, including the SPY, over those trades that were counted in reaching the $60,000 cap.[8]

The fees set forth in this proposal are scheduled to become effective for transactions settling on or after January 10, 2005.

The Exchange also proposes to make a minor change to its $60,000 Firm Related Equity Option and Index Option Cap Schedule by changing the reference to ''$50,000'' to read ''$60,000.'' Although other references to $50,000 were changed to $60,000 in SR–Phlx–2004–94, this reference was inadvertently omitted.

A copy of the applicable portions of the Exchange's Summary of Equity Options Charges and the Exchange's $60,000 ''Firm Related'' Equity Option and Index Option Cap Schedule is available on Phlx's Web site (*http://www.phlx.com/exchange/phlx_rule_fil.html*), at Phlx's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in item IV below. The Exchange has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of assessing the SPY license fee of $.10 per contract side after reaching the $60,000 cap as described in this proposal is to help defray licensing costs associated with the trading of this product, while still capping member organizations' fees enough to attract volume from other exchanges. The cap operates this way in order to offer an incentive for additional volume without leaving the Exchange with out-of-pocket costs.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b)(4) of the Act,[9] in that it provides for the equitable allocation of reasonable dues, fees and other charges among its members and other persons using its facilities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing rule change establishes or changes a due, fee or other charge imposed by the Exchange, it has become effective pursuant to section 19(b)(3)(A)(ii) of the Act[10] and Rule 19b–4(f)(2)[11] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an E-mail to *rule-comments@sec.gov*. Please include File No. SR–Phlx–2005–01 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–Phlx–2005–01. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written

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[7] In addition to the QQQs, the following products are assessed a $.10 license fee per contract side after the $60,000 cap is reached: Russell 1000 Growth iShares (''IWF''); Russell 2000 iShares (''IWM''); Russell 2000 Value iShares (''IWN''): Russell 2000 Growth iShares (''IWO''); Russell Midcap Growth iShares (''IWP''); Russell Midcap Value iShares (''IWS''); NYSE Composite Index (''NYC''); and NYSE U.S. 100 Index (''NY'').

[8] Consistent with current practice, when calculating the $60,000 cap, the Exchange first calculates all equity option and index option transaction and comparison charges for products without license fees, and then equity option transaction and comparison charges for products with license fees (*i.e.*, QQQ license fees) that are assessed by the Exchange after the $60,000 cap is reached. *See* Securities Exchange Act Release No. 50836 (December 10, 2004), 69 FR 75584 (December 17, 2004) (SR–Phlx–2004–70).

[9] 15 U.S.C. 78f(b)(4).

[10] 15 U.S.C. 78s(b)(3)(A)(ii).

[11] 17 CFR 19b–4(f)(2)

communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of the Phlx. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2005–01 and should be submitted on or before February 18, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–323 Filed 1–27–05; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51064; File No. SR-Phlx-2004–73

Self-Regulatory Organizations; Philadelphia Stock Exchange, Inc.; Notice of Filing and Order Granting Accelerated Approval to a Proposed Rule Change and Amendments No. 1 and 2 Thereto To Require the Immediate Display of Customer Options Limit Orders

January 21, 2005.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1], and Rule 19b–4[2] thereunder, notice is hereby given that on November 3, 2004, the Philadelphia Stock Exchange, Inc. (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in items I, II, and III, below, which items have been substantially prepared by the Exchange. Phlx filed Amendment No. 1 to the proposed rule change on January 13, 2005,[3] and filed Amendment No. 2 to the proposed rule change on January 19, 2005.[4] The Commission is publishing this notice to solicit comment on the proposed rule change, as amended, from interested persons, and at the same time is granting accelerated approval to the proposed rule change, as amended.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Phlx proposes to amend Phlx Rules 1014, 1063 and 1080, and to delete Option Floor Procedure Advice A–1, to: (1) Reflect that the Exchange's Automated Options Market (''AUTOM'') System,[5] and not the specialist, will immediately display the full price and size of any limit order that establishes the Exchange's disseminated price or increases the size of the Exchange's disseminated bid or offer, subject to certain exemptions; and (2) establish new rules that require Exchange Registered Options Traders (''ROTs'') and Floor Brokers to place limit orders on the limit order book electronically.

The text of the proposed rule change, as amended, follows. Additions are in *italics*. Deletions are in [brackets].

* * * * *

Rule 1014. Obligations and Restrictions Applicable to Specialists and Registered Options Traders

(a)–(h) No Change.

Commentary:

.01–.17 No change.

.18. An ROT who wishes to place a limit order on the limit order book must submit such a limit order electronically.

* * * * *

Rule 1063. Responsibilities of Floor Brokers

(a)–(e) No change.

Commentary:

.01. A Floor Broker who wishes to place a limit order on the limit order book must submit such a limit order electronically through the Options Floor Broker Management System.

* * * * *

Rule 1080. Philadelphia Stock Exchange Automated Options Market (AUTOM) and Automatic Execution System (AUTO–X)

(a)–(b) No change

(c) AUTO–X. * * *

(i)–(iii) No change.

(iv) Except as otherwise provided in this Rule, in the following circumstances, an order otherwise eligible for automatic execution will instead be manually handled by the specialist:

(A)–(C) No change.

(D) When the [specialist posts] *Exchange's best* [a] bid or offer *is represented by a limit order on the book* [that is better than the specialist's own bid or offer] (except with respect to orders eligible for ''Book Sweep'' as described in Rule 1080(c)(iii) above, and ''Book Match'' as described in Rule 1080(g)(ii) below);

(E)–(H) No change.

(d)–(k) No change.

Commentary:

.01 No change.

.02 The Electronic Order Book is the Exchange's automated [specialist] limit order book, which automatically routes all unexecuted AUTOM orders to the book and displays orders real-time in order of price/time priority. [Orders not delivered through AUTOM may also be entered onto the Electronic Order Book.]

(a)(i) Except as provided in sub-paragraph (a)(ii) below, the AUTOM System will immediately display the full price and size of any limit order that establishes the Exchange's disseminated price or increases the size of the Exchange's disseminated bid or offer.

(ii) The AUTOM System will not display:

(A) An order executed upon receipt;

(B) An order where the customer who placed it requests that it not be displayed, and upon representation of such order in the trading crowd the Floor Broker announces in public outcry the information concerning the order that would be displayed if the order were subject to being displayed;

(C) A customer limit order for which, immediately upon receipt, a related order for the principal account of the specialist, reflecting the terms of the customer order, is routed to another options exchange;

(D) Orders received before or during a trading rotation, however, such limit orders will be displayed immediately upon conclusion of the applicable rotation if they represent the Exchange's best bid or offer;

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[12] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Amendment No. 1, dated January 13, 2005, submitted by Richard S. Rudolph, Director and Counsel, Phlx (''Amendment No. 1''). In Amendment No. 1, Phlx proposes clarifying language to be included in the previously submitted proposed rules.

[4] *See* Amendment No. 2, dated January 19, 2005, submitted by Richard S. Rudolph, Director and Counsel, Phlx (''Amendment No. 2''). In Amendment No. 2, Phlx proposes a minor modification to the previously submitted proposed rules.

[5] AUTOM is the Exchange's electronic order delivery, routing, execution and reporting system, which provides for the automatic entry and routing of equity option and index option orders to the Exchange trading floor. Orders delivered through AUTOM may be executed manually, or certain orders are eligible for AUTOM's automatic execution features: AUTO-X, Book Sweep, and Book Match. Equity option and index option specialists are required by the Exchange to participate in AUTOM and its features and enhancements. Option orders entered by Exchange members into AUTOM are routed to the appropriate specialist unit on the Exchange trading floor. *See* Phlx Rule 1080.

(E) The following order types as defined in Rule 1066: Contingency Orders; One-Cancels-the-Other Orders; Hedge Orders (e.g., spreads, straddles, combination orders); Synthetic Options;

(F) Immediate or Cancel (''IOC'') orders.

(b) Limit orders may only be placed on the limit order book by: (i) An ROT via electronic interface with AUTOM pursuant to Rule 1014, Commentary .18; (ii) a Floor Broker using the Options Floor Broker Management System (as described in Commentary .06 below); or (iii) the AUTOM System for eligible customer and off-floor broker-dealer limit orders.

(c) A limit order to be executed manually by the specialist pursuant to Rule 1080(c)(iv) will be displayed automatically by the AUTOM System until such limit order is executed or cancelled. If such limit order is partially executed, the AUTOM System will automatically display the actual number of contracts remaining in such limit order.

.03 No change.

.04 ROT Limit Orders. * * *

Not later than ten days following approval by the Securities and Exchange Commission of the rules applicable to the Exchange's electronic trading platform, Phlx XL, the Exchange will commence the initial deployment of Phlx XL by allowing specialists and ROTs who are Streaming Quote Traders (''SQTs,'' as defined in the Phlx XL rules) to submit electronic quotations in Streaming Quote Options (as defined in the Phlx XL rules), and ROTs who are not SQTs to submit limit orders onto the limit order book via electronic interface with AUTOM [or manually through a Floor Broker or the Specialist]. Eligible incoming orders and quotations will automatically execute against quotations of specialists and SQTs and orders of ROTs in accordance with the functionality of the Phlx XL system, as set forth in the Phlx XL rules.

* * *

.05–.07 No change.

* * * * *

Option Floor Procedure Advices—A–1: Reserved

[Responsibility of Displaying Best Bids and Offers

(a) A Specialist shall use due diligence to ensure that the best available bid and offer is displayed for those option series in which he is assigned.

Bids and offers for the Specialist's own account, bids and offers on the book, and bids and offers established in the crowd are deemed available for display purposes.

(b) After voicing a bid/offer, the Floor Broker or ROT shall use due diligence to inform the Specialist when s/he is no longer bidding/offering at that price. Specifically, the Floor Broker or ROT must immediately inform the Specialist when s/he is ''out'' of that bid/offer, including due to an execution or departure from the crowd.

FINE SCHEDULE (Implemented on a two-year running calendar basis)

A–1

1st Occurrence—$250.00
2nd Occurrence—$500.00
3rd Occurrence—$1,000.00
4th Occurrence and Thereafter Sanction is discretionary with Business Conduct Committee]

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Phlx included statements concerning the purpose of and basis for the proposed rule change, as amended, and discussed any comments it received on the proposed rule change, as amended. The text of these statements may be examined at the places specified in item III below. The Phlx has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change, as amended, is to establish Phlx rules that reflect the immediate, automatic display of limit orders (with certain exemptions as described below), and to require that Phlx ROTs and Floor Brokers who wish to place limit orders on the limit order book do so electronically.

Currently, Exchange Options Floor Procedure Advice (''OFPA'') A–1[6] requires the specialist to use due diligence to ensure that the best available bid and offer is displayed for those option series in which he is assigned, including limit orders that represent the Exchange's best bid or offer. However, due to the recently enhanced display functionality of the AUTOM System, the Exchange is proposing to remove this responsibility from the specialist and to fully automate that process. Accordingly, the proposal would delete OFPA A–1 in its entirety.

The Exchange also proposes to adopt Commentary .02(a) to Phlx Rule 1080 to provide generally that the AUTOM System will immediately[7] display the full price and size of any limit order that establishes the Exchange's disseminated price or increases the size of the Exchange's disseminated bid or offer. The proposal would delete the current provision in Commentary .02 that states that orders not delivered through AUTOM may also be entered onto the Electronic Order Book, because this can no longer be done manually.

Consistent with the full automation of the display of limit orders on the limit order book, the Exchange proposes to adopt Commentary .02(b) to clarify that limit orders may be placed on the limit order book only by: (i) An ROT via electronic interface with AUTOM pursuant to Phlx Rule 1080, Commentary .18;[8] (ii) a Floor Broker using the Options Floor Broker Management System pursuant to Phlx Rule 1063, Commentary .01;[9] or (iii) the AUTOM System for eligible customer and off-floor broker-dealer limit

[6] *See* Securities Exchange Act Release Nos. 21760 (February 14, 1985), 50 FR 7248 (February 21, 1985) (SR–Phlx–84–13); 39754 (March 13, 1998), 63 FR 13901 (March 23, 1998) (SR–Phlx–97–53); and 44537 (July 11, 2001), 66 FR 37511 (July 18, 2001) (SR–Phlx–2001–36).

[7] The Exchange represents that, for the purposes of this rule, ''immediately'' display means that the AUTOM System will display eligible orders not subject to an exemption automatically and instantaneously upon receipt. Telephone call between Rick Rudolph, Director and Counsel, Phlx, and Nathan Saunders, Attorney, Division of Market Regulation (''Division''), Commission, November 8, 2004.

[8] In November, 2002, the Commission approved the Exchange's proposal to allow on-floor, in-crowd ROTs to place electronic price improving limit orders on the limit order book via electronic interface with AUTOM (''ROT Access''). *See* Securities Exchange Act Release No. 46763 (November 1, 2002), 67 FR 68898 (November 13, 2003) (SR–Phlx–2002–04). The rules governing ROT Access were amended in July 2004 in the Phlx XL proposal by eliminating the requirement that ROT limit orders placed on the limit order book under ROT Access be price-improving limit orders. *See* Securities Exchange Act Release No. 50100 (July 27, 2004), 69 FR 46612 (August 3, 2004) (SR–Phlx–2003–59).

[9] The Options Floor Broker Management System is a component of AUTOM designed to enable Floor Brokers and/or their employees to enter, route and report transactions stemming from options orders received on the Exchange. The Options Floor Broker Management System also is designed to establish an electronic audit trail for options orders represented and executed by Floor Brokers on the Exchange, such that the audit trial provides an accurate, time-sequenced record of electronic and other orders, quotations and transactions on the Exchange, beginning with the receipt of an order by the Exchange, and further documenting the life of the order through the process of execution, partial execution, or cancellation of that order. *See* Phlx Rule 1080, Commentary .06.

orders.[10] In conjunction with this rule, the Exchange proposes to adopt Commentary .18 to Phlx Rule 1014, to require an ROT who wishes to place a limit order on the limit order book to submit such a limit order electronically, and Commentary .01 to Phlx Rule 1063, to establish that a Floor Broker who wishes to place a limit order on the limit order book must submit such a limit order electronically through the Options Floor Broker Management System. The proposed rule change would delete the provision currently contained in Commentary .04 to Phlx Rule 1014 that an ROT may place a limit order onto the limit order book manually through a Floor Broker or the specialist.

Additionally, because the specialist would no longer have the ability to post a limit order, the Exchange proposes to amend Phlx Rule 1080(c)(iv)(D), which currently provides that an order otherwise eligible for automatic execution is instead handled manually by the specialist ''when the specialist posts a bid or offer that is better than the specialist's own bid or offer.'' Currently, Phlx Rule 1080(c)(iv)(D) states that the specialist will handle an order otherwise eligible for automatic execution manually in this situation, except with respect to orders eligible for Book Sweep, where an automatic execution occurs when a contra-side quotation that matches a limit order on the book results in an execution at the NBBO,[11] and Book Match, where an automatic execution occurs when an inbound contra-side order that matches a limit order on the book results in an execution at the NBBO.[12] To accurately reflect that the specialist can no longer ''post'' a bid or offer (as described above), the Exchange proposes to amend Phlx Rule 1080(c)(iv)(D) to provide that an order otherwise eligible for automatic execution would instead be handled manually by the specialist when the Exchange's best bid or offer is represented by a limit order on the book. While generally a limit order on the book would be eligible for automatic execution by way of Book Match or Book Sweep, Phlx Rule 1080(c)(iv)(D) is still necessary, because the specialist still would handle an order manually when a ROT or a Floor Broker in the trading crowd verbally announces to the specialist that he/she intends to trade against the limit order on the book representing the Exchange's best bid or offer. While the specialist no longer has the ability to ''post'' a limit order on the limit order book, the specialist would continue to have the ability to execute such an order, once it is placed on the limit order book electronically, against the ROT or Floor Broker's order, by pointing and clicking on the limit order on the book and entering the contra-side account number against which the limit order on the book will trade.

The proposed rule change also includes in Commentary .02(c) a provision that limit orders to be executed manually by the specialist pursuant to Phlx Rule 1080(c)(iv)[13] would be displayed automatically by the AUTOM system until the limit order is executed or cancelled. If a limit order is partially executed, the AUTOM System would automatically display the actual number of contracts remaining in the limit order.

Finally, the proposed rule change would establish certain exemptions, or partial exemptions, to the limit order display rule. The proposed exemptions provide that AUTOM will not display: (a) Limit orders executed upon receipt; (b) a limit order where the customer who placed it requests that it not be displayed, and upon representation of such order in the trading crowd the Floor Broker announces in public outcry the information concerning the order that would be displayed if the order were subject to being displayed; (c) a customer limit order for which, immediately upon receipt, a related order for the principal account of the specialist, reflecting the terms of the customer order, is routed to another options exchange; (d) a limit order received before or during a trading rotation[14] (however, such limit orders will be displayed immediately upon conclusion of the applicable rotation if they represent the Exchange's best bid or offer); (e) certain contingent and complex order types defined in Phlx Rule 1066, as discussed more fully below; and (f) immediate or cancel limit orders.

Generally, Phlx has proposed exemptions or partial exemptions for certain types of contingent and complex orders because these order types, by definition, are priced in a way that is dependent on a condition or another variable, such that displaying the price of such an order without the other information would not accurately reflect that trading interest.

Contingency Orders (Phlx Rule 1066(c)): These orders are contingent upon a condition being satisfied, and are not executable until the prerequisite condition is satisfied. Phlx Rule 1066(c) contains the following types of contingency orders eligible for delivery via AUTOM that would not be immediately displayed under the proposal: stop (stop-loss), stop-limit, all-or-none, market-on-close, and cancel-replacement orders.

Stop (Stop-Loss) and Stop Limit Orders (Phlx Rule 1066(c)(1)): These orders are not executable until the market reaches a specified price that ''elects'' the order, at which point they convert to a market order. As such, they are not available to trade and have no standing in the quoted markets until the specified price is reached. A trade or a quote can be the ''triggering'' event for the election of a stop order. Because they convert to market orders upon the triggering event, stop orders cannot then be subject to the display requirement.

A stop-limit order is not ''triggered'' until the option contract trades or is bid (offered) at or above (below) the stop price, at which point it converts to a limit order. As such, a stop-limit order has no standing in the quoted markets until the specified price trigger is reached. Once triggered, the stop-limit order converts to a limit order, and thus would be subject to display.

All-or-None Orders (Phlx Rule 1066(c)(4)): While an all-or-none order can be a limit order, instructions require the order be executed in its entirety or not at all. The Commission's Display Rule, applicable to customer limit orders received in the equity market, also provides an exemption for all-or-none orders.[15]

Market-on-Close Orders (Phlx Rule 1066(c)(6)): These orders may have a limit price attached, but are not eligible for representation until the close of trading is imminent. Regardless of the time at which a market-on-close order is entered, the floor broker is required to hold such an order, and is precluded from representing it, until as near as

[10] Off-floor broker-dealers may deliver limit orders for entry onto the limit order book via AUTOM. *See* Phlx Rule 1080(b)(i)(C). The Exchange represents that orders that are not eligible for routing through the AUTOM System would be rejected and sent back either (a) to the firm that submitted the order, for reentry, or (b) to the Floor Broker who submitted the order, to be represented using the Options Floor Broker Management System. Telephone call between Rick Rudolph, Director and Counsel, Phlx, and Nathan Saunders, Attorney, Division, Commission, November 8, 2004.

[11] *See* Phlx Rule 1080(c)(iii).

[12] *See* Phlx Rule 1080(g)(ii).

[13] Phlx Rule 1080(c)(iv) enumerates a variety of circumstances under which orders otherwise eligible for automatic execution are instead handled manually by the specialist.

[14] During a trading rotation, the specialist attempts to find the opening price and until the opening price is established, there is no disseminated market. Once the trading rotation ends and regular trading begins, limit orders received before or during the trading rotation that are not executed at the opening price and remain on the limit order book will be displayed if they represent the Exchange's best bid or offer.

[15] *See* 17 CFR 240.11Ac1–4(c)(7).

possible to the close of trading. Furthermore, because representation and execution of these orders must occur on or as near to the close of trading as possible, it would be difficult if not impossible to determine whether members met an appropriate display standard for such orders.

Cancel-Replacement Order (Phlx Rule 1066(c)(7)): A cancel-replacement order is a contingency order consisting of two or more parts which require the immediate cancellation of a previously received order prior to the replacement of a new order with new terms and conditions. If the previously placed order is already filled partially or in its entirety, the replacement order is automatically canceled or reduced by the number of contracts partially filled. AUTOM would not immediately display all parts of the cancel-replacement order, but rather would display only the order that remains after the previously received order is cancelled.

In addition to contingency orders, the Exchange also proposes to establish an exemption for one-cancels-the-other orders, hedge orders and synthetic options.

One-Cancels-the-Other Orders (Phlx Rule 1066(e)): A one-cancels-the-other order is comprised of two or more orders treated as a collective unit. The execution of any one of the component orders cancels the other(s). If the specialist cannot execute any of the orders upon receipt, then none can be displayed or booked as doing so could result in the approximate simultaneous execution of more than one component order, in direct contravention of the primary order condition.

Hedge Orders (Phlx Rule 1066(f)) and Synthetic Options (Phlx Rule 1066(g)): Hedge orders (*e.g.*, spreads, straddles, and combination orders) and synthetic options are orders that specify instructions to trade more than one options series or product as a package, typically (with respect to hedge orders) at a specified net debit or credit, as opposed to a specific limit price for each leg involved. Therefore, there is no specified limit price for each series involved to display in the quotes. Moreover, the Options Price Reporting Authority (''OPRA'') does not accept complex order quotes at net prices. Therefore, these orders would not be displayed. Each component of these complex orders is, in essence, itself contingent on the ability to execute the other components of the order. Since there is no guarantee that all components will become executable at the same time, if at all, the immediate display of all components could result in the execution of less than all components of the order.

Immediate or Cancel Orders: An immediate or cancel order is a market or limit order which is to be executed in whole or in part as soon as such order is represented in the trading crowd. Any portion not executed is to be cancelled, which means it cannot be displayed. An immediate or cancel order shares most of the same characteristics of an all-or-none order, which is exempt from the Commission's Display Rule.[16] Given the similarity between these order types, the Exchange believes that immediate or cancel orders should also be exempt from the requirements of the Exchange's limit order display rule.

2. Statutory Basis

The Exchange believes that its proposal is consistent with section 6(b) of the Act [17] in general, and furthers the objectives of section 6(b)(5) of the Act [18] in particular, in that it is designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanisms of a free and open market and a national market system, and to protect investors and the public interest, by establishing rules requiring the immediate automated display of limit orders on the Exchange, and by requiring ROTs and Floor Brokers to place limit orders on the book electronically, which should enhance transparency on the Exchange and should enhance the Exchange's ability to provide an electronic audit trail respecting the immediate display of limit orders.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether they are consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–Phlx–2004–73 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–Phlx–2004–73. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2004–73 and should be submitted on or before February 18, 2005.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

The Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange [19] and, in particular, the requirements of section 6(b)(5) of the Act,[20] which requires, among other

[16] *See supra* note 15 and accompanying text.

[17] 15 U.S.C. 78f(b).

[18] 15 U.S.C. 78f(b)(5).

[19] In approving this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[20] 15 U.S.C. 78f(b)(5).

things, that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Specifically, the Commission believes that the immediate display of customer options limit orders that improve the price or size of the best disseminated Phlx quote should promote transparency and enhance the quality of executions of customer limit orders on the Phlx.

The proposed amendments to Phlx rules introduce requirements for limit order display that are comparable to the requirements of the Commission's Display Rule, Rule 11Ac1–4 under the Act,[21] which is applicable to customer limit orders received in the equity market. The Exchange has represented that immediate display of limit orders by the AUTOM system means that eligible limit orders will be displayed automatically and instantaneously, as soon as the order is received on the Exchange. Proposed commentaries .02(b) to Phlx Rule 1080, .18 to Phlx Rule 1014, and .01 to Phlx Rule 1063 provide that the only way limit orders may be sent to the Exchange will be electronically via AUTOM, either by an ROT via electronic interface with AUTOM, by a Floor Broker via the Options Floor Broker Management System component of AUTOM, or by off-floor broker-dealers who transmit orders via AUTOM. Thus, under Phlx's system, all limit orders subject to display must be delivered electronically to the Exchange, and would then be displayed automatically and instantaneously.

The Commission believes that the Exchange's proposal to exempt all-or-none and immediate or cancel orders from the Phlx's limit order display rule is reasonable since these order types are either identical or substantially similar to order types exempt from the Commission's Display Rule.

The Commission also believes that it is consistent with the Act for the Phlx to exempt from the limit order display requirements under its rules stop-limit and stop or stop-loss orders. These orders are contingent orders that are subject to a particular triggering event and, thus, are not available for execution until the triggering event occurs. A stop-loss order becomes a market order when triggered and thus is not subject to the Phlx's limit order display rule because such an order would then be immediately executable. A stop-limit order becomes a limit order when the triggering event occurs. This limit order would be subject to display under the Phlx's rules.

Cancel-replacement orders may be reduced in size if the order intended to be cancelled and replaced has already been filled partially or in its entirety. Thus, a cancel-replacement order would not be immediately displayed, but would be subject to display only after any necessary adjustments were made as a result of the contingency.

Market-on-close orders may not be represented, displayed or booked until as near as possible to the close of trading, and, therefore, the Commission believes it is reasonable to exempt such orders from the Phlx's limit order display rule. Hedge orders (*e.g.*, spread, straddle, and combination orders), synthetic options and one-cancels-the-other orders are complex orders with more than one component and, thus are not suitable for display.

In addition, during a trading rotation, Phlx systems attempt to set an opening price for the series. Until that opening price is established, there is no disseminated market. Therefore, it is reasonable to exempt orders received during a trading rotation from the Exchange's limit order display rule. The Commission notes, however, that once the trading rotation ends, any orders not executed would then be subject to display.

Finally, the Exchange proposes to exempt from its limit order display rule customer limit orders for which, immediately upon receipt, a related order for the principal account of the specialist, reflecting the terms of the customer order, is routed to another options exchange. The Commission believes it is reasonable to exempt such orders since they are subject to execution upon receipt at the other options exchange. Moreover, the Exchange represents that if the order delivered to the other options exchange were canceled, in whole or in part, by the other exchange, then, immediately upon receipt of the cancellation notice, the original customer order would be subject to the Exchange's limit order display rule and automatically displayed.[22]

The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the proposal is published in the **Federal Register**, pursuant to Section 19(b)(2) of the Act.[23] The Commission notes that the proposed rule change, which provides for immediate display of limit orders that better the Exchange's disseminated quote, is substantially identical to the proposals filed by the Chicago Board Options Exchange (''CBOE'')[24] and the American Stock Exchange (''Amex''),[25] although the form of Phlx's proposed rule differs slightly.[26] Phlx also proposes several exemptions to its limit order display rule. The Commission notes that these exemptions, discussed above, are substantially identical to exemptions proposed by CBOE and Amex in their options limit order display proposals. The Amex and CBOE proposals were recently noticed for full 21-day comment periods.[27] No comments were received on the CBOE or Amex proposal.

Accelerated approval of the proposed rule change will permit the Exchange to implement the proposal in an expeditious manner, *i.e.*, simultaneously with the implementation of the similar proposals by CBOE, Amex and the Pacific Exchange, Inc. (''PCX''), which we also approve today.[28] The Commission, therefore, believes that good cause exists, consistent with section 6(b)(5)[29] and section 19(b)[30] of the Act, to accelerate approval of the proposed rule change.

V. Conclusion

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[31] that the proposed rule change, as amended (File No. SR–Phlx–2004–73), be approved on an accelerated basis.

[21] 17 CFR 249,11Ac1–4.

[22] Telephone conversation between Richard S. Rudolph, Director and Counsel, Phlx, and Nathan Saunders, Attorney, Division, Commission, January 14, 2005.

[23] 15 U.S.C. 78s(b)(2).

[24] *See* Securities Exchange Act Release No. 49916 (June 25, 2004), 69 FR 40422 (July 2, 2004) (SR–CBOE–2004–35).

[25] *See* Securities Exchange Act Release No. 50188 (August 12, 2004), 69 FR 51495 (August 19, 2004) (SR–Amex–00–27).

[26] CBOE and Amex seek to place an affirmative display obligation on their Designated Primary Market-makers and Specialists respectively, whereas Phlx's proposed rule provides for automatic display via the AUTOM system.

[27] *See supra* notes 24 and 25.

[28] *See* Securities Exchange Act Release Nos. 51063 (January 21, 2005) (order approving SR–CBOE–2004–35); 51062 (January 21, 2005) (order approving SR–Amex–00–27); and 51061 (January 21, 2005) (order approving SR–PCX–00–15).

[29] 15 U.S.C. 78f(b)(5).

[30] 15 U.S.C. 78s(b).

[31] *Id.*

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[32]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–324 Filed 1–27–05; 8:45 am]

BILLING CODE 8010–01–P

SMALL BUSINESS ADMINISTRATION

Small Business Size Standards: Waiver of the Nonmanufacturer Rule

AGENCY: U.S. Small Business Administration.

ACTION: Notice of termination of waiver of the Nonmanufacturer Rule for Petroleum and Coal Products Manufacturing.

SUMMARY: The U.S. Small Business Administration (SBA) is terminating the waiver of the Nonmanufacturer Rule for Petroleum and Coal Products Manufacturing based on our recent discovery of small business manufacturers for this class of products. Terminating this waiver will require recipients of contracts set aside for small businesses, service-disabled veteran-owned small businesses, SBA's Very Small Business Program or 8(a) businesses to provide the products of small business manufacturers or process on such contracts.

DATES: This termination of waiver is effective on February 14, 2005.

FOR FURTHER INFORMATION CONTACT: Edith Butler, Program Analyst, by telephone at (202) 619–0422; by fax at (202) 481–1788; or by e-mail at *edith.butler@sba.gov*.

SUPPLEMENTARY INFORMATION: Section 8(a)(17) of the Small Business Act, (Act) 15 U.S.C. 637(a)(17), requires that recipients of Federal contracts set aside for small businesses, service-disabled veteran-owned small businesses, SBA's Very Small Business Program or SBA's 8(a) Business Development Program provide the product of a small business manufacturer or processor, if the recipient is other than the actual manufacturer or processor of the product. This requirement is commonly referred to as the Nonmanufacturer Rule.

The SBA regulations imposing this requirement are found at 13 CFR 121.406(b). Section 8(a)(17)(b)(iv) of the Act authorizes SBA to waive the Nonmanufacturer Rule for any ''class of products'' for which there are no small business manufacturers or processors available to participate in the Federal market.

As implemented in SBA's regulations at 13 CFR 121.1204, in order to be considered available to participate in the Federal market for a class of products, a small business manufacturer must have submitted a proposal for a contract solicitation or received a contract from the Federal government within the last 24 months. The SBA defines ''class of products'' based on six digit coding systems. The first coding system is the Office of Management and Budget North American Industry Classification System (NAICS). The second is the Product and Service Code established by the Federal Procurement Data System.

The SBA received a request on November 2, 2004 to waive the Nonmanufacturer Rule for Petroleum and Coal Products Manufacturing. In response, on December 6, 2004, SBA published in the **Federal Register** a notice of intent to the waiver of the Nonmanufacturer Rule for Petroleum and Coal Products Manufacturing.

In response to these notices, SBA discovered the existence of small business manufacturers of that class of products. Accordingly, based on the available information, SBA has determined that there are small business manufacturers of this class of products, and is therefore terminating the class waiver of the Nonmanufacturer Rule for Petroleum and Coal Products Manufacturing, NAICS 324210.

Authority: 15 U.S.C. 637(a)(17).

Dated: January 19, 2005.

Emily Murphy,

Acting Associate Administrator for Government Contracting.

[FR Doc. 05–1585 Filed 1–27–05; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice 4978]

Foreign Terrorists and Terrorist Organizations

In the matter of the revocation of Kahane.net as an alias of Kahane Chai, also known as Kach, also known as Kahane Lives, also known as the Kfar Tapuah Fund, also known as The Judean Voice, also known as The Judean Legion, also known as The Way of the Torah, also known as The Yeshiva of the Jewish Idea, also known as the Repression of Traitors, also known as Dikuy Bogdim, also known as DOV, also known as the State of Judea, also known as the Committee for the Safety of the Roads, also known as the Sword of David, also known as Judea Police, also known as Forefront of the Idea, also known as The Qomemiyut Movement, also known as KOACH, also known as New Kach Movement, also known as newkach.org, also known as Kahane, also known as Yeshivat HaRav Meir, also known as the International Kahane Movement, also known as Kahane.org, also known as Kahanetzadak.com, also known as Kahane Tzadak, also known as the Hatikva Jewish Identity Center, also known as the Rabbi Meir David Kahane Memorial Fund, also known as Friends of the Jewish Idea Yeshiva, also known as Judean Congress, also known as Jewish Legion, also known as The Voice of Judea, also known as No'ar Meir, also known as Meir's Youth, also known as American Friends of Yeshivat Rav Meir, also known as American Friends of the United Yeshiva Movement, also known as The Committee Against Racism and Discrimination (CARD), a Foreign Terrorist Organization pursuant to Section 219 of the Immigration and Nationality Act.

In consultation with the Attorney General and the Secretary of the Treasury, the Secretary of State hereby revokes the designation of Kahane.net as an alias of Kahane Chai, also known as Kach, Kahane.org, and the other aliases listed above, pursuant to section 219 of the INA, based on a finding that circumstances have changed in such a manner as to warrant revocation. This revocation is effective on the date of publication of this notice. In all other respects, the redesignation on October 2, 2003 of Kahane Chai, also known as Kach, Kahane.org, and the other aliases listed above is maintained.

Dated: January 25, 2005.

William P. Pope,

Acting Coordinator for Counterterrorism, Department of State.

[FR Doc. 05–1607 Filed 1–27–05; 8:45 am]

BILLING CODE 4710–10–P

DEPARTMENT OF STATE

[Public Notice 4979]

Foreign Terrorists and Terrorist Organizations

Amendment of a Certain Designation in order to revoke Kahane.net as an alias of Kahane Chai, also known as Kach, also known as Kahane Lives, also known as the Kfar Tapuah Fund, also known as The Judean Voice, also known as The Judean Legion, also known as The Way of the Torah, also known as The Yeshiva of the Jewish Idea, also known as the Repression of Traitors, also known as Dikuy Bogdim, also known as DOV, also known as the State of Judea, also known as the Committee for the Safety of the Roads, also known as the Sword of David, also known as Judea Police, also known as Forefront of the Idea, also known as The Qomemiyut Movement, also known as KOACH, also known as New Kach Movement, also known as newkach.org, also known as Kahane, also known as Yeshivat HaRav Meir, also known as the International Kahane Movement, also known as Kahane.org, also known as

[32] 17 CFR 200.30–3(a)(12).

Kahanetzadak.com, also known as Kahane Tzadak, also known as the Hatikva Jewish Identity Center, also known as the Rabbi Meir David Kahane Memorial Fund, also known as Friends of the Jewish Idea Yeshiva, also known as Judean Congress, also known as Jewish Legion, also known as The Voice of Judea, also known as No'ar Meir, also known as Meir's Youth, also known as American Friends of Yeshivat Rav Meir, also known as American Friends of the United Yeshiva Movement, also known as The Committee Against Racism and Discrimination (CARD).

In consultation with the Attorney General and the Secretary of the Treasury, the Secretary of State hereby amends the designation made under the authority of section 1(a)(ii)(A) of Executive Order 12947 of January 23, 1995, (as amended by Executive Order 13099 of August 20, 1998) to revoke Kahane.net as an alias of Kahane Chai (also known as Kach, Kahane.org, and the other aliases listed above) based on a finding that circumstances have changed in such a manner as to warrant revocation. This revocation is made by amending the referenced designation and is effective on the date of publication of this notice. In all other respects, the designation under the authority of section 1(a)(ii)(A) of Executive Order 12947 (as amended by Executive Order 13099) of Kahane Chai (also known as Kach, Kahane.org, and the other aliases listed above) is maintained.

Dated: January 25, 2005.

William P. Pope,

Acting Coordinator for Counterterrorism, Department of State.

[FR Doc. 05–1608 Filed 1–27–05; 5:00 pm]

BILLING CODE 4710–10–P

DEPARTMENT OF STATE

[Public Notice 4980]

Foreign Terrorists and Terrorist Organizations; Designation

Amendment of a certain designation in order to revoke Kahane.net as an alias of Kahane Chai, also known as Kach, also known as Kahane Lives, also known as the Kfar Tapuah Fund, also known as The Judean Voice, also known as The Judean Legion, also known as The Way of the Torah, also known as The Yeshiva of the Jewish Idea, also known as the Repression of Traitors, also known as Dikuy Bogdim, also known as DOV, also known as the State of Judea, also known as the Committee for the Safety of the Roads, also known as the Sword of David, also known as Judea Police, also known as Forefront of the Idea, also known as The Qomemiyut Movement, also known as KOACH, also known as New Kach Movement, also known as newkach.org, also known as Kahane, also known as Yeshivat HaRav Meir, also known as the International Kahane Movement, also known as Kahane.org, also known as Kahanetzadak.com, also known as Kahane Tzadak, also known as the Hatikva Jewish Identity Center, also known as the Rabbi Meir David Kahane Memorial Fund, also known as Friends of the Jewish Idea Yeshiva, also known as Judean Congress, also known as Jewish Legion, also known as The Voice of Judea, also known as No'ar Meir, also known as Meir's Youth, also known as American Friends of Yeshivat Rav Meir, also known as American Friends of the United Yeshiva Movement, also known as The Committee Against Racism and Discrimination (CARD).

In consultation with the Attorney General, the Secretary of the Treasury, and the Secretary of Homeland Security, the Secretary of State hereby revokes the designation made under the authority of section 1(b) of Executive Order 13224 of September 23, 2001, of Kahane.net as an alias of Kahane Chai (also known as Kach, Kahane.org, and the other aliases listed above) based on a finding that circumstances have changed in such a manner as to warrant revocation. This revocation is made by amending the referenced designation and is effective on the date of publication of this notice. In all other respects, the designation under the authority of section 1(b) of Executive Order 13224 of September 23, 2001, of Kahane Chai (also known as Kach, Kahane.org, and the other aliases listed above) is maintained.

Dated: January 25, 2005.

William P. Pope,

Acting Coordinator for Counterterrorism, Department of State.

[FR Doc. 05–1609 Filed 1–27–05; 5:00 pm]

BILLING CODE 4710–10–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Termination of Review of Noise Compatibility Program, Jackson International Airport, Jackson, MS

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces it has terminated its review of the noise compatibility program, at the request of the Jackson Municipal Airport Authority, under the provisions of 49 U.S.C. 47501 *et seq.*, and 14 CFR Part 150.

EFFECTIVE DATE: The effective date of the FAA's determination of its review of the Jackson International Airport noise compatibility program is January 20, 2005.

FOR FURTHER INFORMATION CONTACT: Kristi Ashley, 100 West Cross St., Suite B, Jackson, MS 39208, (601) 664–9891.

SUPPLEMENTARY INFORMATION: On September 21, 2004, the FAA determined that the noise exposure maps submitted by the Jackson Municipal Airport authority were in compliance with applicable requirements, and began its review of the noise compatibility program. On January 14, 2005, the Jackson Municipal Airport Authority requested that the FAA suspend its review and processing of the noise compatibility program for immediate project closure.

Questions may be directed to the individual named above under the heading **FOR FURTHER INFORMATION CONTACT.**

Issued in FAA Southern Region, Jackson ADO, January 20, 2005.

Rans D. Black,

Manager, Jackson Airports District Office.

[FR Doc. 05–1564 Filed 1–27–05; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Program To Permit Cost-Sharing of Air Traffic Modernization Projects Guidance 2005

AGENCY: Federal Aviation Administration (FAA) DOT.

ACTION: Program guidance for air traffic modernization cost-share program.

SUMMARY: The FAA is authorized to approve up to 10 air traffic modernization cost share projects per year under Vision 100—Century of Aviation Reauthorization Act, (Vision 100), Public Law 108–176, Section 183. The initial cost-share program was conducted under the authorization of Public Law 106–181, Section 304 of the Wendell H. Ford Aviation and Investment Reform Act for the 21st Century (AIR–21). Under the Vision 100, section 183 the FAA is now issuing program guidance based upon the lessons learned from the pilot program implementation. This guidance is to inform potential sponsors of the cost share program, the process to apply for the program and the criteria for approval for cost-sharing projects for this fiscal year. The purpose of Vision 100, Section 183 is to improve aviation safety and enhance mobility of the Nation's air transportation system by encouraging non-Federal investment in air traffic control facilities and equipment. Under this program, the Secretary of Transportation may make

grants to eligible project sponsors. Each eligible project is limited to Federal funding as highlighted in section 2.3.1 with the Federal cost share not to exceed 33 percent of the project's facilities and equipment (excluding operations and maintenance) cost. A project sponsor means any major user of the National Airspace System as determined by the Secretary, including a public-use airport or a joint venture between a public-use airport and one or more U.S. air carriers.

DATES: The FAA's Vice President for Finance may receive initial sponsors' expressions of interest at any time in fiscal year 2005. While the agency has no proposal submission deadline, potential sponsors are encouraged to submit proposals as soon as possible.

ADDRESSES: Sponsors' expressions of interest/proposal should be mailed or delivered, in duplicate, to the Federal Aviation Administration, Director of Capital Expenditures Programs, 800 Independence Avenue, SW., Washington, DC 20590. Electronic submissions will be accepted, but must be followed up with a signed paper copy within five working days, to the address listed above. The electronic submissions should be mailed to *Chris.Witt@faa.gov.* Deliveries may be made between 8:30 a.m. and 5 p.m. weekdays, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Chris Witt of the Finance Capital Expenditure Directorate Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20590; telephone (202) 267–7646.

SUPPLEMENTARY INFORMATION:

1. Background

In performing its mission of providing a safe and efficient air transportation system, the FAA operates and maintains a complex air traffic control system infrastructure. Vision 100, Section 183 authorizes a program to permit cost-sharing of air traffic modernization projects, under which major users of the national aerospace system, which includes a public use airport or airport/airline joint ventures, may procure and install facilities and equipment in cooperation with the FAA. The program is intended to allow project sponsors to achieve accelerated deployment of eligible facilities or equipment, and to help expand aviation infrastructure.

The FAA is authorized to approve up to 10 projects per year under Vision 100, Section 183. Those sponsors whose projects were approved in the AIR 21 pilot program may submit additional proposals under the new authorization. All sponsors who anticipate submitting a request should review the criteria in sections 2.1 and 2.2 before submission.

2. Program Guidance

This section provides the statutory language sponsor eligibility of Vision 100 section 183 and outlines FAA's supplementary criteria for the cost share program. The sponsor eligibility, project eligibility, and evaluation and screening criteria are outlined in Sections 2.1, 2.2 and 2.6 respectively of this guidance.

2.1 Eligible Project Sponsors

2.1.1 Statutory Provisions of Vision 100 for Sponsor Eligibility

A project sponsor means any major user of the National Airspace System as determined by the Secretary, including a public-use airport or a joint venture between a public-use airport and one or more U.S. air carriers.

2.1.2 Supplementary FAA Criteria for Sponsor Eligibility

An eligible project sponsor is any major user of the national airspace system including public-use airport (or group of airports), either publicly or privately owned, acting on its own or in a joint venture with one or more U.S. air carriers. All landing facilities meeting these criteria are eligible, including but not limited to commercial service airports, reliever airports, general aviation airports, and heliports. Eligibility is not limited to airports; other National Airspace System (NAS) major users such as state or regional aviation activities may be eligible.

All eligible sponsors are encouraged to participate. If selected for the program, the sponsor must be willing to enter into a Memorandum of Agreement with the FAA outlining the specific goals to be accomplished, the roles and responsibilities of each party, schedule milestones, and funding contributions of the parties. An eligible sponsor must have an available source of funds to execute the program.

2.2 Eligible Projects

2.2.1 Statutory Provisions for Project Eligibility

The term 'eligible project' means a project to purchase equipment or software relating to the Nation's air traffic control system that is certified or approved by the Administrator of the Federal Aviation Administration and that promotes safety, efficiency, or mobility. Such projects may include:

a. Airport-specific air traffic facilities and equipment, including local area augmentation systems,* instrument landings systems, weather and wind shear detection equipment, and lighting improvements;

b. Automation tools to effect improvements in airport capacity, including passive final approach spacing tools and traffic management advisory equipment; and

c. Equipment and software that enhance airspace control procedures or assist in en route surveillance, including oceanic and offshore flight tracking.

* Note these projects will be eligible, assuming availability and viability of the equipment within the time limitation highlighted in 2.2.2.c.

2.2.2 Supplementary FAA Criteria for Project Eligibility

a. Projects should align with the FAA's strategic Flight Plan goals.

b. The project should be consistent with FAA's air traffic equipment/systems infrastructure and architecture and should be a validated project of a FAA program. The project, when commissioned, should provide measurable benefits that benefit national, regional, or local objectives/interests and the FAA NAS.

c. The project shall be initiated within one year of project approval and completed/commissioned within five years of project approval (allowing for an environmental impact study (if necessary), acquisition, supply support, training programs, etc.).

d. Equipment and facilities should meet applicable FAA advisory circulars and specifications.

e. The project should serve the general welfare of the flying public; it should not be used for the exclusive interest of a for-profit entity.

f. Any facility/equipment acquired under the project should be a new asset, not an asset that the sponsor has already acquired or is committed to acquiring.

g. The project should have a useful and expected life of ten years or more, notwithstanding the possible need to replace project components during its operating life.

h. The cost-share program is not the correct forum for requesting development of RNAV procedures.

i. A sponsor may submit a multiple component project proposal (as outlined in paragraph 2.5) where each component forms part or all of an integrated system. The FAA reserves the option to accept one or multiple components of a proposal.

j. A project may not be co-mingled with other FAA cost-sharing programs.

k. All equipment and facilities should meet appropriate OSHA standards for employee safety and fire protection. Where land is involved, the property

should meet all environmental compliance requirements, including noise, hazardous material, property access, and zoning rights.

2.3 Funding

2.3.1 Statutory Provisions for Funding

The Federal share of the cost of an eligible project carried out under the program shall not exceed 33 percent. No project may receive more than $5,000,000 in Federal funding. The sponsor's share of the cost of an eligible project shall be provided from non-Federal sources, including revenues collected pursuant to Title 49, United States Code 40117.

2.3.2 Supplementary FAA Criteria for Funding

FAA is not obligated to fund one-third of the total project costs; rather, FAA's share may not exceed this threshold. The project sponsor must provide two-thirds or more of the total project cost. The Federal and non-Federal shares of project cost may take the form of in-kind contributions. Equipment in FAA's inventory that has not been previously deployed qualifies as eligible equipment. If selected for the program, a sponsor may use passenger facility charge (PFC) revenues to acquire and install eligible facilities and equipment, but not to fund their operation or maintenance. Normal PFC processing procedures under Federal Aviation Regulation 14 CFR part 158 will be used to approve the imposition of a PFC or the use of PFC revenue as the non-Federal share of a program project.

Federal contributions applied to any other Federal project or grant may not be used to satisfy the sponsor's cost share under this program.

The following criteria apply to the calculation of the cost-sharing ratio:

a. Project costs are limited to those costs that the FAA would normally incur in conventional facilities and equipment funding (*e.g.*, if land/right-of-way must be acquired or leased for a project, its cost can be included in the cost-sharing ratio only if FAA would otherwise incur it in conventional program funding).

b. Operations and maintenance costs of the project, both before and after any sponsor-elected project transfer to the FAA, will not be considered as part of the cost-share contribution. However, these costs must be identified.

c. Non-Federal funding may include cash, substantial equipment contributions that are wholly utilized as an integral part of the project, and personnel services dedicated to the proposed project prior to commissioning, as long as such personnel are not otherwise supported with Federal funds. The non-Federal cost may include in-kind contributions (*e.g.*, buildings). In-kind contributions will be evaluated as to whether they present a cost that FAA would otherwise incur in conventional facilities and equipment funding.

d. Aside from in-kind contributions, only funds expended by the sponsor after the project approval date will be eligible for inclusion in the cost-sharing ratio.

e. Unless otherwise specified by these criteria, the principles and standards for determining costs should be conducted in accordance with OMB Circular A–87, Cost Principles for State, Local, and Indian Tribal Governments.

f. As with other U.S. DOT cost-sharing grants, it is inappropriate for a management/administrative fee to be included as part of the sponsor's contribution. This does not prohibit appropriate fee payments to vendors or others that may provide goods or services to support the project.

FAA funding decisions will be based on the project evaluation and project selection processes discussed later in this notice.

The U.S. Department of Transportation and the Comptroller General of the United States have the right to obtain and assess all documents pertaining to the use of Federal and non-Federal contributions for selected projects. Sponsors should maintain sufficient documentation during negotiations and during the life of the project to substantiate costs.

2.4 Transfer of Facility or Equipment to FAA

2.4.1 Statutory Provisions for Facility or Equipment Transfer

Notwithstanding any other provision of law, and upon agreement by the Administrator, a project sponsor may transfer, without consideration, to the FAA, facilities, equipment, and automation tools, the purchase of which was assisted by a grant made under this section if such facilities, equipment or tools meet Federal Aviation Administration operation and maintenance criteria.

2.4.2 Supplementary FAA Criteria for Facility or Equipment Transfer

Project transfers to the FAA will be at the sponsor's election and in accordance with the criteria listed below.

a. At the time of transfer, the project should be operable and maintainable by the FAA and should comply with FAA Order 6700.20, Non-Federal Navigational Aids and Air Traffic Control Facilities, or any successor Order then in effect.

b. In the event of transfer, software code, data rights, and support tools should be provided to the FAA at no cost to the FAA.

If the project is not transferred to the FAA, the sponsor remains liable for all operations and maintenance costs, including the costs of capital sustainment.

2.5 Application Procedures

Unlike the cost share pilot program, for this fiscal year all applications will be reviewed upon receipt and selected based upon individual merit and alignment with the FAA's goals and objectives as outlined in the strategic planning documents. The statutory limit is ten projects per fiscal year. The following application procedures will be used when applying for cost-share:

a. The purpose of the application is provide sufficient information to conduct detained analysis that evaluates cost, benefits, risk, alignment with strategic direction of the proposed project and to compare the proposal with other NAS needs. It is suggested that the sponsor contact the FAA's cost share office to discuss the potential project before the applicant expends excessive resources on the project application.

b. Eligible sponsors may submit multiple projects and projects with multiple components, but each piece of equipment/activity must be identified and costed separately, with appropriately defined benefits and should be listed in priority order. An example of a multiple component project would be an instrument landing system (ILS) project that may include in addition to the ILS equipment, middle markers and runway lighting for a complete package. The FAA reserves the option to accept one or multiple pieces of each proposal.

c. Projects that would be good candidates for this program may include equipment and systems that monitor weather, support runway incursion reduction, and support regional interest.

d. Under this program, either the FAA or the sponsor may acquire and/or install facilities or equipment. In the case where the FAA manages the procurement, existing FAA contracts will be used where possible.

e. Proposals for new air traffic control towers will only be considered if they enhance the National Airspace System. Per FAA Order 6030.1, FAA Policy on Relocation, movement of an existing air traffic control tower for the convenience/benefit of only the airport

will not be considered. Requests for towers will be considered utilizing the criteria in Order 7031.2C, Airway Planning Standards Number One (APS–1).

2.5.2. Formal Application and Selection of Projects

The proposal should not be more than thirty pages in length. During the evaluation process each sponsor should submit an application with the following elements needed by the FAA to evaluate the merits of the application.

a. *Project Description:* The project description should contain: (1) The identity of the submitting sponsor (including point-of-contact's name, mailing address, telephone number, fax number, and e-mail address) and all participating authorities or entities in the case of joint ventures; (2) project name and location; and (3) a detailed project description. In addition, the sponsor must provide a statement of intent to transfer the project to the FAA, including anticipated transfer date, or intent not to transfer the project to the FAA.

b. *Projected Benefits:* All applications should describe the need for the project and demonstrate it's measurable contributions to safety, efficiency, capacity, productivity and as applicable, at the airport, regional, and system-wide levels. The sponsor may conduct its own analysis, or where the FAA has the equipment/system on an acquisition waterfall the sponsor may opt to summarize existing FAA cost benefit analysis, and/or may use the investment criteria in FAA Order 7031.2C, Airway Planning Standard Number One.

c. *Economic Analysis:* Supporting the projected benefits review the applicant should conduct an economic analysis. The analysis should include a schedule of project costs, including: (1) Up-front costs broken down into proposed shares between the sponsor and the FAA; and (2) annual and life-cycle operations and maintenance costs before and after transfer to the FAA (if the sponsor elects to transfer). The level of effort devoted to the analyses should be tailored to the scope and cost of the project. For complex programs FAA guidance can be found in Report FAA–APO–98–4, Economic Analysis of Investment and Regulatory Programs—Revised Guide, and Report FAA–APO–98–8, Economic Values for Evaluation of Federal Aviation Administration Investment and Regulatory Programs.

d. *Schedule:* The Schedule should list all significant proposed project dates, including the start date, completion date, date of project transfer to the FAA (if applicable), and key interim milestone dates.

e. *Financial Plan:* The Financial Plan should contain: (1) The proposed local and Federal cost shares, (2) evidence of the sponsor's ability to provide funds for its cost share (*e.g.,* approved local appropriation or Memorandum of Agreement); and (3) any commitment the sponsor might choose to offer for the assumption and liability of cost overruns aside from the liability criterion provided earlier in this notice.

f. *Letter of Commitment:* Sponsors should demonstrate a commitment to the project, as evidenced by a Letter of Commitment signed by all project participants (including any participating air carriers). The letter should, at a minimum, include a list of the participating agencies and organizations in the proposed project; the roles, responsibilities and relationship of each participant; and the name, address, and telephone number of the individual representing the sponsor.

g. *Letter of Acknowledgement/Support:* The application will include a letter of acknowledgment/support from the applicable State Department of Transportation and/or other appropriate jurisdiction (to avoid circumventing State and metropolitan planning processes). It is the intent of FAA Headquarters for the appropriate projects to include the FAA's Regional Office in the project review cycle. It would be in the best interest of the applicant to pre-coordinate the projects with the appropriate FAA Regional Office.

The FAA will review and evaluate the application using a panel of technical program experts and senior managers based on the criteria outlined below in Section 2.6. Following its evaluations, the review panel will recommend to the FAA's Air Traffic Operations Senior Vice President for Finance and the appropriate Vice President under whose area of responsibility the system will be installed, if the application in their view should be accepted. If the FAA selects a project for inclusion in the cost share program, an agreement will be executed between the sponsor and the FAA.

2.6 Application Evaluation and Screening Criteria

The FAA will review each of the applications based upon the individual merit of the application. The FAA will consider the following elements in evaluating an application:

a. Compliance with statutory criteria, FAA's supplemental criteria, and application procedures.

b. Degree to which the project provides benefits that contributes to the FAA's documented goals and objectives.

c. Qualitative and quantifiable benefits to the airport, region, and national airspace system.

d. Likelihood of project success in terms of cost, schedule and performance and achieving proposed benefits/outcomes.

e. Evidence that the project can be implemented in accordance with the proposed schedule.

f. Ability of sponsor to provide its cost share.

g. Availability of FAA resources.

h. Degree of Federal leveraging (degree to which the proposal minimizes the ratio of Federal costs to total project costs).

i. Cost to the FAA: post-transfer life-cycle operating and maintenance costs.

2.7 Schedule Summary

Applications may be submitted at any time during the fiscal year. The time required for reviewing and approving/disapproving the typical application is outlined below.

Milestone	Time frame
Applications	
Applications due to FAA.	Anytime.
FAA Responses to Sponsor's Application requesting additional information (may not be necessary).	One month after receipt of application.
FAA Announcement of Decision.	Three months after receipt of application.

2.8 Project Implementation Information

During the life of the project, the FAA may collect data from the sponsor and conduct (with non-project funds) independent evaluations of the project's impact on safety, efficiency, and mobility objectives. This will allow the FAA to ascertain the success of the program.

3. Impact of Revised Guidelines

Under the Vision 100—Section 183, the guidelines shall not be subject to administrative rulemaking requirements under subchapter II of chapter 5 of title 5.

4. References

The following list outlines references cited above:

OMB Circular A–87, Cost Principles for State, Local, and Indian Tribal Governments, revised August 29, 1997.

Report FAA–APO–98–4, Economic Analysis of Investment and Regulatory

Programs—Revised Guide. Available upon request from FAA's Office of Aviation Policy and Plans, telephone (202) 267–3308. It may also be found on the Internet at: *http://api.hq.faa.gov/apo_pubs.htm.*

Report FAA–APO–98–8, Economic Values for Evaluation of Federal Aviation Administration Investment and Regulatory Programs. Available upon request from the FAA's Office of Aviation Policy and Plans, telephone (202) 267–3308. It may also be found on the Internet at: *http://api.hq.faa.gov/apo_pubs.htm.*

FAA Order 6030.1, FAA Policy on Relocation. Available upon request from the FAA telephone (202) 646–2310.

FAA Order 7031.2C, Airway Planning Standard Number One, through Change 12. Available upon request from the FAA's Office of Aviation Policy and Plans, Telephone (202) 267–3308.

FAA Order 6700.20, Non-Federal Navigational Aids and Air Traffic Control Facilities. Available upon request from the FAA's NAS Operations Program Office, telephone (202) 267–3034.

Issued in Washington, DC on January 24, 2005.

J. Robbins Tucker, Jr.,

Director of Finance Capital Expenditures.

[FR Doc. 05–1565 Filed 1–27–05; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Area 4 Taxpayer Advocacy Panel (Including the States of Illinois, Indiana, Kentucky, Michigan, Ohio, West Virginia, and Wisconsin)

AGENCY: Internal Revenue Service (IRS) Treasury.

ACTION: Notice.

SUMMARY: An open meeting of the Area 4 Taxpayer Advocacy Panel will be conducted (via teleconference). The Taxpayer Advocacy Panel is soliciting public comment, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Tuesday, February 22, 2005, at 11 a.m., eastern time.

FOR FURTHER INFORMATION CONTACT: Mary Ann Delzer at 1–888–912–1227, or (414) 297–1604.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Area 4 Taxpayer Advocacy Panel will be held Tuesday, February 22, 2005, at 11 a.m., eastern time via a telephone conference call. You can submit written comments to the panel by faxing to (414) 297–1623, or by mail to Taxpayer Advocacy Panel, Stop 1006MIL, 310 West Wisconsin Avenue, Milwaukee, WI 53203–2221 or you can contact us at *http://www.improveirs.org.* This meeting is not required to be open to the public, but because we are always interested in community input, we will accept public comments. Please contact Mary Ann Delzer at 1–888–912–1227 or (414) 297–1604 for dial-in information.

The agenda will include the following: Various IRS issues.

Dated: January 21, 2005.

Bernard Coston,

Director, Taxpayer Advocacy Panel.

[FR Doc. 05–1554 Filed 1–27–05; 8:45 am]

BILLING CODE 4830–01–P

Corrections

Federal Register

Vol. 70, No. 18

Friday, January 28, 2005

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 983

[Docket No. FV02–983–1 FR]

Pistachios Grown in California; Delay of the Effective Date for Aflatoxin, Size and Quality Requirements

Correction

In rule document 05–182 appearing on page 661 in the issue of Wednesday, January 5, 2005 make the following correction:

In the first column, under **DATES**, in the last line ''August 12, 2005'' should read ''August 1, 2005''.

[FR Doc. C5–182 Filed 1–27–05; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2004–CE–01–AD; Amendment 39–13943; AD 2005–01–18]

RIN 2120–AA64

Airworthiness Directives; Raytheon Aircraft Company Beech 100, 200, and 300 Series Airplanes

Correction

In rule document 05–716 beginning on page 2941 in the issue of Wednesday, January 19, 2005 make the following corrections:

§39.13 [Corrected]

1. On page 2943, in §39.13(e), in the table, under the second column, in the first entry, in the 10th line, ''AD 93–35–07'' should read ''AD 93–25–07''.

2. On the same page, in the same section, in the same table, in the same column, in the second entry, in the third line, ''AD 93–35–07'' should read ''AD 93–25–07''.

3. On the same page in the same section, in the same table, in the same column, in the same entry, in the eighth line, ''AD 93–25–0-7'' should read ''AD 93–25–07''.

[FR Doc. C5–716 Filed 1–27–05; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2004–19583; Airspace Docket No. 04–ACE–73]

Modification of Class E Airspace; Coffeyville, KS

Correction

In rule document 05–971 beginning on page 2948 in the issue of Wednesday, January 19, 2005, make the following correction:

§ 71.1 [Corrected]

On page 2950, in the first column, in § 71.1, after the heading **ACE KS E5 Coffeyville, KS**, in the next line, ''Coffeeyville'' should read ''Coffeyville.''

[FR Doc. C5–971 Filed 1–27–05; 8:45 am]

BILLING CODE 1505–01–D

Federal Register

Friday,
January 28, 2005

Book 2 of 2 Books
Pages 4193–4742

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 400, 403, 411, 417, and 423 Medicare Program; Medicare Prescription Drug Benefit; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 400, 403, 411, 417, and 423

[CMS–4068–F]

RIN 0938–AN08

Medicare Program; Medicare Prescription Drug Benefit

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule implements the provisions of the Social Security Act (the Act) establishing and regulating the Medicare Prescription Drug Benefit. The new voluntary prescription drug benefit program was enacted into law on December 8, 2003 in section 101 of Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Although this final rule specifies most of the requirements for implementing the new prescription drug program, readers should note that we are also issuing a closely related rule that concerns Medicare Advantage organizations, which, if they offer coordinated care plans, must offer at least one plan that combines medical coverage under Parts A and B with prescription drug coverage. Readers should also note that separate CMS guidance on many operational details appears or will soon appear on the CMS website, such as materials on formulary review criteria, risk plan and fallback plan solicitations, bid instructions, solvency standards and pricing tools, plan benefit packages.

The addition of a prescription drug benefit to Medicare represents a landmark change to the Medicare program that will significantly improve the health care coverage available to millions of Medicare beneficiaries. The MMA specifies that the prescription drug benefit program will become available to beneficiaries beginning on January 1, 2006.

Generally, coverage for the prescription drug benefit will be provided under private prescription drug plans (PDPs), which will offer only prescription drug coverage, or through Medicare Advantage prescription drug plans (MA PDs), which will offer prescription drug coverage that is integrated with the health care coverage they provide to Medicare beneficiaries under Part C of Medicare. PDPs must offer a basic prescription drug benefit. MA-PDs must offer either a basic benefit or broader coverage for no additional cost. If this required level of coverage is offered, MA-PDs or PDPs, but not fallback PDPs may also offer supplemental benefits through enhanced alternative coverage for an additional premium. All organizations offering drug plans will have flexibility in the design of the prescription drug benefit. Consistent with the MMA, this final rule also provides for subsidy payments to sponsors of qualified retiree prescription drug plans to encourage retention of employer-sponsored benefits.

We are implementing the drug benefit in a way that permits and encourages a range of options for Medicare beneficiaries to augment the standard Medicare coverage. These options include facilitating additional coverage through employer plans, MA-PD plans and high-option PDPs, and through charity organizations and State pharmaceutical assistance programs. See sections II.C, II.J, and II.P, and II.R of this preamble for further details on these issues.

The proposed rule identified options and alternatives to the provisions we proposed and we strongly encouraged comments and ideas on our approach and on alternatives to help us design the Medicare Prescription Drug Benefit Program to operate as effectively and efficiently as possible in meeting the needs of Medicare beneficiaries.

DATES: These regulations are effective on March 22, 2005.

FOR FURTHER INFORMATION CONTACT: Lynn Orlosky (410) 786–9064 or Randy Brauer (410)786–1618 (for issues related to eligibility, elections, enrollment, including auto-enrollment of dual eligible beneficiaries, and creditable coverage).

Melvin Sanders (410) 786–8355 (for issues related to marketing and user fees).

Vanessa Duran (214) 767–6435 (for issues related to benefits and beneficiary protections, including Part D benefit packages, Part D covered drugs, coordination of benefits in claims processing and tracking of true-out-of-pocket costs, pharmacy network access standards, plan information dissemination requirements, and privacy of records).

Craig Miner, RPh. (410) 786–1889 for issues of pharmacy benefit cost and utilization management, formulary development, quality assurance, medication therapy management, and electronic prescribing).

Mark Newsom (410) 786–3198 (for issues of submission, review, negotiation, and approval of risk and limited risk bids for PDPs and MA-PD plans; the calculation of the national average bid amount; determination and collection of enrollee premiums; calculation and payment of direct and reinsurance subsidies and risk-sharing; and retroactive adjustments and reconciliations.)

Jim Owens (410) 786–1582 (for issues of licensing and waiver of licensure, the assumption of financial risk for unsubsidized coverage, and solvency requirements for unlicensed sponsors or sponsors who are not licensed in all States in the region in which it wants to offer a PDP.)

Jim Slade (410) 786–1073 (for issues related to pre-emption of State law) and (for issues related to solicitation, review and approval of fallback prescription drug plan proposals; fallback contract requirements; and enrollee premiums and plan payments specific to fallback plans.)

Christine Hinds (410) 786–4578 (for issues of coordination of Part D plans with providers of other prescription drug coverage including Medicare Advantage plans, State pharmaceutical assistance programs (SPAPs), Medicaid, and other retiree prescription drug plans; also for issues related to eligibility for and payment of subsidies for assistance with premium and cost-sharing amounts for Part D eligible individuals with lower income and resources; for rules for States on eligibility determinations for low-income subsidies and general State payment provisions including the phased-down State contribution to drug benefit costs assumed by Medicare).

Mark Smith (410) 786–8015 (for issues related to conditions necessary to contract with Medicare as a PDP sponsor, as well as contract requirements, intermediate sanctions, termination procedures and change of ownership requirements.)

Jean LeMasurier (410) 786–1091 (for issues related to employer group waivers and options).

Frank Szeflinski (303) 844–7119 (for issues related to cost-based HMOs and CMPS offering Part D coverage.)

John Scott (410) 786–3636 (for issues related to the procedures PDP sponsors must follow with regard to grievances, coverage determinations, and appeals.)

Mark Smith (410) 786–8015 (for issues related to solicitation, review and approval of fallback prescription drug plan proposals; fallback contract requirements; and enrollee premiums and plan payments specific to fallback plans.)

Jim Mayhew (410) 786–9244 (for issues related to the alternative retiree

drug subsidy and other employer-based sponsor options.)

Joanne Sinsheimer (410) 786–4620 (for issues related to physician self-referral prohibitions.)

Brenda Hudson (410) 786–4085 (for issues related to PACE organizations offering Part D coverage.)

Julie Walton (410) 786–4622 or Kathryn McCann (410) 786–7623 (for issues related to provisions on Medicare supplemental (Medigap) policies.)

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Table of Contents

I. Background
A. Medicare Prescription Drug, Improvement, and Modernization Act of 2003
B. Codification of Regulations
C. Organizational Overview of Part 423
II. Discussion of the Provisions of the Final Rule
A. General Provisions
1. Overview
2. Discussion of Important Concepts and Key Definitions
B. Eligibility and Enrollment
1. Eligibility and Enrollment
2. Enrollment Process
3. Enrollment of Full Benefit Dual Eligible Individuals
4. Disenrollment process
5. Enrollment Periods
6. Effective Dates
7. Involuntary Disenrollment by the PDP
8. Late Enrollment Penalty
9. Information about Part D
10. Approval of Marketing Materials and Enrollment Forms
11. Information Provided to PDP sponsors and MA Organizations
12. Procedures to Determine and Document Creditable Status of Prescription Drug Coverage
C. Voluntary Prescription Benefits and Beneficiary Protections
1. Overview and Definitions
2. Plan Formularies
3. Establishment of Prescription Drug Plan Service Areas
4. Access to Covered Part D Drugs
5. Special Rules for Out-of-Network Access to Covered Part D Drugs at Pharmacies
6. Dissemination of Plan Information
7. Public Disclosure of Pharmaceutical Prices for Equivalent Drugs
8. Privacy, Confidentiality, and Accuracy of Enrollee Records
D. Cost Control and Quality Improvement Requirements for Part D Plans
1. Overview (Scope)
2. Drug Utilization Management, Quality Assurance, and Medication Therapy Management Programs (MTMPs)
3. Consumer Satisfaction Surveys
4. Electronic Prescription Program
5. Quality Improvement Organizations (QIO) Activities
6. Treatment of Accreditation
E. RESERVED
F. Submission of Bids and Monthly Beneficiary Premiums: Plan Approval
1. Overview
2. Requirements for Submission of Bids and Related Information
3. General CMS Guidelines for Actuarial Valuation of Prescription Drug Coverage
4. Determining Actuarial Equivalency for Variants of Standard Coverage and for Alternative Coverage.
5. Test for Assuring the Same Protection against High Out-of-Pocket Costs
6. Review and Negotiation of Bid and Approval of Plans
7. National Average Monthly Bid Amount
8. Rules Regarding Premiums
9. Collection of Monthly Beneficiary Premiums
G. Payments to Part D Plan Sponsors for Qualified Prescription Drug Coverage
1. Overview
2. Definitions
3. General Payment Provisions
4. Requirement for Disclosure of Information
5. Determination of Payment
6. Low-Income Cost-Sharing Subsidy Interim Payments
7. Risk Sharing Arrangements
8. Retroactive Adjustments and Reconciliation
9. Reopening
10. Payment Appeals
H. RESERVED
I. Organization Compliance with State Law and Preemption by Federal Law.
1. Overview
2. Waiver of Certain Requirements in Order to Expand Choice
3. Temporary Waiver for Entities Seeking to Offer a Prescription Drug Plan in more than One State in a Region
4. Solvency Standards for Non-Licensed Entities
5. Preemption of State Laws and Prohibition of Premium Taxes
J. Coordination Under Part D Plans with Other Prescription Drug Coverage
1. Overview and Terminology
2. Application of Part D Rules to Certain Part D Plans on and after January 1, 2006
3. Application to PACE Plans
4. Application to Employer Groups
5. Medicare Secondary Payer Procedures
6. Coordination of Benefits with Other Providers of Prescription Drug Coverage.
K. Application Procedures and Contracts with PDP Sponsors
1. Overview
2. Definitions
3. Application Requirements
4. Evaluation and Determination Procedures for Applications to Be Determined Qualified to Act as a Sponsor
5. General Provisions
6. Contract Provisions
7. Effective Date and Term of Contract
8. Nonrenewal of Contract
9. Modification or termination of contract by mutual consent
10. Termination of Contracts by CMS
11. Termination of Contract by the Part D Plan Sponsor
12. Minimum Enrollment Requirements
13. Reporting Requirements
14. Prohibition of Midyear Implementation of Significant New Regulatory Requirements
15. Fraud, Waste and Abuse
L. Effect of Change of Ownership or Leasing of Facilities during the Term of Contract
1. General Provisions
2. Change of Ownership
3. Novation Agreement Requirements
M. Grievances, Coverage Determinations, and Appeals
1. Introduction
2. General Provisions
3. Grievance Procedures

4. Coverage Determinations
5. Formulary Exceptions Procedures
6. Appeals
7. Effectuation of Reconsideration Determinations
8. Federal Preemption of Grievances and Appeals
9. Employer Sponsored Prescription Drug Programs and Appeals
10. Miscellaneous
N. Medicare Contract Determinations and Appeals
1. Overview
2. Provisions of the Final Rule
O. Intermediate Sanctions
1. Kinds of Sanctions
2. Basis for Imposing Sanctions
3. Procedures for Imposing Sanctions
P. Premiums and Cost-Sharing Subsidies for Low-Income Individuals
1. Definitions
2. Eligibility for the Low-Income Subsidy
3. Eligibility Determinations, Redeterminations and Applications
4. Premium Subsidy and Cost-Sharing Subsidy
5. Administration of Subsidy Program
Q. Guaranteeing Access to a Choice of Coverage (Fallback Prescription Drug Plans)
1. Overview
2. Terminology
3. Assuring Access to a Choice of Coverage
4. Submission and Approval of Bids
5. Rules Regarding Premiums
6. Contract Terms and Conditions
7. Payment to Fallback Plans
R. Payments to Sponsors of Retiree Prescription Drug Plans
1. Introduction
2. Options for Sponsors of Retiree Prescription Drug Programs
3. Definitions
4. Requirements for qualified retiree prescription drug plans
5. Retiree drug subsidy amounts
6. Appeals
7. Change of Ownership
8. Construction
S. Special Rules for States-Eligibility Determinations for Low-Income Subsidies, and General Payment Provisions
1. Eligibility Determinations
2. General Payment Provisions
3. Treatment of Territories
4. State Contribution to Drug Benefit Costs Assumed by Medicare
T. Part D Provisions Affecting Physician Self-Referral, Cost-Based HMO, PACE, and Medigap Requirements
1. Definition of Outpatient Prescription Drugs for Purposes of Physician Self-Referral Prohibition
2. Cost-Based HMOs and CMPS offering Part D coverage
3. PACE Organizations Offering Part D Coverage
4. Medicare Supplemental Policies
III. Provisions of the Final Rule
IV. Collection of Information Requirements
V. Regulatory Impact Analysis

In addition, because of the many organizations and terms to which we refer by acronym in this final rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

ABN	Advanced beneficiary notice
ADAP	AIDS Drug Assistance Program
AEP	Annual coordinated election period
AHRQ	Agency for Healthcare Research and Quality
AI/AN	American Indians and Alaska Natives
AIC	Amount in controversy
ALJ	Administrative Law Judge
AMA	American Medical Association
AMCP	Academy of Managed Care Pharmacy
ANCI	American National Standards Institute
AO	Accreditation organization
ASAP	American Society of Automation in Pharmacy
ASHP	American Society of Health Systems Pharmacists
AWP	Average wholesale price
BBA	Balanced Budget Act
BLS	Bureau of Labor Statistics
CAHP	Consumer Assessment of Health Plan
CBI	Confidential business information
CBO	Congressional Budget Office
CCIP	Chronic care improvement programs
CCP	Comprehensive Compliance Program
CFR	Code of Federal Regulations
CHOW	Change of ownership
CMP	competitive medical plan
CMS	Centers for Medicare & Medicaid Services
COB	Coordination of benefit
COBRA	Consolidated Omnibus Budget Reconciliation Act (of 1985)
CPI-PD	Consumer Price Index for Prescription Drugs and Medical Supplies
CPT	Current Procedural Terminology
CY	Calendar year
DAB	Departmental Appeals Board
DHS	Designated health services
DME	Durable medical equipment
DoD	Department of Defense
DOL	Department of Labor
DUR	Drug utilization review
EOB	explanation of benefits
ERISA	Employee Retirement Income Security Act of 1974
ESRD	End stage renal disease
FAR	Federal Acquisition Regulation
FDA	Food and Drug Administration
FEHBP	Federal Employee Health Benefits Program
FFP	Federal financial participation
FOIA	Freedom of Information Act
FQHCs	Federally qualified health centers
FPL	Federal poverty level
FR	FEDERAL REGISTER
FSA	Flexible savings account
FY	Fiscal year
HEDIS	Health plan Employer Data and Information Set
HHS	Department of Health and Human Services
HIC	Health insurance claim
HIPAA	Health Insurance Portability and Accountability Act of 1996
HMO	Health maintenance organization
HPMS	Health Plan Management System
HRA	Health reimbursement account
HRSA	Health Resources and Services Administration
HSA	Health savings account
ICFs/MR	Intermediate care facilities for the mentally retarded
IDIQ	Indefinite duration, indefinite quantity
IEP	Initial enrollment period
IHS	Indian Health Service
IRE	Independent review entity
I/T/U	Indian Tribes and Tribal organizations, and urban Indian organizations
JCHACO	Joint Commission on Accreditation of Health Care Organizations
LIS	Low-income subsidy
LTC	Long term care
MA	Medicare Advantage (formerly Medicare+Choice)
MA-PD	Medicare Advantage prescription drug plans
MAC	Medicare Appeals Council
MAX	Medicaid Analytic extract
MCBS	Medicare Current Beneficiary Survey
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MSA	Medicare savings account
MSIS	Medicaid Statistical Information System
MSP	Medicare Secondary Payor
MTMP	Medication Therapy Management Program
NAIC	National Association of Insurance Commissioners
NCQA	National Committee for Quality Assurance
NCPDP	National Council for Prescription Drug Programs
NCVHS	National Center for Vital and Health Statistics
NDC	National Drug Code
NHE	National Health Expenditure
NPA	National PACE Association
NPI	National Provider Identifier
OACT	Office of the Actuary (CMS)
OBRA	Omnibus Budget Reconciliation Act
OCR	Office for Civil Rights
OEPI	Open enrollment period for institutionalized individuals
OIG	Office of the Inspector General
OPM	Office of Personnel Management
P&T	Pharmaceutical and therapeutic
PBA	Pharmacy benefit administrator
PBMs	Pharmacy benefit managers
PBP	Plan Benefit Package
PDP	Private prescription drug plan

PDSC	Phased-down State contribution
PFFS	Private fee-for-service plan
PHI	Protected health information
PhRMA	Pharmaceutical Manufacturers and Researchers of America
PPO	Preferred provider organization
PPV	Pharmaceutical Prime Vendor
PSO	Provider-sponsored organization
QDWIs	Qualified disabled and working individuals
QII	Qualified individuals
QIO	Quality Improvement Organization
QMB	Qualified Medicare beneficiaries
REACH	Regional Education About Choices in Health
RHC	Rural Health Center
SCHIP	State Children's Health Insurance Program
SEP	Special enrollment period
SHIP	State health insurance assistance program
SLMB	Special Low-Income Beneficiaries
SOW	Scope of work
SPAP	State Pharmaceutical Assistance Program
SPD	Summary Plan Description
SPOC	Single point of contact
SSA	Social Security Administration
SSI	Supplemental Security Income
SSRI	Selective serotonin reuptake inhibitor
SSSGs	Similarly Sized Subscriber Groups
TANF	Temporary assistance for needy families
TrOOP	True out-of-pocket
U&C	Usual and customary
URAC	Utilization Review Accreditation Commission
USP	U.S. Pharmacopoeia
VA	Department of Veterans Affairs
VDSA	Voluntary data sharing agreement

I. Background

A. Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended Title XVIII of the Social Security Act (the Act) by establishing a new Part D: the Voluntary Prescription Drug Benefit Program. (For ease of reference, we will refer to the new prescription drug benefit program as Part D of Medicare and we will refer to the Medicare Advantage Program described in Part C of title XVIII of the Act -as Part C of Medicare.)

We believe that the new Part D benefit constitutes the most significant change to the Medicare program since its inception in 1965. The addition of outpatient prescription drugs to the Medicare program reflects the Congress' recognition of the fundamental change in recent years in how medical care is delivered in the U.S. It recognizes the vital role of prescription drugs in our health care delivery system, and the need to modernize Medicare to assure their availability to Medicare beneficiaries. This final rule is designed to broaden participation in the new benefit both by organizations that offer prescription drug coverage and by eligible beneficiaries. In conjunction with complementary improvements to the Medicare Advantage program, these changes should significantly increase the coverage and choices available to Medicare beneficiaries.

Effective January 1, 2006, the new program establishes an optional prescription drug benefit for individuals who are entitled to or enrolled in Medicare benefits under Part A and Part B. Beneficiaries who qualify for both Medicare and Medicaid (full-benefit dual eligibles) will automatically receive the Medicare drug benefit unless Medicare has identified the individual as having other creditable coverage through an employer-based prescription drug plan. The statute also provides for assistance with premiums and cost sharing to eligible low-income beneficiaries.

In general, coverage for the new prescription drug benefit will be provided through private prescription drug plans (PDPs) that offer drug-only coverage, or through Medicare Advantage (MA) (formerly known as Medicare+Choice) plans that offer integrated prescription drug and health care coverage (MA-PD plans). PDPs must offer a basic drug benefit. MA-PDs must offer either a basic benefit, or a benefit with broader coverage than the basic benefit, but at no additional cost to the beneficiary. If this required level of coverage is offered, MA-PDs or PDPs, but not fallback plans, may also offer supplemental benefits, called ''enhanced alternative coverage,'' for an additional premium.

All organizations offering drug plans will have flexibility in terms of benefit design, including the authority to establish a formulary to designate specific drugs that will be available, and the ability to have a cost-sharing structure other than the statutorily-defined structure, subject to certain actuarial tests. Most Part D plans also may include supplemental drug coverage such that the total value of the coverage offered exceeds the value of basic prescription drug coverage. The specific sections of the Act that address the prescription drug benefit program are the following:

1860D–1	Eligibility, enrollment, and information.
1860D–2	Prescription drug benefits.
1860D–3	Access to a choice of qualified prescription drug coverage.
1860D–4	Beneficiary protections for qualified prescription drug coverage.
1860D–11	PDP regions; submission of bids; plan approval.
1860D–12	Requirements for and contracts with prescription drug plan (PDP) sponsors.
1860D–13	Premiums; late enrollment penalty.
1860D–14	Premium and cost-sharing subsidies for low-income individuals.
1860D–15	Subsidies for Part D eligible individuals for qualified prescription drug coverage.
1860D–16	Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.
1860D–21	Application to Medicare Advantage program and related managed care programs.
1860D–22	Special rules for employer-sponsored programs.
1860D–23	State pharmaceutical assistance programs.
1860D–24	Coordination requirements for plans providing prescription drug coverage.
1860D–41	Definitions; treatment of references to provisions in Part C.
1860D–42	Miscellaneous provisions.
	Specific sections of the MMA that also relate to the prescription drug benefit program are the following:
Sec. 102	Medicare Advantage Conforming Amendments
Sec. 103	Medicaid Amendments
Sec. 104	Medigap
Sec. 109	Expanding the work of Medicare Quality Improvement Organizations to include Parts C and D.

B. Codification of Regulations

The final provisions set forth here are codified in 42 CFR Part 423–Voluntary Medicare Prescription Drug Benefit. Note that the regulations—

- for Medicare supplemental policies (Medigap) will continue to be located in 42 CFR part 403 (subpart B);
- for exclusions from Medicare and limitations on Medicare payment (the physician self-referral rules) will continue to be located in 42 CFR part 411;
- for managed care organizations that contract with us under cost contracts will continue to be located in 42 CFR part 417, Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans;
- for PACE organizations will continue to be located in 42 CFR part 460.

C. Organizational Overview of Part 423

The regulations set forth in this final rule are codified in the new 42 CFR Part 423–Voluntary Medicare Prescription Drug Benefit. There are a number of places in which statutory provisions in Part D incorporate by reference specific sections in Part C of Medicare (the MA program). The MA regulations appear at 42 CFR Part 422. Since the same organizations that offer MA coordinated care plans will also be required to offer MA-PD plans, we believed it was appropriate to adopt the same organizational structure as part 422. Wherever possible, we modeled the prescription drug regulations on the parallel provisions of the part 422 regulations.

The major subjects covered in each subpart of part 423 are as follows:

Subpart A, General Provisions: Basis and scope of the new part 423, Definitions and discussion of important concepts used throughout part 423, and sponsor cost-sharing in beneficiary education and enrollment-related costs (user fees).

Subpart B, Eligibility, Election, and Enrollment: Eligibility for enrollment in the Part D benefit, enrollment periods, disenrollment, application of the late enrollment penalty, approval of marketing materials and enrollment forms, and the meaning and documentation of creditable coverage. (Please note that other, related topics, are discussed in the following subparts: Subpart P, eligibility and enrollment for low-income individuals; Subpart S, provisions relating to the phase-down of State contributions for dual-eligible drug expenditures; Subpart F, calculation and collection of late enrollment fees; Subpart C, plan disclosure; Subpart Q, eligibility and enrollment for fallback plans; and Subpart T, the definition of a Medicare supplemental (Medigap) policy.)

Subpart C, Benefits and Beneficiary Protections: Prescription drug benefit coverage, service areas, network and out-of-network access, formulary requirements, dissemination of plan information to beneficiaries, and confidentiality of enrollee records. (Please note that actuarial valuation of the coverage offered by plans, as well as the submission of the bid, is discussed in subpart F. Access to negotiated prices is discussed in subpart C, while the reporting of negotiated prices is discussed in subpart G. Formularies are discussed in subpart C, while appeals related to formularies are discussed in subpart M. Incurred costs toward true out-of-pocket (TrOOP expenditures) are discussed in subpart C, while the procedures for determining whether a beneficiary's Part D out-of-pocket costs are actually reimbursed by insurance or another third-party arrangement are discussed in subpart J. Information that plans must disseminate to beneficiaries is discussed in subpart C, while Part D information that CMS must disseminate to beneficiaries is discussed in subpart B.)

Subpart D, Cost Control and Quality Improvement Requirements for Part D Plans: Utilization controls, quality assurance, and medication therapy management, as well as rules related to identifying enrollees for whom medication therapy management is appropriate, consumer satisfaction surveys, and accreditation as a basis for deeming compliance.

Subpart E, Reserved.

Subpart F, Submission of Bids and Monthly Beneficiary Premiums; Plan Approval: Bid submission, the actuarial value of bid components, review and approval of plans, and the calculation and collection of Part D premiums.

Subpart G, Payments to Part D plans for Qualified Prescription Drug Coverage: Data submission, payments and reconciliations for direct subsidies, risk adjustment, reinsurance, and risk-sharing arrangements.

Subpart H, Reserved.

Subpart I, Organization Compliance with State Law and Preemption by Federal Law: Licensure, assumption of financial risk, solvency, and State premium taxes.

Subpart J, Coordination Under Part D With Other Prescription Drug Coverage: Applicability of Part D rules to the Medicare Advantage program, waivers available to facilitate the offering of employer group plans, waivers of part D provisions for PACE plans and 1876 cost plans offering qualified prescription drug coverage, and procedures to facilitate calculation of true out-of-pocket (TrOOP) expenses and coordination of benefits with State pharmaceutical assistance programs and other entities that provide prescription drug coverage. (Please note that subpart C discusses, in more detail, coordination of benefits from the perspective of which prescription drug benefits are covered by Part D and the determination of which incurred beneficiary costs will be counted as TrOOP expenditures. Provisions relating to disenrollment for material misrepresentation by a beneficiary are discussed in subpart B.)

Subpart K, Application Procedures and Contracts with PDP Sponsors: Application procedures and requirements; contract terms; procedures for termination of contracts; reporting by PDP sponsors.

Subpart L, Effect of Change of Ownership or Leasing of Facilities during Term of Contract: Change of ownership of a PDP sponsor; novation agreements; leasing of a PDP sponsor's facilities.

Subpart M, Grievances, Coverage Determinations and Appeals: Coverage determinations by sponsors, exceptions procedures, and all levels of appeals by beneficiaries.

Subpart N, Medicare Contract Determinations and Appeals: Notification by CMS about unfavorable contracting decisions, such as nonrenewals or terminations; reconsiderations; appeals.

Subpart O, Sanctions: Provisions concerning available sanctions for participating organizations.

Subpart P, Premiums and Cost-Sharing Subsidies for Low-Income Individuals: Eligibility determinations and payment calculations for low-income subsidies.

Subpart Q, Guaranteeing Access to a Choice of Coverage (Fallback Plans): Definitions, access requirements, bidding process, and contract requirements for fallback PDPs.

Subpart R, Payments to Sponsors of Retiree Prescription Drug Plans: Provisions for making retiree drug subsidy payments to sponsors of qualified retiree prescription drug plans.

Subpart S, Special Rules for States—Eligibility Determinations for Subsidies and General Payment Provisions: State/Medicaid program's role in determining eligibility for low-income subsidy and other issues related to the Part D benefit.

In addition, in subpart T, this final rule also makes changes to: part 400 relating to definitions of Parts C & D, part 403 relating to Medicare supplemental policies (Medigap), part 411 relating to exclusions from Medicare and limitations on Medicare payment (the physician self-referral rules), part 417 relating to cost-based health maintenance organizations (HMOs), and part 460 relating to PACE organizations.

II. Provisions of the Proposed Rule

We received 7,696 items of correspondence containing comments on the August 2004 proposed rule. Commenters included managed care organizations and other insurance industry representatives, pharmacy benefit management firms, pharmacies and pharmacy education and practice-related organizations, pharmaceutical manufacturers, representatives of physicians and other health care professionals, beneficiary advocacy

groups, representatives of hospitals and other healthcare providers, States, employers and benefits consulting firms, members of the Congress, Indian Health Service, Tribal and Urban Health Programs, American Indians and Alaska Natives, beneficiaries, and others. We also received many comments expressing concerns unrelated to the proposed rule. Some commenters expressed concerns about Medicare unrelated to the Prescription Drug Benefit, while others addressed concerns about health care and health insurance coverage unrelated to Medicare. Because of the volume of comments we received in response to the proposed rule, we will be unable to address comments and concerns that are unrelated to the proposed rule.

Most of the comments addressed multiple issues, often in great detail. Listed below are the areas of the regulation that received the most comments:

- Transition of Coverage for Dual Eligibles from Medicaid to Medicare
- Access to Drugs in Long Term Care Facilities
- Formulary Policies
- Medication Therapy Management Requirements
- Network Access Standards
- Part B/Part D Drug Identification and Coordination
- Dispensing Fees

In this final rule, we address comments received on the proposed rule. For the most part, we will address issues according to the numerical order of the related regulation sections.

A. General Provisions

1. Overview

Section 423.1 of subpart A specified the general statutory authority for the ensuing regulations and indicated that the scope of part 423 is to establish requirements for the Medicare prescription drug benefit program. We proposed key definitions at § 423.4 for terms that appear in multiple sections of part 423.

Consistent with the MMA statute, in many cases we proposed procedures that parallel those in effect under the MA program. Our goal was to maintain consistency between these two programs wherever possible; thus we evaluated the need for parallel changes in the MA final rule when we received comments on provisions that affect both programs.

Comment: Many commenters urged us to finalize regulations by early January—and detailed business requirements soon thereafter. Some also recommended that we make public certain key decisions and data sooner than January in order to promote planning.

Response: We agree that the earliest possible release of program requirements and final rules will facilitate planning and implementation of new business processes required to offer and administer this new program. Consequently we have made numerous draft documents, such as the risk plan solicitation, PDP solvency requirements, formulary review policies, and the actuarial bidding instructions, available for public comment in November and December of 2004 and have expedited the rulemaking process to meet these goals. In response to the lack of specificity regarding the PDP regions in our proposed rule, we conducted extensive outreach in order to obtain public input prior to the publication of our final rule. On December 6, 2004, we announced the establishment of 26 MA regions and 34 PDP regions.

2. Discussion of Important Concepts and Key Definitions (§ 423.4)

a. Introduction

For the most part, the proposed definitions were taken directly from section 1860D–41 of the Act. The definitions set forth in subpart A apply to all of part 423 unless otherwise indicated, and are applicable only for the purposes of part 423. For example, ''insurance risk'' applies only to pharmacies that contract with PDP sponsors under part 423.

Definitions that have a more limited application have not been included in subpart A, but instead are set forth within the relevant subpart of the regulations. For example, in subpart F, we have included all the definitions related to bids and premiums. The detailed definitions and requirements related to prescription drug coverage are included in subpart C, but because of their direct relevance to the bidding process they are also referenced in subpart F.

Following our discussion of important concepts, we provide brief definitions of terms that occur in multiple sections of this preamble and part 423. We believe that it is helpful to define these frequently occurring terms to aid the reader, but that these terms do not require the extended discussion necessary in our section on important concepts.

b. Discussion of Actuarial Equivalence, Creditable Prescription Drug Coverage, PDP Plan Regions, Service Area, and User Fees

- Discussion of the Meaning of Actuarial Equivalence

The concept of actuarial equivalence is applied in several different contexts in Title I of the MMA. In very general terms, actuarial equivalence refers to a determination that, in the aggregate, the dollar value of drug coverage for a set of beneficiaries under one plan can be shown to be equal to the dollar value for those same beneficiaries under another plan. Given the various uses for this term in the Part D provisions, we proposed the following relatively general definition: ''Actuarial equivalence'' means a state of equivalent values demonstrated through the use of generally accepted actuarial principles and in accordance with section 1860D–11(c) of the Act and § 423.265(c)(3) of this part. This concept is discussed in further detail in those sections of this preamble, such as section II.F, where actuarial equivalence comes into play. We will provide further detailed guidance on methods required to demonstrate actuarial equivalence.

Comment: One commenter requested that the definition of actuarial equivalence be refined through examples or more descriptive language.

Response: We agree that it is critical to disclose our requirements for calculation of actuarial values under Part D requirements as fully and as expeditiously as possible to reduce uncertainty on the part of potential plan sponsors. To that end we made available our draft bid preparation rules and processes early in December 2004 for public comment, and we will continue to refine our guidance to bidders through vehicles such as the annual 45-day notice and the CMS website. We have modified our definition to refer to this separate guidance.

- Discussion of the Meaning of Creditable Prescription Drug Coverage

Comments on creditable coverage are addressed in the preamble for subparts B and T.

- Prescription Drug Plan Regions

Prescription drug plan regions are areas in which a contracting PDP sponsor must provide access to covered Part D drugs. Although we included specifications for regions in § 423.112, the regions themselves were not set forth in the proposed rule. To the extent feasible, we tried to establish PDP regions that were consistent with MA regions. The MMA specifically required no fewer than 10 regions and no more than 50 regions, not including the territories. For a further discussion of the PDP regions, see section II.C of this preamble.

Comment: Many commenters expressed concerns about the MA and PDP region decisions. Many argued that

regions should closely mirror existing State insurance markets to maximize participation. Others representing rural constituencies argued for larger regions to encourage offering of coverage in rural areas.

Response: We conducted a market survey and analysis, including an examination of current insurance markets as required in the MMA. Key factors in the survey and analysis included payment rates; eligible population size per region; preferred provider organization (PPO) market penetration; current existence of PPOs, MA plans, or other commercial plans; and presence of PPO providers and primary care providers. Additional factors were also considered, including solvency and licensing requirements, as well as capacity issues. Recognizing the lack of specificity regarding the PDP regions in our proposed rule, we conducted extensive outreach in order to obtain public input prior to the publication of our final decision. On December 6, 2004, we announced the establishment of 26 MA regions and 34 PDP regions. For maps and fact sheets on the regions, please see *http://www.cms.hhs.gov/medicarereform/mmaregions/*.

- Service Area

In the proposed rule we proposed that Medicare beneficiaries would be eligible to enroll in a PDP or an MA-PD plan only if they reside in the PDP's or MA-PD plan's ''Service Area.'' For PDPs the service area is defined as the region or regions for which they must provide access. This is the Region established by CMS either pursuant to proposed § 423.112, or, in the case of fallback plans, the fallback service area pursuant to § 423.859, within which the PDP is responsible for providing access to the Part D drug benefit in accordance with the access standards in proposed § 423.120. Under the MA program, an MA plan's service area is defined in § 422.2. For coordinated care plans, the definition of ''service area'' expressly includes the condition that the service area is an area in which access is provided in accordance with access standards in § 422.112.

We also proposed that for purposes of enrolling in Part D with a PDP, or under an MA-PD plan, the definition of Service Area that governs eligibility to enroll is the area within which the Part D access standards under § 423.120 are met. Beneficiaries in jail or prison do not have access to pharmacies available as required under § 423.120. Therefore, such beneficiaries would not be considered to be in a PDP or MA-PD plan's Service Area for purposes of enrolling in Part D. Incarcerated individuals accordingly would not be assessed a late penalty when they enroll in Part D (either with a PDP or MA-PD plan) upon being released. The same analysis applies with regard to a beneficiary who lives abroad, and does not reside within the boundaries of any PDP Region or MA-PD Service Area. We have modified our definition of service area to clarify our intent as proposed.

Comment: Several commenters asked that we waive the service area requirement for employer group PDP plans.

Response: We agree that we have the authority to waive the service area requirement for employer-sponsored group prescription drug plans, and we plan to do so in appropriate cases. We will provide further details on waivers in separate CMS guidance.

- Sponsor Cost-Sharing in Beneficiary Education and Enrollment Related Costs-User Fees (§ 423.6)

The last section of subpart A proposed regulations implementing the user fees provided for in section 1857(e)(2) of the Act, as incorporated by section 1860D–12(b)(3)(D) of the Act. These fees are currently required of MA plans for the purpose of defraying part of the ongoing costs of the national beneficiary education campaign that includes developing and disseminating print materials, the 1–800–MEDICARE telephone line, community based outreach to support State health insurance assistance programs (SHIPs), and other enrollment and information activities required under section 1851 of the Act and counseling assistance under section 4360 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 103–66).

The MMA expands the user fee to apply to PDP sponsors as well as MA plans. The expansion of the application of user fees recognizes the increased Medicare beneficiary education activities that we would require as part of the new prescription drug benefit. In 2006 and beyond, user fees will help to offset the costs of educating over 41 million beneficiaries about the drug benefit through written materials such as a publication describing the drug benefit, internet sites, and other media. The user fee provisions establish the applicable aggregate contribution portions for PDP sponsors and MA organizations through two calculations.

Comment: Several commenters supported the extension of user fees to PDP sponsors in addition to MA plans. One commenter emphasized the need for Medicare to provide national beneficiary educational materials in accessible formats (including Braille and other languages commonly used by beneficiaries), as well as telecommunications equipment to support beneficiaries with hearing impairments, in order to meet the various needs of Medicare beneficiaries with disabilities. Another commenter urged us to focus beneficiary education efforts on helping beneficiaries make a choice, as opposed to simply describing the array of choices. This commenter also urged us not to overlook the M+C population in its outreach campaign.

Response: We have a long-standing tradition of making our beneficiary education materials accessible in a variety of formats to meet the needs of people with disabilities and special communications barriers. Beneficiary publications on a variety of topics are available in Braille, large print, and audiotape versions, in addition to conventional formats. We expect to continue these practices when educating beneficiaries about MMA topics. In addition, we are finalizing a partnership with the Social Security Administration (SSA) that will allow some of our educational products to be translated into 14 languages (other than English and Spanish) and reach a broader audience.

We are currently planning the development of a range of tools and strategies that will help beneficiaries make a choice that meets their needs. We agree that this action is an essential part of our education process, in addition to building general awareness and understanding. We will address the needs of multiple audiences through our outreach and education efforts, including those with M+C (MA) plans.

c. Definitions of Frequently Occurring Terms

The following definitions were discussed in the preamble to our proposed rule:

Full-benefit dual eligible beneficiary means an individual who meets the criteria established in § 423.772 (Subpart P), regarding coverage under both Part D and Medicaid.

Comment: One commenter asked us to clarify whether individuals eligible for Medicaid at the special income level for long term care qualify as full benefit dual eligibles for a full subsidy.

Response: Yes, all individuals who qualify for Medicaid, including expansion populations and persons eligible for Medicaid in long term care facilities under a State's special income standard which does not exceed 300 percent of the supplemental security income (SSI) payment standard will qualify as full benefit dual eligible beneficiaries eligible for a full subsidy.

Insurance risk means, for a participating pharmacy, risk of the type

commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitutions, nor does it include elements potentially in the control of the pharmacy (for example, labor costs or productivity).

Comment: Several commenters supported our definition of 'insurance risk', including the exclusion of performance-based compensation as this is not commonly viewed as insurance risk.

Response: We will adopt the definition as proposed.

MA means Medicare Advantage, which refers to the program authorized under Part C of Title XVIII of the Act.

MA-PD plan means an MA plan that provides qualified prescription drug coverage.

Medicare prescription drug account means the account created within the Federal Supplementary Medical Insurance Trust Fund for purposes of Medicare Part D.

Part D eligible individual means an individual who is entitled to Medicare benefits under Part A or enrolled in Medicare Part B. For purposes of this part, enrolled under Part B means ''entitled to receive benefits'' under Part B.

Prescription drug plan or *PDP* means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in § 423.272 and that is offered by a PDP sponsor that has a contract with CMS that meets the contract requirements under subpart K or in the case of fallback PDPs also under subpart Q.

PDP region means a prescription drug plan region as determined by CMS under § 423.112.

PDP sponsor means a nongovernmental entity that is certified under this part as meeting the requirements and standards of this part for that sponsor.

Comment: Several commenters noted that the terms PDP sponsor and MA organization offering an MA-PD plan were not consistently used in the proposed rule to represent distinct and mutually exclusive entities. As a result the proposed rule was not always clear regarding when requirements or options applied only to one or the other entity, or both.

Response: We acknowledge that the terminology regarding sponsors and plans was inconsistently applied. We have revised the language in the final rule accordingly and have also standardized the terms 'Part D plan' and 'Part D plan sponsor' when referring to all plans and sponsors in general. Consequently we have relocated these terms from subpart C to this subpart and clarified that references to ''Part D plans'' in the final rule refer to any or all of MA-PD plans, PDPs, PACE plans and cost plans. Likewise, the term ''Part D plan sponsor'' refers to MA organizations offering MA-PD plans, PDP sponsors, and sponsors of PACE plans and cost plans.

Comment: Several commenters asked that we be flexible in its definition of a non-governmental entity to allow either the creation of State-sponsored entities as PDPs or the selection of a preferred PDP entity for Medicaid dual eligible and SPAP populations.

Response: While we understand and support the goals of minimizing client confusion and facilitating continuity of care, we believe the requirements imposed by sections 1860D–41(13) and 1860D–23(b)(2) of the Act do not allow us to approve State-sponsored PDPs or the selection of preferred PDPs for State populations. We would note, however, that we believe we can waive the non-governmental requirement in section 1860D–41(23) of the Act under the employer waiver authority for States that seek to sponsor Part D plans on behalf of their employees. This is discussed in more detail in subpart J of this rule.

d. Financial Relationships between PDP Sponsors, Health Care Professionals and Pharmaceutical Manufacturers

The financial relationships that exist between or among PDP sponsors, health care professionals (including physicians and pharmacists), or pharmaceutical manufacturers may be subject to the anti-kickback statute and, if the relationship involves a physician, the physician self-referral statute. Nothing in this regulation should be construed as implying that financial relationships described in this final rule meet the requirements of the anti-kickback statute or physician self-referral statute or any other applicable Federal or State law or regulation. All such relationships must comply with applicable laws.

In addition to the provisions in these regulation, under section 6(a)(1) of the Inspector General Act of 1978, as amended, OIG has access to all records, reports, audits, reviews, documents, papers and other materials to which the Department has access that relate to programs and operations for which the Inspector General has responsibilities under the Inspector General Act. The provisions in these regulations do not limit the Office of the Inspector General's (OIG) authority to fulfill the Inspector General's responsibilities under Federal law.''

e. ERISA application and requirements

The rules contained in this rulemaking apply for purposes of Title I of the MMA and no inference should be drawn from anything in this rule regarding the applicability of title I of ERISA. In addition, nothing in this rulemaking should be construed as relieving a plan administrator or other fiduciary of obligations under title I of ERISA.

B. Eligibility and Enrollment

We outlined the eligibility and enrollment requirements for Part D plans in subpart B of the August 2004 proposed rule. We received over 100 comments on this subpart. Below we summarize the provisions of the proposed rule and our final rule and respond to public comments. (Please refer to the proposed rule (69 FR 46637) for a detailed discussion of our proposals.)

1. Eligibility for Part D (§ 423.30)

Section 101 of the MMA established section 1860D–1 of the Act, which includes the eligibility criteria an individual must meet in order to obtain prescription drug coverage and enroll in a Part D plan. Section 1860D–1(a)(3)(A) of the Act defines a ''Part D eligible individual'' as an individual who is entitled to Medicare benefits under Part A or enrolled in Part B. Further, in order to be eligible to enroll in a PDP plan, § 423.30(a) of the proposed rule provided that the individual must reside in the plan's service area, and cannot be enrolled in an MA plan, other than a Medicare savings account (MSA) plan or private fee-for-service (PFFS) plan that does not provide qualified prescription drug coverage. In addition, § 423.4 of the proposed rule provided the definition of service area, which describes that for purposes of eligibility to enroll to receive Part D benefits, certain access standards must be met, hence, making certain individuals ineligible to enroll.

Generally, a Part D eligible individual enrolled in an MA plan that does not provide qualified prescription drug coverage (that is, an MA plan) may not enroll in a PDP. There are, however, exceptions under sections 1860D–1(a)(1)(B)(iii) and (iv) of the Act for individuals who are enrolled in either an MA private fee-for-service plan (as defined in section 1859(b)(2) of the Act) that does not provide qualified prescription drug coverage or an MSA plan (as defined in section 1859(b)(3) of the Act). We provided for these

exceptions in § 423.30(b) of the proposed rule.

Except as provided above, in accordance with section 1860D–1(a)(1)(B)(i) of the Act, and as provided in § 423.30(c) of the proposed rule, a Part D eligible individual who is enrolled in an MA-PD plan must obtain prescription drug coverage through that plan. In order to enroll in an MA-PD plan, a Part D eligible individual must also meet the eligibility and enrollment requirements of the MA-PD plan as provided in § 422.50 through § 422.68 of the proposed rule establishing and regulating the MA program (CMS–4069–P) which was also published August 2004.

Except as otherwise provided below, the final rule adopts the eligibility criteria set forth in § 423.30 of the proposed rule.

Comment: Several commenters requested clarification of the definition of a Part D eligible individual. One commenter stated than a literal reading of the proposed definition appears to say that any individual who is eligible for Medicare but not enrolled could get the Part D benefit, and asks if an individual must enroll in Part A or Part B in order to be eligible for Part D. One commenter indicated that it was unclear how CMS would coordinate Part D eligibility with any retroactive eligibility determinations made by SSA.

Response: Section 1860D–1(a)(3)(A) of the Act defines a ''Part D eligible individual'' as ''an individual who is entitled to benefits under Part A or enrolled under Part B.''

In other context, we generally have interpreted the concept of ''entitled'' to benefits to mean that an individual has met all of the necessary requirements for a benefit (that is, is eligible for the benefit), and has actually applied for and been granted coverage. We believe for purposes of applying the definition of ''Part D eligible individual'' under section 1860D–1(a)(3) of the Act, we believe this interpretation of ''entitlement'' is the appropriate interpretation. Accordingly, we will deem an individual ''entitled'' to Part A, and thus a Part D eligible individual, if the individual is eligible for benefits under Part A, and has actually applied for and been granted coverage under Part A. On the other hand, under our Medicare Part B regulations at part 407, an individual is considered to be ''enrolled'' in Part B when he or she has applied for Part B coverage (or is deemed to have applied). Nevertheless, we do not believe this interpretation of ''enrolled'' in Part B is the correct interpretation of section 1860D–1(a)(3)(A) of the Act, and instead interpret ''enrolled under Part B'' to mean that the individual is entitled to receive benefits under Part B.

When establishing eligibility and enrollment rules for the MA program upon its inception, we adopted a similar interpretation of section 1851(a) (3) of the Act. Section 1851(a) (3) of the Act defined the term ''Medicare+Choice eligible individual'' to mean an individual who is entitled to benefits under part A ''and enrolled under part B.'' As we explained in our proposed rule for the Medicare+Choice program (see 63 FR 34979), we believe that the Congress intended that we provide an individual the opportunity to enroll in the Medicare+Choice program only if entitled to actually receive benefits under Part B in addition to Part A. As we explained, under some situations, an individual may apply for or be deemed to have applied for Part B before he or she is actually entitled to receive coverage. For example, if an individual applies for Part B coverage after he or she reaches age 65, the individual may not actually be entitled to Part B coverage under section 1837 of the Act until one or several months after the month of application and enrollment. If we had interpreted section 1851(a) (3) of the Act to permit individuals to enroll in a Medicare+Choice plan when an individual has only been enrolled in Part B, but is not yet entitled to Part B, he or she could be entitled to the benefits under a Medicare+Choice plan before actually being entitled to Medicare Part B coverage. In order to avoid such a result, we interpreted the language ''enrolled'' in Part B in section 1851(a) (3) of the Act to mean ''entitled'' to Part B.

We similarly will interpret section 1860D–1(a)(3)(A) of the Act as providing that an individuals is eligible for Part D only if the individual is entitled to receive benefits under Part A or Part B. Section 1860D–1(b)(1)(B) of the Act requires us to use rules similar to and coordinated with certain rules for enrollment that govern eligibility for the MA program. Hence, we believe that the Congress intended that we provide an individual the opportunity to enroll in part D only if entitled to actually receive benefits under Part B (or Part A); otherwise an individual would be entitled to receive coverage of Part D drugs under PDP before being entitled to receive benefits under original fee-for-service Medicare.

Our regulations at § 422.2 define an MA eligible individual as someone who meets the requirements of § 422.50, which outlines the various criteria that an individual must meet to be eligible to elect an MA plan, including: entitlement to Parts A and B, residency in a plan's service area, making an enrollment election and agreeing to abide by the rules of the MA plan. We intend to apply a parallel approach to the Part D program. We will amend § 423.4 to define a Part D eligible individual as an individual who meets the requirements at § 423.30, that is, the individual is entitled to Medicare benefits under Part A or enrolled in Part B and lives in the service area of the Part D plan. We clarify, however, that ''enrolled'' in Part B means that the individual not only has applied for and enrolled in Part B, but is also receiving coverage for Part B services, in accordance with part 407.

We have included in § 423.30 to be eligible to enroll in a Part D plan, the individual must also reside in the Part D plan's service area and not be enrolled in another Part D plan.

We have clarified Part D eligibility for those individuals for whom eligibility determinations for Medicare Part A or B have been made retroactively, which results in retroactive entitlement to these programs. The MA statute at section 1851(f) of the Act provides that initial elections shall take effect upon the date the individual becomes entitled to Part A or B, except as the Secretary may provide ''in order to prevent retroactive coverage.'' Under the MA program, an individual who has received a retroactive eligibility determination for Medicare Part A or B is not permitted to enroll in an MA plan retroactively. Again, using section 1860D–1(b)(1)(B) of the Act that directs us to establish rules similar to those in MA, we envision individuals enrolling in a Part D plan prospectively and have revised § 423.30 so that individuals who become entitled to Medicare Part A or Part B benefits for a retroactive effective date are deemed Part D eligible as of the month in which notice of Medicare Part A or Part B entitlement is provided.

Such revisions at § 423.4 and § 423.30 will clarify that an individual is eligible for Part D at the same time an individual is eligible to enroll in Part D.

Comment: Commenters requested clarification on the eligibility of incarcerated individuals. One commenter did not believe that we had the authority to create such exclusion. Another requested clarification of the ability of individuals released from incarceration on probation or parole to enroll in Part D.

Response: In the preamble of the proposed rule, we explained that individuals who are incarcerated likely do not have access to Part D services, as they cannot obtain their prescription drugs from network pharmacies, yet

technically the jail or prison may be located within the larger geographic area encompassing a PDP's service area. As a result, the individual would be subject to a late enrollment penalty for not enrolling in a Part D plan. As a result, we believe that it is appropriate to provide in § 423.4 that a PDP's service area would exclude areas in which incarcerated individuals reside (that is, a correctional facility) and as a result, incarcerated individuals would be ineligible to enroll in a PDP and we have revised the definition to clarify this point. Upon release from incarceration, such as for probation or parole, individuals will be considered eligible for Part D by living in a PDP service area, if they meet other Part D eligibility requirements.

Comment: One commenter suggested that we consider individuals who are residents of a State mental institution to be out of the service area and therefore ineligible for enrollment in a Part D plan.

Response: We would not consider individuals who are residing in a State mental institution to be out of the service area. Medicare beneficiaries residing in such institutions have access to Medicare benefits under Parts A and B and therefore would be entitled to enroll in a Part D plan. However, we do recognize that individuals in a State mental institution may be limited to the pharmacy network contracted with the facility. Therefore, we will provide such individuals a Special Enrollment Period (SEP) to enable them to join the appropriate Part D plan based upon their situation. We will clarify this in guidance following publication of this rule.

Comment: One commenter asked that we clarify § 423.30(c) in the final rule to indicate when an individual in an MA-PD plan can change plans.

Response: The provisions explaining the opportunities for individuals to make PDP enrollment choices are fully set forth at § 423.38 of the final rule. The requirements for MA plans are outlined under § 422.50 through § 422.80.

Comment: One commenter suggested that we permit beneficiaries enrolled in an MA plan to enroll in a PDP or disenroll from the MA plan and enroll in an MA-PD plan.

Response: Section 1860D–1(a)(1) of the Act specifically prohibits an MA plan enrollee from enrolling in a PDP except in the case of enrollees of a MA PFFS plan that does not provide qualified prescription drug coverage or enrollees of an MSA plan. All individuals, including enrollees of MA plans, can enroll in a Part D plan during the established enrollment periods, as described at § 423.38 of the final rule.

2. Enrollment Process (§ 423.32)

Section 1860D–1(b)(1) of the Act requires that we establish a process for the enrollment, disenrollment, termination, and change of enrollment of Part D eligible individuals in prescription drug plans. The statute further requires that this process use rules similar to, and coordinated with, the enrollment, disenrollment, termination, and change of enrollment rules for MA plans under certain provisions of section 1851 of the Act. Thus, we proposed, where possible, to adopt the MA enrollment requirements provided under § 422.50 through § 422.80.

Generally, a Part D eligible individual who wishes to make, change, or discontinue an enrollment during applicable enrollment periods must file an enrollment with the PDP directly. However, we will allow PDPs to use other enrollment mechanisms, as approved by us. In addition, § 423.32 of the final rule provides that beneficiaries will remain enrolled in their PDP without having to actively re-enroll in that PDP at the beginning of each calendar year. Except as otherwise provided below, the final rule adopts the enrollment rules set forth in § 423.34 of the proposed rule.

Comment: Several commenters submitted identical comments on various aspects of the coordination of the enrollment process reflected at both § 423.34(b) and § 423.42(a).

Response: Commenters provided similar comments about the enrollment process at § 423.34(b)(1) of the proposed rule and the coordination of enrollment and disenrollment process at § 423.42(a) of the proposed rule. After reviewing these comments, we recognized that these sections were duplicative and could cause confusion. To address this problem, we have reorganized the following subjects in subpart B into a more logical order: the enrollment process at § 423.32 (previously proposed § 423.34); auto-enrollment process for dual eligible individuals at § 423.34 (previously proposed § 423.34(d); the disenrollment process at § 423.36; the enrollment periods in § 423.38; and the effective dates at § 423.40. We believe that this will simplify and clarify these provisions.

Comment: Several commenters supported the inclusion of regulatory provisions that would permit enrollment through means other than the submission of signed, hard-copy enrollment forms in order to facilitate flexibility for future enrollments. These commenters supported allowing alternative mechanisms for enrollment, particularly electronic enrollments, to enable beneficiaries with access to computers to enroll or disenroll through secure websites established by PDP sponsors. Another commented that we should make the same enrollment mechanisms that are available to Medicare Advantage plans available to PDP sponsors. A few commenters requested clarification as to the ''other mechanisms'' referenced by us in the proposed rule, specifically what types of enrollment are envisioned and the populations to which these ''other mechanisms'' would be applied. One commenter recommended we allow electronic enrollments through a CMS-hosted web site, and that we develop a standard registration process to authenticate the enrollments. Another stated that processing applications via the Internet would require significant systems changes and that the regulation appeared to lack requirements necessary to process applications in such a manner.

Response: We were pleased by the general support for flexibility and creativity in this important part of the enrollment process, and we anticipate working in collaboration with all of our partners to develop enrollment processes that will be convenient, reliable and secure for all beneficiaries. We will adopt this provision as proposed at § 423.32(b), rather than specify or limit the types of alternative enrollment processes that may be used. We will continue to assess the technology available and provide additional operational guidance in the future, including specific systems requirements and other information necessary to implement these processes.

Comment: We received several comments requesting clarification of what parties are authorized to act on behalf of a beneficiary for enrollment purposes. One commenter noted that the regulation does not appear to recognize a beneficiary's ''authorized'' or ''personal'' representative who could be designated to make decisions for individuals and refers to the personal representative definition that we created in subpart P of the proposed rule. Another commenter was concerned that individuals in long-term care facilities do not have a designated surrogate decision maker in place to make such a decision and lack the cognitive capacity to select a PDP. While some commenters stated that we should allow an individual's personal representative to enroll a person into a PDP, others requested that we recognize specific representatives who could effectuate

such an enrollment within the regulatory text (for example, SPAP).

Response: In the regulation, we refer to a Part D eligible ''individual'' who wishes to enroll. An individual who has been appointed as the legal representative to execute such an enrollment on behalf of the beneficiary, in accord with State law, would constitute the ''individual'' for purposes of making the enrollment or disenrollment. As with the Medicare Advantage provisions, we will recognize State laws that authorize persons to effect an enrollment for Medicare beneficiaries. We will include more information on this clarification in future operational guidance.

Comment: Several commenters asked that we clarify that nothing would prevent a person or entity from assisting a beneficiary in completing and submitting his or her application to the PDP, as the MA program allows at § 422.60(c).

Response: We agree and have revised the regulatory language at § 423.32(b) to allow for such assistance, consistent with the MA regulations.

Comment: One commenter suggested that we set forth an appeals process for beneficiaries who are denied enrollment.

Response: Although we agree with the commenter that we should establish a procedure for beneficiaries to dispute enrollment denials, we do not believe that a formal appeals process is necessary. Instead, we intend to address beneficiary complaints regarding enrollment in a similar manner as we have done under the MA program. Under the MA program, individuals are advised through their notice of denial of enrollment that if they disagree with the decision to deny enrollment, they may contact the MA organization. We monitor MA organizations periodically to ensure that they are providing this notification. We also respond to specific inquiries from beneficiaries and investigate possible situations where MA organizations have failed to notify beneficiaries of the process or where an organization may have incorrectly denied a beneficiary's enrollment. If we discover a beneficiary was incorrectly denied enrollment we can require the MA organization to enroll that individual, as provided in our manual instructions. We believe our current process provides adequate remedies to beneficiaries and will therefore establish a similar process for PDPs. We decline to establish a separate appeals process for these denials at this time.

Comment: One commenter requested that we specify in the final rule that PDPs must provide written notice of enrollment decisions to each consumer.

Response: In § 423.32(d) we require PDPs to provide all individuals prompt notice of acceptance or denial of enrollment in the PDP in a format and manner specified by CMS. We will provide specific instructions on the format and manner of these required notices in operational guidance and intend to provide model language and materials for PDPs to use as well. Looking ahead, we believe that beneficiaries may want to receive documents (such as notices) in a variety of formats, rather than just in writing. To that end, we decline to require a specific format in regulation, thereby preserving the flexibility to foster innovation and creativity to satisfy beneficiary and industry expectations in the future.

Comment: One commenter suggested that individuals enrolled in PACE should remain enrolled in the PACE organization for purposes of Part D coverage effective January 1, 2006. Another commenter suggested a similar process be established for cost plans.

Response: Section 1860D–21(f) of the Act provides that a PACE plan may elect to provide qualified prescription drug coverage to its Part D eligible enrollees. Section 1860D–21(e) of the Act establishes a similar directive to cost-based HMO or competitive medical plan (CMP) plans. Discussion of the application of the Part D benefit to both PACE and cost-based HMO or CMP plans can be found under subpart T of the proposed rule. For PACE plans, we stated that PACE plans generally will be treated similar to MA local plans. Applying the appropriate MA rules from § 422.66, PACE enrollees will receive their Part D benefits through the PACE plan if the PACE plan has elected to provide such coverage. Beneficiaries who are enrolled in PACE plans that provide such coverage as of December 31, 2005 will remain enrolled in that plan on January 1, 2006. For cost-based HMO or CMP plans, we state that cost contracts may offer Part D coverage only to individuals also enrolled for Medicare in the cost contract. As a result of the provisions for PACE and cost-based HMO or CMP plans, we revised § 423.32(f) to provide that individuals who are in PACE or cost-based HMO or CMP plans that provide prescription drug coverage on December 31, 2005 will remain enrolled in that plan and be enrolled in the Part D benefit offered through that plan as of January 1, 2006.

3. Enroll Full-Benefit Dual Eligible Individuals (§ 423.34)

In the proposed rule, § 423.34(d) required that full benefit dual eligible individuals who fail to enroll in a PDP or MA-PD during their initial enrollment period would be automatically enrolled into an appropriate Part D plan, specifically a PDP with a Part D premium that does not exceed the low-income premium subsidy amount. When there is more than one available PDP in a region, full benefit dual eligible individuals would be auto-enrolled on a random basis.

All beneficiaries in an MA plan with any prescription drug coverage on December 31, 2005 will be deemed enrolled on January 1, 2006 in an MA-PD plan offered by the same MA organization in accordance with § 422.66(e)(2) and (e)(3) of Title II of the final regulation even if the monthly beneficiary premium exceeds the low-income premium subsidy amount. For full-benefit dual eligible individuals only, the proposed rule provided that those already enrolled in an MA plan without any prescription drug coverage would be auto-enrolled into an MA-PD plan offered by the same organization, and that has a monthly Part D premium that does not exceed the low-income premium subsidy amount. The proposed rule clarified that those auto-enrolled into a Part D plan may affirmatively decline Part D coverage or change Part D plans.

In a related area, § 423.36(c) of the proposed rule provided a SEP for full-benefit dual eligible individuals that permits them to change Part D plans at any time. Separately, there already exists a SEP for full-benefit dual eligible individuals to enroll in or disenroll from a Medicare Advantage plan at any time, and this will be expanded to include MA-PD plans. This SEP is provided in operational guidance (see section 30.4.4–5 of Chapter 2 of the Medicare Managed Care Manual), in accordance with section 1851(e)(4)(D) of the Act, which gives us the authority to provide Special Enrollment Periods for exceptional circumstances. Taken together, the PDP and MA-PD plan SEPs mean a full-benefit dual eligible individual may switch from Original Medicare and a PDP into an MA-PD plan and vice versa; from one PDP to another; and from one MA-PD plan to another MA-PD plan at any time.

We requested comment on two areas: whether we or States should conduct auto-enrollment, and how to address an inherent conflict in the statute, whereby the statute requires auto-enrollment of full-benefit dual eligible individuals

into a Part D plan with a premium that does not exceed the low-income premium subsidy amount, but does not speak to those instances in which an individual is enrolled in an MA organization whose premium for the available MA-PD plan(s) exceeds the low-income premium subsidy amount.

Except as otherwise provided below, the final rule adopts the enrollment rules for full-benefit dual eligible individuals set forth in § 423.34(d) of the propose rule.

Comment: Several commenters supported CMS performing the auto-enrollment function. They viewed it as the most appropriate entity because it is in the best position to randomly assign beneficiaries to MA-PD plans or PDPs in the region, and to establish links with each MA-PD plan or PDP in each region, thereby more efficiently auto-enrolling individuals. Some commenters also suggested that we consider adding an enrollment broker to the process for populations with special health care needs.

A number of other commenters recommended that States either be required or have the option to perform the auto-enrollment function, as they view the States as having more readily available data identifying dual eligible individuals and a vested interest in ensuring these individuals are enrolled in appropriate Part D plans. This option was also viewed as advancing care coordination and ensuring continuity of care. It was noted that these options also present a disincentive for States to maximize enrollment, since the phased-down State contribution payments are tied to the number of Part D eligible individuals enrolled in Part D plans. Commenters also acknowledged that, if we were to afford States the option of conducting the auto-enrollment function, we would have to develop its own systems for auto-enrollment in States that lack the capacity to develop such systems. Commenters supporting this option felt strongly that we should reimburse States for all of their costs related to enrollment activities they are required to perform.

Some commenters recommended that an independent third party coordinate the enrollment process. Those parties could include State and local officials and representatives of nonprofit organizations specializing in care for seniors. One also suggested that the contracted agent would need to be compliant with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule and should have no financial incentives regarding a full-benefit dual eligible individual's assignment beyond the contract between it and CMS.

Response: We agree with those who commented that we, or a contractor on our behalf, should perform the auto-enrollment function because we can better ensure consistent, timely implementation. In addition, we would not have to develop and implement a separate administrative structure to oversee auto-enrollment being performed by some or all of the States. Finally, it would likely be more cost effective for us to have a single entity perform auto-enrollment, rather than pay 51 separate entities. For these reasons, we will modify the final regulation to specify that we will conduct the auto-enrollment process.

At this time, we do not envision contracting with an enrollment broker to provide more intensive choice counseling for beneficiaries subject to auto-enrollment. Because the statute makes us ultimately responsible for the auto-enrollment process, we will, at least initially, conduct it ourselves. Instead of hiring a new third party, we believe it would be more effective to partner with existing stakeholders to conduct broad-based outreach and education; provide clear and comprehensive information to beneficiaries; and refer individuals to either the 1–800–MEDICARE toll-free line or to Part D plans for additional information. However, if we decide in the future to contract with an independent enrollment broker, we agree with the commenter that the entity would need to be free of conflicts of interest and comply with HIPAA privacy rules. We note that any delegation to a third party would make the third party a business associate of ours for HIPAA purposes, since the entity would be performing a function on behalf of us.

Comment: Many commenters recommended that we define ''random'' to include auto-enrollment based on beneficiaries' particular drug needs, pharmacy affiliation, or on their classification as a special needs population. Many commenters expressed concerns about how random assignment will impact individuals who are on drug regimens on which they have been previously stabilized. They were concerned that these individuals would be auto-enrolled in a ''low-cost'' plan that may not cover the drugs they need. Without direct access to the coverage they need, this population would have no real choice but to switch medications, even though changing medications can be difficult and lead to adverse health outcomes, reactions, and so on.

Several other commenters expressed similar concerns about individuals who reside in long-term care facilities. In addition, some long-term care facilities require residents to use a pharmacy selected and contracted by the facility. One commenter requested that we define ''random,'' specifically detail how we envision the random process would work, and seek further public comment.

Response: We share the commenters' concerns with ensuring access to necessary prescription drug coverage for vulnerable populations. For ensuring continued access to existing drugs prescribed for an individual, please refer to comments on § 423.120(b) of the final regulation. For ensuring access to long-term care facilities' contracted pharmacies, please refer to comments on § 423.120(a) of the final regulation.

The systems challenges associated with anything other than a random process would be significant, and possibly result in inappropriate assignment or delayed implementation. For example, we have drug utilization data for Medicaid beneficiaries, but there is a time lag in receiving those data. Furthermore, we do not currently have access to information about the pharmacies that contract with long-term care facilities. Finally, we realize that pharmacy affiliation and particular drug needs are only two of the variables that impact a beneficiary's choice of a Part D plan. For example, a beneficiary may also consider cost-sharing, formulary structure, customer service and, in the case of MA-PD plans, whether she or he would want to receive all of her or his Medicare benefits from one organization.

Given these data limitations, and the many and varied reasons for choosing a Part D plan, we do not believe we are in a position to make a judgment about what is best for individual beneficiaries, and decline to change the proposed regulations. However, we will make every effort to ensure that beneficiaries and community organizations receive enough information in time for them to determine the appropriate plan for the beneficiary. The SEP provided for full-benefit dual eligible individuals in the statute and in our final rule at § 423.38(c)(4) also ensures that they can change plans to better accommodate their pharmaceutical needs and pharmacy affiliations.

Comment: One commenter recommended that we establish a bid process whereby PDPs with an expected enrollment by full-benefit dual eligible individuals that is higher than the proportion in the total Medicare eligible population in the relevant PDP region

automatically qualify for inclusion in the auto-enrollment process. The commenter further recommended that, if such a plan has a monthly beneficiary premium above the low-income premium subsidy amount, we should permit a ''waiver'' based on a subsidy or payment of that excess premium by CMS or another entity in order to reduce the premium to an amount equal to or below the low-income premium subsidy amount.

Response: Those plans available for purposes of auto-enrollment are ones that have premiums at or below the low-income premium subsidy amount. This includes fallback plans in areas where they exist. It is our intent to implement the Part D program and adhere to the statute as closely as possible, assuming tenable options are available to do so. In the case of PDPs that serve a disproportionate share of full-benefit dual eligible individuals, and whose premium exceeds the low-income premium subsidy amount, we believe there are tenable options, that is, other PDPs with premiums at or below the low-income premium subsidy amount. However, we note that risk-adjustment should correct for the higher costs incurred by plans with larger proportions of full-benefit dual eligible individuals.

Comment: A few commenters recommended that we not limit the Part D plans available for auto-enrollment to just those plans with premiums below the low-income premium subsidy amount, as this limits full-benefit dual eligible individuals to the ''lowest cost'' plans, which may offer a less generous benefit. The commenters suggested that, regardless of whether these individuals enroll on their own or are auto-enrolled, they should be permitted to enroll in any plan and not be charged any additional premium. At a minimum, a beneficiary's medical provider could attest that a higher premium plan will better meet his or her medical needs and therefore be allowed to enroll in a higher premium plan without the added premium.

Response: We appreciate the commenters' concern that full-benefit dual eligible individuals be able to enroll in the plan best suited for them, not just ''low cost'' plans. We note that a full-benefit dual eligible individual is free to enroll in any Part D plan during the initial enrollment period or annual coordinated election period.

For auto-enrollment, however, section 1860D–1(b)(1)(C) of the Act only permit us to, auto-enroll full-benefit dual eligible individuals into those plans with premiums at or below the low-income premium subsidy amount. In addition, those full-benefit dual eligible individuals randomly auto-enrolled in a particular plan may still choose another plan pursuant to a special enrollment period.

In addition, as we do not have the authority under section 1860D–14(a)(1)(A) of the Act to increase the low-income premium subsidy amount (as defined under section 1860D–14(b)(2)(B) of the Act), full-benefit dual eligible individuals who elect to enroll in a plan with a premium exceeding the low-income premium subsidy amount must pay the difference in premium. We are also precluded under sections 1860D–13(a)(1)(F) and 1854(c) of the Act from requiring or even permitting Part D plans from waiving any premium in excess of the premium subsidy amount, including allowing MA-PD plans to use rebate dollars to reduce the premium only for this portion of their enrolled population.

Comment: We received numerous comments related to the timing of the auto-enrollment process for full-benefit dual eligible individuals. Commenters identified the possibility of a gap in coverage for some of those individuals if the auto-enrollment did not occur until the close of the Initial Enrollment Period on May 15, 2006, since Medicaid coverage of Part D drugs ends several months earlier, on January 1, 2006. They proposed that we require auto-enrollment of these individuals to be completed prior to Medicaid coverage ending on December 31, 2005. Some commenters recommended that the process be completed as early as November 15, 2005, and one commenter suggested starting the 2005 Initial Enrollment Period for full-benefit dual eligible individuals prior to November 15, 2005. Another commenter recommended that auto-enrollment precede Part D eligibility by 6 months, and that Medicaid coverage of Part D drugs be continued until auto-enrollment can be done.

Response: We did not intend to implement a process that would create a gap in drug coverage for full-benefit dual eligible individuals. We do not believe that the Congress intended for such a gap to occur. Therefore, we will modify the final rule so that the auto-enrollment of these individuals will begin as soon as Part D plans with premiums at or below the low-income premium subsidy amount are known prior to January 1, 2006. We will also modify the final rule to provide that those full-benefit Medicaid individuals who become eligible for Medicare after January 1, 2006, will be enrolled as soon as their Medicare Part D eligibility is determined. For the suggestion to start the 2005 Initial Enrollment Period for full-benefit dual eligible individuals before November 15, 2005, we are precluded from doing so, as this date is explicitly identified in section 1860D–1(b)(2)(A) of the Act as the date upon which enrollment in Part D may commence.

Comment: Many other commenters suggested that we delay implementation of the Part D program for full-benefit dual eligible individuals by at least five or six months, and some recommended a year's delay, although the commenters recognized that such a delay would require a legislative change. The commenters' concern was based on the limited time to transition drug coverage for these full-benefit dual eligible individuals from Medicaid to Medicare. The commenters expressed concern about the feasibility of identifying, educating, and enrolling the population of full-benefit dual eligible individuals in time for a smooth transition of drug coverage. Some commenters highlighted the need to ensure adequate time for physicians and patients to navigate administrative barriers and change medications to comply with formularies. One commenter suggested Medicare beneficiaries who currently participate in Medicaid buy-in programs (that is, qualified Medicare beneficiaries (QMB), special low-income beneficiaries (SLMB), and qualified individuals (QI1)) be permitted to keep Medicaid drug coverage after Part D starts.

A few commenters recommended that, assuming Part D coverage begins for full-benefit dual eligible individuals on January 1, 2006, Medicaid coverage of Part D drugs be extended past December 31, 2005, and continued until such time as full-benefit dual eligible individuals are enrolled in Part D.

One commenter recommended that full-benefit dual eligible individuals who are American Indians or Alaska Natives (AI/AN) be exempt from Part D and continue to be eligible for Medicaid drug coverage after January 1, 2006. The commenter argued that this would prevent loss of revenues to pharmacies operated by Indian Health Services (IHS), Tribal Clinics, and Urban Indian Clinics, who may receive lower payments from Part D plans than they currently receive from Medicaid, and eliminate barriers for this population.

Response: As the commenters correctly point out, a delay in the implementation of the Part D program, including auto-enrollment for full-benefit dual eligible individuals would require a change to the statute. Similarly, extending Medicaid coverage of prescription drugs covered under Part D would also require a legislative

change. Absent such changes, we cannot delay implementation, extend Medicaid coverage of Part D drugs, nor can we exclude full-benefit dual eligible individuals who are AI/AN, or participants in Medicaid buy-in programs from Part D.

Comment: A couple of commenters requested clarification about the circumstances under which a beneficiary may affirmatively decline participation in Part D. They expressed concern that individuals with diminished mental faculties may not fully understand the impact of their decision, and that States would likely bear additional costs associated with full-benefit dual eligible individuals whose health deteriorates due to their failure to take necessary medications. One commenter urged that States be able to obtain FFP to provide prescription drug coverage in these instances. Another commenter asserted that permitting a full-benefit dual eligible individual to affirmatively decline enrollment in Part D contradicts numerous statutory and regulatory provisions that require this population's enrollment in Part D. One commenter urged CMS to make disenrollment contingent upon selection of another Part D plan to ensure there is no lapse in coverage. Finally, one commenter suggested expanding the ability to affirmatively decline enrollment in Part D to Medicare beneficiaries who are not auto-enrolled.

Response: The Congress specified that prescription drug coverage under this program is voluntary, and section 1860D–1(b)(1)(C) of the Act specifically stipulates that auto-enrollment does not prevent a full-benefit dual eligible individual from declining or changing such enrollment. Absent any legislative change, we cannot intervene with an individual's right to decline coverage. Nor can we adopt the suggestion to permit Federal financial participation (FFP) for State Medicaid agencies that choose to provide drug coverage for full-benefit dual eligible individuals who affirmatively decline auto-enrollment. Section 1935(d)(1) of the Act stipulates that no FFP is available for any Part D drugs or cost-sharing for Part D drugs for full-benefit dual eligible individuals who are eligible for Part D, even if they are not enrolled in a Part D plan. However, we will be making every effort to ensure that beneficiaries and community organizations have sufficient information to assist individuals in making the most appropriate choices about participating in Part D.

Concerning the comment that we should make disenrollment from a Part D plan contingent upon enrolling in another Part D plan to prevent a coverage gap for full-benefit dual eligibles, we decline to do so in regulation, but will continue to work develop strategies to prevent a coverage gap in this instance.

We decline to expand the ability to affirmatively decline Part D enrollment to individuals who are not auto-enrolled or for whom we do not facilitate enrollment into a Part D plan. This population is comprised of those who are not deemed or determined eligible for the low-income subsidy. If these individuals do not want Part D coverage, they can simply choose not to enroll in a Part D plan.

Comment: One commenter suggested that there should be flexibility for CMS to change the plan into which a beneficiary has been auto-enrolled should the plan no longer meet the needs of the enrollee.

Response: We agree that it would be prudent to retain the flexibility to enroll an individual in subsequent years in a different plan from the one into which we originally enrolled the individual, and have modified the final rule to provide for this. We note that this will require an exception to the maintenance of enrollment provision in § 423.32(e), so we have modified the final rule to provide for one.

We envision this may only be necessary in certain limited circumstances. For example, we may want to consider doing this if the plan's premium in a subsequent year exceeded the low-income premium subsidy amount. We will ensure that beneficiaries are fully notified, and have the option to remain in their original plan. We will examine the need for this as the program evolves and provide operational guidance should we implement it.

Comment: A number of commenters responded to our request in the preamble for solutions to an inherent conflict in the statute. In this instance, the statute requires auto-enrollment of full-benefit dual eligible individuals into a Part D plan with a premium at or below the low-income premium subsidy amount. Section 423.34(d) of the proposed rule stipulated that those in an MA-only plan would be auto-enrolled into an MA-PD plan in the same organization that has a premium that does not exceed the low-income premium subsidy amount. However, there may be instances in which an individual is enrolled in an MA-only plan offered by an MA organization, and all the MA-PD plans in that organizations have premiums that exceed the low-income premium subsidy amount.

We note that most MA enrollees will be deemed to be enrolled into an MA-PD plan in accordance with § 422.66(e)(2) and (e)(3). However, deeming does not address those who elect an MA-only plan that does not offer any drug coverage in 2005, nor qualified prescription drug coverage thereafter.

Several commenters supported auto-enrolling these full-benefit dual eligible individuals into an MA-PD plan offered by the same organization with the lowest Part D premium, even if it was higher than the low-income premium subsidy amount. This would provide seamless continuation of their Medicare benefits through the same organization. Commenters noted that these individuals retain the right to decline Part D coverage, and have a SEP that permits them to change PDPs or MA-PD plans at any time.

One commenter noted that excluding full-benefit duals from auto-enrollment in an MA-PD plan with a premium higher than the low-income premium subsidy amount would give those MA plans an unfair advantage by removing from their risk pool full-benefit dual eligible individuals, who tend to have higher drug utilization.

Response: We agree with commenters' concerns about ensuring continuity of care through the same MA organization, if possible. However, as we discussed in the preamble to the proposed regulation, there is an inherent statutory conflict that would seem to preclude using auto-enrollment authority to accomplish this. Section 1860D–1(b)(1)(C) of the Act directs the Secretary to auto-enroll full-benefit dual eligible individuals who do not enroll in a PDP or MA-PD plan on a random basis into a PDP with a premium at or below the low-income premium subsidy amount; it does not identify an MA-PD plan as an entity into which an individual could be auto-enrolled.

General principles of statutory interpretation requires us to reconcile two seemingly conflicting statutory provisions rather than allowing one provision to effectively nullify the other provision. We had proposed to resolve this by interpreting the reference to ''prescription drug plans'' in section 1860D–1(b)(1)(C) of the Act as including both PDPs and MA-PD plans, thereby allowing auto-enrollment of an MA full-benefit dual eligible individual into an MA-PD offered by the same organization offering his or her MA plan if the premium for such plan did not exceed the low-income premium subsidy amount.

Upon further consideration, we believe there continue to be legal concerns as to whether we have the authority to auto-enroll full-benefit dual eligible individuals into an MA-PD plan. Rather than rely on auto-enrollment authority under section 1860D–1(b)(1)(C) of the Act to ensure continuity of Part D coverage for full-benefit dual eligible individuals enrolled in MA-only plans, we instead will rely on our general authority to establish enrollment procedures under section 1860D–1(b)(1)(A) of the Act to establish a facilitated enrollment process that substantially fulfills the intent of ensuring no prescription drug coverage gap for these individuals.

We will therefore facilitate enrollment into Part D for full-benefit dual eligible individuals enrolled in a MA plan that does not offer qualified prescription drug coverage by assigning them to an MA-PD plan with the lowest premium offered by the same MA organization, even if the plan's MA monthly prescription drug beneficiary premium exceeds the low income premium subsidy amount. We will inform them in advance of this assignment. If the beneficiary fails to affirmatively elect an alternative plan or declines enrollment in Part D, she or he will be enrolled into the plan into which she or he has been assigned. In this instance, a beneficiary's silence would be deemed consent to the enrollment choice we are making on their behalf. We note that the right to affirmatively decline in § 423.34(e), on affirmatively declining Part D enrollment, and the Special Enrollment Period in § 423.38(c)(4), apply equally to all full-benefit dual eligibles, whether they are auto-enrolled or have their enrollment facilitated.

In the case of a full-benefit dual eligible for whom we facilitate enrollment into an MA-PD plan with a premium higher than the low-income premium subsidy amount, we acknowledge that this creates a new financial obligation for the enrollee to pay the balance of the monthly MA monthly prescription drug beneficiary premium not covered by the low-income premium subsidy amount. However, this option best preserves informed enrollee choice, is consistent with statutory intent, respects the beneficiary's initial choice to enroll in an MA plan, and ensures continuity of prescription drug coverage. These individuals will have information about other plan choices available and retain their right to a Special Enrollment Period to choose another plan at any time, as provided by section 1861D–1(b)(3) of the Act for PDPs, and section 1851(e)(4)(D) of the Act and section 30.4.4–5 of Chapter 2 of the Medicare Managed Care Manual for MA-PD plans.

Comment: A few commenters generally supported auto-enrolling full-benefit dual eligible individuals into an MA-PD plan, but urged CMS to find a solution that would ensure no additional costs were imposed on beneficiaries. Some of the commenters that supported auto-enrollment into the MA-PD plan with the lowest Part D premium provided suggestions as to how to minimize the financial impact on beneficiaries. A few suggested that for those who are institutionalized, the excess premium should be considered an incurred medical expense and deducted from their monthly share of cost to the facility. For non-institutionalized beneficiaries, in States with State Pharmacy Assistance Programs (SPAPs), SPAPs should be allowed to pay the balance. For full-benefit dual eligible individuals who are medically needy, the balance should be considered an incurred medical expense contributing towards their spend-down. Otherwise, individuals should be counseled about the premium discrepancy and about the right to disenroll from an MA plan and enroll in Original Medicare with a PDP.

Response: We appreciate these suggestions for minimizing the financial impact on beneficiaries. We intend to highlight the impact of our facilitating enrollment into an MA-PD plan with a premium higher than the low-income premium subsidy amount to these beneficiaries and advise them of their ability to switch plans. We note that under Medicaid, whatever portion of the premium the individual pays would be an incurred medical expense, including any portion of the premium that is paid by the SPAP. Since incurred medical expenses are deducted from income when determining patient liability for an institutionalized individual, and are deducted from income for medically needy spend-down purposes, the commenter's suggestions correctly characterize how Medicaid would treat any premium difference paid by the individual. The commenter is also correct in noting that SPAPs will be allowed to pay the balance for their enrollees, but we note this is an option for all enrollees of an SPAP, not just non-institutionalized enrollees. Since these options are already permitted under the regulatory language in the proposed rule, we will not modify the regulation further to specify them.

Comment: One commenter suggested that we permit MA-PD plans to waive the portion of their premium above the low-income premium subsidy amount. The commenter suggested that explicit authorization by CMS would be a contract amendment, not an inducement to a beneficiary to enroll, which would ensure that the waiver of the excess premium does not implicate the Federal anti-kickback rules or be considered disparate treatment.

Response: We appreciate the intent of the commenter's suggestion. However, we are precluded from permitting MA-PD plans to waive a portion of the Part D premium for a subset of their enrollees by section 1854(c) of the Act, which requires uniform premiums for all enrollees of an MA plan.

Comment: A few commenters urged CMS to prohibit auto-enrollment of full-benefit dual eligible individuals into MA-PD plans. Instead, these MA enrollees should be auto-enrolled into a PDP for their Part D benefit. The commenters note that these beneficiaries could always switch to an MA-PD plan.

Response: Section 1861D–1(a)(1)(B)(ii) of the Act specifies that, with limited exceptions, individuals in an MA plan may not also enroll in a PDP. The only exceptions are those enrolled in a MSA plan, or in a MA private fee-for-service plan or cost-based HMO or CMP that does not offer qualified prescription drug coverage, may enroll in a PDP. Thus, auto-enrolling these individuals into a PDP would require us to also disenroll them from their MA plan, which could be inconsistent with our current MA requirements § 422.66(e), which provide that an individual who elects an MA plan is considered to have continued to have made that election until he or she voluntarily changes that election, or the plan is discontinued or no longer serves the service area.

Comment: Finally, one commenter suggested that if no MA-PD plan is available, or if the Part D premium of the available MA-PD plan exceeds the low-income premium subsidy amount, CMS should auto-enroll these beneficiaries into another organization's MA-PD plan whose premium does not exceed the low-income premium subsidy amount.

Response: For the concern that no MA-PD plan would be available, we note that section 1860D–21(a) of the Act requires all MA organizations to offer at least one MA-PD plan.

Involuntarily disenrolling the individual from his or her MA plan, and auto-enrolling him or her into another MA-PD plan offered by another MA organization, is inconsistent with MA requirements at § 422.66(e) described above.

Comment: A few commenters urged expanding Part D auto-enrollment in the

case of full-benefit dual eligible individuals who are in an organization's Medicaid managed care product, but currently receive Part A and B benefits through Original Medicare. Specifically, the commenters recommended that these beneficiaries be auto-enrolled into an MA-PD plan that is offered under common ownership and control of the organization offering the Medicaid managed care plan.

Response: Please refer to responses to comments on § 422.66(d) in Title II of the final regulation for a discussion on this issue.

Comment: A few commenters proposed that, where a full-benefit dual eligible individual in Original Medicare will be auto-enrolled into a PDP that is affiliated with an MA Special Needs Plan, CMS auto-enroll the individual into the MA Special Needs Plan for their Part A and B benefits, as a way to promote better overall coordination of care. To preserve the beneficiary choice, the commenter suggested the regulation provide an opportunity for the individual to ''opt out'' within some specified period of time (for example, 90 days).

Response: The statute prohibits beneficiaries who have Part D coverage through a PDP from getting their Medicare A and B coverage through an MA-only plan. As a result, we decline to make the suggested change.

Comment: One commenter asked CMS to clarify that, if a full-benefit dual eligible individual is auto-enrolled into an MA-PD plan with a premium higher than the low-income premium subsidy amount, that the State Medicaid program would not be obliged to pay the balance on behalf of the beneficiary.

Response: We confirm that the State Medicaid agency has no obligation to pay any Part D premium in excess of the low-income premium subsidy amount. Further, section 1905(a) of the Act, which provides Federal medical assistance for Medicare cost-sharing (as defined in section 1905(p)(3)(A) of the Act), does not include Part D premiums.

Comment: A few commenters recommended that we consider establishing a process for automatically enrolling or at least facilitating the enrollment into Part D plans all individuals deemed eligible for the full low-income subsidy. In effect, this would expand auto-enrollment to individuals in Medicare Savings Programs. These are individuals for whom State Medicaid agencies pay for Medicare cost sharing, but who are not eligible for comprehensive Medicaid benefits and thus are not considered full-benefit dual eligible individuals. They include QMB, SLMB, and QI1. To the extent that we accept this recommendation, the commenters suggested we also broaden the SEP provision to cover any full subsidy eligible individual who is auto-enrolled in a Part D Plan.

A few commenters advocated expanding auto-enrollment even further to all those who receive the low-income subsidy. This would include not only those deemed eligible for the subsidy, but also those who have to apply and be determined eligible. Auto-enrollment would ensure that these individuals are not subject to a late enrollment penalty.

Response: We agree that there are compelling reasons to promote Part D enrollment of all individuals deemed or determined eligible for the low-income subsidy. These individuals typically are less healthy and often face barriers to care. Effective medication management and prescription drug coverage can lead to reduced inpatient hospital expenditures, making it more cost-effective to provide drug coverage.

Facilitating enrollment into Part D would promote access to drug coverage for these beneficiaries by ensuring that they have drug coverage starting in 2006, while also preserving the voluntary nature of enrollment in Part D. Doing so would also ensure that beneficiaries with limited means would not be liable for a late enrollment penalty for failing to enroll in Part D when first eligible.

We intend to pursue many steps to assist beneficiaries, particularly low-income beneficiaries, in taking advantage of the new Medicare drug coverage. Such steps could include facilitating enrollment into Part D for those beneficiaries. We will provide details in operational guidance to be issued shortly after the publication of the final regulation, including details on the population for whom we will facilitate enrollment. By facilitating enrollment, we mean giving beneficiaries an opportunity to choose a Part D plan first; if they do not choose, we would notify them that we intend to facilitate their enrollment into a specific plan prospectively. If the beneficiary fails to affirmatively elect an alternative plan or declines enrollment in Part D by a given date, she or he would be enrolled into the plan into which she or he has been assigned. In this instance, a beneficiary's silence would be deemed consent to the enrollment choice we are making on their behalf. If we facilitate enrollment in this manner, we would likely follow rules for assigning beneficiaries to Part D plans similar to those for the auto-enrollment and facilitated enrollment process for full-benefit dual eligibles: MA enrollees would be enrolled into an MA-PD plan with the lowest Part D premium; Original Medicare beneficiaries would be enrolled in a PDP with a Part D premium that does not exceed the low-income premium subsidy amount, and, if there is more than one such PDP available, the individual would be randomly enrolled into one of the plans available. In establishing a process for this facilitated enrollment, we would rely upon discretion afforded the Secretary under section 1860D–1(b)(1)(A) of the Act to establish enrollment processes for Part D eligible individuals. Similarly, we would extend some of the same protections afforded the full-benefit dual eligible population who are auto-enrolled to those whose enrollment we facilitate. These protections would include a Special Enrollment Period, the right to affirmatively decline Part D enrollment, and where possible, facilitating enrollment into plans whose premiums do not exceed the low-income premium subsidy amount.

Comment: One commenter suggested expanding auto-enrollment to PACE enrollees, that is, CMS auto-enroll them into their PACE organization for purposes of Part D coverage effective January 1, 2006, unless the PACE enrollee makes another enrollment choice. PACE organizations would provide their enrollees an opportunity to opt out of enrollment in Part D (and, as a result, out of the PACE organization).

Response: We agree that PACE enrollees should not be required to take any additional steps to obtain their Part D benefit through their PACE organization. Individuals who enroll in a PACE organization elect to get all their Medicaid (if eligible for Medicaid) and Medicare benefits through the PACE organization. As noted in response to a similar comment on § 423.32 of the final regulation, we will modify the final regulation to deem individuals enrolled in a PACE organization as of December 31, 2005 to be enrolled with that PACE organization for their Part D benefit as of January 1, 2006. This precludes the need to expand auto-enrollment to PACE enrollees, so we decline to make that change.

Comment: One commenter noted that no provision was made for auto-enrollment of full-benefit dual eligible individuals enrolled in Medicare cost-based HMO or CMPs. The commenter suggested that for full-benefit dual eligible individuals enrolled in a cost-based HMO or CMP, CMS auto-enroll these individuals into the cost-based HMO or CMP for Part D benefits if the cost-based HMO or CMP offers Part D,

even if the Part D premium is higher than the low-income premium subsidy amount. If the cost-based HMO or CMP does not offer Part D benefits, the commenter recommends auto-enrolling the beneficiary into a PDP.

Response: We agree that we should ensure that full-benefit dual eligible individuals, and potentially others eligible for the low-income subsidy who are enrollees of a cost-based HMO or CMP obtain Part D benefits. As noted in response to a similar comment on § 423.32 of the final regulation, we will modify the final regulation to specify that all individuals enrolled in a cost-based HMO or CMP that offers any prescription drug coverage as of December 31, 2005, will be deemed to be enrolled in the cost-based HMO or CMP for Part D benefits as of January 1, 2006, if the cost-based HMO or CMP opts to provide Part D benefits, and regardless of whether the Part D premium exceeds the low-income subsidy amount.

We believe the same legal concerns noted above for auto-enrolling full-benefit dual eligible individuals into MA-PD plans arise for auto-enrolling them into a cost plan HMO or CMP. As a result, we decline to expand auto-enrollment a suggested by this commenter. Instead, we will use a facilitated enrollment process discussed above to accomplish substantially the same end. We will facilitate the enrollment of full-benefit dual eligible individuals enrolled in a cost plan HMO or CMP that offers Part D benefits and who fail to enroll in a Part D plan into the Part D benefits offered by their cost plan HMO or CMP. If the cost plan HMO or CMP does not offer Part D benefits, the individual will be enrolled in a PDP. We may similarly facilitate the enrollment of other cost plan enrollees eligible for the low-income subsidy who fail to elect a Part D plan into the Part D benefit offered by their cost plans.

Comment: One commenter requested clarification as to whether auto-enrollment into a PDP will only occur for Medicare beneficiaries who receive comprehensive health care benefits (full hospital and physician services) from both Medicare and Medicaid, or whether auto-enrollment also applies to Medicare beneficiaries that receive pharmacy-only benefits through Medicaid.

Response: The final rule will limit auto-enrollment to only those dual eligible individuals who receive comprehensive health benefits from both Medicare and Medicaid. As noted above, we may facilitate enrollment of all others deemed or determined eligible for the low-income subsidy into Part D plans. To the extent that a Medicare beneficiary with pharmacy-only Medicaid benefits is in the population whose enrollment we facilitate, we would facilitate that individual's enrollment into a Part D plan.

Comment: One commenter recommended that we explore auto-enrolling residents of long term care facilities who are not full-benefit dual eligible individuals, and permitting these beneficiaries to disenroll or choose another Part D plan. The commenter was especially concerned about residents who lack the cognitive capacity to select a PDP and who do not have a designated surrogate decision-maker in place.

Response: Generally, enrollment in Part D is voluntary. Section 1860D–1(b)(1)(C) of the Act provides for auto-enrollment of full-benefit dual eligible individuals. As noted above, we may facilitate enrollment of others deemed or otherwise determined eligible for the low-income subsidy into Part D plans. To the extent that a resident of a long term care facility is in the population whose enrollment we facilitate, we would facilitate that individual's enrollment into a Part D plan.

Since the Act limits auto-enrollment to full-benefit dual eligible individuals, we decline to auto-enroll long-term care residents who do not receive the low-income subsidy. While we acknowledge that access to prescription drug coverage is critical for this population, we believe they generally have the resources and support to make timely enrollment decisions. We will, however, continue to explore options regarding enrollment for all individuals in long-term care facilities.

Comment: A number of commenters urged CMS to permit SPAPs to act as authorized representatives and enroll some or all of the beneficiaries they serve into the SPAP's preferred PDP. These beneficiaries should be permitted to decline enrollment in the SPAP's preferred PDP or to change to another Part D plan.

Response: With regard to the issue of authorized representatives, we defer to State law, as discussed in response to comments on § 423.32. However, it is important to note that SPAPs that act as the authorized representative for the individual must also comply with the nondiscrimination provisions at § 423.464(e). Please see responses to related comments in subpart J.

Comment: One commenter noted that it appears that a full-benefit dual eligible individual cannot enroll in an MA-PD plan if the individual is not already an MA enrollee. The commenter urged that MA-PD plans that bid at or below the low-income premium subsidy amount should be an enrollment option for all full-benefit dual eligible individuals.

Response: During the Part D initial enrollment period that starts November 15, 2005, full-benefit dual eligible individuals who are in Original Medicare are free to change to an MA-PD plan. Further, we have established in our operational guidance a Special Enrollment Period (SEP) that permits full-benefit dual eligible individuals to enroll in and disenroll from an MA plan at any time, and will extend this SEP to MA-PD plans. This will ensure that MA-PD plans are an option for all full-benefit dual eligible individuals.

As indicated previously, any individual enrolled in a PACE organization as of December 31, 2005 will be deemed to be enrolled with that organization for their Part D benefit as of January 1, 2006.

The chart below provides a summary of the enrollment rules for all beneficiaries, including those with and without the low-income subsidy, in accordance with § 423.32, § 423.34, and § 422.66.

Population	Enrollment Rules
General Medicare Population	(1) A beneficiary who chooses to enroll a Part D plan must do so as follows: Original Medicare ➜ Original Medicare with separate PDP MA Plan without drug coverage ➜ MA-PD plan Medical Savings Account (MSA) Plan ➜ MSA with separate PDP PFFS with Part D ➜ PFFS with Part D Private Fee-For-Service Plan (PFFS) without Part D ➜ PFFS with separate PDP Cost Plan with Part D ➜ Cost plan Part D or cost plan with separate PDP

Population	Enrollment Rules
	Cost Plan without Part D ➜ Cost Plan with separate PDP (2) A beneficiary enrolled in an entity that offers any drug coverage in 2005, CMS deems him or her enrolled as follows* : MA Plan ➜ MA-PD Plan Cost Plan ➜ Cost Plan with Part D PACE Organization ➜ PACE Organization (3) On a case-by-case basis, CMS may allow an MA organization to process "seamless" enrollments into the organization's MA-PD plan if individuals are enrolled in a health plan offered by that MA organization that includes prescription drug coverage upon their entitlement to Medicare.
Full-Benefit Dual Eligible Beneficiaries	(1) A beneficiary who chooses to enroll in a Part D Plan follows the same rules as above; otherwise CMS auto-enrolls or facilitates enrollment for him or her as follows: Original Medicare ➜ PDP MSA Plan ➜ PDP PFFS Plan without Part D ➜ PDP Cost Plan with Part D ➜ Cost plan with Part D Cost Plan without Part D ➜ PDP MA-Only Plan ➜ MA-PD Plan (2) For a beneficiary enrolled in an entity that offers any drug coverage in 2005, CMS deems him or her enrolled as follows: MA Plan ➜ MA-PD Plan Cost Plan ➜ Cost Plan with Part D PACE Organization ➜ PACE Organization (3) On a case-by-case basis, CMS may allow an MA organization to process "seamless" enrollments into the organization's MA-PD plan if individuals are enrolled in a health plan offered by that MA organization that includes prescription drug coverage upon their entitlement to Medicare.
* Those in an MA Plan without any drug coverage in 2005 will not be deemed into an MA-PD plan, but instead must actively choose one if they want Part D benefits. ** We may facilitate enrollment for other beneficiaries eligible for the low income subsidy; if so, we would likely follow these same rules. For additional detail, please see discussion on: § 423.32—Beneficiary's choice § 422.66(d)(5)—"Seamless" enrollment on case-by-case basis § 422.66(e)(2)–(3)—Deemed enrollment in 2005 § 423.34—Auto-enrollment and facilitated enrollment	

4. Disenrollment process (§ 423.36)

Section 1860D–1(b)(1)(A) of the Act authorizes us to establish a process to allow disenrollment from prescription drug plans. In the proposed rule, we outlined the rules for a Part D eligible individual who wishes to change or discontinue an enrollment during applicable enrollment periods, including filing a disenrollment with the PDP directly or enrolling in another PDP.

While we initially envision a paper disenrollment process, we retain the flexibility for other secure and convenient mechanisms that we may approve in the future. Any such mechanism will be available at the option of each PDP sponsor. We believe it is important to clarify that, as other mechanisms are approved and implemented, we will require all PDPs offer a minimum standard process, which at this time would be a paper process, along with any optional election mechanism available to prospective enrollees and plan members in conjunction with the paper process. In the future, as technology evolves, another process may be a more appropriate minimum standard. Except as provided below, the final rule adopts the disenrollment rules set forth at § 423.42 of the proposed rule.

Comment: One commenter asked that we clarify whether an enrollment in a different PDP would automatically disenroll the beneficiary from his or her previous PDP effective the first day of enrollment in a new PDP and asked who is responsible for that notification.

Response: We envision creating a process similar to that created for the MA program, under which an individual who is eligible to enroll in another PDP will automatically be disenrolled from the previous PDP upon enrollment in the new PDP. The PDP to which the individual submits an enrollment is required to provide a notice of acceptance or denial, as provided in § 423.32(d). We will notify the previous PDP of the disenrollment and that PDP will inform the individual that he or she has been disenrolled. As for the specifics of the notice requirements, we will issue guidance to PDPs following the publication of this rule.

Comment: One commenter requested that we clarify in the regulations that proper beneficiary protections for retroactive disenrollments are in place for beneficiary requests that are made but not properly acted upon.

Response: We will treat an individual's request for disenrollment that was made but not properly acted upon as if the disenrollment had properly occurred. We will provide guidance to PDPs as to how to handle the processing of such requests, including proper notification to the beneficiary.

Comment: One commenter asked CMS to address the issue for those retirees who enroll in both a PDP and the employer sponsored plan due to their confusion over the variety of new coverage options. The commenter indicated that this not only results in duplicative coverage and unnecessary premium costs. In addition, the commenter was concerned because

many retirees may not be aware that a consequence of enrolling in Part D may be the discontinuation of their employer group benefits, often permanently prevented from ever being able to rejoin the group once he or she enrolls in other coverage, such as Part D. One commenter requested that we allow for retroactive disenrollment from Part D and refund of the Part D premiums for these retirees who enrolled by mistake into a PDP.

Response: We recognize that during the initial enrollment period that some retirees may be confused about how their employer-based coverage may coordinate with Part D coverage. While we feel that establishing a retroactive disenrollment process specifically for this reason would generally be inappropriate, we can establish a process in which we would work with employer group sponsors, PDPs and MA-PDs to educate beneficiaries prior to open enrollment and at the time of enrollment. In addition, we intend to establish a process for the PDPs and MA-PDs to verify an enrollment request for those individuals who have been identified to CMS as having been claimed by an employer group sponsor to receive the employer based subsidy. We will also include information in beneficiary education and enrollment materials targeted to those individuals who already have other prescription drug coverage to provide assistance in determining whether enrollment in Part D would be appropriate for that individual. We will issue operational guidance on this process shortly following publication of the final rule.

5. Part D Enrollment Periods (§ 423.38)

In the proposed rule, as directed by the MMA, we established three coverage enrollment periods: (1) the initial enrollment period (IEP); (2) the annual coordinated election period (AEP); and (3) SEPs. Generally, in accordance with section 1860D–1(b)(2)(B) of the Act, the IEP for Part D is the same as the initial enrollment period established for Part B. In addition, as part of the implementation of the Part D program, and in accordance with section 1860D–1(b)(2)(A) of the Act, we have established an initial enrollment period for Part D from November 15, 2005 until May 15, 2006 for those individuals who are already eligible to enroll in a Part D plan as of November 15, 2005.

In accordance with section 1860D–1(b)(1)(B)(iii) of the Act, the AEP for Part D is concurrent with the annual coordinated election period for the MA program under section 1851(e)(3) of the Act. It is during this annual period in which all PDP plans must open enrollment to Medicare beneficiaries. For coverage beginning in 2006, the annual coordinated election period begins on November 15, 2005 and ends on May 15, 2006. As a result, the initial enrollment period for individuals who are eligible to enroll in a Part D plan as of November 15, 2005 and the annual coordinated election period will run concurrently during this time frame. In accordance with section 1851(e)(3)(B)(iv) of the Act, § 423.36(b)(2) of our proposed rule provides that, for 2007 and subsequent years, the annual coordinated election period will be November 15 through December 31 for coverage beginning on January 1 of the following year.

The MMA also establishes SEPs. SEPs allow an individual to disenroll from one PDP and enroll in another PDP. Similarly, the SEP rules that will apply for individuals in an MA-PD plan will be provided under § 422.62(b). We will include in regulation those SEPs that have been specifically named in the statute. Those SEPs established for exceptional circumstances for PDPs and MA-PDs, as authorized by section 1860D–1(b)(3)(C) of the Act and section 1851(e)(4) for MA-PDs of the Act, respectively, will be provided in our manual instructions. The final rule adopts the enrollment periods as proposed.

Comment: We received several comments regarding SEPs. Several commenters supported the SEPs for exceptional conditions we proposed to provide through manual guidance. Specifically, these include certain SEPs already established in the MA program for circumstances where a plan terminates its contract or the individual changes his or her permanent residence. These commenters also supported an SEP to enroll in a PDP for individuals disenrolling from an MA-PD plan during the MA Open Enrollment Period, and for institutionalized individuals. Other commenters suggested we establish various other SEPs, including the following:

- A subsidy-eligible individual who leaves private prescription drug coverage for any reason, including his or her inability to pay;
- A change in a person's health status that makes a current plan choice no longer suitable to his or her needs;
- Individuals eligible for the low-income subsidy, other than full benefit dual eligible individuals;
- If there are substantial changes to the plan's formulary;
- Individuals with ''life-threatening situations;''
- Individuals whose situations are pharmacologically complex;
- All individuals for the first 18 months of the program as it may be a confusing time;
- All beneficiaries leaving MA plans throughout the year so that they can enroll in a PDP;
- Medicare-eligible retirees whose plan sponsor changes their retiree drug coverage so that it no longer meets the criteria for creditable coverage;
- Individuals enrolled in, or desiring to enroll in PACE, as the PACE program has continuous enrollment and disenrollment; and
- Full benefit dual eligibles at any time, including every time a PDP changes its plan in a way that directly effects these individuals, such as removing a drug from its formulary, changing the co-payment tier for a drug, or denying their appeal concerning a non-formulary drug or an effort to change the co-payment tier.

Response: We appreciate this feedback. As previously mentioned, we have historically included in regulation only those SEPs that have been specifically named in the statute. The SEPs explicitly provided for in statute include an SEP for full-benefit dual eligible individuals, individuals who permanently change their residence so that they no longer reside in their PDP's service area, and individuals enrolled in a PDP whose contract is terminated.

We will issue guidance regarding the above SEPs and other additional SEPs that we choose to establish following publication of the regulation. We intend to establish in this guidance an SEP for those individuals eligible for the low-income subsidy whose enrollment into a Part D plan will be facilitated, individuals in long-term care facilities, individuals enrolled in, or desiring to enroll, in PACE and individuals enrolled in employer group health plans. However, we decline to establish SEPs for other reasons included in the comments described above, because we do not view these circumstances as exceptional. However, we retain the right to establish additional SEPs in the future and will do so in our operational guidance. Furthermore, we may establish SEPs on a case-by-case basis, where warranted by an immediate exceptional circumstance, such as an individual with a life-threatening condition or illness. For the commenter's request that we provide an SEP for the first 18 months of the program, we do not believe that such an SEP is warranted in the circumstances. First, we are committed to ensuring all beneficiaries have adequate information to make informed choices about participating in the Part D program. Second, the statute provides for an

extended AEP and provides a concurrent IEP at the beginning of this program. These extended enrollment periods, in conjunction with the planned education and information campaigns, will provide all beneficiaries with adequate time and information to make an enrollment decision. Therefore, we do not believe that such an SEP is warranted.

Comment: A few commenters recommended that we should provide a SEP to permit those individuals who will receive the low-income subsidy under subpart P but who are not full-benefit dual eligible individuals to change to a plan of their choosing.

Response: We strongly agree that we should permit those individuals who are enrolled or whose enrollment is facilitated by CMS the opportunity to change to a plan of their choosing. Since we are generally limiting in regulation those SEPs specified in statute, we will provide for this SEP in operational guidance.

Comment: One commenter recommends that we change the provision of an SEP for the involuntary loss of creditable coverage to include individuals who lose such coverage due to failure to pay premiums. The commenter believes the provision as proposed is too restrictive and should be modified.

Response: Section 1860D–1(b)(3)(A)(iii) of the Act is clear that disenrollments for failure to pay premiums will be considered a voluntary disenrollment action. We therefore do not believe it appropriate to treat this disenrollment as an exceptional circumstance justifying an SEP.

Comment: One commenter asked if MA-PD plans are required to participate in the AEP.

Response: The MA enrollment periods are discussed in the MA regulations at § 422.62. The AEP applies to both PDP and MA-PD plans.

Comment: One commenter requested clarification of how many times an individual may use an SEP to enroll in a PDP and encouraged CMS to limit the number of times an SEP may be used to enroll.

Response: The duration and applicability of an SEP is specific to each SEP and may vary from one specific circumstance to another. For example, an SEP in the MA program for individuals affected by a plan termination is specific to the circumstances surrounding that specific action and limited in duration. Other SEPs apply more generally to individuals, for example, full-benefit dual eligible dual individuals. We will provide detailed guidance concerning each SEP following the publication of this rule.

Comment: One commenter requested clarification of proposed § 423.36(c)(3) regarding the SEP for individuals whose enrollment or nonenrollment in Part D is caused by an error of a Federal employee or any person authorized by the Federal government to act on its behalf. The commenter suggests that we include all sponsors of Part D plans as ''persons authorized by the Federal Government to act on its behalf.''

Response: We have interpreted this statutorily required SEP to apply to Federal government employees, staff, and contractors hired by the Federal government to perform government duties. We would not consider Part D plans to be performing enrollment functions as a subcontractor on the behalf of CMS; rather, Part D plans must perform certain enrollment functions as requirement of their direct contract with CMS. While it is unlikely that an SEP would be necessary, we will correct any errors made by the plan and not hold the individual liable for the plan's mistake. Thus, we may allow an SEP in individual situations, if appropriate.

Comment: One commenter asked if SEP enrollment in a PDP could be retroactive in order to maintain continuity of care.

Response: An SEP enrollment in a PDP will generally be prospective. We establish the effective date for SEPs and can accommodate unusual circumstances on a case-by-case basis.

Comment: One commenter suggested that we establish an SEP with no late enrollment penalty if a Medigap issuer or other entity fails to provide adequate or accurate notice of whether such coverage is creditable.

Response: Section 423.38(c)(2) of the final rule establishes an SEP for all individuals who are not adequately informed when their creditable prescription drug coverage is lost or changes so that it is no longer creditable prescription drug coverage or that the individual never had such creditable coverage. We believe that these provisions adequately protect an individual who does not receive the required notice from a Medigap issuer or other entity. Regarding the late enrollment penalty, the provision of an SEP is not directly related to, nor does it have a direct effect upon, the imposition of applicable late enrollment penalties. The late enrollment penalty is discussed in more detail at § 423.46 and its relationship to creditable prescription drug coverage is discussed at § 423.56. Specifically, at § 423.56(g) of the final rule we describe the available remedy for an individual who was not adequately informed that their prescription drug coverage is not creditable.

Comment: One commenter believed the enrollment process should ensure that residents of a long-term care facility are enrolled in a PDP that provides access to the pharmacy located in the long-term care facility.

Response: We understand the issue raised by the commenter. Individuals who are in a long-term care facility will be given an SEP to ensure they can choose the PDP that is appropriate for their situation. This will be clarified in guidance following publication of this rule.

6. Effective Dates of Coverage and Change of Coverage (§ 423.40)

Section 1860D–1(b)(1)(B)(iv) of the Act directs us to apply the effective date requirements provided under the MA program at section 1851(f) of the Act. As described above, the three enrollment periods provided under Part D are the IEP, the AEP, and SEP. In the proposed rule, we established the following effective dates for these enrollment periods:

a. Initial Enrollment Period

In accordance with section 1851(f)(1) of the Act, as incorporated into Part D under section 1860D–1(b)(1)(B)(iv) of the Act, an enrollment made during the initial enrollment period will generally be effective the first day of the calendar month following the month in which the individual enrolled in Part D. An enrollment made prior to the month of entitlement to Part A or enrollment in Part B is effective the first day of the month the individual is entitled to Part A or enrolled in Part B. Since the Part D provisions are not effective until January 1, 2006, we clarified that in no case may enrollment in Part D be effective prior to this date. We also clarified that initial enrollments made between November 15 and December 31, 2005 will be effective January 1, 2006. An enrollment made during or after the month of entitlement to Part A or enrollment in Part B is effective the first day of the calendar month following the month in which the enrollment in Part D is made.

b. Annual Coordinated Election Period

In accordance with section 1851(f)(3) of the Act, as incorporated into Part D under section 1860D–1(b)(1)(B)(iv) of the Act, an enrollment made during the annual coordinated election period is effective as of the first day of the following calendar year, that is, January 1st. One exception to this rule occurs during 2006 in the special annual coordinated election period in 2006, in

which elections made between January 1, 2006 though May 15, 2006 will be effective the first day of the calendar month following the month in which the enrollment in Part D is made.

c. Special Enrollment Period

A SEP is effective in a manner that we determine to ensure continuity of health benefits coverage.

The final rule adopts the effective dates as proposed.

Comment: Three commenters suggested that we specify a distinct effective date for the SEPs in the final rule (as described in § 423.38(c) of the proposed rule) to ensure adequate consumer protection. Two commenters suggested adding: ''but no later than the first day of the second calendar month following the month of the request for the enrollment change'' to the end of this section. The third commenter suggested we add: ''changes made before the 20th of the month are effective the first day of the second month following'' the change.

Response: We have outlined the specific effective date requirements for SEPs granted in the MA program in operational guidance and will follow the same process for the Part D program. We believe that in so doing, we retain our ability to react quickly to changes or unforeseen circumstances.

7. Involuntary Disenrollment by the PDP (§ 423.44)

Section 1860D–1(b)(1)(B) of the Act generally directs us to use disenrollment rules similar to those established under section 1851 of the Act. The proposed disenrollment provisions for PDPs were outlined in § 423.44 of our proposed rule, including the basis for disenrollment—both optional and required—and guidance for notice requirements.

Specifically, we proposed at § 423.44(b)(2) that a PDP is required to disenroll an individual who dies, no longer resides in the PDP's service area, loses entitlement or enrollment to Medicare benefits under Part A and is no longer enrolled in Part B, or knowingly misrepresents to the PDP that he or she has received or expects to receive reimbursement for covered Part D drugs through other third-party coverage. The proposed rule also required a PDP to disenroll an individual if the PDP sponsor's contract is terminating.

In addition to providing requirements for mandatory disenrollments, we also provided under § 423.44(d) of our proposed rule that PDPs may disenroll individuals who do not pay monthly premiums or whose behavior is disruptive, consistent with section 1860D–1(b)(1)(B)(v) of the Act.

As with the MA program, PDP sponsors will be required in the final rule to provide proper notice to the beneficiary, as outlined at proposed § 423.44(c), and afford him or her due process in accordance with the procedures outlined in our operational instructions prior to disenrolling the individual. For example, a PDP that wishes to disenroll a beneficiary for disruptive behavior must receive our prior approval and demonstrate to our satisfaction that it has made a good faith effort to resolve the issue prior to requesting the disenrollment. We will review these requests on a case-by-case basis, taking into account all of the facts and circumstances of a particular case, prior to making its decision. PDP sponsors must apply their policies for optional disenrollment for failure to pay premiums and disruptive behavior consistently among individuals enrolled in their plans, unless we permit otherwise, and must do so consistent with applicable laws regarding discrimination on the basis of disability.

Except as otherwise provided below, the final rule adopts the involuntary disenrollment rules set forth in § 423.44 of the proposed rule.

Comment: Several commenters urged CMS to establish a process for individuals to appeal disenrollment decisions. Several commenters believed that individuals should have access to an outside independent review process, especially if these individuals are disenrolled without an SEP. Another commenter stated that involuntary disenrollments must be heavily scrutinized and an appeal right be available on an expedited basis.

Response: As we discussed under a previous comment regarding appeals for enrollment denials, we do not believe that a formal appeals process is necessary. Instead, we intend to address beneficiary complaints regarding disenrollment in a manner addressed under the MA program. Under the MA program, MA plans are required to follow a specific process, which includes notice of potential disenrollment if the individual does not address situation. We currently provide assistance to MA organizations to handle beneficiary inquiries and complaints regarding disenrollment through staff assigned to each MA organization. We envision a similar process being established under the PDP program.

Comment: Several commenters pointed out an error in the numbering of the regulatory text for disruptive behavior at proposed § 423.44(b)(1).

Response: We concur and have corrected the numbering.

Comment: A commenter requested that we clearly define how long an individual would need to reside out of the PDP service area before we would consider the individual as no longer residing in the service area. One commenter did not think that it was reasonable to apply a 6-month time limit to PDPs; PDPs should not be required to disenroll individuals if the PDP can provide individuals access to benefits out of the service area through a PDP in another region, or the PDP's network of pharmacies in other regions, or mail order pharmacies. One commenter believed the decision should be left to the individual as to when he or she has permanently moved out of the PDP service area. A few commenters did not believe that a person's residency should be a factor in a plan's basis for disenrollment. Another commenter stated that a PDP should not be required to disenroll an individual if the PDP meets licensure requirements in the State where the individual has moved and the PDP has a national pharmacy network in place. Another commenter suggested that PDP maintain members if they are an established sponsor and meet certain network adequacy requirements in the region in which the beneficiary moves.

Response: We agree that disenrolling a beneficiary after being temporarily out of the service area for a certain period of time may be less appropriate for PDPs than in the MA program. The MMA directs us to use rules similar to (and coordinated with) the MA residency requirements at section 1851(b)(1)(A) of the Act, which provides that an individual may elect an MA plan only if the plan serves the geographic area in which the individual resides, except as the Secretary may otherwise provide. However, the MA regulation at § 422.74(d)(4) generally provides for disenrollment of an individual if that individual is out of the service area, even temporarily, for 6 months, unless the MA organization offers visitor or traveler benefits that provide for benefits while outside of the service area. We believe that the nature of the prescription drug benefit and the ability for many individuals to access the benefit through mail order or chain drug stores provide greater flexibility in accessing the prescription drug benefit while temporarily being out of the PDP's service area. However, while an individual has greater flexibility to be temporarily outside the service area and still access the PDP benefit, we maintain that the individual must maintain his or her permanent residence within the

PDP's service area to be a member of the PDP. If the PDP learns of a change in the individual's permanent address, the PDP would initiate the disenrollment process. It is, however, an individual's responsibility to notify the PDP if the individual permanently moves out of the service area. We will provide further guidance to PDPs on the process of disenrollment when an individual permanently moves out of the service area following publication of this rule.

Comment: One commenter asked how a PDP will learn of loss of entitlement to Part A or Part B.

Response: We will notify the PDPs of the loss of Part A or B benefits. We will issue detailed operational guidance for PDPs prior to 2006.

Comment: A few commenters requested that we further clarify the provision that an individual who ''knowingly misrepresents to the PDP that he or she has received or expects to receive reimbursement for covered Part D drugs through other third party coverage'' (that is, whether his or her costs are expected to be reimbursed through insurance or otherwise, such as a group health plan) must be disenrolled. These commenters also asked how ''knowingly'' will be determined and what entity would be responsible for investigating such a case. One commenter indicated that a beneficiary should not be penalized for unintended errors or inadvertent omissions, and that many beneficiaries will be confused at the outset about their PDP coverage and how it may coordinate with other insurance.

Response: Section 1860D–2(b)(4)(D)(ii) of the Act provides that ''material misrepresentation'' by an individual as to whether his or her costs are expected to be reimbursed through insurance or otherwise (through a group health plan or other third party payment arrangement) shall be grounds for termination by the PDP. Since section 1860D–2(b)(4)(D)(ii) of the Act also provides that a PDP sponsor may periodically ask Part D eligible individuals about such reimbursement, the statute establishes a penalty for an individual who ''materially'' misrepresents such information. This provision is not intended to disenroll individuals who simply make an error, but instead apply to those individuals who knowingly provide such false information. We would be responsible for reviewing and issuing the final decision on such a case. We plan to issue further guidance on this for PDPs prior to 2006.

Comment: We received several comments on the disenrollment for nonpayment of premium provision, both supporting and opposing inclusion of such a process. Several commenters requested that we clarify the details of disenrollment for nonpayment of premium, including what we view as ''reasonable efforts'' to collect the premium. Several commenters recommended providing a minimum grace period for repayment before permitting disenrollment. One commenter requested that we waive payment of past premiums for full-benefit dual eligible individuals or low-income subsidy individuals. Some commenters believe that it is inappropriate for us to disenroll any individual from Part D for nonpayment of premium. One commenter stated that individuals enrolled in a PACE plan should not be subject to the disenrollment requirements under § 423.44 of the proposed rule.

Response: Section 1860D–1(b)(1)(B)(v) of the Act specifically directs us to apply rules to PDPs that are similar to (and coordinated with) the MA provisions at section 1851(g) of the Act related to disenrollment for nonpayment of premium. While some commenters objected to disenrollment by the PDP on those grounds, we note that such disenrollment is at the PDP sponsor's option and PDP sponsors therefore have the ability to apply this rule to their plan enrollees. In contrast, under Part B, individuals who fail to pay their Part B supplementary medical insurance premiums must be disenrolled from Part B. While we do not review and approve such disenrollments, we maintain that if a PDP chooses the option to disenroll a beneficiary for nonpayment of the premium, we would require that the PDP apply this policy consistently, as we direct, amongst all its members and could not ''waive'' the premium for a certain group of its members. As indicated in the preamble of subpart T of this rule, we will issue additional guidelines that will include a comprehensive listing of Part D waivers applicable to PACE organizations. However, we agree that PACE organizations should not be subject to the disenrollment requirements of § 423.44 as they are duplicative of the PACE disenrollment requirements associated with § 460.164 of the PACE regulation.

Comment: Several commenters recommended that we permit plans to deny reinstatement following disenrollment for failure to pay premiums unless the enrollee pays the outstanding amount that is due. Other commenters stated that PDP should not be required, under any circumstance, to re-enroll individuals who are disenrolled for nonpayment of the premium.

Response: We have provided in the final regulation at § 423.44(d)(1)(iii) that a PDP may decline future enrollment to individuals who have been disenrolled for failure to pay premiums until past due premiums are paid to the PDP. However, we would not allow a PDP to prohibit an individual from enrolling in its plan if the individual has paid all past due premiums to the PDP.

Comment: We received a substantial number of comments on proposed § 423.44(d)(2) to allow PDP sponsors to disenroll individuals who exhibit disruptive behavior.

One commenter supported the definition established in the proposed rule, while several commenters supported the due process safeguards afforded by our approval of disenrollment requests. Two commenters suggested that we provide guidance to PDP sponsors on the symptoms of mental illness and dementia and other personality disorders to distinguish between disruptive behavior and behavior resulting from a medical condition. There were other commenters who asked us to clearly define the terms and requirements for disenrolling a beneficiary for disruptive behavior. These commenters recommended that we include in the final rule such requirements as documentation of a PDP sponsor's effort to provide a reasonable accommodation for individuals with disabilities and sufficient notice of the sponsor's actions during the course of the disenrollment process.

Numerous commenters expressed concern that the proposed definition of disruptive behavior does not adequately protect individuals whose behavior is induced by disability, mental illness, cognitive impairment, or certain prescribed drugs and who rely on prescription drug therapy to stabilize their behavior. Some commenters recommended that we prohibit PDP sponsors from disenrolling certain populations for disruptive behavior, explaining that State Medicaid programs will not be able to claim Federal matching funds for prescription drugs spending on behalf of full-benefit dual eligibles who have been disenrolled by a PDP sponsor. Other commenters suggested that we develop more stringent criteria for PDP sponsors requesting to disenroll a full-benefit dual eligible individual. Several commenters stated that, in cases where an individual is unstable, disruptive behavior could be related to unsuccessful attempts to find the proper medication. There were also a number

of commenters who asserted that we lacked statutory authority to permit PDPs sponsors to disenroll individuals for disruptive behavior. Two commenters questioned the appropriateness of applying a policy of involuntary disenrollment for disruptive behavior to PDPs. One commenter suggested that we allow an individual who is disruptive to designate an authorized representative to access services on his or her behalf.

Response: In the final rule, we aim to strike a balance between allowing PDP sponsors to disenroll individuals who exhibit disruptive behavior and creating adequate protections for individuals who face involuntary disenrollment from a PDP. In accordance with the statute (at section 1860D–1(b)(1)(B)(v) of the Act), we must establish a process that is similar to and coordinated with the process under the MA program that permits MA organizations to disenroll an individual for disruptive behavior. At the same time, we recognize the impact of such a disenrollment on an individual's ability to access prescription drug coverage under the Medicare program, and the need for adequate safeguards for individuals whose disruptive behavior is due to mental illness or a medical condition. Continuity of care for these individuals is essential, especially if they are taking prescription medications that can minimize the debilitating impact of their illness and restore their functioning.

Therefore, in revising our proposed definition of disruptive behavior in § 423.44(d)(2)(i) of the final rule, we focus on behavior that substantially impairs a PDP sponsor's ability to arrange or provide care for the individual or other plan members. Behavior that is related to the use of medical services or compliance (or non-compliance) with medical advice is not disruptive behavior.

We also agree with commenters that arranging or providing care for individuals with mental illness, cognitive impairments such as Alzheimer's disease or other dementias, and medical conditions and treatments that may cause disruptive behavior warrant special consideration, and therefore revise § 423.44(d)(2)(v) to require PDP sponsors to provide a reasonable accommodation to individuals in such exceptional circumstances that we deem necessary. Such accommodation is intended to ensure that the individual can maintain Medicare prescription drug coverage and may include granting an individual a SEP to choose another plan, or requiring the plan to continue the individual's enrollment until the Annual Coordinated Election Period, when the individual has an opportunity to enroll in another plan. We will determine the type of accommodation necessary after a case-by-case review of the needs of all parties involved. This review will be conducted as part of our review and approval of the PDP sponsor's request, as required in regulations at § 423.44(d)(2)(v), and will include expert opinion from our staff with appropriate clinical or medical background.

In addition, we recognize that circumstances may arise where an individual is only able to obtain qualified prescription drug coverage from a fallback prescription drug plan operating in his or her service area. In such instances, allowing a fallback entity to disenroll an individual may create substantial barriers to accessing prescription medications under the Medicare program. Section 1860D–11(g)(4)(B) of the Act grants us authority to establish additional requirements specifically for fallback prescription plans. Under this authority, we reserve the right at § 423.44(d)(2)(vi) to deny a fallback prescription drug plan's request to disenroll an individual for disruptive behavior.

In the proposed rule, we established procedures that PDP sponsors must follow prior to requesting to disenroll a member for disruptive behavior. Under proposed § 423.44(c), a PDP sponsor must give an individual timely notice of the disenrollment, which includes an explanation of the individual's right to a hearing under the PDP's grievance procedures. We further required at proposed § 423.44(d)(2)(ii) a sponsor to make a serious effort to resolve the problems presented by the individual, including the use or attempted use of the organization's grievance procedures. Finally, we established under proposed § 423.44(d)(2)(iii) that a PDP sponsor must document the individual's behavior, its own efforts to resolve the problem, and the use or attempted use of its internal grievance procedures. We are preserving all of these requirements in the final rule at § 423.44(c) and § 423.44(d)(2)(iii) and (d)(2)(iv).

We believe that the final rule achieves the twin goals of permitting involuntary disenrollment based on an individual's disruptive behavior, while also establishing necessary protections for individuals who are subject to our disenrollment rules.

Comment: Several commenters contended that allowing a PDP sponsor to disenroll an individual for disruptive behavior provides an opportunity for PDP sponsors to discriminate against individuals with disabilities, mental illness, Alzheimer's, and other cognitive conditions.

Response: We appreciate the commenters concern about the need to ensure that individuals are not discriminated against on the basis of their disability. However, the Part D plans are not provided the authority to make the decision on such a disenrollment. In addition to establishing safeguards in the final rule for individuals with special needs by requiring PDP sponsors to make reasonable accommodations where we deem necessary, it is CMS who reviews the request for disenrollment and makes the decision to approve or deny the request. In our review, we will include our staff with the appropriate clinical or medical expertise review the case before a final decision is made.

Comment: Several commenters noted that the proposed rule denies protection to individuals who comply with medical advice by trying an on-formulary drug instead of the drug originally prescribed and subsequently experience an adverse reaction that triggers the disruptive behavior. A few commenters asked us to prohibit PDPs from disenrolling an individual because of his or her refusal or inability to adhere to a treatment plan developed by the PDP or other health care professionals associated with the plan.

Response: We agree with the commenters and clarify in the final rule at § 423.44(d)(2)(i) that an individual cannot be considered disruptive if such behavior is related to the use of medical services or compliance (or non-compliance) with medical advice or treatment.

Comment: Two commenters supported the flexibility afforded PDP sponsors by our allowing PDP sponsors to limit re-enrollment for individuals who are disenrolled for disruptive behavior, and one of these commenters specifically asked us to establish criteria for re-enrolling an individual such as a minimum waiting period and a commitment by the individual to discontinue such behavior. On the other hand, there were many commenters who opposed the ability of a PDP sponsor to decline re-enrollment of an individual. These commenters contended that prohibiting an individual from re-enrolling in a PDP for a specified period could cause undue harm and lapses in coverage, especially if the individual is not able to enroll in another PDP. One commenter requested that we specify the maximum period of time that a PDP sponsor may prohibit re-enrollment of

an individual who has been disenrolled for disruptive behavior.

Response: In the proposed rule, we enabled PDP sponsors to request, at their option, the ability to decline future enrollment by an individual who had been disenrolled for disruptive behavior. While we retain this option for PDPs in the final rule, we require these sponsors to request future conditions on re-enrollment as part of their disenrollment request. At the same time, we reserve the right in accordance with § 423.44(d)(2)(v) to review each request on a case-by-case basis. In the review process, we will give due consideration to exceptional circumstances that may warrant reasonable accommodations in addition to the appropriateness of conditions on re-enrollment.

Comment: There were several commenters who objected to the expedited disenrollment process. The commenters noted that the expedited process lacks even the minimal standards and requirements that are in place to protect beneficiaries in these circumstances.

Response: It is our intent to ensure that all individuals facing involuntary disenrollment for disruptive behavior have sufficient opportunity, as provided by the notice requirements, to change their behavior or grieve the PDP sponsor's decision to request involuntary disenrollment from us. We have therefore removed this provision from the final regulation.

Comment: One commenter asked us to clarify whether a full-benefit dual eligible individual who is disenrolled for disruptive behavior is entitled to a SEP.

Response: In accordance with the § 423.38(c)(4), a full-benefit dual eligible individual as defined under section 1935(c)(6) of the Act is entitled to a SEP. A full benefit dual eligible individual who is involuntarily disenrolled for disruptive behavior remains entitled to a Special Enrollment Period.

Comment: We received two comments asking us to adopt an interpretation of nonpayment of cost sharing as disruptive behavior as we had discussed in the preamble of the proposed rule for MA organizations.

Response: We appreciate the feedback provided on the consideration to include nonpayment of cost-sharing as disruptive for the purposes of applying the provisions under disruptive behavior. We will consider these comments in developing guidance for the disruptive behavior provisions.

8. Late Enrollment Penalty (§ 423.46)

Section 1860D–13(b) of the Act establishes late enrollment penalties for beneficiaries who fail to maintain creditable prescription drug coverage for a period of 63 days following the last day of an individual's initial enrollment period and ending on the effective date of enrollment in a Part D plan. We outlined this process for imposing the penalty in the proposed rule. We also proposed that an uncovered month is any month in which an individual does not have creditable coverage at any time during that month. We also reference the calculation of the amount of the penalty, which was described at § 423.286(d)(3) of the proposed rule. The final rule adopts the rules for late enrollment penalties as proposed.

Comment: Several commenters requested that we waive the late enrollment penalty for certain individuals, such as full-benefit dual eligible individuals, subsidy eligible individuals, individuals who are eligible for a special enrollment period and individuals who are involuntarily disenrolled. One commenter asked that State Medicaid programs be allowed to request and obtain such a waiver. Other commenters urged CMS to delay the implementation of the late enrollment penalty for one to two years, or be flexible with the application of the penalty, stating the Part D program was new and complex. Another commenter asked if we would provide any exception to the penalties for exceptional circumstances, such as natural disaster, family death, or clinical justification. A few commenters did not see a late penalty appeals process in the regulation and requested that we add an opportunity to appeal the late penalty.

Response: There is nothing in the statute that would provide us with the authority to waive or delay the late enrollment penalty at any time unless an individual was not adequately informed that his or her prescription drug coverage as described at § 423.56 was not creditable. Only in this limited situation will we be able to deem the individual's prescription drug coverage as creditable, regardless of whether it actually is creditable, so as not to impose the late penalty. Further, it is clear that the statute intended this provision to apply to full-benefit dual eligible individuals since the application of the penalty is specifically referenced in the definition of the full premium subsidy under section 1860D–14(a)(1)(A) of the Act, for which full-benefit dual eligible individuals are eligible. Specifically, section 1860D–14(a)(1)(A) of the Act provides that full subsidy eligible individuals, including full-benefit dual eligible individuals, are responsible for 20 percent of any late enrollment penalty for the first 60 months during which such penalty is imposed. As discussed in the proposed rule, we will develop a process for individuals to apply to CMS for reconsideration of the penalty. We appreciated the feedback that organizations provided on setting up such a process.

Comment: Several commenters asked CMS to clarify that those who do not receive a notice that their prescription drug coverage was not creditable (or received the wrong notice) are not subject to the late enrollment penalty.

Response: As provided in § 423.56(g) of the final rule, an individual who is not adequately informed that his or her prescription drug coverage was not creditable may apply for our review and make a determination if this occurred. If we determine that the individual did not receive adequate notice or received incorrect information, we may deem the individual to have had creditable coverage so that the late enrollment penalty will not be imposed.

Comment: One commenter asked CMS to clarify how the 63-day period would be counted. The commenter recommended from the end of the IEP to the date of the application for the low-income subsidy since individuals may delay a decision until he or she knows whether there will be a subsidy.

Response: The count of the 63-day period will commence the day following the end of the individual's IEP or, once the IEP has passed, the day following the last day of creditable coverage or Part D enrollment (in a PDP or MA-PD plan). The application of the 63-day period will be consistently applied to all individuals, regardless of when an individual may or may not apply for the low-income subsidy.

Comment: One commenter asked how the late enrollment penalty will be coordinated with the late enrollment penalty for Part B.

Response: We are currently developing operational and system requirements to implement the late enrollment penalty process. Additional guidance will be provided to PDPs and individuals with specific information as to how this will occur.

9. Part D Information That CMS Provides to Beneficiaries (§ 423.48)

As provided under section 1860D–1(c)(1) of the Act, we will conduct activities designed to broadly disseminate information about Part D coverage to individuals who are either eligible or prospectively eligible for Part

D benefits. In the proposed rule, we indicated that this information will be made available to beneficiaries at least 30 days prior to their initial enrollment period.

Each organization offering a PDP or MA-PD plan must provide us annually with the information to disseminate to individuals who are currently or prospectively eligible for Part D benefits. The information dissemination activities for Part D will be similar to, and coordinated with, the information dissemination activities that we currently perform for Medicare beneficiaries under sections 1851(d) and 1804 of the Act.

As required under section 1860D–1(c)(3) of the Act, we proposed to include the following comparative information for qualified prescription drug coverage provided by PDPs and MA-PD plans as part of our dissemination of Part D information and our efforts to promote informed beneficiary decisions:

- Benefits and prescription drug formularies;
- Monthly beneficiary premium;
- Quality and performance;
- Beneficiary cost-sharing; and
- Results of consumer satisfaction surveys.

We also proposed to provide information to beneficiaries regarding the methodology we will use for determining late enrollment penalties, as provided in § 423.286(d) of our proposed rule.

In carrying out the annual dissemination of Part D information, we will conduct a significant public information campaign to educate beneficiaries about the new Medicare drug benefit and to ensure the broad dissemination of accurate and timely information. We will work with SSA and the States to ensure that low-income individuals eligible for or currently enrolled in Part D benefits are aware of the additional benefits available to them and how to receive those benefits. In order to maximize the enrollment of Part D eligible individuals, this public information campaign would include outreach, information, mailings, and enrollment assistance with and through appropriate State and Federal agencies, including SHIPs, and will coordinate with other Federal programs providing assistance to low-income individuals. In addition, we will undertake special outreach efforts to disadvantaged and hard-to-reach populations, including targeted efforts among historically underserved populations, and coordinate with a broad array of public, voluntary, private community organizations, plan sponsors and stakeholders serving Medicare beneficiaries to explain the options available under this program. Materials and information will be made available in languages other than English where appropriate.

This information will enable beneficiaries to make informed decisions regarding their Part D coverage options. Organizations offering a PDP or MA-PD plan will be required to provide this information in a format and to use standard terminology that we will specify in further operational guidance.

In the interest of broadly disseminating information that promotes informed decision-making among Part D enrollees and prospective Part D enrollees, as required under Section 1860D–1(c) of the Act, we would extend the price comparison requirements to PDP sponsors and MA organizations offering MA-PD plans and making comparative information about Part D plans' negotiated prices available to beneficiaries through *www.medicare.gov*.

Since the introduction of *www.medicare.gov* in 1998, we have substantially increased the amount of personalized information available to Medicare beneficiaries, making it one of the government's most comprehensive and customer-oriented sites available to the public. The web site hosts twelve separate database applications to help individuals make their own health care decisions. The most significant ones are: the Medicare Personal Plan Finder (which contains costs, benefits, quality, satisfaction and disenrollment measures), Nursing Home Compare (which contains basic characteristics, staffing information and inspection results), the Prescription Drug and Other Assistance Programs application (which contains the most extensive, nationally complete listing of the Medicare-approved discount drug cards, including price comparisons, as well as other government and private programs designed to help with prescription drug costs), and the Medicare Eligibility Tool (which assists users in determining when they are eligible, how to enroll and what they need to consider when joining Medicare). Other tools providing customized results include: the Participating Physician and Supplier Directories, Home Health and Dialysis Facility Compare, Your Medicare Coverage, Helpful Contacts, Publications, and Frequently Asked Questions. By updating all information on the web site at least once a month, the information provided to Medicare beneficiaries via *www.medicare.gov* is the most reliable and consistent information available.

Much of the information available through *www.medicare.gov* is also available via the 1–800–MEDICARE helpline. 1–800–MEDICARE is a major information channel for providing the most personalized and reliable information to people with Medicare. The beneficiary can call 1–800–MEDICARE to find out the most reliable information on public and private programs that offer discounted or free medication, programs that provide help with other health care costs, and Medicare health plans that include prescription drug coverage. The caller can always talk to a live person at 1–800–MEDICARE to get the facts they need. We can also give the beneficiary personalized brochures containing information on their health plan choices, nursing homes and Medicare participating physicians in their area. 1–800–MEDICARE is available 24 hours a day, 7 days a week, to provide the one-on-one service that our Medicare beneficiaries need to make appropriate health care decisions.

The final rule adopts the information requirements set forth in the proposed rule.

Comment: Several commenters were concerned that the web site should reflect accurate information that is presented in an appropriate context and in a way that is useful for beneficiaries to use. Many commenters noted that the web site should provide beneficiaries with the ability to compare plans on the basis of estimating their out-of-pocket spending, including premiums and applicable cost sharing. Several commenters encouraged CMS to rely not only on price as the factor in determining which Part D plan fits beneficiary needs. Another commenter urged CMS to include specific information regarding which drugs are covered by each plan. Other commenters indicated that other information that the beneficiaries would need to consider would be the level of coinsurance, the amount a beneficiary would pay during any period he or she is liable for 100 percent of the cost sharing, whether the drug is on or off the formulary, and other cost management techniques that may apply, such as step therapy and prior authorization. Another commenter stated that we must post prices on its website of retail pharmacies that offer maintenance supplies of medications. One commenter stated that beneficiaries need to know whether the pharmacy is included in the plan's network.

Response: We appreciate this feedback and will consider this when

developing the requirements for the Part D price comparison web tool.

Comment: Another commenter stated that we need to ensure that any website includes price comparisons about generic drugs compared to their innovator brands, as well as generics compared to other brand name drugs in a similar therapeutic class.

Response: This comment will be considered when developing the requirements for the Part D price comparison web tool. As with the current price comparison tool for the Medicare-approved drug discount card program, we include pricing information for both brand and generic drugs.

Comment: One commenter noted that correct information may not be provided to seniors if we require plans to post the maximum price that could be charged, since the maximum price is typically the pharmacy's usual and customary cash price.

Response: It is our understanding that usual and customary pricing data is not readily accessible; therefore, we anticipate posting the maximum negotiated prices for prescription drugs on the website with the understanding that beneficiaries will pay the lower of the negotiated or usual and customary price at the point of sale. It is anticipated that the prices displayed on the website would reflect what enrollees would expect to pay at the point of sale for their prescriptions under the respective plans.

Comment: One commenter asked that we define the process for the information sharing exchange between PDPs and CMS.

Response: The process has not been defined at this time. Once we have developed the data requirements and process for submission of data, we will share this information with all prospective Part D plans.

Comment: Several commenters believe that the price comparison tool should not be a requirement for PDP sponsors or MA organizations offering MA-PD plans.

Response: It is important for beneficiaries to have access to all information in order to make informed choices. We are committed to providing Medicare beneficiaries with information about both PDPs and MA-PD plans through the price comparison tool. Therefore, we will keep this requirement.

Comment: One commenter expressed a general concern with the disclosure of negotiated prices and the negative impact that disclosure of such information could have on competition. The commenter further noted that negotiated prices may be subject to confidentiality agreements. The commenter suggested that we disclose only estimated or average prices and that this information only be posted on the specific website of the Part D plan.

Response: As mentioned previously, it is anticipated that the prices displayed on the website will reflect what enrollees would expect to pay at the point of sale for their prescriptions under the respective plans.

Comment: A commenter stated it was unacceptable for CMS not to provide quality and performance information in the first year or second year of the Part D program.

Response: Quality data will not be available for the first year since this is a new program and historical data will not be available for reporting. For year two, the regulation simply states that if it is impractical to obtain data or if it is not available, it will not be reported; this is not the same as stating that it will not be available for the second plan year. From the perspective of many beneficiaries, cost and availability are the most important quality issues. Hence, we will be able to report timely in response to these issues.

Comment: One commenter urged the agency to work closely with pharmacies to ensure that any price comparison website is understandable and free of errors before it is made public.

Response: Historically, we have worked closely with beneficiaries, stakeholders, partners, and advocacy groups to ensure the information disseminated meets the needs of the Medicare population we serve. We will continue this practice in the development of the website for Part D plan information.

Comment: One commenter stated that we are silent on the notification timeframe for beneficiaries. CMS simply refers to the 30-day notice period. The commenter thinks that beneficiaries will need much more than 30 days to digest all of the information they will receive from CMS to enable them to make informed choices about their Part D coverage. The commenter urges information to be disseminated as soon as possible and urges CMS to plan numerous information campaigns now and involve numerous organizations in developing education activities and materials. Another commenter suggests dissemination activities occur at least 60 days prior to the initial enrollment period for Part D, which begins November 15, 2005.

Response: We are planning outreach and education activities that will occur throughout 2005 and 2006. Detailed information about drug plans and their individual benefit structures will be released as soon as possible after this information is approved. It is impossible to send out plan data any sooner due to submission dates for plan information and the process steps needed to translate the raw data into consumer-friendly information, as well as the print production steps for the publication that will house this comparative information.

Comment: One commenter asked what information we will provide to SSA, SHIPs, and other groups to educate beneficiaries about the late enrollment penalty.

Response: We will provide important details about the penalty associated with late enrollment in the information provided to SSA and SHIPs, as well as in SHIP training materials. In addition, we will develop materials that can be used by employers, unions, partners, advocacy groups and other stakeholders to educate beneficiaries about the late enrollment penalty.

Comment: One commenter stated that we must give greater attention to developing materials and education campaigns focused on informing beneficiaries, especially those with special needs, about the new drug benefit and to help them to enroll in the best plan available.

Response: We are planning a multi-tiered education program to repeatedly reach all beneficiaries. This program will include plans for specific important target audiences, including those with special needs. Mailings and outreach activities to dual eligibles are currently being planned. Education and outreach materials developed for beneficiaries will be thoroughly tested with the target audience.

Comment: Another commenter stated that we should mail, no later than October 15, 2005, standardized, easy-to-understand notices to full-benefit dual eligible individuals that, among other things: inform them of their eligibility to receive the low-income subsidy if they enroll in a PDP; list of choices of health plans, clearly denoting those that meet the benefit premium assistance limit, and contact information for each plan; explain that full-benefit dual eligible individuals will be randomly enrolled in a prescription drug plan at a specified date if they fail to opt out or enroll in a plan themselves; explain how they may change their drug plans if they wish at any time; and inform them of where in their community they can go to get help with enrollment. The commenter also recommended that these notices should be tested for readability by focus groups and experts.

Response: We plan to consumer test beneficiary notices and send out the information noted by the commenter above by October 15, 2005. We are considering using the mailing to inform the full-benefit dual eligible individuals about what plan they will be auto-enrolled in if they fail to elect a Part D plan by December 31, 2005 or affirmatively opt of Part D, and that they have a right to choose to enroll in a different plan.

Comment: One commenter stated that the website should be provided in languages other than English to reflect the language spoken in a PDP service area.

Response: We appreciate this feedback and will consider this when developing the requirements for the website.

Comment: CMS should include in the final rule binding and enforceable standards defining information plans must provide to beneficiaries with various types of disabilities. For example, this information must be available to individuals who are blind or have low-vision. Further, CMS must require PDP internet websites to be accessible for individuals with vision impairments.

Response: Our websites are accessible to people with various disabilities, including those who are blind or have low-vision. Under our marketing requirements in § 423.50, we require Part D plans to demonstrate that marketing resources are allocated to marketing to the vulnerable populations, as well as beneficiaries age 65 and over. It is also important to note that Section 508 of the Rehabilitation Act of 1973 allows individuals with disabilities to access electronic information.

Comment: Commenters stated that the proposed rule focused largely on support through Internet sources and the 1–800 Medicare number, and argued that both are necessary and helpful but insufficient to meet the needs of many duals, as well as those eligible for the low-income subsidy.

Response: Although the basis for information dissemination is through publications, *www.medicare.gov* and 1–800–MEDICARE, we do not plan to solely rely on these resources to reach the population as a whole. We will work closely with SSA, SHIPs, Area Associations on Aging as well as other national stakeholders and partners, to provide assistance to those who may qualify for the low-income subsidy. Through a broad network of support from community based organizations, we will make considerable efforts to reach those beneficiaries who do not have access to the Internet or are uncomfortable calling 1–800–MEDICARE.

Comment: CMS should also make detailed information about PDPs available electronically to others in accessible formats that would enable them to conduct independent analyses about what plan would be best for a particular individual.

Response: Because the actual plan data underlying the price comparison tool is considered proprietary, we do not anticipate making the underlying data available electronically to outside organizations. Since nothing in the MMA addresses disclosure of plan data, the Freedom of Information Act (FOIA) rules apply. FOIA Exemption 4 protects certain confidential commercial information that is submitted to a Federal agency. Determinations about the applicability of FOIA Exemption 4 to plans' pricing data would be made on a case-by-case basis depending on whether the submitter of the data could demonstrate that disclosure of this information would likely cause substantial competitive harm to the submitter's competitive position. If FOIA Exemption 4 is found to protect submitted price information, we cannot disclose this information because to do so would violate the Trade Secrets Act (18 U.S.C. 1905).

Comment: Several commenters stated that we should develop specific outreach and education strategies for vulnerable populations, including disabled Medicare beneficiaries and dual eligibles. Another commenter stated that PDPs should be required to include specific plans for encouraging enrollment of hard-to-reach populations, including individuals with mental illness. Another commenter indicated that outreach efforts must involve community-based groups on a collaborative basis and not just use these groups as conduits for distributing written materials produced by CMS regarding the new benefit. Resources must be provided to enable these groups to educate beneficiaries about their choices and help enroll them. This collaboration with community groups must begin as soon as possible to establish the infrastructure needed once Part D goes into effect.

Response: We are developing an extensive outreach campaign for these individuals and are working closely with U.S. Department of Health and Human Services' Office of Disability to ensure that this important audience is reached.

Comment: One commenter strongly urged CMS to develop a specific plan for facilitating enrollment of beneficiaries with disabilities that incorporates collaborative partnerships with State and local agencies and disability advocacy organizations.

Response: In addition to working closely with the HHS Office of Disability to ensure we reach this group of individuals, we plan to broaden local partner networks though the Regional Education About Choices in Health (REACH) campaign to provide training, information and planning support to provide outreach and assistance to these populations. REACH is a national education and publicity campaign implemented at the local level by our Regional Offices and their partners. The REACH campaign works through partnerships to increase awareness of the Medicare program and resources among hard to reach populations.

Comment: A commenter suggested that we should develop and implement effective outreach strategies utilizing the Medicare Beneficiary Ombudsman authorized under section 923 of the MMA.

Response: Section 923 of the MMA states that, to the extent possible, the Ombudsman shall work with SHIPs to facilitate the provision of information to individuals entitled to benefits under Part A or enrolled under Part B, or both regarding MA plans and changes to those plans. We will ensure that SHIPs receive sufficient training in all aforementioned subjects so that SHIPs can provide information and assistance to beneficiaries referred to them by the Ombudsman. The Ombudsman operational design assumes that 1–800–MEDICARE will refer callers to appropriate sources, including SHIPs, for resolution of complaints and appeals and, when necessary, refer them directly to the Ombudsman as a last resort.

Comment: We received two comments that strongly recommended that we clarify the SHIPs mandate to ensure that they address the needs of individuals with disabilities, including non-elderly individuals.

Response: Section 4360 of the Omnibus Budget Reconciliation Act (OBRA) 1990, which created SHIP, requires that SHIPs provide information, counseling and assistance to Medicare eligible beneficiaries, including beneficiaries with disabilities. All CMS SHIP grant announcements expressly reference beneficiaries with disabilities as intended recipients of SHIP services. In addition, we provide training and information on the special needs and issues related to this population. We agree with the commenters and will clarify the SHIP mandate through the methods described here to address this need.

Comment: One commenter suggested that we partner with and fund community-based disability organizations to conduct outreach, information, and referral activities on the new Part D benefit.

Response: While we agree to partner with these organizations in these activities, funding these groups are subject to available funds in our budget.

Comment: One commenter was concerned about beneficiaries being inundated with marketing and outreach materials. Since many beneficiaries will need counseling on plan selection, this commenter asked for clarification regarding whether counseling will be available, what the States' role will be, and whether there will be Federal financial participation available for such costs.

Response: States that had SPAPs on October 1, 2003 will have Federal assistance available to them through the transitional grant program authorized under section 1860D–23(d) of the Act. These States will use the transitional grant funds to educate SPAP enrollees about the plans that are available to them under part D, as well as provide technical assistance, phone support, counseling, and other activities the SPAP believes will promote the effective coordination of enrollment in Part D. States that do not have a SPAP operational as of October 1, 2003 will not have these transitional funds available to them.

In addition, we will continue to provide grants to the States through the SHIP. SHIP is a national program that offers one-on-one counseling and assistance to people with Medicare and their families. Through grants directed to States, SHIPs provide free counseling and assistance via telephone and face-to-face interactive sessions, public education presentations and programs, and media activities. We expect SHIP counseling to be an important source of information for beneficiaries about Part D.

Comment: One commenter was concerned that the targeted and hands-on outreach, education and decision support and enrollment services, particularly outreach to lower income, rural and disabled beneficiaries is not adequate.

Response: Through the REACH campaign, we plan to broaden local partner networks in order to provide training, information and planning support to provide outreach and assistance to these populations. Through a broad network of support from community-based organizations as well as national stakeholders and partners, considerable effort will be made to reach those beneficiaries who do not have access to the Internet or who are uncomfortable calling 1–800–MEDICARE.

Comment: One commenter stated that we should consider preparing educational materials that would help pharmacists understand the benefits and other material that they can use to educate beneficiaries.

Response: We are working with our provider education staff to develop materials for all providers, including pharmacists, for educational use.

10. Approval of Marketing Materials and Enrollment Forms (§ 423.50)

Section 1860D–1(b)(1)(B)(vi) of the Act directs us to use rules similar to those established under section 1851 of the Act to review PDPs' marketing materials and application forms.

In the proposed rule, we generally replicated the marketing provisions established under § 422.80 for MA plans as appropriate for PDPs. Therefore, we proposed at § 423.50(a) guidance for our review of marketing materials, definition of marketing materials, deemed approval, and standards for PDP marketing. We do recognize that the differences between PDPs and MA plans will require different marketing requirements and we requested comments on this issue. We have drafted the final rule to apply the marketing requirements to all Part D sponsors, although we may waive the Part D provisions in deference to similar MA, PACE and cost plan requirements.

We also proposed to add § 423.50(a)(3) in order to streamline the marketing review process for all PDP sponsors for those materials which pose the lowest risk of confusing or misleading beneficiaries. This aspect of the File and Use program allows the PDP sponsor, prior to distribution, to submit and certify that for certain types of marketing materials it followed all applicable marketing guidelines, or for certain other marketing materials that it used, without modification, proposed model language as specified by CMS.

Except as otherwise provided below, the final rule adopts the marketing rules set forth in § 423.50 of the proposed rule. Although the following area generally applies to Fallback plans, subpart Q specifically addresses issues related Fallback plans.

In addition to marketing materials and enrollment forms, comments provided the opportunity to respond to enrollment issues related to SPAPs, pharmacist and physician marketing to beneficiaries, and organizations marketing additional products in conjunction with PDP services.

Comment: We received several comments on types and quantity of information that should be disseminated to beneficiaries. Many commenters suggested that specific formulary information needs to be provided including specific drugs (top 25–50), pricing and premium information, benefit structure, pharmacy networks, plan availability by region, medication management services offered (and who is eligible for them), appeals and exception process and information on plan performance. Most agreed that this information should be mailed, as well as provided on the Internet and that comparison tables with this information for all plans in a geographic region should be provided so that beneficiaries can compare plans side-by-side. One commenter was concerned that beneficiaries would be overwhelmed with materials and expressed concern about the potential for adverse selection. It was suggested that strict and detailed regulations on marketing be issued to protect beneficiaries. One commenter suggested that we need more detail in the final rule around patient education.

Response: We agree with the commenters that beneficiaries will need information on the Part D plans available in their areas. Our goals in providing information has always been to ensure that beneficiaries have access to timely, accurate and reliable information that helps them make informed health care decisions. Our education and outreach efforts related to Part D are no exception. We will employ multiple tactics, including publications, direct mailings, the Internet (*www.medicare.gov*), toll-free telephone numbers, and localized grassroots partnerships to help beneficiaries access the level of detailed information that they want and need to make their best choice among Part D plans. Our tiered communications approach recognizes that different beneficiaries have varying information needs and what might be an overwhelming level of detail to some individuals may only meet the baseline needs of another. By using multiple, integrated education and outreach approaches and thoroughly market testing our products and messages during development, we are working to strike the best balance of providing the right information at the right time. In addition, we are committed to making sure plans provide clear, accurate information on covered benefits, including formulary, pharmacy networks, and costs. We intend to require such information in guidance rather than specifying the full range of materials in the regulations so that we

can modify our requirements in a timely manner to meet beneficiary needs.

Comment: We received several comments regarding the use of various marketing vehicles to promote PDPs. Several of the commenters supported the distribution of information through websites, 800 numbers, written communications and telemarketing. One commenter stated that marketing should be limited to mail contacts only due to concerns regarding fraud. One commenter stated that the restrictions on marketing need to be expanded due to the potential for fraud. Many commenters opposed telemarketing and one was explicitly against email as well.

Response: Section § 1860(D)(1)(b) of the Act allows for similar marketing rules for the drug benefit as those for MA. We intend to follow this guidance and promote marketing guidelines that are in line with those under the MA program. The MA program supports the use of websites, 800 numbers, mailings, email and telemarketing for plan marketing. By allowing plans multiple routes for marketing, we believe that greater numbers of beneficiaries will be reached and thus enrolled in drug benefit plans. We believe this is an important goal given the penalty for late enrollment in Part D. We understand that this is contrary to what we allowed in the drug discount programs. We did not allow the drug discount card programs to participate in telemarketing practices because many of the drug card sponsors were stand alone start-up companies that did not have a previous history of doing business. We expect that the PDP sponsors will have previous experience administering drug plans, insurance or other lines of similar business, with established reputations, much like MA plans.

Marketing guidelines are in the process of being established, and these will set forth in greater detail what will be expected of the plans. PDP sponsors may be barred from engaging in certain practices if abuses occur. In addition, PDPs will be prohibited from requesting beneficiary identification numbers over the telephone or via email as related to marketing activities.

Comment: One commenter stated that the States should be able to steer its SPAP enrollees toward the most appropriate plan.

Response: Section 1860D–23(b)(2) of the Act defines an SPAP as a State program which, in determining eligibility and the amount of assistance to a Part D eligible individual under the program, provides assistance to such individuals in all Part D plans and does not discriminate based upon the Part D plan in which the individual is enrolled. We further interpreted that provision in the preamble of the proposed regulation such that a SPAP may not designate a preferred PDP, even if the State allows beneficiaries to choose a non-preferred plan and provides for benefits equivalent to that which it also provides for the preferred plan (referred to as wrap-around benefits). We believe that, regardless of whether the SPAP is authorized under State law to make enrollment decisions on behalf of the beneficiary, we interpret using that authority to steer beneficiaries to a preferred PDP or MA-PD plan would be interpreted to violate the non-discrimination provision under section 1860D–23(b)(2) of the Act.

Section 1860D–23(d) of the Act provides for grants to SPAPs, in existence as of October 1, 2003, which were awarded in September of 2004 for fiscal year 2005, for the purpose of educating their members about options to access Medicare drug benefit coverage and about comparing options so they can choose the best value to them. We will reach out to SPAPs with information to help people with Medicare understand their drug plan options. We will also assist SPAPs in adapting this information to ensure that their members understand the way that the new Part D plans coordinate with their SPAP benefit and supporting their members in making informed decisions about drug benefit plan options. Outreach to SPAPs would also include instruction on the educational/outreach/assistance activities SPAPs could pursue while not discriminating against Part D plans.

SPAPs cannot discriminate amongst plans; however, they may provide beneficiaries with comparable education on all of the available Part D plans (PDPs, MA-PD plans, and PACE and cost-based HMO or CMPs offering qualified prescription drug coverage) in terms of the following: which plans have lower premiums after application of any uniform SPAP premium subsidy; which plans offer formularies that cover the drugs utilized by the beneficiaries so that beneficiaries can continue to use the same drugs; which plans offer the drugs used by the beneficiary at the most favorable combination of deductibles, coinsurance/co-pays, and negotiated prices; which plans use the same network pharmacies as the SPAP so that beneficiaries can continue to use the same pharmacy; and which plans (if any) have ID cards that include an emblem or symbol indicating its coordination with the SPAP to facilitate secondary payment at the point of service.

In addition, SPAPs are prohibited from recommending Part D plans based on their financial interest in minimizing their cost of providing coverage that supplements (wraps-around) their members Part D benefits. They are required to mirror our process auto-enrolling full-benefit dual eligible individuals among PDPs on a random basis in the event that members do not actively select a Part D plan during their IEP or after enroll in the SPAP.

Part D plans benefit coordination requirements include establishing procedures to share information with SPAPs on enrollment files, the processing and payment of claims, claims reconciliation reports and whether the beneficiary has satisfied the out-of-pocked limit. Part D plans are encouraged to work with all SPAPs to co-brand the Part D benefits by providing (in its electronic claim response to the pharmacy) information on payment of premiums and coverage, and whether claims should be sent to an SPAP for processing. Plans should also consider including the SPAPs' benefits in marketing and educational materials to beneficiaries, which includes SPAP benefit information, eligibility criteria, order of party payment, and a phone number for SPAP enrollment and claims payment information.

Comment: Two commenters were concerned that SPAP beneficiaries will be confused by materials and decline enrollment if premiums, deductibles and coverage gaps are discussed since SPAP participants were never required to pay these amounts. It was also stated that marketing materials for this population should include coordination of benefit (COB) information.

Response: We expect that SPAPS will provide information to beneficiaries on their drug plan choices in their States. We expect that plans will work cooperatively with SPAPs to co-brand materials, when appropriate, to ensure that beneficiaries are provided with comprehensive, appropriate, coordinated information that will facilitate education and understanding of their benefits. Requirements for coordination of benefits with other providers of prescription drug coverage are described under § 423.464 (e). We expect Part D plans to work with SPAPs on coordination of benefit activities to ensure that beneficiaries are provided seamless care that is easily understandable.

Comment: We received multiple comments regarding the specific requirements for marketing materials. Many commenters agreed that marketing materials should be available in Spanish and in other languages that

are in the plan's service area. Two commenters stated that marketing materials should be developed at an appropriate health literacy level. Two commenters stated that the information will need to be adapted for the blind/low vision, those with cognitive disabilities, in Braille, large print and on audio or computer disks. It was also stated that there should be a requirement that the Internet site be accessible for the visually impaired and that interpreters and alternative communication methods should be mandated. Another commenter stated that a subpart should be devoted to notice requirements.

Response: We agree that there are special needs of beneficiaries that will need to be provided for. The regulation currently dictates that marketing materials need to be available in low-literacy formats. While we do not require materials to be available in other languages, it is highly encouraged. In addition, basic enrollee information should be developed to accommodate the visually impaired. Call centers must be able to accommodate non-English speaking/reading beneficiaries. Plan sponsors should have appropriate individuals or translation services available to call center personnel to answer questions that beneficiaries may have concerning aspects of the drug benefit. We are working on developing guidance shortly following publication of the final rule that is similar to the MA requirements to ensure appropriate information is available to beneficiaries.

Comment: Several commenters stated that marketing materials should be consistent with other Medicare programs.

Response: We are currently developing additional marketing guidelines and expect them to be similar to other Medicare programs (for example, the MA and the Medicare-approved prescription drug discount card programs), to the extent possible, in order to reduce the administrative burden for plans that participate in these programs.

Comment: We received many conflicting comments regarding whether providers (pharmacists and physicians) should be allowed to market to beneficiaries. This includes the display of materials from Part D sponsors as well as verbally steering beneficiaries to particular plans. Several commenters were in support of pharmacies marketing MA/PD and PDPs; some of these commenters stated that equal attention should be provided to all plans in the particular area. In addition, some commenters specifically mentioned that they were in support of physicians marketing Part D plans.

Other commenters were against marketing of Part D plans in the pharmacy setting; three specifically mentioned the prohibition of physicians from marketing to beneficiaries. Most stated that the reasons for their positions were that physicians or pharmacists could steer a beneficiary to inappropriate Part D plans.

Response: Both the MA and the Medicare-approved prescription drug discount card programs allow some provider marketing to occur. Our position is that it is appropriate to allow providers and pharmacies to market to beneficiaries. This marketing provides beneficiaries with access to information about the options available to them under Part D that they may not have received through other sources because beneficiaries often look to their health care professionals to provide them with complete information regarding their health care choices. Therefore, we believe that providers and pharmacies should provide prospective enrollees with information on the full range of options available to them under Part D. This process is similar to the process followed for the discount drug card program, where pharmacies may provide information on where beneficiaries may get complete information regarding all the Medicare-approved discount cards available in the region in their service area. We would require Part D sponsors that want their network pharmacies to provide marketing materials to prospective enrollees to include in their contracts language requiring the pharmacies Part D eligible individuals with information on all Part D options available in the service area. This requirement would be specified in the further guidance issued by CMS. Any remuneration offered to providers in exchange for providing to patients information about particular Part D plans must comply with applicable Federal and State laws on fraud and abuse.

Comment: Two commenters stated that Part D sponsors should be prohibited from using Medicare discount card enrollee and applicant information to provide leads for marketing their Part D plans.

Response: We acknowledge the importance of beneficiary privacy, and the marketing limitations that drug cards operate in accordance with section 1860D–31(h)(7) of the Act. The drug card provisions under section 1860D–31 of the Act contemplate a transition from the drug card program to Part D, and we are considering what will be the specific drug card responsibilities of drug card sponsors during transition. From that understanding we will assess whether PDP sponsors currently offering a drug card may use of beneficiary drug card information to market their Part D plans and we will provide further guidance to the drug card sponsors and Part D sponsors at a later time. We note, however, that the HIPAA Privacy Rules may limit the ability of drug card sponsors to disclose their enrollees' information to un-affiliated Part D sponsors.

Comment: One commenter suggested that the File & Use program should be delayed one year until we have more experience with evaluating the practice of the PDPs, and that the term ''performance requirements'' needs to be defined.

Response: We will define the eligibility and performance requirements associated with the File & Use program in further guidance.

Comment: There was concern over the amount of time that was stated was necessary for a review of PDP and MA-PD marketing materials. Some suggestions included decreasing the time of this review from 45 days to 30 days, and instituting a 10-day review period for resubmitted materials. In addition, if unaltered model materials were used, the review should be limited to 10 days.

Response: We agree that that timelines for reviewing marketing materials should be shortened. However, we intend on maintaining the proposed timelines for Part D marketing materials as defined in the statute. We will work to develop a review process that is as efficient as possible. We will develop a range of model materials for Part D sponsors.

Comment: We also received a comment that the amount of materials that must be individually approved should be limited. There was also concern that we may not have enough staff to review the materials and that the process needs to be open, fair and constructive.

Response: We will develop a range of model materials for Part D sponsors to choose from to improve efficiency of the marketing review process. Materials that utilize ''model language'', without modification, are subject to a streamlined review process. We will work to develop a review process that is as efficient and effective as possible utilizing standardized criteria to review the materials.

Comment: Two commenters stated that it is unacceptable that marketing materials are deemed approved if we fail to approve them within the time

period and materials should be reviewed multiple times for multiple regions.

Response: It is a statutory requirement that we approve marketing materials within 45 days or that they are then deemed approved. In developing sub regulatory marketing guidance and processes, we will work to ensure that our reviews are completed within the statutory timeframe.

Comment: Commenters stated that guidelines for CMS review under § 423.5(c)(i),(ii), and (iii) of the proposed rule need to be more specific. These sections lay out the information that Part D plans need to provide to beneficiaries.

Response: We will provide greater detail in the sub regulatory guidance in order to facilitate any necessary future changes that would need to be made.

Comment: Many commenters gave input as to whether additional products, such as financial services, should be marketed to Medicare beneficiaries in conjunction with the Part D benefit. Several of the organizations expressed their concerns over the fact that beneficiaries may be confused with receiving additional information for other products and services in conjunction with information about the Part D benefit. The major concern is that beneficiaries would choose not to participate in Part D because they did not like some of the other products or that they may mistakenly believe that we have approved these products. One commenter suggested that individuals must actively agree to receive marketing materials other than enrollment materials. Some commenters suggested that financial institutions should not be encouraged to participate as PDPs, since the potential for abuse, as in selection of healthier beneficiaries into plans and avoidance of financial services to less healthy individuals, is enormous.

Some health plans commented that they are in favor of allowing PDP sponsors to market additional health-related and non-health-related products to beneficiaries. These products could be provided for an additional fee or at no additional cost to the beneficiary. The belief is that the additional tools could help beneficiaries manage their expenses and financial securities. One organization also stated that if PDP sponsors are permitted to provide these additional products, than MA-PD plans should be allowed to similarly provide these additional products.

Response: We do not want to restrict beneficiaries from receiving materials about of health-related and non-health-related services that may be of benefit to them in managing their health or payments for health care. All organizations that are qualified to be a Part D sponsor are encouraged to participate in providing services under Part D. In situations where plans want to use or disclose protected health information (PHI), for purposes of marketing these other products or services, for example beneficiary enrollment information, Part D plans must comply with the HIPAA Privacy Rule and obtain a written authorization from the beneficiary prior to using the beneficiary's PHI to market non-health-related products and services. In other cases where Part D plans implement general marketing mailings that do not use beneficiary PHI, we would not object to plans providing such information to beneficiaries as long as the information is not contingent upon PHI to do so. For example, a plan may obtain a general mailing list from a non-related marketing vendor to mail materials to all individuals over age 65 in a geographic area to promote its products. The use of beneficiary names and addresses obtained from a plan and used for mailings to beneficiaries only, would presumably use PHI. Consequently, plans could not market non-health-related products through mailings using beneficiary information absent authorization.

Comment: One commenter recommended that any Part D sponsor offering other health coverage to its Part D plan enrollees be required to provide anti-duplication notices like those that are required under the National Association of Insurance Commissioners (NAIC) model regulation for Medigap policies. The purpose of these anti-duplication notices is to advise Medicare beneficiaries as to whether other non-Medigap types of coverage being offered to them might duplicate coverage they already have under Medicare.

Response: The disclosure statements that are required under the NAIC model regulation for Medigap policies were adopted by the NAIC pursuant to anti-duplication provisions contained in section 171(d) of the Social Security Act Amendments of 1994 (SSAA'94–Pub. L. 103–432) that amended section 1882(d)(3)(A) of the Act. These statements apply to all issuers of health insurance coverage that is offered to Medicare beneficiaries that is neither a Medigap policy nor a type of coverage that is listed as exempt from this requirement in a **Federal Register** notice that CMS [then HCFA] published on June 12, 1995. Section 171(d) required CMS to either publish the disclosure statements developed by the NAIC or publish its own. The FR notice through which CMS accepted the 10 separate disclosure statements developed by the NAIC for the various types of coverage commonly offered to Medicare beneficiaries contained a list of types of policies not requiring disclosure statements (See 60 FR 30880).

Among the types of coverage not requiring the use of a disclosure statement were managed care organizations with Medicare contracts under section 1876 of the Act. The notice went on to explain that these types of policies are exempt because ''these plans do not 'duplicate' Medicare benefits; rather their purpose is to actually provide all covered Medicare benefits directly to enrolled beneficiaries.'' In 1995, cost and risk managed care organizations with contracts under section 1876 of the Act were the primary alternative to fee-for-service Medicare. Medicare+Choice plans were authorized by the Balanced Budget Act (BBA) in 1997, and the program has now been renamed Medicare Advantage by MMA. MMA also provided for private prescription drug plans (PDPs) to contract to deliver Medicare prescription drug benefits under Medicare Part D. Because Part D plans will actually provide all covered Medicare drug benefits directly to enrolled beneficiaries, we wish to clarify that these entities will not have to provide anti-duplication notices for their provision of coverage pursuant to their Medicare Part D contracts. However, if Part D plans choose to market to their enrollees other (non-Medigap) health insurance products that are not part of their contracts under Part D, these other types of health insurance products will have to bear the disclosure statements required by section 1882(d)(3)(A) (vi) of the Act and the NAIC model regulation unless the other coverage comes within one of the specified exemptions.

11. Information Provided to PDP sponsors and MA Organizations

Section 1860D–1(b)(4)(A) of the Act authorizes us to provide information about Part D eligible individuals to PDP sponsors and MA organizations to facilitate the marketing and enrollment of beneficiaries in their PDP and MA-PD plans. This information is intended to ensure participation in the Part D program, as well as to reduce costs to those plans.

In the final rule, it is not necessary to provide regulatory text implementing this provision; however, we intend to provide additional guidance shortly following publication of this rule, as explained below.

Comment: We received several comments on this MMA provision. Several of the commenters supported the provision of such information to organizations, with a few offering to work with CMS to develop guidance and ensure that the appropriate beneficiary protections are in place. Many who supported this initiative believed that, at a minimum, the name, address, and telephone number of the individual should be provided. Another commenter believed that the statute permits organizations to contact beneficiaries through written, electronic, or phone communication. Another commenter stated that the individual's dual eligible or low-income subsidy status should also be provided. The commenter also noted that we should provide the information to organizations upon request, as opposed to being limited to only receiving such information at certain times of the year. The commenter also believed that the statute would permit PDP sponsors to obtain marketing information on low-income and dual eligible individuals directly from States and SPAPs.

Several commenters also opposed such information being provided to organizations. One commenter believed that providing such information to Part D competitors would generate more problems and ''incite'' more negative beneficiary reaction that would outweigh any value in enhancing beneficiary outreach. Other commenters were concerned that such information would be used to ''cherry pick'' healthier and less expensive beneficiaries. Several commenters noted that if we were to provide such information to organizations, such information should be limited to the minimum amount necessary. They stated that certain information, such as health or financial information or telephone numbers should not be provided. Further, beneficiaries should be given the option to request that we not share their information with plans. Several commenters did not believe that PDPs or MA-PD plans should be able to use the information for telemarketing purposes. Another commenter indicated that we should only disclose information to the plan if the plan's marketing material contains formulary and drug pricing information and is accompanied by an application form.

Response: We decline to provide specifics on the provision of this information at this time but reserves the right to provide this information to plans in the future. We will develop further guidance on this issue shortly after publication of this rule.

12. Procedures to Determine and Document Creditable Status of Prescription Drug Coverage (§ 423.56)

Section 1860D–13(b)(6) of the Act identifies certain entities, which we describe in our proposed rule that must disclose whether the prescription drug coverage that they provide to their members who are Part D eligible is creditable prescription drug coverage.

Sections 1860D–13(b)(4) (A) through (G) of the Act lists seven forms of potential creditable prescription drug coverage: Coverage under a PDP or under an MA-PD plan; Medicaid; a group health plan (including coverage provided by a Federal or a nonfederal government plan and by a church plan for its employees); a State pharmaceutical assistance program; veterans' coverage of prescription drugs, prescription drug coverage under a Medigap policy; and military coverage (including Tricare). Many of these terms are defined elsewhere in Federal regulations; some of them are under the jurisdiction of other Federal agencies.

In addition to the forms of creditable coverage identified in sections 1860D–13(b)(4) (A)-(G) of the Act, section 1860D–13(b)(4)(H) of the Act provides the Secretary with the flexibility to identify ''other coverage'' that could be considered to be creditable prescription drug coverage. We proposed, at § 423.56, to expand the list of types of creditable prescription drug coverage.

As discussed in § 423.46 of the proposed rule, upon becoming eligible for Part D, beneficiaries must decide whether to enroll in Part D, or forego that opportunity and face a possible financial penalty should they later decide to enroll. Beneficiaries who decide not to enroll in Part D because they have creditable prescription drug coverage will not face such a penalty if they later decide to enroll in Part D.

According to section 1860D–13(b)(5) of the Act, an enrollee who would otherwise be subject to a late enrollment penalty may avoid the penalty if his or her previous coverage met the standards of ''creditable prescription drug coverage''. Under section 1860D–13(b)(5) of the Act, previous coverage will only meet those standards ''if the coverage is determined (in a manner specified by the Secretary) to provide coverage of the cost of prescription drugs the actuarial value of which (as defined by the Secretary) to the individual equals or exceeds the actuarial value of standard prescription drug coverage.''

In the proposed rule, we interpreted ''to the individual'' in this case as being to the average individual under the plan, as opposed to the sponsor of the plan. For purposes of determining creditable coverage, we proposed a ''gross'' test: will the expected plan payout on average be at least equal to the expected plan payout under the standard benefit? We also proposed at § 423.56(c) that any entity seeking to offer coverage of the type described in § 423.56 must attest to the actuarial equivalence (or non-equivalence) of its prescription drug coverage in their notice to Medicare beneficiaries and in a submission to CMS, and must maintain documentation of the actuarial analysis and assumptions supporting the attestation.

In coordination with the provisions regarding the late enrollment penalty, we proposed at § 423.56 to establish a process under which these entities will disclose the creditable status of their prescription drug coverage to us and to each part D eligible beneficiary enrolled in such coverage.

Section 1860D–13(b)(6)(C) of the Act, implemented at § 423.56(g) of the proposed rule, provides that an individual who was not adequately informed that his or her prescription drug coverage was not creditable prescription drug coverage may apply to CMS to have such coverage treated as creditable prescription drug coverage for purposes of not having the late penalty imposed.

Comment: One commenter stated that Medicaid should not be considered creditable prescription drug coverage, for the purposes of Part D, because no Medicaid benefit for Part D covered prescription drugs is available to Part D eligible beneficiaries.

Response: All entities listed under § 423.56(b), except PDPs and MA-PDs under (b)(1) and PACE plans and cost-based HMOs and CMPs offering qualified prescription drug coverage, must provide notice to both CMS and its members whether the prescription drug coverage provided is or is not creditable. The purpose of the notice of creditable coverage is to ensure that individuals are aware of whether such coverage is creditable prescription drug coverage and its implication to the late enrollment penalty.

Medicaid is prohibited from providing Part D drugs to full-benefit dual eligible individuals. However, since there may be other individuals who are not receiving the full range of benefits from Medicaid but who will continue to receive some drug coverage from the State, these individuals must also receive this notice providing status of the coverage.

Comment: One commenter requested that we include SPAP in the definition

of types of coverage that may be creditable.

Response: The proposed rule at § 423.56(b)(4) includes SPAPs as potentially creditable. Section 1860D–13(b)(4)(D) of the Act specifies these programs, as described in section 1860D–23(b) of the Act, as such. To ensure this concept is clear, we will revise § 423.56(b)(4) to include the acronym ''SPAP.''

Comment: We received a comment indicating that the value of prescription drug coverage under PACE will likely equal or exceed the actuarial value of Part D standard prescription drug coverage as a result of existing requirements in sections § 460.90 and § 460.92 of the PACE regulation. The commenter recommended incorporating PACE into the CMS definition of creditable prescription drug coverage found in § 423.56(a).

Response: We agree with the commenter and have incorporated PACE into the definition of potentially creditable prescription drug coverage found in § 423.56(b). Additional discussion of the applicability to Part D benefits and requirements to PACE are outlined in subpart T of the final rule.

Comment: A few commenters inquired about the actuarial equivalence test that the entities listed will be required to meet, since the actuarial equivalence reference in § 423.265 refers to bid submissions. Commenters supported both the concept of ''gross'' test and an ''aggregate test'' for calculation of the actuarial equivalence for plans, including group health plans which offer several benefit packages to determine if the prescription drug coverage is creditable.

Response: The basic actuarial equivalence value test for the determination of creditable coverage of alternative coverage is determined by calculating whether the expected plan payout on average will be at least equal to the expected plan payout under defined prescription drug coverage (gross test). We believe Section 1860D–22(a)(2) of the Act is subject to two reasonable interpretations of calculating the creditable coverage test (gross test). Under the first interpretation, the actuarial equivalence standard for determining creditable coverage would be applied to the alternative coverage as a whole, and under the second interpretation the actuarial standard would be applied for each benefit option (including separate cost-sharing arrangements) within a single group health plan. Whereas our proposed rule required plans to apply the actuarial equivalence standard at the aggregate level, for the final rule we instead require plans to apply the actuarial equivalence standard to each benefit option within its plan.

Our rationale for revising the actuarial equivalence test is to ensure that beneficiaries are adequately informed that their coverage is or is not creditable prescription drug coverage. A sponsor may offer many different benefit options to beneficiaries. One of those benefit options may not pass the gross test but be included in an overall (or ''aggregate'') text. As a result, this would leave beneficiaries in certain benefit options with a determination that their coverage is creditable, when in actuality it is not. For example, a sponsor has a group in which richer benefits are offered, compared to another group that has more limited benefits. If the sponsor would aggregate the two benefits together, the lower benefit will end up as ''creditable'' when the benefit packages are averaged together.

We will issue guidance on the aspects of actuarial equivalence shortly following publication of the final rule.

Comment: One commenter asked if any coverage that is less than full pharmacy benefits could be considered creditable prescription drug coverage, such as coverage for maintenance or coverage of specific disease-only drugs.

Response: We believe that the definition of creditable prescription drug coverage would prohibit us from concluding that such coverage is creditable. To be creditable prescription drug coverage, the coverage must equal or exceed the actuarial value of defined standard prescription drug coverage, as we will define in guidance referenced in the previous response. It is likely that coverage of a very limited scope such as the commenter refers will not likely meet our actuarial equivalence test.

Comment: In response to our request for comments on other forms of coverage that may potentially be considered creditable, two commenters requested that we cost-based HMOs and CMPs authorized under section 1876 of the Act as potential providers of creditable prescription drug coverage. Both commenters also suggest that we include a provision allowing CMS to designate other types of coverage as potentially creditable prescription drug coverage in the future without requiring such an addition be accomplished through the rule making process. Another commenter suggested that coverage provided by State high risk insurance pools also be included in the types of coverage that may be creditable.

Response: We agree with these suggestions and have revised § 423.56(b) to include cost-based HMOs and CMPs and coverage offered by State high risk pools, as defined under the HIPAA regulations at § 146.113(a)(1)(vii), as well as a provision permitting CMS to recognize other types of coverage as potentially creditable prescription drug coverage, which we would do so in separate guidance as determined necessary.

Comment: Several commenters supported permitting the disclosure of the creditable prescription drug status of coverage through the inclusion of this information in already existing beneficiary materials, such as Summary Plan Descriptions (SPDs), or annual notices. One commenter suggested that because beneficiaries are already familiar with these documents, they provide a more recognizable and familiar avenue for this important information. On the other hand, several commenters supported requiring all notices of the creditable status of coverage to ''stand alone;'' that is; to be provided separately in a specific notice to each individual. Some commenters expressed concern that if this disclosure were not highlighted in a separate notice, the important message could go unnoticed and inadvertently subject an individual to the late enrollment penalty. Another commenter suggested that all notices be linked to ERISA disclosure documents (that is, SPDs), and to HIPAA or COBRA required notices. One commenter suggested that notice of creditable status could be incorporated into already existing beneficiary information materials, while notice of non-creditable status should stand alone. Lastly, a commenter requested that we specify the elements that would be required to be included in these notices.

Response: We specifically requested comment on the disclosure of creditable prescription drug notice requirements and appreciate the feedback received. Based on the comments we received we believe that linking the notice of creditable status to other required documents is an acceptable vehicle provided it is conspicuous and includes standard information elements. This approach appropriately recognizes the importance and familiarity of materials that beneficiaries currently receive regarding coverage they have. Further, we believe that it is important to encourage compliance with the provision of these notices by eliminating duplication and the undue burden associated with it. To that end, we have revised § 423.56(c) to allow notices of creditable and non-creditable status to be provided in the same manner, and will provide specific guidance following the publication of the rule. This guidance will require that

a notice of creditable and non-creditable status be provided, at minimum, prominently with other beneficiary information materials, and will include model language for both types of notices.

We may specify different requirements for those entities identified at § 423.56(b) that are required to provide these notices, where appropriate, to reduce beneficiary confusion and minimize administrative burden. For example, as explained in our discussion of § 423.34 above, we intend to notify full benefit dual eligible individuals that they are eligible for the low-income subsidy. This notice will also inform individuals that Medicaid will no longer cover those prescription drugs covered under Part D and that any additional prescription drug coverage provided by Medicaid would not be creditable coverage under Part D. Including this information in the same notice will avoid duplication of effort and possible beneficiary confusion.

Comment: Several commenters felt that requiring an attestation by group health plans of actuarial equivalence for creditable coverage when the sponsor of such coverage elects not to enroll in the retiree drug subsidy program under subpart R was an unnecessary cost and an administrative burden. The commenters believed that for those employer groups that offer prescription drug coverage to active employees who might be Part D eligible individuals, such coverage should be assumed to be ''creditable'' and should only have to provide notices to those qualified retirees and dependents who are Part D eligible individuals. The commenters also suggested that notices could be published in summary plan descriptions, on employer website and via e-mail.

Response: Section 1860D–13(b)(6)(B) of the Act requires specific entities that offer prescription drug coverage to provide notices to all Part D eligible individuals enrolled in their plans regarding whether such prescription drug coverage is creditable. This would include sponsors (as defined under § 423.880) not electing the Retiree Drug Subsidy, as described in subpart R. A notice of creditable or non-creditable coverage must be provided to active Medicare eligible employees and Medicare eligible dependents so that a late enrollment penalty will not be imposed when the beneficiary enrolls in Part D coverage.

We will provide further guidance on a simplified method of determining creditable coverage for those sponsors not electing the retiree drug subsidy.

We will also provide guidance to sponsors on the form, manner, and timing of such notice requirements, following publication of this final rule. Notices may be provided, at minimum, prominently with other plan participant information materials (for example, summary plan descriptions, or HIPAA notices) that the sponsor is required to provide as long as it is conspicuous and includes standard information elements as determined in our guidance. This approach appropriately recognizes the importance and familiarity of materials that beneficiaries currently receive regarding coverage they have.

Comment: Many commenters responded to our request for comments on the timing of the delivery of creditable coverage status notices to Part D eligible individuals. Several of these commenters suggested that the initial notice should be required to be delivered prior to the commencement of the AEP which begins on November 15, 2005. One commenter suggested that notices also be issued at least 60 days prior to the effective date of any change to current coverage. Another commenter suggested that entities required to deliver these notices should do so within 30 to 45 days of the end of Part D enrollment periods.

Response: We appreciate the feedback we received regarding the timing of notices to disclose creditable prescription drug coverage. We agree that, in order to ensure beneficiaries are making informed choices regarding enrollment in Part D, notice must be provided to all Part D eligible individuals each year prior to the commencement of the AEP, which begins on November 15th. We also believe there are three other key times when notice must be provided: (1) prior to the commencement of the individual's initial enrollment period in Part D; (2) prior to the effective date of enrollment in such coverage or any change in creditable status of that coverage; and, (3) upon request by the beneficiary. We will revise § 423.56(f) to require that notice be provided, at minimum, at these 4 times.

Comment: One commenter requested that we clarify the meaning of the words in § 423.56(b) of the proposed rule ''with the exception of PDPs and MA-PD plans.'' for the duty to furnish notices of creditable coverage to beneficiaries. The commenter also requested clarification of the duty of Cost plans offered under section 1876 of the Act that provide qualified prescription drug coverage to furnish such notice. Lastly, the commenter asked us to clarify if the provision at § 423.56(d) of the proposed rule regarding the disclosure of creditable status to CMS applies to any entity that is exempted from notice requirements according to § 423.56(b).

Response: It is our view that the practical need for disclosure of creditable status notices is directly related to a beneficiary's understanding of their options related to enrolling in Part D and any consequences should they choose not to, such as the late enrollment penalty. It also provides the beneficiary with information about how their coverage compares to what is available under a Part D plan. Beneficiaries enrolled in a PDP, MA-PD plan, PACE plan or cost plan that provides qualified prescription drug coverage are enrolled in Part D, and therefore not subject to any consequence of choosing not to enroll. Including these types of coverage in the list of coverage that may be considered creditable ensures that at no time could a beneficiary who has maintained enrollment in a legitimate Part D plan be subject to the late enrollment penalty for the same time period. However, sending notice of creditable status seems superfluous since, as these plans are Part D plans, the creditable status is automatic.

The statute at 1860D–13(b)(6)(B) of the Act exempts PDP sponsors and MA organizations from providing notice of creditable coverage to its members. Since sections 1860D–21(e) and (f) of the Act provide that we treat cost-based HMO and CMPs and PACE organizations that elect to provide qualified prescription drug coverage similar to MA-PD local plans, such cost-based HMO and CMP and PACE organizations offering qualified prescription drug coverage will also be excepted from this notice requirement. We will revise the notice requirements under § 423.56(c) to reflect that PACE plans and 1876 Cost plans offering qualified prescription drug coverage as excepted entities from the notice requirements under § 423.56(c). We also note that PACE plans and section 1876 of the Act cost plans that do not offer qualified prescription drug coverage must provide notices, as required. To ensure that Part D plan members understand their options, we will ensure that an explanation of the late enrollment penalty and the concept of creditable coverage are included in plan documents.

Similarly, a requirement for organizations that provide Part D benefits to submit separate notice would be duplicative by their nature as CMS approved Part D plans, they are creditable. We will revise § 423.56(e) to clarify that all entities providing CMS-approved Part D coverage do not have

to disclose creditable status of Part D coverage to us under this paragraph.

Comment: One commenter suggests that we consider ways that entities could provide the required notice of creditable status to beneficiaries and CMS via electronic means.

Response: We recognize that most plan documents have been historically provided to beneficiaries in hard-copy (that is, paper) but know from the comments received from plan sponsors and business advocates that participants are receiving plan information through other electronic means, such as websites and e-mail. Most beneficiaries are probably accustomed to receiving materials in one of these manners. We feel that paper documents have better ensured that the beneficiary receives and understands the information. In addition, paper documents will provide beneficiaries a hard copy that they can present whenever needed to show proof of creditable coverage. Since beneficiaries may already be choosing to receive information electronically, we will explore this option as we develop operational guidance for creditable notice requirements.

As for entities notifying us of the creditable status of their coverage, we will describe the form and manner in which entities disclose this information to us in operational guidance and will consider various options for entities to do so.

C. Voluntary Prescription Benefits and Beneficiary Protections

1. Overview and Definitions (§ 423.100)

Proposed subpart C of part 423 implemented sections 1860D–2, 1860D–4(a), 1860D–4(b), 1860D–4(i), 1860D–4(k), 1860D 11(a), 1860D–21(a), 1860D–21(c)(3), and 1860D 21(d)(2) of the Act. This subpart set forth requirements regarding—

- Definitions for terms that are frequently used in this subpart.
- The benefits offered by Part D sponsors.
- The establishment of prescription drug plan service areas.
- Access standards with regard to covered Part D drugs.
- Part D sponsor formularies.
- Information dissemination by Part D sponsors.
- Disclosure to beneficiaries of pricing information for generic versions of covered Part D drugs.
- Privacy, confidentiality, and accuracy of PDP sponsors' beneficiary records.

Below we summarize the provisions of subpart C and respond to public comments. (Please refer to the proposed rule (69 FR 46646) for a detailed discussion of our proposals.)

a. Part D Drug

The definition of a covered Part D drug in § 423.100 of our proposed rule closely followed the statutory definition in section 1860D–2(e) of the Act. According to this definition, a covered Part D drug was available only by prescription, approved by the Food and Drug Administration (FDA), used and sold in the United States, and used for a medically accepted indication (as defined in section 1927(k)(6) of the Act). A covered Part D drug included prescription drugs, biological products, insulin as described in specified paragraphs of section 1927(k) of the Act, and vaccines licensed under section 351 of the Public Health Service Act. The definition also included ''medical supplies associated with the injection of insulin (as defined in regulations of the Secretary).'' We proposed to define those medical supplies to include syringes, needles, alcohol swabs, and gauze.

In accordance with section 1860D–2(e)(2) of the Act, the definition of a covered Part D drug specifically excluded drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under section 1927(d)(2) of the Act, with the exception of smoking cessation agents. In accordance with section 1927(d)(2) of the Act, the drugs or classes of drugs that may currently be excluded or otherwise restricted under Medicaid include: (1) agents when used for anorexia, weight loss, or weight gain; (2) agents when used to promote fertility; (3) agents when used for cosmetic purposes or hair growth; (4) agents when used for the symptomatic relief of cough and colds; (5) prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations; (6) nonprescription drugs; (7) outpatient drugs for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee as a condition of sale; (8) barbiturates; and (9) benzodiazepines.

The definition of a covered Part D drug also excluded any drug for which, as prescribed and dispensed or administered to an individual, payment would be available under Parts A or B of Medicare for that individual (even though a deductible may apply).

Except as otherwise provided below, the final rule adopts the definition of ''covered Part D drug'' set forth in § 423.100 of the proposed rule.

Comment: Several commenters were confused about the distinction between drugs that may be covered under Part D given the definition of the term ''covered Part D drug'' in section 1860D–2(e) of the Act and those drugs that are actually included on a Part D plan's formulary.

Response: In order to clarify when we are referring to a drug that may be covered under Part D and one that not only is covered by Part D but is also included on a particular Part D plan's formulary, we refer to drugs that may be covered under Part D, consistent with the definition of the term ''covered Part D drug'' in section 1860d–2(e) of the Act, simply as ''Part D drugs.'' We use the term ''covered Part D drug'' to refer to a drug that not only is a Part D drug, but that is included in a Part D plan's formulary or treated (through a coverage determination or appeal described in subpart M of this preamble) as being included in a Part D plan's formulary, and is obtained at a network pharmacy or at an out-of-network pharmacy in accordance with § 423.124 of our final rule. Both terms are defined in § 423.100 of our final rule.

Comment: One commenter recommended that we consider expanding the definition of ''medically accepted indication'' beyond the FDA-approved indications to include uses in official compendia or research. Another commenter was concerned that the definition of ''medically accepted indication'' may allow Part D sponsors to limit their payments for use of Part D drugs solely to FDA-approved indications even though clinical standards allow for alternative uses. Another commenter was concerned that pharmacists will be penalized for dispensing prescriptions that are prescribed for an indication that is not a medically accepted indication. This commenter indicated that pharmacists cannot be expected to contact each physician for each prescription in question to determine if the drug is being prescribed for a medically-accepted indication.

Response: To qualify as a Part D drug, a drug or biological must be used for a medically accepted indication, as defined under section 1927(k)(6) of the Act. This definition states that a medically accepted indication means not only any use for a covered outpatient drug which is FDA-approved, but also a use which is supported by one or more citations included or approved for inclusion in any of the compendia listed in section 1927(g)(1)(B)(i) of the Act-the American Hospital Formulary Service Drug Information, United States

Pharmacopoeia-Drug Information, the DRUGDEX Information System, and American Medical Association Drug Evaluations. We cannot extend the meaning of ''medically accepted indication'' to cover uses in research, as one commenter notes, since the definition of ''medically accepted indication'' in section 1927(k)(6) of the Act does not include the reference in section 1927(g)(1)(B)(ii) of the Act to peer-reviewed medical literature. Thus, a ''medically accepted indication'' is limited by statute to a use for a covered outpatient drug which is approved by the FDA, or the use of which is supported by one or more citations in the compendia listed above. It will be Part D plans' responsibility to ensure that covered Part D drugs are prescribed for a medically accepted indication; plans may, for example, rely on utilization management policies and procedures (which we will review as part of our comprehensive review of Part D plan benefits) to ensure that drugs are prescribed and used for medically accepted indications. We clarify that pharmacists will not be required to contact each physician to verify whether a prescription is being used for other than a medically accepted indication.

Comment: Some commenters recommended including coverage for all EPA-recommended disposal methods and disposal solutions as part of the definition of ''medical supplies associated with injection of insulin''. The commenters noted that proper disposal of needles and lancets are necessary to patient safety and important to public health. Some commenters requested that the definition include lancets, blood glucose test strips, glucometers, syringes, and needles. One commenter suggested that gauze not be included.

Response: We are interpreting the term ''medical supplies associated with the injection of insulin'' in section 1860D–2(e)(1)(B) of the Act as comprising syringes, needles, alcohol swabs, gauze, and insulin delivery devices not otherwise covered by Part B, such as insulin pens, pen supplies, and needle-free syringes. Given that section 1860D–2(e)(2)(B) of the Act excludes products covered by Part B from the definition of a Part D drug, test strips and lancets, which are covered under Part B, cannot be covered under Part D. While we recognize the importance of needle disposal systems, we also do not consider the systems to be directly associated with injection. Thus, these devices fall outside of our interpretation of medical supplies associated with the injection of insulin.

We note that it is our intention to narrowly construe further Part D plan determinations of what constitutes ''medical supplies associated with the injection of insulin'' in order to ensure that such determinations are consistent with the examples we have provided, and that they do not lead to an inappropriate expansion of the Part D benefit.

Comment: Some commenters asked for clarification on coverage of smoking cessation products, specifically regarding whether over-the-counter products will be covered under Part D. Another commenter suggested that in order to cover smoking cessation products, Part D plans should require proof of smoking cessation classes.

Response: Section 1860D–2(e)(1)(A) of the Act specifies that a Part D drug is a drug that may be dispensed only upon a prescription. Although section 1860D–2(e)(1)(B) of the Act specifically allows smoking cessation agents to be covered under Part D, such agents must not otherwise be excluded from coverage under Part D. Over-the-counter smoking cessation products (for example, gum and most patches), by virtue of being not being drugs that may be dispensed only upon a prescription, therefore cannot be considered Part D drugs, even though they are smoking cessation products. Smoking cessation products that may be dispensed only upon a prescription, however (for example, some patches, oral inhalants, nasal sprays, and Zyban), may be considered Part D drugs provided they meet all other applicable requirements under the definition of a Part D drug in § 423.100 of the final rule. We do not have the authority to require Part D plans to condition coverage of permissible smoking cessation agents on proof of smoking cessation classes.

Comment: One commenter requested clarification in the final rule that Part D plans are not prohibited from providing drugs on the exclusion list (under section 1927(d)(2) of the Act, other than smoking cessation drugs) if they are provided through an enhanced benefit.

Response: As provided in § 423.104(f)(1)(ii)(A) of our final rule and in accordance with section 1860D–2(a)(2)(A)(ii) of the Act, Part D plans may only provide coverage of drugs that are specifically excluded as Part D drugs under section 1860D–2(e)(2)(A) of the Act, that is, drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under section 1927(d)(2) of the Act, with the exception of smoking cessation agents—if they do so as supplemental benefits through enhanced alternative coverage and if they would otherwise meet the definition of a Part D drug under section 1860D–2(e)(1) of the Act, but for the application of section 1860D–2(e)(2)(A) of the Act.

Comment: Many commenters urged us to remove benzodiazepines from the exclusion list indicating the multiple therapeutic uses of this drug. One commenter was concerned that excluding drugs such as these from the Part D benefit would force health care providers to alter how they treat patients based on which medications are Part D drugs. Many commenters noted that benzodiazepines serve as valuable therapy for anxiety disorders, bipolar disorder, Parkinson's disease, seizures, and other conditions. Some commenters noted that excluding drugs such as benzodiazepines that are inexpensive, first-line therapies would require more expensive drugs to be prescribed simply because they are covered. Some commenters were concerned about the dangers of beneficiary withdrawal from benzodiazepines if these drugs are not covered under Part D. Some commenters were concerned about loss of drug coverage for benzodiazepines for dual eligibles, especially because benzodiazepines are covered in many States. Many commenters also urged us to remove barbiturates from the exclusion list, citing similar reasons as those listed for benzodiazepines.

Some commenters urged us to make an exception for vitamins used under special circumstances, specifically with ESRD patients. Another commenter was concerned about the exclusion of renal vitamins under Part D and requested that we allow the coverage of water-soluble vitamins lost during dialysis to be covered under Part D. Another commenter noted that prescription vitamins are relatively inexpensive.

Some commenters requested coverage of over-the-counter medications for beneficiaries with certain conditions. One commenter asked us to reconsider excluding over-the-counter drugs that were formerly prescription-only drugs and now have over-the-counter status. Another commenter recommended including a provision allowing over-the-counter drugs to be covered if prescribed in the same manner as a prescription item. Another commenter asked us to consider over-the-counter drugs and medications for unintended weight loss as a covered drug under Part D. One commenter suggested that we amend the exclusion for ''agents used for symptomatic relief of cough or cold'' to ''non-prescription agents used for symptomatic relief of cough or cold''.

Response: Section 1860D–2(e)(2) of the Act clearly requires us to exclude certain drugs from the definition of a Part D drug. According to the statute, the definition of a Part D drug specifically excludes certain drugs or classes of drugs that may be excluded from Medicaid coverage under section 1927(d)(2) of the Act, including agents when used for anorexia, weight loss, or gain; agents when used for cosmetic purposes or hair growth; agents when used for symptomatic relief of cough and colds; prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations; outpatient drugs for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee as a condition of sale; nonprescription drugs; barbiturates; and benzodiazepines. We have no flexibility to allow Part D coverage of any of these drugs, including over-the-counter drugs used to treat certain medical conditions, except as provided in § 423.104(f)(1)(ii)(A) of the final rule, which permits Part D plans to provide coverage of drugs that otherwise meet the definition of a Part D drug under section 1860D–2(e)(1) of the Act and are not otherwise excluded under section 1860D–2(e)(2)(B) of the Act, if they do so as supplemental benefits through enhanced alternative coverage. We also note that insurance or otherwise, group health plans, or third party payment arrangements (including States under Medicaid and State Pharmaceutical Assistance Programs) may, at their discretion, provide Part D enrollees with supplemental coverage for drugs excluded from coverage under Part D.

Comment: One commenter said that many of the categories of excludable drugs in section 1927(d)(2) of the Act refer to drugs when used for a specific purpose and that it is inappropriate to simply exclude these drugs when they may be covered depending on the specific clinical use. This commenter recommended that that we provide coverage for potentially excludable drugs when they are prescribed for a clinical use not covered by section 1927(d)(2) of the Act. Two examples provided were ''weight loss agents'' when used not for cosmetic purposes, but for the treatment of morbid obesity, and decongestant combination products, which while commonly prescribed to treat coughs and colds, could be used for the treatment of allergic conditions.

Response: Drugs that are excluded from coverage under Part D when used as agents for certain conditions may be considered covered when used to treat other conditions not specifically excluded by section 1927(d)(2) of the Act, provided they otherwise meet the requirements of section 1860D–2(e)(1) of the Act and are not otherwise excluded under section 1860D–2(e)(2)(B) of the Act. To the extent this is the case, and a drug is dispensed for a ''medically accepted indication'' as described in the statute, weight loss agents may be covered for the treatment of morbid obesity, and decongestant products for example, may be covered when used to treat allergies. However, we clarify that Part D plans may establish utilization management processes in order to ensure that such drugs are being prescribed for medically accepted indications that are not excluded under section 1927(d)(2) of the Act (for example, decongestant products when used for ''symptomatic relief of coughs and colds'').

Comment: One commenter suggested excluding drugs that have non-prescription drug alternatives available as Part D drugs. Two commenters supported excluding drugs that are ''lifestyle'' drugs such as Viagra, Levitra, and Cialis.

Response: We do not have the authority to exclude the drugs if they meet all the criteria of a Part D drug as provided under section 1860D–2(e)(1) of the of the Act and are not otherwise excluded under section 1860D–2(e)(2) of the Act. However, we clarify that Part D plans may subject these drugs to utilization management processes provided we do not find such processes to discourage enrollment by certain Part D enrollees as part of the benefits package review we will conduct (and which is discussed in detail elsewhere in this preamble).

Comment: One commenter supports the current statutory language regarding the manufacturer tying arrangements exclusion, whereas another commenter supports expanding this prohibition but does not specify how we should expand it. One commenter opposes any CMS effort to mandate the interactions between Part D plans and pharmaceutical manufacturers, and another asks us to affirm that this exclusion will not interfere with Part D plan decisions to cover drugs/diagnostic test combinations if manufacturers do not require the purchase of the combinations. Yet another commenter points out that the tying arrangement exclusion would exclude drugs from Part D coverage that are tied to one pharmacy system because of requirements for patient monitoring.

Response: We appreciate the clarification provided by the various commenters. We are not expanding the manufacturer tying arrangement exclusion of coverage under Part D in our final rule. We believe that existing Federal fraud and abuse laws, including the anti-kickback statute at section 1128B(b) of the Act, as well as the civil monetary penalty provision at Section 1128A(a)(5) of the Act, provide clear guidance regarding what are and are not inappropriate manufacturer tying arrangements. Manufacturers remain responsible for ensuring that they do not engage in any tying arrangements that violate the anti-kickback statute or, where applicable, the civil monetary penalty provision prohibiting inducements to beneficiaries.

Comment: Some commenters asked for clarification on which vaccines are covered under the Part D benefit and suggested that we provide additional guidance on how non-Part B vaccines are to be covered under Part D, including administrative fees. Another commenter requested that we strongly encourage Part D plans to include all vaccines that are not covered under Part B on their formularies.

Response: The definition of a Part D drug in section 1860D–2(e) of the Act clarifies that Part D may cover a biological product described in sections 1927(k)(2)(B)(i) to (k)(2)(B)(iii) of the Act—to include a vaccine licensed under section 351 of the Public Health Service Act. Since section 1860D–2(e)(2)(B) of the Act excludes an otherwise covered Part D drug from coverage under Part D ''if payment for such drug as so prescribed and dispensed or administered with respect to that individual is available (or would be available but for the application of a deductible) under Part A or B for that individual,'' certain drugs and vaccines would be covered under Part D only to the extent they are not covered under Part B.

In addition to excluding Part B vaccines from coverage under Part D, section 1860D–2(e)(3) of the Act provides that a Part D plan may exclude from coverage covered Part D drugs for which payment may not be made under section 1862(a) of the Act if applied to Part D. Section 1862(a)(1)(A) generally excludes from payment items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, except those vaccines identified in section 1862(a)(1)(B) of the Act as covered Part B vaccines. Section 1862(a)(1)(A) of the Act, however, excepts from this rule vaccines covered under Part B. Therefore, if these provisions are read literally, Part D plans would be permitted to exclude

from coverage preventative vaccines that are covered Part D drugs because they are not ''reasonable and necessary for the diagnosis or treatment of an illness or injury.''

However, we argue that whereas section 1862(a)(1)(B) of the Act requires coverage under Part B of covered Part B vaccines, by analogy, section 1862(a)(1)(B) of the Act as applied to Part D should be read as requiring coverage under Part D of vaccines that are covered Part D drugs. This argument is buttressed by the fact that the Congress specifically defined Part D drugs under section 1860D–2(e)(1) of the Act to include vaccines. Moreover, section 1860D–2(e)(3) of the Act references all of section 1862(a) of the Act, and the only way to give meaning to the reference to section 1862(a)(1)(B) of the Act is to extend the provision to permit coverage of Part D vaccines. In other words, if section 1862(a)(1)(B) of the Act as applied to Part D were read literally as only permitting coverage of Part B vaccines, the reference in section 1860D–2(e)(3)(A) of the Act to section 1862(a)(1)(B) of the Act would be rendered meaningless.

Building on the argument that by analogy section 1862(a)(1)(B) of the Act should be extended to Part D so as to require coverage of non-Part B vaccines under Part D, the standard under Part D should reflect a standard similar to section 1862(a)(1)(b) of the Act but adapted to apply to preventative vaccines. Therefore, we believe such standard should be vaccines that are ''reasonable and necessary for the prevention of illness.'' Plans will need to develop explicit criteria that can be applied on a case-by-case basis to determine that the administration of Part D vaccine is ''reasonable and necessary'' and that the Part D vaccine is therefore a covered Part D drug. Presumably these will comply with any widely accepted practice guidelines. If widely accepted practice guidelines are not available for certain vaccines, Part D plans will need to develop criteria that they can support with sound clinical reasoning.

Currently, most vaccines of interest to the Medicare population are covered under Part B. Although Part B makes only three exceptions (influenza, pneumococcal, and hepatitis B vaccines for high risk patients) to its rule requiring injury or direct exposure, these three exceptions probably account for the majority of vaccinations needed by an elderly population. Since many of the remaining vaccines on the market are administered during childhood, we do not expect that Part D will cover a large number of vaccines. However, as more vaccines are developed and practice guidelines develop, Part D plans might face a growing burden with supplying vaccinations to significant numbers of their Part D patient populations. Therefore, the ability of Part D plans to limit payment to those situations that are ''reasonable and necessary for the prevention of illness'' will become more and more important.

Given the definition of dispensing fees we have incorporated in the final rule, the costs of Part D-covered vaccine administration could not be covered as part of a dispensing fee. Neither could those costs be covered as separate administrative fees, since as discussed elsewhere in this preamble, other than medication therapy management programs (described in subpart D), we do not expect medical or clinical services to be included in administrative fees.

As discussed in subpart J, Part D-covered vaccines administered in a physician's office will be covered under the out-of-network access rules at § 423.124 of our final rule. The costs of vaccine administration may be included in physician fees under Part B since Part B pays for the medically necessary administration of non-covered drugs and biologicals. However, there is currently no ready mechanism for physicians to bill Part D plans for Part D-covered vaccine costs. In the short-term, we will require that a Part D enrollee self-pay the physician for the Part D-covered vaccine cost and submit a paper claim for reimbursement by his or her Part D plan. This approach is consistent with how beneficiaries accessing covered Part D drugs at an out-of-network pharmacy will be reimbursed by Part D plans for costs associated with those drugs. Once Part D is implemented, we will get a better sense for the actual volume of Part D-covered vaccines (and other covered Part D drugs appropriately dispensed and administered in a physician's office) and the need and most appropriate mechanisms for any automatic cross-over procedures such that physicians could submit claims for reimbursement of Part D-covered vaccine ingredient costs directly to the appropriate Part B carrier. Any such automatic cross-over procedures would mean that beneficiaries would not have to submit paper claims and, instead, physicians could submit a single claim for reimbursement of both the Part D-covered vaccine ingredient costs and the administration fee directly to the appropriate Part B carrier, which would forward the Part D charge to the appropriate Part D plan.

Comment: One commenter asked that we cover individually compounded medications or combinations of medications. Another commenter stated that we should not consider compounded drugs as meeting the definition of a Part D drug, as it is contrary to the definition in the MMA and would put patients at risk.

Response: Historically, extemporaneous compounding has filled an important role in pharmacy practice and continues to be an important part of contemporary pharmacy practice. While less than one percent of prescriptions are compounded, these compounded prescriptions often provide medically necessary drug therapies that would otherwise be unavailable to patients. Compounding also provides many independent pharmacies with the opportunity to offer services that competitively differentiate them from the chain industry. In addition, compounded prescription drug products are frequently reimbursed under commercial prescription drug benefit plans. Therefore, excluding compounded prescription drug products from Medicare Part D would be a significant change from current pharmacy practice.

Section 1860D–2(e)(1)(A) of the Act defines a Part D drug as including a drug that may be dispensed only upon a prescription and that is described in section 1927(k)(2)(A)(i), (A)(ii) or (A)(iii) of the Act. As a matter of simplification, we refer to these products as ''FDA approved prescription drug products,'' and note that, as used in this part of the preamble, that term incorporates the non-FDA approved drug products specifically described under sections 1927(k)(2)(A)(ii) and (A)(iii) of the Act.

Compounded prescription drug products may contain: (1) all FDA approved prescription drug products; (2) some FDA approved prescription drug products; or (3) all non-FDA approved drug products. While the strictest reading of section 1927(k)(2) of the Act appears to indicate that non-FDA approved compounded prescription drug products are not Part D drugs, we believe that FDA-approved prescription drug product components of a non-FDA approved compounded prescription drug product could be considered to be Part D drugs. The definition of a Part D drug is not based on the final form of the drug as dispensed to the beneficiary; rather, section 1860D–2(e)(1)(A) of the Act speaks to a drug ''that may be dispensed'' only upon a prescription and that meets the requirements of section 1927(k)(2) of the Act. Therefore,

the FDA approved component can satisfy section 1860D–2(e)(1)(A) of the Act even if the finished product does not. Although reimbursement must be limited to the FDA approved prescription drug components (that is, no reimbursement is available for compounded products containing only products that are not approved by the FDA, or otherwise described under sections 1927(k)(2)(A)(ii) and (A)(iii) of the Act, or only over-the-counter products), these usually account for the most significant drug costs and, accordingly, current commercial practice often limits reimbursement to the most expensive component only. In addition, the labor costs associated with mixing a compounded drug product that contains at least one FDA approved prescription drug component can be included in dispensing fees (as defined in § 423.100 of our final rule).

Comment: Two commenters suggested covering medical foods under the Part D benefit because medical foods contain vitamins and nutrition that are beneficial to beneficiaries with certain diseases such as End Stage Renal Disease (ESRD). Another commenter asked that we cover parenteral nutrition therapy.

Response: It is not clear what the commenter meant by ''medical foods.'' If ''medical foods'' refers to products that are vitamins and mineral products, these are excluded from the definition of Part D drugs and are not a covered Part D benefit. In addition, enteral nutrients are not regulated as drugs by the FDA and are therefore not covered under Part D.

On the other hand, parenteral nutrition frequently contains primary components such as amino acids, nitrogen products, and dextrose mixtures that are regulated by the FDA as drugs and therefore meets the definition of a Part D drug if prescribed for a medically accepted indication and not otherwise excluded under section 1860D–2(e)(2) of the Act. Vitamins and minerals added to parenteral nutrition are not be considered Part D drugs, and costs associated with these vitamins or minerals cannot be paid for under Part D.

Part D plans would only need to include parenteral nutrition coverage for reasonable and necessary medically accepted indications that are not covered under Parts A or B. These situations would likely involve long-term care facility or home infusion patients who do not qualify for Part B coverage under the prosthetic benefit provision for permanent dysfunction of the alimentary tract. This could include temporary situations in which patients are unable to swallow or absorb nutrients from the alimentary tract, either for physical or cognitive reasons. We are currently unable to estimate the potential impact of such coverage on Part D expenditures. However, Part D plans will need to establish appropriate policies and procedures in order to limit Part D coverage of parenteral nutrition to patients with medically accepted indications that are not otherwise covered by Parts A or B. In addition, we note that Part D plans are not responsible for the costs of supplies and equipment related to parenteral nutrition therapy.

Comment: One commenter suggested additional supplies to consider for Part D coverage: spacers and aerochambers for administration of inhalation products, devices for administration of eye drops, and flushing supplies (for example, saline and heparin for home infusion therapy).

Response: Section 1860D–2(e)(1) of the Act provides us with authority to deem medical supplies to be Part D drugs to the extent they are associated with the injection of insulin. Thus, the supplies mentioned by this commenter cannot be covered under Part D, as they are not associated with the injection of insulin. We clarify that although heparin is a Part D drug, a heparin flush is not used to treat a patient for a medically accepted indication, but rather to dissolve possible blood clots around an infusion line. Therefore, heparin's use in this instance is not therapeutic but is, instead, necessary to make durable medical equipment work. It would therefore not be a Part D drug when used in a heparin flush.

Comment: One commenter recommended that Part D drugs should include liquid, chewable, transdermal and other special dosage forms and delivery mechanisms to accommodate swallowing limitations and intravenous medications, such as antibiotics.

Response: The definition of a Part D drug at section 1860D–2(e) of the Act places no limitations on drug dosage forms and delivery mechanisms provided that a drug or biological product is not otherwise excluded by the statute. We expect Part D plans to provide an adequate benefit that includes coverage of special dosage forms and delivery mechanisms to fit the needs of all their enrollees.

Comment: Several commenters supported our proposed framework for Part D coverage wrapping around Part B coverage at the individual level. However, other commenters recommended that drugs currently covered under Part B be excluded from coverage under Part D until the mandated study on the transitioning of Part B prescription drug coverage into Part D is released. Another commenter recommended that individual drugs be paid by either Part B or Part D in all circumstances.

Response: The statutory definition of the term ''covered Part D drug'' would, under section 1860D–2(e)(2)(B) of the Act, exclude any drug for which, as dispensed and administered to an individual, payment would be available under Parts A or B of Medicare for that individual (even though a deductible may apply). By including the language ''as so prescribed and dispensed or administered,'' section 1860D–2(e)(2)(B) of the Act makes a distinction between what would be paid for under Part D as opposed to Part B. This language indicates that the Congress was aware that some drugs could qualify for payment under Part B in some circumstances and Part D in others, depending on the way those drugs are dispensed or administered. Given the statutory definition of the term ''covered Part D drug'', we cannot preclude drugs that may be covered under Part B under some circumstances (for example, when they are furnished ''incident to'' a physician's service), but that are not covered under Part B under other circumstances, from being covered under Part D under such other circumstances (for example, because they are self-administered by the patient at home). Such a policy would require statutory changes by the Congress. The various issues raised by the drugs covered under Part B for the administration of the Part D drug benefit will be addressed in our report mandated by section 1860D–42(c) of the Act.

Comment: We solicited comments concerning any drugs that may require special guidance with regard to their coverage under Part D, and any gaps that may exist in the combined ''Part D & B'' coverage package. A number of commenters requested that we further clarify the relationship between drugs covered under Medicare Part B and drugs that will be covered under Part D. These commenters would like us to clarify how Part D plans can recognize Part B covered drugs since no universal list exists, Part B coverage differs by patient and situation, and Part B coverage policies differ regionally. They raise concerns about appropriately limiting coverage of drugs under Part D while achieving our goal of wrapping around Medicare Part B to the greatest extent possible.

Response: We acknowledge that there are numerous complexities involved in the distinction between drugs covered

under Parts B and D, as well as with wrapping around existing drug coverage under Part B. Nevertheless, section 1860D–2(e)(2)(B) of the Act states that Part D plans must exclude any drug that would otherwise be considered a Part D drug for which, as so prescribed and dispensed or administered to that individual, payment would be available under Parts A or B (even though a deductible may apply). Furthermore, we believe that the language ''as so prescribed and dispensed or administered'' indicates the Congress's awareness that the determination regarding whether a particular drug is covered under Part B or Part D could differ on a case-by-case basis.

Despite the complexities, we believe Part D plans can best wrap around existing Part B coverage under Part D by understanding the scope of the definition of covered Part D drug, becoming familiar with the general categories of Part B covered drugs, and planning for potential Part B interactions that are likely to be encountered in specific settings with regard to some of these categories.

Part D drugs are not limited to typical outpatient prescription drugs. The definition includes injectable prescription drugs (for example, intramuscular, intravenous, and infusible drugs, as well as vaccines). Some Part D plans may lack experience with covering the drugs under an outpatient prescription drug benefit program because they are more commonly covered under commercial medical benefits, as opposed to commercial prescription drug benefits.

The implementation of the Part D benefit does not alter coverage or associated rules for drugs currently covered under Part B. Part B covers drugs in a variety of settings. In almost all of these settings the question of whether coverage should be provided under Part D will not arise since the drugs are being provided in the context of a service or procedure. For a limited number of categories, however, pharmacists and infusion providers will have to determine whether to bill Part B or Part D, and Part D sponsors will need to confirm whether Part D is being billed correctly. In some cases, this determination can be made on the basis of the drug. For example, in the case of oral anti-cancer drugs, there is a list of drugs covered under Part B based on certain statutory criteria. All other oral anti-cancer drugs will be covered under Part D, provided they otherwise meet the definition of a Part D drug. In other cases, the pharmacist or infusion provider would need information about the member in order to bill appropriately. For example, in the case of drugs used in immunosuppressive therapy, Part B should be billed in the case of a beneficiary whose transplant has been covered by Medicare. Part D should make payment in all other instances. We will provide more information and guidance on the relation between Part B and Part D coverage in separate guidance to Part D plans.

Based upon the definition of the term ''Part D drug'' and the general categories of coverage under Part B, we believe that Part D plans could implement utilization management strategies to identify potential Part B drug coverage overlap for individuals and verify appropriate coverage accordingly. For example, if a Part D beneficiary were filling a retail prescription for an antiemetic, prior authorization could be used to ensure that the drug is not covered by Part B. Similarly, prior authorization could be used to flag drugs dispensed via home infusion that are covered under the Part B durable medical equipment policy. Plans will need to ensure that they do not cover any drugs which, as prescribed and dispensed or administered, are covered under Part B in a specific region under its local medical review policy (LMRP).

We clarify that MA organizations must follow fee-for-service coverage rules as provided in section 1852(a)(1) of the Act in determining whether to pay for a drug under its Part A/Part B or Part D benefits. Payment for injectable drugs that Medicare considers to be usually not self-administered should be paid under the Part A or Part B benefits if provided in a physician's office, and under Part D if dispensed by a network pharmacy. Even if an MA plan offers coverage under Part D of an injectable drug that Medicare considers to be usually not self-administered (for example, Avonex) the plan cannot deny coverage of this drug under its Part A or Part B benefits when furnished in a physician's office.

Comment: Several commenters noted that excluding Part B drugs from coverage under Part D regardless of whether the consumer is enrolled in Part B is seriously detrimental to consumers who enroll in Part B but who cannot effectuate their enrollment for many months due to the Part B enrollment timeframes. Consumers without Part B coverage, but who intend to enroll, could enroll in Part D in April of 2006 but would not be able to gain coverage for Part B drugs until 15 months later (enrollment in January effective in July). These commenters argue that we should make an exception for beneficiaries in this predicament such that their Part D plans could cover Part B drugs. This is especially important for full-benefit dual eligible individuals in this situation, since they would be unable to fall back on Medicaid to obtain coverage for Part B-covered medications. They recommend that Part D plans be required to cover Part B medications for a consumer for up to 15 months (the maximum amount of time it could take to effectuate an enrollment under Part B).

Response: Section 1860D–2(e)(2)(B) of the Act specifies that a drug prescribed to a Part D eligible individual that would otherwise qualify as a Part D drug cannot be considered a covered Part D drug if payment for such drug ''... is available (or would be available but for the application of a deductible) under part A or B for that individual.'' We interpreted this to mean that if payment could be available under Part A or Part B to the individual for such drug, then it will not be covered under Part D. Thus, for all Part D eligible individuals, drugs covered under Parts A and B are available if they choose to pay the appropriate premiums.

This will be the case even if a beneficiary has Part A, but not Part B, or vice versa, since, as we explain in subpart F of this preamble and at § 423.265(c) of the Act, Part D sponsors must offer a uniform benefit package in order to carry out the Congress's intent in section 1860D–13(a)(1)(F) of the Act. If Part B covered drugs were included in the Part D benefit package only for those enrollees without Part B, but not for others, it would not be possible for Part D sponsors to offer uniform benefit packages for a uniform premium to all enrollees. In addition, we believe that payment for a drug under Part A or B is available to any individual who could sign up for Parts A or B, regardless of whether they actually enrolled or are waiting to be enrolled, as these commenters describe. All individuals who are entitled to premium-free Part A are eligible to enroll in Part B. This includes individuals who are entitled to Part A based on age, disability, and ESRD. All individuals who are entitled to Part B only are age 65 or older and, in almost all instances, not eligible for premium-free Part A. However, they are eligible to buy into Part A for a premium.

Comment: Some commenters recommended that we introduce more consistent coverage rules by adopting national standards rather than relying on local carriers for coverage and payment decisions.

Response: Policies with regard to coverage of infusible drugs covered as DME supplies are uniform across the

country. Some differences do exist between carriers with regard to which injectable drugs will be covered under Part B ''incident to'' a physician service. These differences in coverage in a physician's office setting, however, should not impact whether a Part D plan will cover a prescription for an injectable drug presented at a participating pharmacy. The statute does not exclude ''all drugs'' covered under Medicare, but rather, drugs when Medicare coverage under Part B is available ''as so prescribed and dispensed or administered.''

Comment: One commenter asked about the interface between the hospice benefit and Part D, specifically whether we anticipated that Part D would account for or impact the delivery of hospice drugs.

Response: As provided in section 1861(dd)(1) of the Act, the hospice benefit covers all medications related to a beneficiary's terminal illness. There is no change in Medicare coverage of these drugs. However, all other medications provided to the beneficiary are currently paid for either out-of-pocket or by private insurance. These drugs could now be covered by Part D plans on either a primary or secondary basis depending on the presence or nature of other insurance. Given the life expectancy of beneficiaries receiving hospice benefits, we do not expect this to be a large expense for Part D plans.

b. Dispensing Fees

The MMA does not define the term ''dispensing fee,'' although the terms ''dispensing fee'' and ''dispense'' appear several times throughout the MMA. Because the statute is ambiguous on the meaning of ''dispensing fee,'' in the proposed rule we did not propose a specific definition of ''dispensing fee,'' but instead offered three different options we believed would be reasonable, permissible definitions of the term and invited comments on which option would be most appropriate under Part D.

- Option 1: The dispensing fee will include only those activities related to the transfer of possession of the covered Part D drug from the pharmacy to the beneficiary, including charges associated with mixing drugs, delivery, and overhead. The dispensing fee will not include any activities beyond the point of sale (that is, pharmacy follow-up phone calls) or any activities for entities other than the pharmacy.
- Option 2: The dispensing fee will include the activities included in Option 1, but in addition will include amounts for the supplies and equipment necessary for the drugs to be provided in a State in which they can be effectively administered.
- Option 3: The dispensing fee will include the activities in Option 2, but in addition will include activities associated with ensuring proper ongoing administration of the drugs, such as the professional services of skilled nursing visits and ongoing monitoring by a clinical pharmacist.

We also requested comments regarding any implications for our proposed options for defining dispensing fees vis-à-vis the administration of other drugs (for example, vaccines and injectable long-acting antipsychotic drugs).

Comment: The majority of commenters favored Option 1 claiming that this definition is consistent with current industry practice regarding dispensing fees. Several said that professional services involved in providing medications should more appropriately be covered under Parts A and B, and another commenter opined that Options 2 and 3 were burdensome for Part D sponsors. Another commenter expressed concern that what is currently covered under Part B should not be shifted to Part D through the dispensing fees. Other commenters stated that, although they supported Option 1, they believed that the definition proposed for Option 1 was too narrow. One commenter suggested that pharmacists are required to provide patient counseling for Medicaid patients under OBRA 1990 and that they should be reimbursed for those efforts. They also felt that the definition of what it means to dispense a drug should be clarified. One commenter argued that supplies, equipment and professional services needed to deliver a drug should be covered under ancillary fees negotiated between pharmacies and Part D plans and should not be included in dispensing fees. Another commenter pointed out that requiring PBMs to pay for professional services, as contemplated under Option 3, would require them to renegotiate tens of thousands of contracts with the pharmacies in their networks.

Several commenters supported Option 2. One commenter focused on medication packaging and the need to cover packaging specifically designed for the cognitively impaired or those with physical impairments.

Other commenters favored adoption of Option 3. Some of these commenters argued that the Congress meant for home infusion to be covered and that failure to pay for the supplies, equipment and services involved in delivering home infusion drugs was tantamount to failure to cover the drug itself. Since Part D specifically covers those drugs, (antibiotics, pain management, chemotherapy, parenteral nutrition, immune globulin and other infused drugs) they argued that we must require that dispensing fees cover the resources needed to deliver them. Other commenters argued that new treatment modalities were allowing patients to remain at home, a cost-effective setting, to receive their medications, and that some patients might not be able to receive their medications at home should the definition of dispensing fee fail to cover the service, equipment, and supplies needed to deliver the medications in the home setting. One commenter specifically noted the need to cover supplies and services surrounding infusion of long-term anti-psychotic medications in community mental health centers. Two commenters focused on the need to pay for physician services involved in home infusion of certain drugs given that many infections and adverse events take place in this setting. Direct physician supervision of these services is required to mitigate these potential problems.

Other commenters argued for Part D plan flexibility in establishing dispensing fees that would be appropriate for the setting and medication at issue, allowing each Part D plan to define dispensing fee. One commenter thought that Part D plans should be allowed to use tiered dispensing fees to encourage the use of generic drugs. One commenter indicated that point of sale systems in place today already support multiple variations of dispensing fees based on drug or amount of effort required to prepare or administer medication and such systems could handle the multiple variations for the drug benefit. Another commenter specified that the transmission standard should be the National Council of Prescription Drug Program's Telecommunication Standard Version 5.1.

Response: We agree with the majority of commenters that Option 1—including only those activities related to the transfer of possession of the covered Part D drug from the pharmacy to the beneficiary, including charges associated with mixing drugs, delivery, and overhead is the most appropriate definition of the term ''dispensing fees'' for Part D, and we have included a definition of dispensing fees in § 423.100 of our final rule consistent with Option 1.

Although we recognize that Options 2 or 3 would eliminate current gaps in coverage relative to home infused drugs, such approaches would also extend the definition of dispensing fee beyond the

mere transfer of possession of the drug, and certainly beyond what we believe to have been Congressional intent regarding the scope of an outpatient drug benefit. The inclusion of professional services in the definition of dispensing fees is also problematic given the potential for double billing with regard to some of the skilled nursing costs associated with home infusion. In many cases, these skilled nursing costs are separately billable to Part A, Medicaid, or supplemental insurance, and we are concerned about Part D supplanting these other sources of payment.

We believe Option 1 represents the best reading of the statute, since it will limit dispensing fees to a transfer of possession of the drug and will not include any fees associated with administering the drug. We also note that where the Congress wished for us to include the cost of supplies under Part D, it specifically directed us to do so (for example, by requiring that the supplies associated with the injection of insulin be included in the definition of the term Part D drug).

Even though some commenters suggest that the supplies, equipment, and services associated with Options 2 and 3 could be paid for through a separate fee or additional compensation to home infusion and other providers, we caution that such separate administrative fees would not be allowed under Part D. Other than medication therapy management programs, as described in section 1860D–4(c)(2) of the Act, we do not expect medical or clinical services to be included in administrative fees. Please refer to the subpart G preamble discussion of the types of costs that Part D plans may include as administrative costs in their bids. Thus, the costs for professional services associated with home infusion could not be included in the premium bid. In addition, professional services, including those associated with home infusion, may not be included in Part D plan supplemental coverage, given that section 1860D–2(a)(2) of the Act defines supplemental coverage as consisting of: (1) a reduction in the deductible, coinsurance percentage, initial coverage limit, or any combination thereof; or (2) coverage of drugs that are excluded from the definition of a ''Part D drug'' because of the application of section 1927(d)(2) or (3) of the Act.

Provided that Part D plans include only those activities allowed under our definition of dispensing fees in the dispensing fees negotiated with network pharmacies and offer standard contracting terms and conditions to all pharmacies, we note that Part D plans have the flexibility to vary the actual dispensing fee paid to pharmacies. For example, Part D plans may need to increase the dispensing fees paid to rural or long-term care pharmacies in order to obtain their participation in networks and meet the pharmacy access standards.

As detailed elsewhere in this preamble, Part D plans will be required to ensure adequate access to home infusion services as part of their pharmacy network access standards. Thus, enrollees will have access to home infusion services, though they may have to pay for supplies, equipment, and professional services out-of-pocket particularly if they are enrolled in a Part D plan and have no source of supplemental coverage.

As we noted in the proposed rule, our definition of dispensing fees under Part D will not carry over to Part B of the Medicare program. Section 1842(o)(2) of the Act gives the Secretary discretionary authority to pay a dispensing fee to a licensed pharmacy that furnishes certain covered Part B drugs and biologicals to Medicare beneficiaries. While the term ''dispensing fee'' is not defined in section 1842(o)(2) of the Act, the considerations under Medicare Part B, a more comprehensive health insurance product that has separate payment mechanisms for durable medical equipment and professional services, are different from those under Part D.

Comment: Some commenters did not support a particular option for defining the term ''dispensing fees,'' but were more concerned about including certain activities in the definition of dispensing fees (for example, staff, equipment, automation, facilities overhead, time inputting information into a computer, resolving problems with PBMs and prescribing practitioners, counseling the patient, waste disposal, turning the medication over to the patient, particularly when it involved home delivery, and actually packaging the medications). Many of these commenters noted that pharmacists merit a small profit and that dispensing fees should not be specifically designed simply to meet costs. Others felt that terms used in the proposed options were too vague. Specifically, they wanted the meaning of dispensing to be defined to include the costs they outlined. They also wanted to account for the level of complexity and include clear definitions of reconstituting, mixing and compounding drugs, which they believe involve very different equipment, skill and time resources.

Response: We have defined the term ''dispensing fees'' in § 423.100 of our final rule to include reasonable pharmacy costs associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee. We specify that reasonable pharmacy costs may include costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing quality assurance activities consistent with § 423.153(c)(2) of our final rule, measurement or mixing of the covered Part D drug, filling the container, physically providing the completed prescription to the Part D enrollee, delivery costs, special packaging costs, and overhead costs associated with maintaining the facility and equipment necessary to operate the pharmacy. We clarify that in using the term ''reasonable'' pharmacy costs, our intent is to convey that such costs be appropriate for the typical beneficiary in that pharmacy setting. We believe that our definition clarifies commenters' concerns about the inclusion of some overhead costs, time spent inputting information into a computer and resolving problems with PBMs and prescribing practitioners, transferring the medication to the patient, and special packaging costs.

We clarify that reasonable delivery costs include only those costs appropriate for the typical beneficiary in a particular pharmacy setting. Thus, while it would be appropriate for Part D plans to reimburse long-term care, mail-order, and home infusion pharmacies for home delivery costs via the dispensing fee, this would not be the case for retail pharmacies (where the term ''delivery'' would be limited to the transfer of a covered Part D drug from the pharmacist to the patient at the point of sale) because the typical retail customer does not require home delivery. While retail pharmacies may offer home delivery services, Part D plans may not reimburse those pharmacies for these costs, and the delivery cost must be borne by the beneficiary.

As concerns patient counseling, dispensing fees for covered Part D drugs may include pharmacy costs associated with quality assurance activities consistent with § 423.153(c)(2) of our final rule. Section 423.153(c)(1) of our final rule requires Part D plans to represent that pharmacists in their network pharmacies comply with minimum standards for pharmacy practice established by the States. Since almost all States have established requirements for pharmacy practice

related to counseling, we believe that the offer of counseling that pharmacists currently provide their customers will continue consistent with current pharmacy practice in compliance with State requirements. .Any pharmacist counseling activities in addition to those established by the States will have to be negotiated and paid for separately under Part D plans' medication therapy management programs (discussed in greater detail elsewhere in this preamble).

As provided in section 1860D–11(i) of the Act, we cannot intervene in negotiations between pharmacies and Part D plans. Thus, the extent to which Part D plans reimburse pharmacies for their entire dispensing costs (or even in excess of their dispensing costs) will depend on the outcome of those negotiations. In addition, we clarify that we expect Part D plans and pharmacies to account for pharmacy profit as part of negotiated prices—either as part of overhead costs accounted for in dispensing fees or in the reimbursement rates for ingredient costs negotiated with pharmacies.

We clarify that we interpret the term ''mixing'' as used in our definition of the term ''dispensing fees'' to encompass reconstituting and compounding of covered Part D drugs. Further, we note that Part D plans have the flexibility to pay differential dispensing fees to pharmacies based on higher labor costs—for example, for a compounded product relative to a non-compounded covered Part D drug. Plans could also used differential dispensing fees to encourage the use of generics over brand-name drugs as appropriate.

Comment: Another commenter wanted dispensing fees for non-profit entities to reflect their preferred acquisition costs, arguing that without this, Part D would be assisting tax-exempt non-profit competitors of small business pharmacies.

Response: As mentioned previously, we have defined the term ''dispensing fees'' in § 423.100 of our final rule to include pharmacy costs associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee. Plans may wish to consider non-profit entities' preferred acquisition costs in the ingredient cost reimbursement negotiated with those entities as part of negotiated prices on covered Part D drugs. However, it is unclear to us why dispensing fees should vary among non-profit and for-profit pharmacies based on differences in acquisition costs.

Comment: Several commenters emphasized the need to provide dispensing fees tailored to long term care pharmacies. They focused on the need to reimburse long-term care pharmacists for 24-hour care, the specialized packaging that is required, emergency preparation and delivery of medications, and the distinct type of medications typically prepared and delivered.

Response: The definition of dispensing fee in § 423.100 of our final rule encompasses some of the services—for example, specialized packaging, delivery, and preparation of medications (not including the actual administration of those medications)—typically provided by long-term care pharmacies. Additional long-term care pharmacy services could be reimbursed via medication therapy management programs established by Part D plans for institutionalized Part D enrollees.

Comment: Some commenters emphasized the need for the dispensing fee to cover all of the costs involved in providing a medication.

Response: As provided in section 1860D–11(i) of the Act, we cannot intervene in negotiations between pharmacies and Part D plans. Thus, the extent to which Part D plans reimburse pharmacies for their entire dispensing costs will depend on the outcome of those negotiations. Given Part D plans' need to secure a network of providers that meets our access standards, we believe that Part D plans will have every incentive to adequately reimburse pharmacies via dispensing fees for the costs involved with providing covered Part D drugs to Part D enrollees.

c. Long-Term Care Facility

We requested comments regarding the definition of the term long-term care facility in § 423.100 of our proposed rule, which we interpreted to mean a skilled nursing facility (as defined in section 1819(a) of the Act), or a nursing facility (as defined in section 1919(a) of the Act). We were particularly interested to explore whether we should include in the definition facilities other than skilled nursing and nursing facilities—particularly intermediate care facilities for the mentally retarded (ICFs/MR), described in § 440.150, and other types of facilities in which full-benefit dual eligible individuals may reside and which may exclusively contract with long-term care pharmacies in a manner similar to current practice in skilled nursing and nursing facilities.

Comment: We received a number of comments urging us to expand the definition of the term ''long-term care facility'' in the proposed rule. Some of the suggested additions include ICFs/MR; assisted living facilities; other facilities recognized by State law as eligible for payment under Sections 1915(c) (Home and Community Based waivers), 1616(e), and 1115 of the Act; group homes for the developmentally disabled; and other forms of congregate living arrangements regulated by the States. Some commenters suggested that many of these facilities operate under exclusive contracts with long-term care pharmacies. Other commenters urged us not to make the presence of exclusive contracts with long-term care pharmacies the only criterion for defining congregate living arrangements as long-term care facilities, as these beneficiaries could benefit significantly from subsidies for low-income institutionalized Part D enrollees.

Response: We have expanded the definition of the term ''long-term care facility'' in § 423.100 of our final rule to encompass not only skilled nursing facilities, as defined in section 1819(a) of the Act, but also any medical institution or nursing facility for which payment is made for institutionalized individuals under Medicaid, as defined in section 1902(q)(1)(B) of the Act. We note that we have eliminated the reference to nursing facilities as defined in section 1919(a) of the Act, as such facilities are captured as nursing facilities for which payment is made for institutionalized individuals under Medicaid. Such an expansion would include ICFs/MR and inpatient psychiatric hospitals along with skilled nursing and nursing facilities in the definition of a long-term care facility, provided those facilities meet the requirements of a medical institution that receives Medicaid payments for institutionalized individuals under section 1902(q)(1)(B) of the Act. We do not believe that the definition of term long-term care facility should be expanded to include other facilities recognized by State law but not by Medicare or Medicaid, regardless of whether some of these facilities contract on an exclusive basis with long-term care pharmacies. Furthermore, we do not believe that our definitions of terms associated with institutionalized Part D enrollees should conflict. Our revised definition of the term ''long-term care facility'' is consistent with the definition of ''institutionalized'' in subpart P of this rule and will allow for residents of a number of institutional settings to benefit from the special rules for access to covered Part D drugs established for residents of long-term care facilities. 2. Requirements Related to Qualified Prescription Drug Coverage (§ 423.104)

Under section 1860D–11(e)(2)(A) of the Act, we may approve as Part D sponsors only those entities proposing to offer qualified prescription drug

coverage in accordance with our requirements. As provided in section 1860D–2(a)(1) of the Act, qualified prescription drug coverage may consist of either standard prescription drug coverage or alternative prescription drug coverage.

a. Standard Prescription Drug Coverage

As provided under section 1860D–2(b) of the Act, ''standard prescription drug coverage'' consists of coverage of covered Part D drugs subject to an annual deductible; 25 percent coinsurance (or an actuarially equivalent structure) up to an initial coverage limit; and catastrophic coverage after an individual incurs out-of-pocket expenses above a certain threshold. In 2006, the annual deductible will be $250, the initial coverage limit will be $2,250, and the out-of-pocket threshold will be $3,600.

Once a Part D enrollee reached the annual out-of-pocket threshold, in 2006, his or her nominal cost-sharing will be equal to the greater of: (1) 5 percent coinsurance; or (2) a copayment of $2 for a generic drug or a preferred multiple source drug and $5 for any other drug, or an actuarially equivalent structure. (See Table C–1 for a summary version of standard prescription drug coverage benefits for 2006.)

Section 1860D–2(b) of the Act provides that, beginning in 2007, the annual deductible, initial coverage limit, out-of-pocket threshold, and beneficiary cost-sharing after the out-of-pocket threshold is met are to be adjusted annually. In accordance with section 1860D–2(b)(6) of the Act, these amounts will be increased over the previous year's amounts by the annual percentage increase in average per capita aggregate expenditures for Part D drugs for the 12-month period ending in July of the previous year. We requested comments regarding the methods and data sources we might use to determine the annual percentage increase in the first several years of the Part D program.

TABLE C–1
STANDARD PRESCRIPTION DRUG COVERAGE BENEFITS FOR 2006

	Cost-Sharing Percentage	Beneficiary Out-of-Pocket Costs	Plan Payment Percentage	Plan Payment
Annual Deductible ($0-$250 in spending on covered Part D drugs)	100 percent	$250	0 percent	$0
Initial Benefit ($250.01-$2,250 in spending on covered Part D drugs)	25 percent[1]	$500[2]	75 percent[1]	$1,500
No coverage of costs ($2,250.01-$5,100[3] in spending on covered Part D drugs)	100 percent	$2,850[3]	0 percent	$0
Catastrophic Coverage (after the enrollee has incurred out-of-pocket costs on covered Part D drugs greater than $3,600; this is generally equivalent to $5100[3] in covered Part D drug spending)	The greater of: (1) 5 percent; or (2) $2 for a generic or preferred multiple source drug/$5 for other drugs.[1]	—	95 percent	—

[1] Entities have the option of substituting a cost-sharing structure that is actuarially equivalent.
[2] $500 is the maximum out-of-pocket costs if coverage is based on 25 percent coinsurance. Under an actuarially equivalent cost-sharing structure, the maximum out-of-pocket costs and the maximum plan payment for any Part D enrollee could be higher or lower.
[3] This figure may, in fact, be higher to the extent that a Part D enrollee is reimbursed for out-of-pocket costs for covered Part D drugs covered under his or her plan by a group health plan, insurance or otherwise, or other third party arrangement.

In our proposed rule, we interpreted the provisions of section 1860D 2(b) of the Act to provide for two distinct types of standard prescription drug coverage-''defined standard coverage'' and ''actuarially equivalent standard coverage.'' Section 1860D–2(b)(2)(A)(ii) of the Act provides that Part D sponsors offering actuarially equivalent standard prescription drug coverage will be permitted to substitute cost-sharing requirements (including tiered structures tied to Part D plan formularies and particular pharmacies in a Part D plan's network) for costs above the annual deductible and up to the initial coverage limit, provided that those alternative cost-sharing requirements are actuarially equivalent to an average expected coinsurance of 25 percent for costs above the annual deductible and up to the initial coverage limit. Alternative cost-sharing arrangements under actuarially equivalent standard coverage could include reducing cost-sharing to $0 for generic or preferred covered Part D drugs, as provided under section 1860D–2(b)(5) of the Act, as long as the cost-sharing structure is actuarially equivalent to an average expected coinsurance of 25 percent for costs above the annual deductible and up to the initial coverage limit.

Based on our interpretation of section 1860D–2(b)(5) of the Act, we also proposed allowing Part D plans offering actuarially equivalent standard coverage to establish cost-sharing of an amount that is actuarially equivalent to the expected cost-sharing above the out-of-pocket threshold. We proposed requiring that any alternative cost-sharing structure for costs in the catastrophic range (whether under actuarially equivalent standard coverage or enhanced alternative coverage) be actuarially equivalent to standard prescription drug coverage's structure of the greater of 5 percent coinsurance or $2/$5 copayments. We noted that any such alternative cost-sharing arrangements would be reviewed, along with the rest of a Part D plan's benefit design, to ensure that they do not discourage enrollment by certain Part D eligible individuals.

Except as otherwise provided below, the final rule adopts the criteria for standard prescription drug coverage set

forth in § 423.104(e) of the proposed rule.

Comment: Several commenters felt that the benefit structure established in our proposed regulations was too complex and should be simplified to minimize beneficiary confusion.

Response: We do not have the statutory authority to simplify the benefit further, as suggested by this commenter. The MMA provides private plans with a great deal of flexibility to vary their benefit structures consistent with Congressional intent to ensure that Medicare beneficiaries have choices regarding outpatient prescription drug coverage under Part D that fit their particular needs and minimize beneficiary and Medicare costs.

Comment: One commenter asked how cross-licensed drugs will be classified as generics or as brands for the purpose of cost-sharing. The commenter also asks what the co-payments would be for multiple source drugs that are ordered ''dispensed as written.''

Response: The amount of cost-sharing, and any variations in cost-sharing based on brands, generics, or other classifications will be determined by Part D plans.

Comment: Two commenters suggested alternative data sources to use in determining the annual percentage increase in the first several years of the Part D program. The first commenter recommended two data sources to use for years 2007 and 2008—the annual estimates of prescription drug expenditures in the CMS National Health Accounts data (based on census data and sample surveys of private retail pharmacy sales) and employer retiree health plan data (released by Pharmacy Benefit Managers and benefit consulting firms). Either of these sources of data could be used as a starting point, but should be adjusted to account for any difference in trend for Medicare-eligible individuals compared to the overall prescription trend. In addition, the trend in Part D will likely differ from the overall prescription drug trend due to the large volume negotiating power which could control the trend or allow manufacturers leeway to raise drug prices. FEHBP experience may be useful in accounting for such large volume influences in Part D. This commenter also suggested using our Office of the Actuary (OACT) procedure in place for Medicare Advantage to make coverage limit adjustments the following year for over- or under-stated trends. The commenter also noted that the Medicare Current Beneficiary Survey (MCBS) and the Medicare 5 percent sample are not available in a timely enough fashion to be useful data sources.

Another commenter recommended that we use the OACT spending growth projections that will underlie the Fiscal Year (FY) 2007 President's Budget Medicare baseline that will be published in February 2006. We could use the March 2006 OACT Medicare baseline estimates as a reference check on the OACT projections. OACT and the Congressional Budget Office (CBO) are preferred because they use the latest available empirical data based on MCBS, these data are the basis for the Medicare Trustees' Reports, and the data are widely accepted. In addition, this commenter recommended that OACT use the Consumer Price Index for Prescription Drugs and Medical Supplies (CPI-PD), issued in a timely fashion by the Bureau of Labor Statistics (BLS), as the basis for projecting the price inflation component of per capita Part D spending growth. This commenter thought that utilization growth should be based primarily on the analysis of the latest available MCBS data.

Response: We appreciate the ideas suggested by the commenters and will take these recommendations into consideration as we develop our strategy for determining the annual percentage increase in the first several years of the Part D drug benefit program. We will provide further detail regarding the sources of data to be used and how the annual percentage increase will be determined via operational guidance to Part D sponsors prior to the deadline for bid submissions.

b. Incurred Costs/TrOOP Limit

According to section 1860D–2(b)(4)(C) of the Act, beneficiary costs for Part D drugs are only considered incurred (for purposes of applicability toward beneficiary spending against the annual out-of-pocket limit) if they are incurred—

(1) Against any annual deductible, any applicable cost-sharing for costs above the annual deductible and up to the initial coverage limit, and any applicable cost-sharing for costs above the initial coverage limit and up to the out-of-pocket threshold;

(2) By the Part D enrollee (or by another person on behalf of that individual); paid on behalf of a low-income individual under the Part D subsidy provisions described in § 423.782 of the proposed rule; or paid on behalf of the enrollee under a SPAP defined in § 423.454 of the proposed rule; and

(3) On covered Part D drugs (in other words, Part D drugs that are either included in a Part D plan's formulary or treated as being included in a Part D plan's formulary as a result of a coverage determination, redetermination, or appeal under § 423.566, § 423.580, § 423.600, § 423.610, § 423.620, and § 423.630 of our final rule).

We also proposed that beneficiary costs incurred under the following circumstances count as incurred costs (with Part D plans explicitly accounting for such price differentials in the actuarial valuation of their coinsurance in their bids): (1) any differential between a network retail pharmacy's negotiated price and a network mail-order pharmacy's negotiated price for an extended (for example, 90-day) supply of a covered Part D drug purchased at a retail pharmacy; and (2) any differential between an out-of-network pharmacy's usual and customary price for a covered Part D drug purchased in accordance with the out-of-network access rules and the plan allowance for that covered Part D drug. As further explained below, because we have clarified that the differential for a 90-day supply dispensed at a retail network pharmacy will generally be a differential in cost-sharing and not negotiated price (in other words, the difference in cost sharing for the 90-day supply between the retail and mail-order network pharmacies), we have modified the definition of incurred costs in § 423.100.

Section 1860D–2(b)(4)(C)(ii) of the Act provides that any costs for which a Part D individual is reimbursed by insurance or otherwise, a group health plan, or another third-party payment arrangement do not count toward incurred costs; only costs paid by a Part D enrollee, or on behalf of a Part D enrollee by another person, will count as incurred, or TrOOP costs. This provision thus creates a distinction between all enrollee out-of-pocket expenditures and those that are counted as TrOOP expenditures.

Except as otherwise provided below, the final rule adopts the rules applicable to incurred costs set forth in § 423.100 of our proposed rule.

Comment: Several commenters urged us to count all beneficiary spending on Part D drugs whether on a Part D plan's formulary or not toward TrOOP.

Response: Section 1860D–2(b)(4)(C)(i) of the Act specifically excludes from the definition of the term ''incurred costs'' those costs incurred for Part D drugs that are not included (or treated as being included on a formulary as a result of a coverage determination, redetermination, appeal, or exception) on a Part D plan's formulary. Therefore, we do not have the statutory authority to permit the payments to count toward a Part D enrollees' TrOOP limit.

Comment: Many commenters supported our proposal that beneficiary costs incurred as a result of any differential between a network retail pharmacy's negotiated price and a network mail-order pharmacy's negotiated price for an extended (for example, 90-day) supply of a covered Part D drug purchased at a retail pharmacy count as an incurred costs for the purposes of TrOOP. Only one commenter opposed allowing such differentials to count toward TrOOP.

Many commenters supported our proposal that beneficiary costs incurred as a result of any differential between an out-of-network pharmacy's usual and customary price for a covered Part D drug purchased in accordance with the out-of-network access rules and the plan allowance for that covered Part D drug count as an incurred costs for the purposes of TrOOP. Only one commenter specifically opposed our proposal, stating that if the differential were allowed to count toward TrOOP, the use of retail pharmacies would not be cost-neutral to Part D plans because individuals who use retail pharmacies would reach the out-of-pocket limit sooner.

Response: We agree with the majority of commenters that it is appropriate to allow beneficiary payment differentials to count toward TrOOP in cases in which a beneficiary accesses a covered Part D drug consistent with the out-of-network policy in § 423.124(a) of our final rule.

Section 423.120(a)(6) of our proposed rule provided that a Part D enrollee who obtained a 90-day supply of a covered Part D drug at a network pharmacy that is a retail pharmacy rather than a network mail-order pharmacy would be required to pay for any differential in the negotiated price for the covered Part D drug. However, consistent with section 1860D–4(b)(1)(D) of the Act, which requires that the Part D enrollee pay for ''any differential in charge'' when accessing a 90-day supply of a covered Part D drug at a network retail pharmacy instead of a network mail-order pharmacy, we have clarified in § 423.120(b)(10) of our final rule that the beneficiary is not responsible for the difference in negotiated price but, rather, for any higher cost-sharing associated with purchasing the drug at a retail pharmacy rather that a mail-order pharmacy. Any such difference in cost-sharing would therefore automatically count toward a beneficiary's TrOOP expenditures, since the covered Part D drug in question is being purchased at a network pharmacy.

Comment: Several commenters asked us to define the term ''person'' such that a family member can pay for enrollees' cost-sharing on their behalf.

Response: Section 1860D–2(B)(4)(C)(ii) of the Act specifically mentions a family member as an example of a person who may pay cost-sharing on behalf of a beneficiary. We clarify that our proposed rule defined the term ''person'' to include a ''natural person.'' Such a definition of the term ''person'' thus permits other individuals, such as family members, to pay for covered Part D drug cost-sharing on behalf of Part D enrollees. We have therefore retained this definition of the term ''person'' in § 423.100 of our final rule.

Comments: Several commenters supported our proposed definition of the term ''person,'' which would allow financial assistance for beneficiary cost-sharing rendered by ''bona fide'' charities to count toward enrollee's out-of-pocket threshold. Some commenters requested that we clarify what constitutes a ''bona fide'' charity. Another commenter objected to Part D plan member financial assistance programs being treated differently from third-party charities for purposes of TrOOP.

Response: Our broad definition of the term ''person'' captures not only ''bona fide'' charities, but other charitable organizations as well. We note that any arrangement in accordance to which a charitable organization pays a Medicare beneficiary's cost-sharing obligations must comply with all applicable fraud and abuse laws, including, where applicable, the anti-kickback statute at section 1128B(b) of the Act, as well as the civil monetary penalty provision prohibiting inducements to beneficiaries at section 1128A(a)(5) of the Act. Thus, even if a charity is not a bona fide charity for purposes of Federal fraud and abuse law, any drug payments it makes on behalf of Part D enrollees would count toward TrOOP unless otherwise excluded as payments by a group health plan, insurance or otherwise, or similar third party arrangement. Charities that are established, maintained, or otherwise controlled by an employer or union will likely fall under our definition of ''group health plan,'' and any benefits supplementing Part D benefits that they provide will therefore be excluded from TrOOP on this basis.

Comment: We noted in the proposed rule that we were considering whether assistance in paying enrollees' out-of-pocket cost-sharing obligations provided through prescription drug patient assistance programs sponsored by pharmaceutical manufacturers would be allowed under Federal fraud and abuse laws, including the anti-kickback statute, section 1128B(b) of the Act, as well as the civil monetary penalty provision at Section 1128A(a)(5) of the Act.

We received a number of comments requesting clarification regarding whether assistance in paying enrollees' out-of-pocket cost-sharing obligations provided through pharmaceutical manufacturer-sponsored patient assistance programs (PAPs) would be permissible under Federal fraud and abuse laws and request that we work with the OIG to develop guidelines. Some commenters believe that financial assistance and product donations provided by PAPs should be allowed to count toward beneficiaries' TrOOP expenditures. Some of these commenters recommended that product donations be counted as incurred costs and valued at the price beneficiaries would have paid at a network pharmacy (the negotiated price). One commenter recommended that we allow manufacturers to provide funds to Part D plans so that Part D plans can apply appropriate criteria and make payments on behalf of manufacturers. Another commenter cautions us that without a change in the current interpretation of Federal fraud and abuse laws preventing PAPs from providing cost-sharing assistance, many low-income beneficiaries may avoid filling scripts, resort to splitting pills, and interrupt critical drug therapy.

Response: Regardless of whether a manufacturer patient assistance program is a bona fide charity for the purpose of Federal fraud and abuse laws, any drug payments it makes on behalf of Part D enrollees would count toward TrOOP unless these organizations qualify as group health plans, insurance or otherwise, or similar third-party payment arrangements. However, any arrangements pursuant to which a charitable organization pays a Medicare beneficiary's cost-sharing obligations must comply with Federal fraud and abuse laws, where applicable, including the anti-kickback statute at section 1128(b) of the Act, as well as the civil monetary penalty provision prohibiting inducements to beneficiaries at section 1128A(a)(5) of the Act.

A related issue although it is not mentioned in the proposed rule is whether pharmacies can waive or reduce Part D cost-sharing obligations given Federal fraud and abuse laws and, if they can, whether such waived or reduced cost-sharing should count toward a beneficiary's TrOOP limit. Although we did not receive comments on this matter, we would like to clarify our policy. Under the new exception to

the anti-kickback statute added by section 101(e) of the MMA, pharmacies are permitted to waive or reduce cost-sharing amounts provided they do so in an unadvertised, non-routine manner after determining that the beneficiary is financially needy or after failing to collect the cost-sharing amount despite reasonable efforts, as set forth in section 1128A(i)(6)(a) of the Act. In addition, a pharmacy may waive or reduce a beneficiary's Part D cost-sharing without regard to these standards for beneficiaries enrolled in a Part D plan eligible for the low-income subsidy under section 1860D–14 of the Act, provided the pharmacy has not advertised that the waivers or reductions of cost-sharing are available. Depending on the circumstances, pharmacies that waive or reduce cost-sharing amounts for covered Part D drugs without following the requirements of the pharmacy waiver safe harbor could be subject to civil monetary penalties and exclusion from participating in Federal health care programs, as well as criminal fines and imprisonment under the anti-kickback statute.

We will allow waivers or reductions of Part D cost-sharing by pharmacies to count toward TrOOP. Not allowing such waived or reduced cost-sharing to count toward TrOOP would make it more burdensome for Part D plans given the need to track down whether cost-sharing was actually incurred by a beneficiary rather than a pharmacy. Moreover, we believe this option is consistent both with the definition of ''person'' in the proposed rule (making waiver or reduction of cost-sharing applicable toward an enrollee's incurred costs), and with Congressional intent in amending the anti-kickback statute to provide for a pharmacy waiver safe harbor.

Comment: Several commenters asked that coverage supplementing the benefits available under Part D coverage provided by various government programs be allowed to count as incurred costs for purposes of TrOOP. These government insurers and programs included Medicaid (using State-only funds), Medicaid Section 1115 ''Pharmacy Plus'' waiver programs, Federally qualified health centers (FQHCs), the Department of Veterans Affairs health care program, and local or State indigent drug programs.

In addition, a substantial number of commenters urged us to allow coverage that supplements the benefits available under Part D coverage that is provided by AIDS Drug Assistance Programs (ADAPs) funded under the Ryan White CARE Act to count as incurred costs. These commenters argued that ADAPs are an integral component of the safety net for HIV/AIDS patients because they fill coverage gaps in public and private insurance for critical HIV/AIDS drug treatments. They argue that if ADAP supplemental coverage payments do not count as incurred costs, ADAPs will have little incentive to coordinate coverage with Part D plans, particularly if Part D plans impose user fees on ADAPs. Many of these commenters also urged us to define ADAPs as SPAPs so that their supplemental coverage will be considered incurred costs for the purposes of TrOOP.

Several commenters also objected to the inclusion of IHS and Indian Tribes and Tribal organizations, and urban Indian organizations (collectively I/T/U) facilities in the definition of ''insurance or otherwise'' in § 423.100 of our proposed rule. Since IHS beneficiaries—by custom and regulation—may not be charged any cost-sharing, I/T/U facilities must provide supplemental coverage for all cost-sharing that would have been assessed by a Part D plan. For this reason, the commenters argue, our proposed regulations essentially ensure that most IHS beneficiaries will never incur costs above the out-of-pocket threshold and thus subject AI/AN enrollees and the I/T/U pharmacies that serve them to severe financial penalties in comparison to non-AI/ANs and non-I/T/U pharmacies. I/T/U facilities will have to continue to use their limited appropriated funds to pay the prescription drug costs of AI/AN beneficiaries. Commenters further argue that the proposed exclusion of financial assistance for cost-sharing provided by I/T/U facilities is not required by the statute and is simply an interpretation of the term ''insurance or otherwise.'' Given the Federal government's obligation to provide health services to AI-ANs based on the government-to-government relationship between the United States and Tribes, these commenters argue that IHS and tribal health programs are not ''insurance or otherwise,'' but instead ''persons'' given that I/T/U facilities are the functional equivalent of ''family members.'' We were also asked to clarify why supplemental coverage of deductible costs counts toward a beneficiary's deductible limit, but supplemental coverage of cost sharing above the deductible and initial coverage limit, does not count toward TrOOP.

Response: Section 1860D–24(a)(1) of the Act extends the coordination of benefits provisions required for SPAPs to entities providing other prescription drug coverage—including Medicaid programs, Section 1115 waiver demonstrations, group health plans, Federal Employee Health Benefits Program (FEHBP), military coverage (including TRICARE), and ''such other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of Part D eligible individuals as the Secretary may specify.'' Section 1860D–24(b) of the Act defines includes among these entities providing other prescription drug coverage some government payers, which when coupled with section 1860D–24(a)(2) of the Act, which specifically applies the TrOOP provisions at 1860D–2(b)(4)(D) of the Act to Rx plans suggests that the Congress intended for the term ''insurance or otherwise'' to include government benefit plans or programs that provide health care or pay the cost of covered Part D drugs. Although section 1860D–24(b) of the Act does not list all the government health care programs we consider to be ''insurance or otherwise,'' in the absence of a meaningful distinction between those entities specifically listed in section 1860D–24(b)—Medicaid, SPAPs, TRICARE, and FEHBP—and other government health care programs, allowing payments from such other programs to count toward TrOOP would be arbitrary. Further, in giving the Secretary the authority to identify other entities providing other prescription drug coverage under section 1860D–24(b)(5) of the Act, the Congress contemplated that its list of entities providing other prescription drug coverage was not exhaustive.

For additional clarification of this issue, we have split the definition of ''insurance or otherwise,'' in our proposed rule into two separate definitions—''insurance'' and ''or otherwise''—in our final rule. The term insurance (at § 423.100 of our final rule) refers to a health plan that provides, or pays the cost of covered Part D drugs, including, but not limited to health insurance coverage, a MA plan, and a PACE organization. We note that our definition of ''insurance'' does not modify the definition of ''health plan'' at 45 CFR 160.103 of the HIPAA Administrative Simplification Regulations, or any interpretation thereof issued by the Department of Health and Human Services.

We believe that the phrase ''or otherwise'' refers to government-funded health programs. We have defined the term ''government-funded health programs'' at § 423.100 of our final rule to mean any program established, maintained, or funded—in whole or in part—by the Federal government, the

governments of States or political subdivisions of States, or any agency or instrumentality of these governments which uses public funds in whole or in part to provide to, or pay on behalf of, an individual the cost of Part D drugs. Thus, insurance or otherwise encompasses not just traditional health insurance coverage that is not considered a group health plan, but also government programs and entities (including the Department of Veterans Affairs (VA), IHS, Federally Qualified Health Centers (FQHCs), Department of Labor (DOL) Federal Workers' Compensation Program), government insurers (including Medicaid, Medicaid 1115 demonstrations, and the State Children's Health Insurance Program (SCHIP)), and government-sponsored funds (including black lung benefits, Ryan White CARE Act funds, and State special funds that assist certain individuals with their medical costs, such as a special fund for AIDS patients).

We believe we have defined these terms consistent with the Congress's intent of reducing incentives for current employers, other insurers, and government programs to reduce their current levels of coverage. Because costs for covered Part D drugs paid by insurance or otherwise on behalf of a Part D enrollee do not, as previously discussed, count as incurred costs, any coverage that supplements the benefits available under Part D coverage that are provided to beneficiaries by Medicaid, Medicaid Section 1115 ''Pharmacy Plus'' waiver programs, the VA health care program, the IHS, ADAP programs, and local or State indigent drug programs would not count as an incurred cost for purposes of TrOOP. We note, however, that to the extent that a State provides assistance with covered Part D costs to Part D enrollees with State-only funds and meets the requirements of a State Pharmaceutical Assistance Program as specified in § 423.464(e)(1), such assistance does count as an incurred cost as provided by section 1860D–2(b)(4)(C)(ii) of the Act. However, if an entity providing for or paying the cost of drugs receives a government grant none of which is used to pay for drugs (for example, a low-income housing grant)—such an entity is not considered a government-funded program. On the other hand, if an entity pays for drugs using a mix of private and public funds, the entity is considered a government-funded health program, and all of its drug spending is excluded from TrOOP.

As mentioned above, Pharmacy Plus program costs, including State spending, cannot be counted towards TrOOP because Pharmacy Plus programs are funded under Medicaid and therefore do not qualify as SPAPs. For this reason, we believe that, generally, States will be better off and will realize savings if they restructure their prescription drug programs as SPAPs, rather than continuing their Pharmacy Plus programs. Their savings could be used in a variety of ways, such as directly paying for their enrollees' Part D premiums, wrapping around the Part D benefit by paying for the required cost-sharing, or paying Part D plans for supplemental benefits.

According to IHS estimates, we anticipate that a large proportion of AI/ANs will be eligible for low-income subsidies under Part D, which should significantly limit the financial impact on I/T/U facilities. For those AI/ANs not eligible for the low-income subsidies and enrolled in a Part D plan, the IHS will still obtain some benefit from Part D coverage because I/T/U facilities participating in Part D plan networks will be reimbursed for 75 percent of spending (on average) between the deductible and the initial coverage limit. Moreover, AI/AN enrollees will experience no difference in the way they obtain their prescription drugs to the extent that they use I/T/U pharmacies or IHS-contracted pharmacies.

ADAPs cannot be considered SPAPs because these programs receive Federal funding. As discussed in subpart J, we have interpreted section 1860D–23(b) of the Act, which requires SPAPs to be State programs that provide financial assistance for the purchase of provision of prescription drugs, to mean that an SPAP must provide such assistance with State funds. Therefore, the definition of the term SPAP excludes any program in which program funding is from Federal grants, awards, contracts, entitlement programs, or other Federal sources of funding (though we clarify that this does not exclude some Federal administrative funding or incidental Federal monies). Since ADAPs receive Federal funding, they cannot be defined as SPAPs under § 423.454 of our final rule. However, according to HRSA estimates, we anticipate that a substantial majority of ADAP enrollees will qualify for low-income subsidies. For those ADAP enrollees who do not receive a full or partial subsidy, we estimate that the Part D benefit would pay 75 percent, on average, of an enrollee's covered Part D drug expenditures between the deductible and initial coverage limit. To ensure coordination of benefits for the HIV/AIDS and population, as well as to eliminate any barriers to enrolling in Part D benefits, the ADAP program may wish to pay for their beneficiaries' premiums to eliminate any barriers to Part D benefits.

Per several commenters' request, we also wish to clarify that section 1860D–2(b)(4)(C) of the Act defines the term ''incurred costs'' only for the out-of-pocket threshold. Thus, the fact that coverage that supplements the benefits available under Part D coverage that is provided by certain entities is excluded from the definition of incurred costs for purposes of TrOOP has no bearing on counting that supplemental coverage against the deductible. In other words, ADAPs, IHS, and other programs providing coverage that supplements the benefits provided under Part D may subsidize costs incurred against a Part D enrollee's deductible for those patients unable to afford these costs. The provision of the supplemental coverage will not affect an enrollee's ability to satisfy the deductible and therefore qualify for reduced cost-sharing between the deductible and the initial coverage limit. In addition, these entities are not precluded from paying for a Part D enrollee's cost-sharing above the out-of-pocket threshold once a beneficiary has accumulated incurred costs in excess of the out-of-pocket threshold.

Comment: We requested comments regarding the treatment of health savings account (HSAs), flexible savings arrangements (FSAs), health reimbursement arrangements (HRAs), and medical savings accounts (MSAs) vis-à-vis our definitions of ''group health plan,'' ''insurance or otherwise,'' and ''third party payment arrangements.'' Many commenters suggested that HSAs, FSAs, MSAs, and HRAs be excluded from our proposed definition of ''group health plan'' such that any distributions used by Part D enrollees to pay out-of-pocket costs associated with cost-sharing for covered Part D drugs are allowed to count as incurred costs. These commenters agreed that these funds are analogous to beneficiaries' bank accounts. Some of these commenters asked that we specify that payment of out-of-pocket expenses via these accounts count toward TrOOP only when such accounts are bona fide arrangements set up in accordance with IRS rules and guidance, such funds are not limited to paying prescription drug expenses, and individuals have control over how the funds from these accounts are utilized. One commenter notes that any exemption of HSAs, FSAs, MSAs, and HRAs from our definition of ''group health plan'' should be written carefully to avoid circumvention of Medicare Secondary Payer (MSP) laws. Another

commenter noted that from Part D plans' perspective, it makes the most sense administratively and operationally to allow funds from these accounts to count toward incurred costs because it will be difficult for them to identify and differentiate between different sources of enrollee funds and carve out the payments from TrOOP calculations. One commenter noted that HRAs present a more difficult case, since they are by definition employer-funded only. However, this commenter noted that, from an administrative perspective, it may be difficult to distinguish between HRAs and other types of personal health savings vehicles.

In contrast, several commenters disagreed that HSAs and similar accounts should be exempted from our definition of ''group health plan.'' Some of these commenters believed that contributions from one type of employer-sponsored benefit should not receive differential treatment than other types, particularly when contributions from employer-sponsored group health coverage are not being counted as incurred costs. One commenter thought that we had no statutory authority to create a special rule to exempt HSAs from our definition of ''group health plan.'' This commenter was concerned about non-employer sponsored HSAs, that these funds are not like bank accounts given the tax breaks associated with them, that allowing these funds to count toward TrOOP discriminates against retirees with employer-sponsored drug coverage, and that we would create a substantial windfall and unjustified double taxpayer subsidy.

Response: We agree with the majority of the commenters that HSAs, FSAs, and MSAs are essentially analogous to a beneficiary's bank account, and that distributions from these personal health savings vehicles should count as incurred costs for the purposes of the out-of-pocket threshold. However, as one commenter noted, we believe that HRAs are fundamentally different from these personal health saving vehicles because they are required to be solely employer-funded. Although employers are permitted to contribute funds to HSAs, FSA, and MSAs and may administer the benefits associated with these accounts, employees are not foreclosed from contributing to these vehicles as they are under HRAs. Excluding FSAs, MSAs, and HSAs from the definitions of ''insurance'' and ''group health plan'' for purposes of calculation of TrOOP expenditures will further our objective of encouraging beneficiaries to set aside their own money for drug expenses by allowing those funds to count toward enrollees' TrOOP expenditures. In order to clarify that distributions from HSAs, FSAs, and MSAs can be counted toward a Part D enrollee's incurred costs, we have revised the definitions in § 423.100 of our final rule accordingly and added a definition of ''personal health savings vehicles'' that is limited to HSAs, FSAs, and Archer MSAs.

We note that the term ''group health plan'' is used in reference to TrOOP, creditable coverage, and the retiree subsidy in our final rule, but that we do not define the term uniformly in our final rule. Section 1860D–22(c) of the Act explicitly defines ''group health plan'' to include ERISA plans, which may include an FSA, MSA, and, in limited circumstances, an HSA. The reference to ''group health plan'' under the creditable coverage provisions in section 1860D–13(b)(4)(C) of the Act states that a group health plan includes a qualified retiree prescription drug plan as defined under section 1860D–22 of the Act, which is in turn based on the definition of ''group health plan'' under section 1860D–22(C) of the Act and thus may include an MSA or, in limited circumstances, an FSA or HSA. In contrast, the TrOOP provisions simply refer to a ''group health plan,'' without specifying what this term may include. Given that the statutory references to ''group health plan'' under the TrOOP and creditable coverage provisions use different language, and that the policies underlying these issues are different, we have adopted two different definitions of the term ''group health plan'': one with regard to the TrOOP provisions, and another with regard to the remaining provisions of Part D, including the creditable coverage and the retiree subsidy provisions. While the Congress specifically enumerated two types of coverage to be considered group health plans with regard to creditable coverage, the TrOOP provisions do not.

We also note that the definition of a ''group health plan'' used to implement the Part D drug benefit will differ from the definition of ''group health plan'' used by the Medicare Secondary Payer (MSP) program for recovery of Medicare payments. While both of our Part D definitions of ''group health plan'' are based on the ''ERISA'' definition set forth at 29 U.S.C. 1167(1), the MSP definition is taken from the Internal Revenue Service (IRS) definition of ''group health plan'' at 26 U.S.C. 5000(b)(1). Therefore, the definitions of ''group health plan'' in § 423.100 and § 423.4 of our final rule do not permit circumvention of the MSP laws since they will not apply in the MSP context.

b. Alternative Prescription Drug Coverage

Section 1860D–2(c) of the Act provides that a Part D sponsor may offer an alternative prescription drug benefit design, provided that the Part D sponsor applies for and receives our approval for the proposed alternative. In order to receive approval to offer an alternative prescription drug benefit design, a Part D sponsor will have to meet the requirements related to actuarial equivalence described in section 1860D–2(c)(1) of the Act, and must use defined standard coverage (and not actuarially equivalent standard coverage) as a fixed point of comparison.

- Basic Alternative Coverage

Beyond the required parameters for alternative coverage discussed above, we interpreted the provisions of section 1860D–2(c) of the Act, together with section 1860D–2(a)(1) of the Act, as providing for two forms of alternative coverage—either ''basic alternative coverage'' or ''enhanced alternative coverage.'' Basic alternative coverage refers to alternative coverage that is actuarially equivalent to defined standard prescription drug coverage. Enhanced alternative coverage refers to alternative coverage that exceeds defined standard coverage by offering supplemental benefits.

Within the parameters for alternative prescription drug coverage described above, a Part D sponsor with a basic alternative prescription drug benefit design can theoretically—by combining features such as a reduction in the deductible, changes in cost-sharing, and a modification of the initial coverage limit—still maintain an actuarial value of coverage equal to defined standard prescription drug coverage.

- Enhanced Alternative Coverage

Section 423.104(f) of our proposed rule permitted Part D sponsors to provide qualified prescription drug coverage that includes supplemental benefits. We referred to any Part D benefit package that includes supplemental benefits as ''enhanced alternative coverage.''

Enhanced alternative coverage includes basic prescription drug coverage and supplemental benefits. The requirements for the supplemental benefits that may be included in enhanced alternative coverage are found in section 1860D–2(a)(2) of the Act. These supplemental benefits will supplement basic prescription drug coverage, providing for a package of benefits that exceeds the actuarial value of defined standard coverage. Supplemental benefits can consist of:

+ Reductions in cost-sharing that increase the actuarial value of the coverage beyond that of defined standard coverage; or

+ Coverage of drugs that are specifically excluded from the definition of Part D drugs under section 1860D–2(e)(2)(A) of the Act and § 423.100 of our proposed rule.

Under section 1860D–2(a)(2)(B) of the Act, a PDP sponsor would not be permitted to offer a prescription drug plan that provided enhanced alternative coverage in a particular service area unless it also offers a prescription drug plan that provides only basic prescription drug coverage (which we defined as either standard prescription drug coverage or basic alternative coverage, with access to negotiated prices) in that same area.

Similarly, as provided under section 1860D–21(a)(1)(A) of the Act, beginning on January 1, 2006, an MA organization cannot offer an MA coordinated care plan in a service area unless that plan, or another MA plan offered by the same organization in the same service area, includes required prescription drug coverage. As defined in § 423.100 of our proposed rule, required prescription drug coverage, for the purposes of an MA organization offering an MA-PD plan, included either: (1) basic prescription drug coverage; or (2) enhanced alternative coverage, provided there is no MA monthly supplemental beneficiary premium applied under the MA-PD plan. The enhanced alternative coverage could be provided without a monthly supplemental beneficiary premium only if a MA-PD plan applied a credit against the otherwise applicable premium of rebate dollars available under section 1854(b)(1)(C) of the Act.

Rebate dollars represent the dollars available for supplemental (and other) benefits when an MA plan's risk-adjusted non-drug bid is under the risk-adjusted non-drug monthly benchmark amount. In other words, to the extent that an MA-PD plan chooses to provide enhanced alternative coverage for no additional premium through the application of rebate dollars, the enhanced alternative coverage would constitute required coverage for the purposes of meeting the requirement in section 1860D–21(a)(1)(A) of the Act.

As provided under section 1860D–21(a)(1)(B)(i) of the Act, an MA organization could not offer prescription drug coverage (other than that required under Parts A and B of Medicare) to enrollees of a medical savings account (MSA) plan. Under section 1860D–21(a)(1)(B)(ii) of the Act, an MA organization also could not offer prescription drug coverage (other than that required under Parts A and B of Medicare) under another type of MA plan—including a private fee-for-service plan—unless the drug coverage it provided under that MA plan consisted of qualified prescription drug coverage and met our requirements regarding required prescription drug coverage.

Given changes in § 417.440(b) of our final rule (described in subpart T), we clarify in our final rule the requirements associated with the offering of enhanced alternative coverage by cost plans. As provided in § 423.104(f)(4)(i) of our final rule, a cost plan that elects to offer qualified prescription drug coverage under Part D may offer enhanced alternative coverage only as an optional supplemental benefit (under § 417.440(b)(2)(ii)), and only if the cost plan also offers basic prescription drug coverage.

As provided in § 423.104(f)(4)(ii) of our final rule, a cost plan that elects to offer Part D coverage as an optional supplemental benefit (under § 417.440(b)(2)(ii)) may only do so if the coverage it offers consists of qualified prescription drug coverage. However, a cost plan that does not offer qualified prescription drug coverage may provide prescription drug coverage that is not qualified prescription drug coverage, and the requirements of Part D do not apply to the coverage.

Except as otherwise provided below, the final rule adopts the rules of alternative coverage set forth in § 423.104(f) and § 423.104(g) of our proposed rule.

Comment: One commenter recommended that we issue regulations encouraging basic alternative coverage including optional drugs because it will offer beneficiaries a more comprehensive benefit package.

Response: We do not have the statutory authority to allow basic alternative coverage to include drugs that are statutorily excluded from the definition of Part D drugs. Coverage of drugs otherwise excluded from the definition of Part D drug under section 1860D–2(e)(2)(A) of the Act is considered a supplemental benefit as provided under section 1860D–2(a)(2) of the Act. As specified in § 423.100 of our proposed and final rules, basic alternative coverage must be actuarially equivalent to defined standard coverage and cannot include any supplemental benefits. The only way that Part D plans may provide supplemental benefits, to include coverage of drugs excluded from the definition of Part D drugs under section 1860–D(2)(e)(2)(A) of the Act, is by providing enhanced alternative coverage.

Comment: One commenter sought clarification as to whether alternative coverage would be subject to the same kind of out-of-pocket cost limits and coverage thresholds instituted under standard prescription drug coverage.

Response: In accordance with section 1860D–2(b)(A)(i)(I) of the Act, Part D plans offering enhanced alternative coverage may only reduce certain cost-sharing specifically, a reduction in the deductible, a reduction in the coinsurance percentage or copayments applicable to covered Part D drugs obtained between the annual deductible, and the initial coverage limit, or an increase in the initial coverage limit. Section 1860D–2(A)(i) does not permit Part D plans to offer enhanced alternative drug coverage consisting of a reduction of the out-of-pocket threshold under § 423.104(d)(5)(iii) of our final rule. Section 1860D–2(c)(3) of the Act also requires that Part D plans offering alternative prescription drug coverage provide the same protection against high out-of-pocket expenditures as defined standard coverage. Thus, enhanced alternative coverage may fill in some of the coverage gaps in defined standard coverage, but it cannot affect the true out-of-pocket threshold described in § 423.104(d)(5)(B)(iii) of our final rule, which will be $3,600 in 2006. In other words, beneficiaries must still incur $3,600 (in 2006) in true out-of-pocket expenses before they can benefit from the Medicare catastrophic coverage cost-sharing amounts (the greater of 5 percent coinsurance or $2/$5 copayments), and before Part D plans are eligible to receive reinsurance subsidies from Medicare. As with actuarially equivalent standard coverage, Part D plans can provide an actuarially equivalent version of the coverage provided after the true out-of-pocket threshold is met. In addition, enhanced alternative coverage can improve this coverage.

Comment: Several commenters opposed the provisions of § 423.104(f) of our proposed rule and recommended that the final rule exclude provisions for enhanced alternative coverage. These commenters argue that this section exceeds the statutory authority supplied to the Secretary under the MMA and that allowing such Part D plans to be offered would make it impossible to make a valid comparison between Part D plans, thus making it more difficult for beneficiaries to choose a Part D plan.

Response: We disagree with these commenters. Section 1860D–2(a)(2) of the Act provides that qualified prescription drug coverage may include supplemental prescription drug

coverage consisting of: (1) reductions in cost-sharing (for example, a reduction in the deductible, a reduction in the coinsurance percentage or copayments applicable to covered Part D drugs obtained between the annual deductible and the initial coverage limit, or an increase in the initial coverage limit), provided these reductions in cost-sharing increase the actuarial value of the benefits provided above the actuarial value of basic prescription drug coverage; or (2) coverage of drugs that are specifically excluded as Part D drugs under section 1860D–2(e)(2)(A) of the Act. ''Enhanced alternative coverage'' is simply our term for qualified prescription drug coverage that includes these supplemental benefits specifically permitted by the statute. We understand commenters' concerns about beneficiaries' ability to compare Part D plan features given the benefit flexibility design accorded to Part D plans under the MMA and will work to ensure that our comparative information is as standardized and user friendly as possible.

c. Negotiated Prices

Section 1860D–2(d)(1) of the Act requires that a Part D sponsor provide beneficiaries with access to negotiated prices for covered Part D drugs. As required by section 1860D–2(d)(1)(B) of the Act, negotiated prices will have to take into account negotiated price concessions for covered Part D drugs such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, and would include any applicable dispensing fees. Access to negotiated prices will be provided even when no benefits would otherwise be payable on behalf of an enrollee due to the application of a deductible, the initial coverage limit, or other cost-sharing.

As required under section 1860D–2(d)(1)(C) of the Act, prices negotiated with manufacturers for covered Part D drugs by either (1) a Part D plan, or (2) a qualified retiree prescription drug plan for covered Part D drugs provided on behalf of Part D eligible individuals will not be taken into account in making best price determinations under the Medicaid program.

Section § 423.104(h)(3) of our proposed rule required that Part D sponsors disclose to us all aggregate negotiated price concessions including discounts, direct or indirect subsidies, and direct or indirect remunerations, they obtain from each pharmaceutical manufacturer that are passed through to the Medicare program in the form of lower subsidies or to beneficiaries in the form of: (1) lower monthly beneficiary premiums; or (2) lower covered Part D drug prices at the point of sale.

As provided under section 1860D–2(d)(2) of the Act, information on negotiated prices reported to us for the purposes of ascertaining the level of pass-through will be protected under the confidentiality provisions applicable to Medicaid pricing data under section 1927(b)(3)(D) of the Act. However, that these confidentiality protections did not preclude audit and evaluation of negotiated price concession information by the HHS OIG.

As provided under section 1860D–2(d)(3) of the Act and codified in § 423.104(h)(4) of our proposed rule, we are authorized to conduct periodic audits either directly or through contracts with other organizations of the financial statements and records of Part D sponsors pertaining to the Part D plans they offer. As required in section 1860D–2(d)(3) of the Act, this auditing will be performed with the ultimate goal of protecting the Medicare program against fraud and abuse, as well as ensuring proper disclosures and accounting under Part D.

Except as otherwise provided below, the final rule adopts the rules for negotiated prices set forth in § 423.104(h) of our proposed rule.

Comment: Some commenters believed that the phrase ''take into account'' in our definition of negotiated prices is not strong enough, and that we should establish minimum requirements for the proportion of total negotiated price concessions passed through to beneficiaries. Suggestions ranged from a majority (75 to 80 percent) to 100 percent of negotiated price concessions.

Response: Section 1860D–2(d)(1)(B) of the Act specifically requires that negotiated prices ''shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations.'' Had the Congress intended that all negotiated price concessions be passed through to beneficiaries, they would have used a phrase other than ''take into account'' in the definition of the term ''negotiated prices.''

In addition, section 1860D–2(d)(2) of the Act specifically requires that Part D plans disclose to us aggregate negotiated price concessions that are passed through to enrollees and to us through lower subsidies, lower monthly premiums, and lower prices through pharmacies and other dispensers. In requiring Part D plans to disclose to us the extent to which they pass through negotiated price concessions to enrollees and to us, section 1860D–2(d)(2) of the Act anticipates that Part D plans might not pass through all negotiated price concessions. Therefore, we interpret the definition of the term negotiated prices in section 1860D–2(d)(1)(B) of the Act as requiring Part D plans to pass on to enrollees some, but not necessarily all, of these price concessions and have clarified this interpretation in our definition of the term ''negotiated prices'' in § 423.100 of our final rule. We believe that market competition will encourage Part D plans to pass through to enrollees a high percentage of the negotiated price concessions they obtain in the form of negotiated prices at the point of sale. Establishing minimum threshold levels for the pass-through of negotiated price concessions would have the effect of undercutting market competition, as Part D plans might cluster their negotiated prices around that threshold.

Comment: Some commenters recommended that we clarify how price concessions will be passed through to the pharmacy and to the beneficiaries. Some of these commenters specifically asked us to ensure that Part D plans, not pharmacists, bear the costs of discounts.

Response: The Part D benefit was established by the MMA as a market-based model under which marketplace competition ensures that enrollees receive low prices for prescription drugs. Given this market-based approach envisioned by the Congress, we are wary of regulating negotiations between private parties particularly regarding the specifics of price negotiations so as to ensure that enrollees receive competitive prices on their covered Part D drugs. We note, as well, that pharmacies are not required to contract with Part D plans. To the extent that pharmacies believe that the discounts they are being asked to offer are too high, they can refuse to participate in Part D plan pharmacy networks. Given our pharmacy access standards at § 423.120(a)(1), we expect that pharmacies will have some leverage vis-à-vis the payment provisions in Part D plan contracts.

Comment: Two commenters stated that they considered our requirement that pharmacies pass through negotiated prices during coverage gaps and for non-covered formulary drugs to be price controls.

Response: Section 1860D–2(d)(1) of the Act requires, as implemented under § 423.104(g)(1) of our final rule, that a Part D sponsor provide enrollees with access to negotiated prices for covered Part D drugs even when no benefits would otherwise be payable on behalf of an enrollee due to the application of a deductible, the initial coverage limit, or other cost-sharing. We interpret the

reference to the lack of payable benefits due to the application of the initial coverage limit as referring to that portion of covered Part D drug expenditures between the initial coverage limit and the threshold for catastrophic coverage. In that expenditure range, a beneficiary enrolled in standard prescription drug coverage would be responsible for 100 percent cost-sharing. These are still covered Part D drugs, and enrollees should be able to benefit from negotiated prices during the coverage gap.

We clarify that negotiated prices do not have to be made available for non-covered Part D drugs. However, as we stated in the preamble to our proposed rule, we are interpreting the phrase ''or other cost-sharing'' as a reference to Part D plan designs that include, as part of their formulary design, access to negotiated prices on certain drugs but at a tier within their formulary in which the Part D plan would pay no benefits and the enrollee would be responsible for 100 percent cost-sharing (in other words, a negotiated price would be available and the drug would be on the Part D plan's formulary, but the beneficiary would always be responsible for 100 percent of the drug's negotiated price). These drugs would therefore be formulary drugs and would have to be offered at negotiated prices. As stated elsewhere in this preamble, however, we note that we will review formulary design as part of our benefit package review to ensure that Part D plans do not establish formulary structures (including tiered cost-sharing) that substantially discourage enrollment by certain beneficiaries. To the extent that Part D plans propose using certain cost-sharing tiers (including, but not limited to, 100 percent cost-sharing tiers) in a discriminatory fashion, they would not be allowed.

In addition, we clarify that we interpret the requirement that negotiated prices always be provided to mean that uniform negotiated prices must be available to beneficiaries for a particular drug when purchased from the same pharmacy. In other words, the negotiated price for a particular drug will be the same, at a particular pharmacy, regardless of whether a beneficiary's drug spending is between $0 and the deductible, between the deductible and initial coverage limit, between the initial coverage limit and the out-of-pocket threshold, or in excess of the out-of-pocket threshold. We believe that non-uniform negotiated prices would discourage enrollment by certain Part D eligible individuals in violation of section 1860D–11(e)(2)(D)(i) of the Act and, therefore, plans will not be able to apply differential negotiated prices to any drug purchased from a given pharmacy.

Comment: Other commenters recommended that the definition of the term ''negotiated price'' reflect the price to the Part D plan net of any rebates, discounts, or other price concessions paid to the Part D plan for a covered Part D drug prescription obtained from either a retail or mail-order pharmacy. Some commenters asked that price concessions not be allowed to artificially lower the cost of mail order prescriptions.

Response: Part D sponsors will negotiate prices with pharmacies and manufacturers, and we assume based on current market practices that negotiated prices will vary within a retail pharmacy network, as well as between retail and mail-order pharmacies. How a Part D sponsor nets out negotiated price concessions in its negotiated prices is at the discretion of the Part D sponsor, but we expect that competition will create incentives for Part D sponsors to offer reasonable negotiated prices. Ultimately, however, these pricing issues are between a Part D sponsor and the network pharmacies and manufacturers with whom the Part D plan negotiates price concessions.

Comment: Some commenters recommended that Part D plans be required to reimburse pharmacies to recover costs of purchasing, handling, and dispensing products to beneficiaries.

Response: As provided elsewhere in this preamble, negotiated prices will include any dispensing fees for covered Part D drugs related to the transfer of possession of the covered Part D drug from the pharmacy to the beneficiary, including charges associated with mixing drugs, delivery, and overhead. As provided in section 1860D–11(i) of the Act, we cannot intervene in negotiations between pharmacies and Part D plans. Thus, the extent to which Part D plans reimburse pharmacies for their entire dispensing costs will depend on the outcome of those negotiations.

Comment: Two commenters noted that our definition of the term ''negotiated prices'' appears to envision network model Part D plans, but that MA organizations and cost plans that own and operate their own pharmacies do not negotiate reimbursement rates with contract pharmacies. One commenter recommended that negotiated prices for such MA organizations and cost plans be defined as the prescription charge established by the organization, and that such charge include the acquisition cost of the drug, dispensing, operational, capital, overhead, and margin costs. The commenter suggested that, in determining whether Part D plans' negotiated prices meet the standard of section 1860D–2(d)(1)(B) of the Act, we could either compare an MA organization's negotiated prices to negotiated prices of network model Part D plans in the same market or, alternatively, require the MA organization to demonstrate how it takes price discounts it receives from manufacturers into account in its pricing methodology or formula. Another commenter suggested that we permit such MA organizations to establish a pricing methodology that reflects a good faith effort to reflect prices analogous to those that would be negotiated by an MA organization with third party pharmacy providers, and that we consult with affected MA organizations in establishing this policy.

Response: We clarify that our definition of the term ''negotiated prices'' in § 423.100 of the final rule requires that ''discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remunerations'' be taken into account in establishing covered Part D drug negotiated prices. Plans do not have to take into account pharmacy discounts to the extent that no such discounts exist. Moreover, we note that our definition of the term ''dispensing fees'' in § 423.100 of the final rule indicates that, in the case of pharmacies owned and operated by a health plan, dispensing fees are understood to be the equivalent of all reasonable pharmacy costs included in the definition (those related to the transfer of possession of a covered Part D drug to a Part D plan enrollee), including the salaries of pharmacists and other pharmacy workers as well of the costs associated with maintaining the pharmacy facility and equipment necessary to operate the pharmacy. For purposes of evaluating the validity of a Part D plan's bid, including its negotiated prices for covered Part D drugs, we will request and evaluate disaggregated negotiated price concession data only to the extent that such detail is necessary in order to justify actuarial assumptions or as part of an audit.

Comment: One commenter asked that we define the meaning of the terms ''direct or indirect subsidies'' and ''direct or indirect remunerations.'' Another commenter suggested that negotiated price concessions reported to us should include formulary placement incentives, market share movement incentives, administrative fees paid to

Part D plans, and direct and indirect forms of remuneration. One commenter asked that we provide clarification on how rebates will be calculated, reflected in negotiated prices, and reported to us.

Response: We note that Part D plans may fulfill the requirements of section 1860D–2(d)(2) of the Act through the data submission requirements discussed in further detail in subpart G. In other words, we should be able to determine the proportion of total aggregate price concessions passed through to either the Medicare program or to enrollees based on the cost data Part D plans will be required to submit to us. Although all negotiated price concessions be they direct or indirect subsidies, direct or indirect remunerations, rebates, or discounts must be reported to us, as provided in § 423.104(g)(3) of our final rule, we will require that Part D plans break out any fair market value administrative fees pharmaceutical manufacturers may pay Part D sponsors. The use of the term indirect with direct is meant to be all-inclusive. In other words, we clarify that this means any and all subsidies or remunerations. We will specify in operational guidance the format and frequency of these reports, as well as what constitutes direct or direct subsidies, direct or indirect remunerations, rebates, and discounts.

Comment: We received a number of comments regarding our aggregate negotiated price concession disclosure requirements. Several commenters asked us to clarify that only aggregate price concessions passed through to us and to enrollees will be reported to us, rather than the amount or proportion of total price concessions obtained by a Part D plan. Other commenters thought that Part D plans should be required to disclose all price concessions, not just the proportion passed through to Part D enrollees. A number of other commenters asked that we require the disclosure of negotiated price concession by drug.

Response: We clarify that, as provided under section 1860D–2(d)(2) of the Act, and specified in § 423.104(g)(3) of our final rule, we will require that all aggregate negotiated price concession data and not just the proportion passed through to beneficiaries be reported to us for purposes of Part D plan bids. However, as explained in subpart G, it may be necessary for us to receive disaggregated negotiated price concession data from Part D plans in order to ensure accurate payment to Part D plans. We will provide further information regarding negotiated price concession reporting in separate guidance.

Comment: Several commenters recommended that Part D plans share all negotiated price concession data reporting with SPAPs.

Response: Since nothing in the MMA addresses disclosure of negotiated price information to SPAPs, FOIA rules apply. FOIA applies to requests for data from States. FOIA Exemption 4 protects certain confidential commercial information that is submitted to a Federal agency. Determinations about the applicability of FOIA Exemption 4 to a Part D plan's pricing data would be made on a case-by-case basis depending on whether the submitter of the data could demonstrate that disclosure of this information would likely cause substantial competitive harm to the submitter's competitive position. If FOIA Exemption 4 is found to protect submitted price information, we cannot disclose this information to States because to do so would violate the Trade Secrets Act (18 U.S.C. 1905).

Comment: One commenter stated the ''best price'' provision undermined the original intent of section 1927 (c)(1)(C) of the Act and would have a negative financial impact on the Medicaid prescription drug program.

Response: We believe the Congress intended that there be no Federal barriers to Part D sponsors negotiating the lowest prices possible for their plan members. If negotiated prices counted towards ''best price,'' this could create a disincentive for manufacturers to offer discounts. Further, the purpose of ''best price'' exemptions in section 1927(c)(1)(C) of the Act is to ensure that manufacturers offer Medicaid programs strong rebates that are market-driven, without penalizing the manufacturers indirectly for the discounts they offer by law under other Federal drug programs. Exempting negotiated prices under the new Medicare prescription drug benefit is consistent with that purpose. The issue of effects on Medicaid best price is discussed in the impact analysis.

Comment: One commenter asked for further guidance regarding the ''best price'' exemption, stating that Part D providers should be able to negotiate simultaneously for commercial prices, which would count toward ''best price,'' and for Medicare/qualified retiree prices, which would not count toward ''Best Price.''

Response: Under section 1860D–11(i) of the Act, we have no authority to regulate price concessions between manufacturers and Part D plans. Consequently, we cannot prohibit or require Part D plans from negotiating simultaneously for commercial prices, which would be included in the calculation of the Medicaid drug rebate best price, and Medicare prices, which would not be included in the calculation of the Medicaid drug rebate best price. If Part D plans wish to simultaneously negotiate their commercial and Medicare prices, they are free to do so.

Comment: One commenter suggested that we recommend to the Congress alternatives to the existing ''best price'' rebate formula. The commenter recommended a flat rebate formula to generate savings for State Medicaid programs, while eliminating the negative impact of the ''best price'' formula on the prescription drug market generally.

Response: This regulation does not address the best price provisions of the Medicaid drug rebate statute as we do not have the statutory authority under Title I of the MMA to modify the Medicaid rebate program.

3. Establishment of Prescription Drug Plan Service Areas (§ 423.112)

Section 1860D–11(a)(2) of the Act provides us with the authority to establish PDP regions, and such PDP regions must be established in a manner that is consistent with the establishment of MA regions. Section 1860D–11(a)(2)(B) of the Act stipulates that PDP regions must be, to the extent practicable, consistent with MA regions as established under section 1858(a)(2) the Act. However, we may establish PDP regions that vary from MA regions if we determine that access to Part D benefits would be improved by establishing different regions. Section 1860D–11(a)(2)(C) of the Act stipulates that we designate a separate PDP region (or regions) for the U.S. territories.

Except as otherwise provided below, the final rule adopts the requirements related to the establishment of prescription drug plan service areas set forth in § 423.112 of the proposed rule.

Comment: We received a number of comments on the establishment of PDP regions both in response to the provisions of our proposed rule and as follow-up to a public meeting held in Chicago on July 21, 2004. The majority of commenters favored establishing 50 State-based regions or, more generally, a larger number of smaller regions—close to that of State-level regions. Issues identified in support of 50 State-based regions included the large assumption of risk associated with the establishment of larger regions; insufficient time for Part D plans to negotiate and develop networks, or to renegotiate providers' contracts and form partnerships; potential difficulties in meeting State licensure and solvency requirements; and greater ease in terms of

coordination between Part D plans and SPAPs in providing coverage that supplements the benefits available under Part D coverage. Several commenters recommended an intermediate number of regions between the 10 and 50 regions authorized by the MMA. One commenter cautioned us to develop an appropriate number of regions in order to ensure that beneficiaries particularly those in rural areas have meaningful access to Part D choices. Yet another commenter recommended that we align PDP and MA regions in order to preclude beneficiary confusion by MA enrollees as they try to understand their options during the initial enrollment period for Part D coverage.

Several other commenters specifically recommended that a standalone region be created for Puerto Rico separate from the 50 States and any of the other U.S. territories. These commenters believe it is necessary for Puerto Rico to be placed in its own PDP region because a multi-state PDP region for Puerto Rico would compromise the viability of Part D on the island. They argue that Puerto Rico-based plans have years of experience working with the local Medicare population and its distinct linguistic and cultural traditions and will be disadvantaged when competing with U.S. companies to build provider networks outside Puerto Rico. Some commenters also thought that combining Puerto Rico and another State or States (for example, Florida or New York) will drive up premiums for Puerto Rican enrollees. On the other hand, one commenter argued that a standalone region for Puerto Rico would isolate it, and preferred to stay in the New York region under the MA and PDP programs.

Response: We conducted a market survey and analysis, including an examination of current insurance markets as required in the MMA. Key factors in the survey and analysis included payment rates; eligible population size per region; PPO market penetration; current existence of PPOs, MA plans, or other commercial plans; and presence of PPO providers and primary care providers. Additional factors were also considered, including solvency and licensing requirements, as well as capacity issues. In response to the lack of specificity regarding the PDP regions in our proposed rule, we conducted extensive outreach in order to obtain public input prior to the publication of our final rule. On December 6, 2004, we announced the establishment of 26 MA regions and 34 PDP regions. For maps and fact sheets on the on the regions, please see *http://www.cms.hhs.gov/medicarereform/mmaregions/*.

4. Access to Covered Part D Drugs (§ 423.120)

a. Pharmacy Access Standards

As required by section 1860D–4(b)(1)(C) of the Act, Part D plans must secure the participation in their pharmacy networks of a sufficient number of pharmacies that dispense drugs directly to patients (other than by mail order) to ensure convenient access to covered Part D drugs by Part D plan enrollees. To achieve that goal, we are authorized to establish access rules that are no less favorable to enrollees than rules for convenient access established in the statement of work solicitation (#MDA906–03–R–0002) by the Department of Defense (DOD) on March 13, 2003, for purposes of the TRICARE Retail Pharmacy program. Consistent with the TRICARE standards, our proposed rule required that Part D plans establish pharmacy networks in which:

- In urban areas, at least 90 percent of Medicare beneficiaries in the Part D plan's service area, on average, live within 2 miles of a retail pharmacy participating in the plan's network;
- In suburban areas, at least 90 percent of Medicare beneficiaries in the Part D plan's service areas, on average, live within 5 miles of a retail pharmacy participating in the prescription drug plan's or MA-PD plan's network; and
- In rural areas, at least 70 percent of Medicare beneficiaries in the Part D plan's service area, on average, live within 15 miles of a retail pharmacy participating in the plan's network.

As provided under section 1860D–21(c)(3) of the Act and codified in § 423.120(a)(3)(i) of our proposed rule, we are authorized to waive the pharmacy access standards in § 423.120(a)(1) in the case of an MA-PD plan or cost plan that provides access (other than via mail order) to qualified prescription drug coverage through pharmacies owned and operated by the MA organization that offers the plan or the cost plan. However, in order for the pharmacy access standards to be waived, the MA-PD plan or cost plan in question is required to have a pharmacy network that, per our determination, provides comparable pharmacy access to its enrollees as provided under § 422.112.

Similarly, section 1860D 21(d)(2) of the Act provides that if a private fee-for-service MA plan offering qualified prescription drug coverage provides coverage for drugs, including covered Part D drugs, purchased from all pharmacies regardless of whether they are network pharmacies under contract with the MA plan, and provided that beneficiaries are not charged any cost-sharing above and beyond what they will be charged under standard prescription drug coverage—the pharmacy access requirements will also be waived.

As provided under section 1860D–4(b)(1)(A) of the Act, Part D sponsors will be required to permit the participation in their Part D plan networks of any pharmacy that was willing to accept the plan's terms and conditions. Based on section 1860D–4(b)(1)(B) of the Act, our proposed rule clarified that a Part D sponsor will have the option of reducing cost-sharing for its enrolled beneficiaries below the level that would otherwise apply for covered Part D drugs dispensed through network pharmacies. We interpreted this provision as permitting Part D sponsors from varying cost-sharing not only based on type of drug or formulary tier, but also on a particular pharmacy's status within the Part D plan's pharmacy network-in essence authorizing distinctions between ''preferred'' and ''non-preferred'' pharmacies.

As stipulated under section 1860D–4(b)(1)(E) of the Act and § 423.120(a)(4)(ii) of our proposed rule, pharmacies could not be required to accept insurance risk as a condition of participation in a Part D sponsor's pharmacy network. We defined ''insurance risk'' in relation to a network pharmacy as referring to risk of the type commonly assumed only by insurers licensed by a State, but not including payment variations designed to reflect performance-based measures of activities within the control of a pharmacy, such as formulary compliance and generic drug substitutions, or elements potentially in the control of the pharmacy (for example, labor costs, and productivity).

Section 1860D–4(b)(1)(D) of the Act requires Part D sponsors to allow their enrollees to receive benefits at a network retail pharmacy instead of a network mail-order pharmacy, if they so choose. Consistent with the statute, our proposed rule allowed Part D plan enrollees who choose to obtain an extended supply of a covered Part D drug through a network retail pharmacy to be responsible for any differential between the network retail pharmacy's and the network mail-order pharmacy's negotiated price for that covered Part D drug. We sought comments on our proposal that this price differential be counted as an incurred cost against the annual out-of-pocket threshold and note that, as discussed elsewhere in this preamble, we have modified the level

playing field provision at § 423.120(b)(10) of our final rule to clarify that an enrollee will be responsible for any higher cost-sharing (and not a differential in negotiated price) associated with purchasing a 90-day supply of a covered Part D drug at a network retail pharmacy, as well as our definition of incurred costs at § 423.100 of the final rule.

Except as otherwise provided below, the final rule adopts the access standards set forth in § 423.120(a) of the proposed rule.

Comment: In our proposed rule, we interpreted the TRICARE access standards such that a prescription drug plan or regional MA-PD plan would have been required to meet or exceed the access standards across each region in which it operates, and a local MA-PD plan would have to meet or exceed the access standards in its local service area.

Some commenters supported this application of the TRICARE access standards in our proposed rules (regional for prescription drug plans and MA-PD plans). A number of commenters expressed concerns about the adequacy of our proposed application of the access standards and urged us to apply the standards at the local (zip-code) level. A number of other commenters urged us to apply the TRICARE standards at the State level. Several other commenters recommended that Part D plans meet the access standards at the broadest geographic area served by the plan (for example, regional, multi-regional, or national).

Response: Although section 1860D–4(b)(1)(C)(ii) of the Act directs us to adopt access standards no less favorable to enrollees than those set forth in the March 13, 2003, statement of work solicitation (#MDA906–03–R–0002) of the Department of Defense under the TRICARE Retail Pharmacy Program, we note that the statement of work does not specify the geographic level at which to apply the TRICARE standard. We therefore believe that we have discretion to apply the TRICARE standards at the geographic level we believe to be most appropriate.

Although we considered applying the TRICARE standard at the local (zip code or county) level for Part D plans, we believe such application would make it impossible for Part D plans to meet the standards particularly the rural standard—in some parts of the country. On the other hand, we believe that application of the access standards at the broader, regional level would not adequately ensure convenient access for beneficiaries given the potential for Part D plans to ''average out'' the access standards across many urban, suburban, and rural areas in a region—thus meeting the access standards in the aggregate but potentially leaving certain parts of a region without convenient access to retail pharmacies.

We agree with commenters who proposed a State-level application of the TRICARE pharmacy access standards for regional MA-PD plans and prescription drug plans, and have made changes to § 423.120(a)(1) accordingly such that a prescription drug plan or regional MA-PD plan will have to meet or exceed the access standards across urban, suburban, and rural areas, respectively, in each State in which it operates, a local-MA-PD plan would have to meet or exceed the access standards across urban, suburban, and rural areas, respectively, in each service area (including multi-county service areas) in which it operates, and a cost plan would have to meet or exceed the access standards across urban, suburban, and rural areas, respectively, in each geographic area in which it operates. In other words, a prescription drug plan or regional MA-PD that operates in a multi-region or national service area could not meet the access standards proposed in § 423.120(a)(1) by applying them across the entire geographic area serviced by the plan; instead, it would have to meet the standards in each State of its multi-region or national service area. We believe that such an interpretation is a reasonable compromise between application at the local level and application at the regional or national level, and maximizes Part D plan flexibility while ensuring convenient access to network pharmacies for Part D enrollees.

Comment: Some commenters expressed concern that TRICARE's rural access standard was insufficient to provide convenient access to network pharmacies in rural areas and urged us to adopt a more adequate definition of rural. Others argued for an exceptions process for remote, isolated areas in which it is simply not feasible to establish pharmacy networks that comply with our requirements.

Response: We are aware of the difficulties faced by rural beneficiaries in accessing medical care. We believe that TRICARE's definition of ''rural'' is adequate and have not modified it in our final rule (though we will monitor the access standards over time to ensure they continue to provide convenient access to all beneficiaries). Furthermore, we believe access in rural areas will be improved given our revised interpretation of the access standards, whereby we will evaluate access at the State (and not the regional) level. However, we are aware—based on our experience implementing the Medicare Prescription Drug Discount Card and Transitional Assistance Program—that there are likely to be several States in which meeting the rural access standard will be impossible or impracticable given the lack of infrastructure. We expect to establish an exceptions process, which we will outline in operational guidance to Part D plans that will account for any problem areas and mitigate any disincentives plans may have to avoid doing business in parts of the country in which meeting the pharmacy access standards would be a challenge.

In addition, and as explained elsewhere in this preamble, and codified in § 423.120(a)(2) of our final rule, we will allow Part D plans to count certain non-retail pharmacies—specifically, I/T/U, Federally Qualified Health Center (FQHC), and Rural Health Center (RHC) pharmacies—toward the pharmacy access requirements in § 423.120(a)(1) of our final rule. We believe this policy will help ensure convenient access in rural areas.

Comment: Several commenters asked that we ensure that national Part D plans are created. These commenters thought that national Part D plans would be of benefit to beneficiaries who travel regularly or who reside in more than one State in a given year (for example, ''snowbirds''), and urged that the ramifications of choosing a local MA-PD plan or a regional Part D plan be made clear to beneficiaries who may not realize the implications of such limited geographic access when they select Part D plan coverage.

Response: Although a Part D sponsor may offer a Part D plan in more than one PDP or MA region, it is not required to do so. Therefore, we cannot require national Part D plans, though we certainly recognize the benefits of such plans for some beneficiaries given the limited applicability of our out-of-network access policy. We note that our pharmacy access standards would not in any way preclude Part D sponsors from contracting with pharmacies outside their Part D plans' service areas, provided that the plans meet the pharmacy access requirements within their service areas. Such a feature would be of particular use to beneficiaries who spend significant amounts of time outside their Part D plan's service area (for example, snowbirds) and could make a particular Part D plan that offered such benefits more attractive to beneficiaries who travel regularly. National Part D plans are also of interest to employers who have retirees living throughout the country, and the

employer group waiver authority discussed in subpart J could facilitate these employer-only national Part D plans. We also note that, as part of our information dissemination requirements in § 423.128(b) of the final rule, Part D plans will be required to inform beneficiaries about the plan's service area, as well as the locations of network pharmacies.

Comment: Several commenters asked us to make allowances for ''snowbirds,'' stating that our regulations should allow Part D sponsors to offer ''visitor/traveler'' benefits available under the MA program. One commenter specifically suggested the application of the MA requirements, which allow an organization to provide such benefits to an individual who is temporarily out of the area for up to 12 months. A few commenters stated that we should require prescription drug Part D plans to offer visitor/traveler benefits. One commenter suggested, however, that we allow exceptions for regional Part D plans and those with out-of-network services. One commenter suggested that we consider allowing Part D plans to offer ''travel'' networks without requiring them to contract in those regions, suggesting that this could be an interim approach pending evaluation of the cost/payment experience for both Part D plans and us.

Response: We appreciate the feedback provided by the commenters on applying a visitor/traveler benefit to prescription drug plans as has been provided to the MA program. We do not have the authority to establish a visitor/traveler benefit. However, as noted above, our pharmacy access standards would not in any way preclude Part D sponsors from contracting with pharmacies outside their plans' service areas, provided that plans meet the pharmacy access requirements within their service areas, and such access is not provided outside the United States.

Comment: We interpreted the access requirements in section 1860D–4(b)(1)(C) of the Act as requiring Part D plans to count only retail pharmacies as part of their networks for the purpose of meeting the access standards, and we proposed defining a retail pharmacy as any licensed pharmacy from which covered Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy. We also requested comment regarding whether we should allow Part D plans to count pharmacies that are operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (I/T/U pharmacies) toward their network access requirements when the pharmacies are under contract with the Part D plan, and it would be impossible or impracticable for the plan to meet the access standard in rural areas of its service area without the inclusion of some or all of these pharmacies. In addition, we solicited comments on permissible ways to ensure enrollee access to FQHC and rural pharmacies, since these pharmacies could potentially provide access to covered Part D drugs in remote, rural areas.

Several commenters support counting only retail pharmacies towards Part D plans' access requirements. Other commenters supported allowing I/T/U pharmacies to count toward Part D plans' pharmacy access requirements to the extent that we do not require Part D plans to offer I/T/U pharmacies a standard contract, at a minimum.

Response: We agree that, in most cases, only retail pharmacies, which we define in § 423.100 of our final rule as any licensed pharmacy from which covered Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy, should count toward our pharmacy access standards. Examples of non-retail pharmacies include I/T/U, FQHC, Rural Health Center (RHC), and hospital and other provider-based pharmacies, as well as Part D-owned and operated pharmacies that serve only plan members.

However, as explained elsewhere in this preamble, we are concerned about access to pharmacies in rural and underserved areas. As one way of addressing this concern, § 423.120(a)(2) of our final rule allows Part D plans to count certain non-retail pharmacies—specifically, I/T/U, FQHC, and RHC pharmacies toward the pharmacy access requirements in § 423.120(a)(1) of our final rule.

FQHCs and RHCs face many of the same barriers to inclusion in commercial plan networks as do I/T/U pharmacies, which we discuss in greater detail elsewhere in this preamble. Beneficiaries served by FQHCs and RHCs are often served in those settings because of their financial and geographic circumstances. We believe that allowing Part D plans to count these pharmacies toward their access requirements will incentivize plans to make an extra effort to solicit and include these pharmacies in their networks. As the number of these pharmacies is limited and, with the exception of I/T/U pharmacies, can generally offer services to a broad-based population, we do not believe that this exception will have a significant impact on convenient access to pharmacies in rural areas for the general population. However, we intend to review Part D plans' proposed pharmacy networks to ensure that their inclusion of I/T/U, FQHC, and RHC pharmacies does not substitute for the inclusion in Part D plan networks of retail pharmacies. We also note that this policy should not be interpreted as requiring broader access to I/T/U, FQHC, and RHC pharmacies than is currently permissible.

Comment: Several commenters expressed concern about the inclusion of rural and FQHC pharmacies in Part D plan networks, with some advocating for requiring plans to contract in some cases, under preferential contracting terms and conditions with these pharmacies. Other commenters opposed requiring Part D plans to contract with specific kinds of pharmacies, asserting that the any willing pharmacy and pharmacy network access requirements are sufficient to ensure an adequate pharmacy network for all beneficiaries. One commenter asked that, to the extent we require Part D plans to contract with certain pharmacies, plans would only be required to offer standard terms and conditions.

Response: With the exception of I/T/U pharmacies, we will not require Part D plans to contract with non-retail pharmacies including FQHC or rural pharmacies. We believe our access standards for rural areas and the Statewide application of access rules generally will ensure adequate access in rural areas. However, as discussed elsewhere in this preamble, we will allow Part D plans to count I/T/U, FQHC, and RHC pharmacies toward their access requirements as an incentive for Part D plans to contract with these pharmacies, which are critical providers in underserved areas.

Comment: One commenter believes we should mandate that Part D plans solicit inner city and rural pharmacies that meet the Small Business Administration's small business standard for participation in their pharmacy networks and should give them access to any terms that the Part D plan offers to a subset of pharmacies.

Response: We believe the pharmacy access standards, as well as their application at the State level, in § 423.120(a)(1) of our final rule, will ensure adequate access to covered Part D drugs for all Part D enrollees in urban, suburban, and rural areas. Given the standards, pharmacies' bargaining power will be strengthened in underserved areas. Ultimately, however, it is at Part D plans' discretion how they will establish pharmacy networks—

including the offering of contracting terms and conditions that are different than standard contracting terms and conditions and the establishment of preferred pharmacies provided they meet our pharmacy access standards, non-discrimination provisions, and other applicable requirements under Part D. We believe that the type of market intervention requested by the commenter is contrary to the Congress's intent that we not interfere in the private negotiations between Part D plans and pharmacies. We will therefore not mandate that Part D plans solicit inner city and rural retail pharmacies or that they automatically deem them preferred pharmacies within their networks.

Comment: We sought public comments regarding whether we should consider using the authority in section 1860D–4(b)(1)(C) of the Act to require that Part D plans contract with a sufficient number of home infusion pharmacies in their service area to provide reasonable access for Part D enrollees.

Several commenters supported requiring Part D plans to contract with a sufficient number of home infusion pharmacies in their service areas to ensure adequate access for beneficiaries. One commenter noted that this requirement would result in savings for the Medicare program by reducing expenditures under Parts A and B. In addition, these pharmacies allow beneficiaries to safely receive their medications at home by providing training and skilled support so beneficiaries can avoid the inconvenience of hospitals, clinics, and doctor visits. One commenter urged us to expand our proposed requirement to include all specialty pharmacies, not just home infusion pharmacies.

Other commenters recommended not mandating Part D plans to contract with these non-retail pharmacies but rather encourage participation because it would reduce negotiating leverage of plans with these pharmacies.

One commenter urged that home infusion pharmacies should not be counted toward network TRICARE standards.

Response: We agree with commenters who believe that we should use our authority under section 1860D–4(b)(1)(C) of the Act to require Part D plans to provide adequate access to home infusion pharmacies. Given coverage of home infusion drugs under Part D, we do not believe it is an option for Part D plans not to include at least some home infusion pharmacies in their networks in order to provide enrollees with meaningful access to those drugs. This is particularly a concern with regard to prescription drug plans which, unlike other Part D plans, do not benefit from reduced medical costs associated with home infusion and may therefore have little incentive to contract with home infusion pharmacies. Therefore, we have added a new provision to our final regulations at § 423.120(a)(4) which requires Part D plans to demonstrate to us that they provide adequate access to home infusion pharmacies consistent with CMS operational guidance to Part D plans. We expect that Part D plans will demonstrate adequate access based in part on the number of enrollees in their service areas and the geographic distribution and capacity of home infusion pharmacies in those service areas. We have not included specialty pharmacies that do not provide home infusion services in this requirement however, as it is unclear whether beneficiaries will need routine access to such pharmacies or would not be adequately served through our out-of-network access rules. We clarify, that we have made a distinction between specialty pharmacies and long-term care pharmacies. We note that home infusion pharmacies will not count toward Part D plans' pharmacy access requirements because they are not retail pharmacies.

Comment: We requested comments regarding the advantages and disadvantages of using the authority provided under section 1860D–4(b)(1)(C)(iv) of the Act to require Part D plans to approach some or all long-term care pharmacies in their service areas with at least the same terms available under their standard pharmacy contracts, or, alternatively, to not require (but strongly encourage) Part D sponsors to negotiate with and include long-term care pharmacies in their Part D plans' pharmacy networks. In addition, we requested comments regarding how to balance convenient access to long-term care pharmacies with appropriate payment to long-term care pharmacies under the provisions of the MMA.

Some commenters were adamant that the current one-to-one relationship between the long-term care pharmacies and nursing homes be preserved, as it is critical to ensuring safety and convenient access to drugs for Medicare beneficiaries residing in nursing homes. One commenter suggested that Part D plans should also provide standardized long-term care pharmacy contracts that recognize long-term care pharmacies' essential role.

Some commenters recommended that the final regulation require Part D plans to contract with any willing long-term care pharmacy. A number of commenters would prefer that we do not require Part D plans to contract with any particular non-retail pharmacies (including long-term care pharmacies) because both our access standards and the any willing pharmacy requirement adequately address our objective of ensuring access to Part D drugs for all enrollees. One commenter notes that Part D plans will need to include long-term care pharmacies in their networks to meet access standards, and that this will encourage Part D plans to contract with long-term care pharmacies. Another believes that we struck a balance with the option for long-term care pharmacies to provide benefits in- or out-of-network because it gives long-term care pharmacies and Part D plans the appropriate negotiating flexibility to reach mutually satisfactory arrangements for providing services to long-term care residents. Also, one commenter points out that some long-term care pharmacies would not be able to meet all the operational standards necessary to participate in Part D, and Part D plans would have to negotiate special reimbursement rates with these pharmacies. Some commenters believe that we should promote appropriate payment methodologies (for example, via dispensing fees or separate fee schedules to pay for specialized services) that would enable all long-term care pharmacies to join networks and provide a meaningful benefit. Another variation suggested was that a Part D plan should be required to include at least one long-term care pharmacy in its network and to contract with any long-term care pharmacy that agrees to the Part D plan's standard contract.

One commenter reasoned that there should be a balance in the contracting requirement; for example, long-term care pharmacies that service X percent of beneficiaries should also be required to contract with at least one Part D plan. But, without this balance, the commenter felt the Part D plans and long-term care pharmacies should be strongly encouraged to contract with each other. A few commenters believed that we should encourage, but not require, Part D plans to contract with long-term care pharmacies and that we should explicitly state in regulation that long-term care residents can access long-term care pharmacies as out-of-network providers when those pharmacies do not contract with particular Part D plans. Other commenters believe that it is sufficient to require that long-term care pharmacies be offered standard

contracting terms and conditions by Part D plans.

Response: Section 1860D–4(b)(1)(C)(iv) of the Act provides that, in establishing rules for convenient access to network pharmacies, we may include standards with respect to access to long-term care pharmacies for Part D enrollees who reside in long-term care facilities. For a variety of reasons, including the quality aspects of Federal nursing home regulations, it is generally the case that long-term care facilities have chosen to contract with a single long-term care pharmacy. Given this state of affairs, our proposed rule assumed that Part D enrollees residing in a long-term care facility could not reasonably be expected to access their Part D drugs at another pharmacy if their facility's long-term care pharmacy is not part of their Part D plan's network. In the proposed rule, we proposed that enrollees residing in long-term care facilities whose contracted long-term care pharmacies did not participate in their Part D plans' networks could continue to use those long-term care pharmacies consistent with our proposed out-of-network access policy. However, given the narrow statutory authority to establish out-of-network access rules provided by section 1860D–4(b)(1)(C)(iii) of the Act, we do not believe as discussed in greater detail elsewhere in this preamble that access to out-of-network pharmacies on a routine basis can be justified. Thus, beneficiaries residing in long-term care facilities that do not contract with a pharmacy included in their Part D plan network will not be able to access covered Part D drugs at the out-of-network long-term care pharmacy through the out-of-network access rules in § 423.124 of our final rule.

However, it is important to note that we will provide a SEP for prescription drug plan enrollment and disenrollment for beneficiaries entering in, living in, or leaving an institution. In addition, individuals enrolled in an MA-PD plan have an unlimited open enrollment period for institutionalized individuals (OEPI). While MA organizations may choose individually, at the plan level, whether or not to be open for enrollments during this period, they must always accept disenrollments.

Given the risk associated with institutionalized beneficiaries, relying on the market alone to ensure that Part D plans include a sufficient number of long-term care pharmacies in their networks may not be sufficient. We note that relying on the pharmacy access standards in § 423.120(a)(1) of our final rule will also not ensure sufficient access to long-term care pharmacies, since many of these pharmacies are not retail pharmacies and therefore would not count toward those requirements. Absent a contracting mandate, Part D plans may view contracting with long-term care pharmacies given the risk associated with institutionalized beneficiaries as too risky. To the extent that we require Part D plans to solicit long-term care pharmacies in their service areas to join their networks, plans may be forced to negotiate preferential contracting terms and conditions (relative to the terms they would offer any other pharmacy willing to participate in its network) for long-term care pharmacy-specific specialized packaging and services with a number of long-term care pharmacies in order to meet our requirement. In addition, although the statute includes an ''any willing pharmacy'' requirement, even if we require Part D plans to contract with any long-term care pharmacy in a service area, we cannot compel long-term care pharmacies to accept the plans' terms and conditions.

We believe it is essential to inject competition into the long-term care pharmacy market while preserving the relationships and levels of service that long-term care facilities now enjoy vis-à-vis their contracted long-term care pharmacies. To that end, we have used our authority under section 1860D–4(b)(1)(C)(iv) of the Act to require, in § 423.120(a)(5) of our final rule, that Part D plans offer standard contracting terms and conditions, including performance and service criteria for long-term care pharmacies that we will specify in operational guidance to all long-term care pharmacies in their service areas. In other words, we are establishing an ''any willing pharmacy'' requirement specifically for long-term care pharmacies, coupled with a requirement that Part D plans develop standard contracting terms and conditions for long-term care pharmacies, such that any pharmacy in a service area could become an eligible long-term care pharmacy by certifying that it meets certain performance and service criteria for providing pharmacy services to long-term care facilities. These criteria would be incorporated into a Part D plan's standard contracting terms and conditions for long-term care pharmacies. We will provide further detail regarding these criteria in operational guidance, but we expect that they will address access to urgent and emergency medications on a 24/7 basis, standardized prescribing systems, and the availability of one of several standard delivery packaging and delivery systems for routine medications. We expect to review the reasonableness of Part D plans' standard contracting terms and conditions for long-term care pharmacies. We note that entities other than current long-term care pharmacies (for example, retail pharmacies) could become an eligible long-term care pharmacy by meeting these standards of practice, so long as they also meet specific State law requirements, if any, for such entities. Plans in a region would be required to contract with any willing long-term care pharmacy in that region, provided those pharmacies were able to reach agreement with Part D plans on all standard contract terms and conditions including payment rates.

As provided in § 423.120(a)(5) of our final rule, we will require Part D plans to demonstrate that they have contracts with a sufficient number of long-term care pharmacies to ensure convenient access to prescription drugs for institutionalized beneficiaries within the service area. We will provide more detailed information in CMS guidance regarding what constitutes convenient access, but we expect that Part D plans will demonstrate convenient access based in part on the number of enrollees in their service areas and the geographic distribution, capacity, and contracting relationships with long-term care facilities of long-term care pharmacies in those service areas.

We expect that each long-term care facility will select one or more eligible network pharmacies to provide a Part D plan's long-term care drug benefits to all of its residents enrolled in a Part D plan. In order to minimize the number of pharmacy suppliers and maintain patient safety, long-term care facilities will likely select long-term care pharmacies that meet Part D standards and participate in the largest number of Part D plan long-term care networks. To maintain convenient access and minimize out-of-pocket expenses, Part D plan enrollees would obtain Part D benefits from the eligible long-term care pharmacy selected by the facility. The SEP and OEPI available to institutionalized beneficiaries, which will provide beneficiaries with the ability to change Part D plans to the extent that their current Part D plan does not include their facility's long-term care pharmacy in its network, will further incentivize long-term care pharmacies to participate in as many Part D plan long-term care networks as possible.

All long-term care pharmacies in a region will have to negotiate terms and conditions with as many Part D plans as possible or risk losing this business to

another more competitive long-term care pharmacy. This competition will preserve the one-to-one long-term care pharmacy long-term care facility relationship favored by so many commenters, but will require a negotiation between the long-term care pharmacy and the Part D plan to maintain that relationship. Given our rules for access to Part D drugs for institutionalized Part D enrollees, all Part D products and services would be removed from existing long-term care pharmacy contracts because payments for drugs for dual eligible individuals under Medicaid will become obsolete. This will likely necessitate the renegotiation of existing long-term care facility/long-term care pharmacy contracts. Separating the cost of the drug and dispensing fee from other long-term care pharmacy specialized services (for example, drug administration) may provide for more appropriate negotiation of these services and costs between long-term care facilities and pharmacies. We note that Part D plan payments under medication therapy management programs, described in further detail elsewhere in this preamble, may represent an additional revenue stream to long-term care pharmacy services for some of the special services provided by these pharmacies but not reimbursed through dispensing fees.

We believe that our long-term care pharmacy access rules will align incentives to accomplish several goals, including ensuring that long-term care pharmacies come to the table in good faith; negotiation of more competitive pricing than currently exists in the long-term care pharmacy market; and allowing for the one long-term care facility-one long-term care pharmacy relationship to remain intact, to the extent that long-term care facilities would like to keep it that way.

Comment: Two commenters favored the carve-out of beneficiaries in long-term care facilities through the establishment of a separate PDP region in which plans could bid, at risk, to serve this population.

Response: We understand that, given the institutionalized population's special needs, a carve-out of this population may seem logical. However, given the risk associated with institutionalized beneficiaries, we believe that carving out such a high-risk population would result in significant adverse selection and could result in unsustainable beneficiary premiums for the institutionalized population. In addition, our research related to risk adjustment is still in progress, and until that research is completed, we cannot be certain as to whether our risk adjustment model could adequately mitigate the risk inherent in this population under the highly unique circumstances of a plan serving only a carved-out institutionalized population. Consequently, particularly in the first few years after the implementation of the Part D program, we wonder whether potential Part D sponsors would be willing to serve a carved-out institutionalized population and therefore ensure access to Part D drugs for Part D enrollees residing in long-term care facilities. We are also concerned that beneficiaries entering and leaving long-term care facilities will be forced to change Part D plans to the extent that institutionalized beneficiaries are carved out into a separate PDP region. For these reasons, we will not create a separate PDP region for institutionalized beneficiaries and, as discussed above, will ensure convenient access to covered Part D drug in long-term care facilities as provided in § 423.120(a)(5) of our final rule.

Comment: We requested comments regarding whether we should use our authority under section 1860D–4(b)(1)(C)(iv) of the Act to require-or, instead, strongly encourage-that Part D sponsors approach any I/T/U pharmacies in their Part D plan service areas with at least the same terms available under the plan's standard pharmacy contracting terms and conditions.

Some commenters believe that we must use our authority under section 1860D–4(b)(1)(iv) of the Act to require Part D plans to contract with I/T/U pharmacies because, without this requirement, private plans will have little or no financial incentive to contract given the uniqueness of both the AI/AN population and I/T/U pharmacies. Simply encouraging contracts will not work because of the uniqueness and remoteness of I/T/U facilities and the perceived cost and time to contract with these pharmacies. These commenters urge us to require, in regulation, that Part D plans contract with I/T/U pharmacies using specific contract provisions. They urge us to consider one of several approaches to ensuring that I/T/U pharmacies experience no reduction in revenue as a result of the transition from Medicaid to Medicare Part D: supplemental payments from Part D plans or the Federal government to supplement the difference between the amount paid by the Part D plan and the amount the I/T/U pharmacy would have received under Medicaid, a carve-out of AI/AN enrollees for Part D plans willing to serve only those beneficiaries through I/T/U pharmacies, and an exemption of dual eligibles from Part D (with continued prescription drug coverage under Medicaid).

Response: There are currently 235 I/T/U pharmacies serving 107,000 senior and disabled AI/ANs in 27 States. In some areas, I/T/U pharmacies may be the only facilities capable of providing medication therapy management services to certain AI/AN beneficiaries due to language and cultural barriers. It is our understanding that I/T/U pharmacies are not currently well integrated in commercial pharmacy networks. We agree with the commenters who believe that—in the absence of a contracting requirement—Part D plans may make assumptions regarding the administrative costs (whether real or perceived) of contracting with I/T/U pharmacies and may not actively solicit the inclusion of these pharmacies in their networks. The lack of I/T/U pharmacies in Part D plan networks would render enrollment in Part D of little use to AI/AN beneficiaries who rely primarily on I/T/U facilities for their health care. For this reason, we have added a provision to our final regulations, at § 423.120(a)(6), requiring that Part D plans offer contracts to all I/T/U pharmacies in their service areas.

However, we recognize that contracting with I/T/U pharmacies is potentially more complex than contracting with retail pharmacies given that there are a number of provisions in the standard contracts of commercial health plans that would likely need to be modified or deleted given statutory or regulatory restrictions to which I/T/U pharmacies are subject, as well as the particular circumstances of I/T/U pharmacies (for example, I/T/U pharmacies purchase drugs off the Federal Supply Schedule (FSS) or through the 340B program; can only serve AI/ANs; may have less experience than retail pharmacies, or none at all, with point-of-sale technology; are not typically well integrated into commercial pharmacy networks; generally stock a more limited range of drugs than would be required under a Part D formulary; and always waive co-pays). Thus, standard contracting terms and conditions will not be sufficient for Part D plans to obtain the participation of I/T/U pharmacies in their networks. We are therefore requiring Part D plans to include a special addendum to their standard contracting terms and conditions in order to account for these differences. We will work with major stakeholders to develop a model special addendum that will take the special

circumstances of I/T/U pharmacies into account. As provided in § 423.120(a)(6) of our final rule, we will require Part D plans to demonstrate that they have contracts with a sufficient number of I/T/U pharmacies to ensure convenient access to prescription drugs for AI/AN enrollees within the service area. We expect to review the reasonableness of Part D plans' standard contracting terms and conditions for I/T/U pharmacies.

While we understand the Indian Health Service's concerns regarding reductions in revenue resulting from the transition of drug coverage from Medicaid to Medicare, we clarify that we do not have the statutory authority to require supplemental payments from Part D plans or the Federal government to supplement the difference between the amount paid by the Part D plan and the amount the I/T/U pharmacy would have received under Medicaid; a carve-out of AI/AN enrollees for Part D plans willing to serve only those beneficiaries through I/T/U pharmacies; or an exemption of dual eligibles from Part D (with continued prescription drug coverage under Medicaid). As we develop the model special addendum for I/T/U contracts, we will consider how, within our statutory authority, we might ensure that I/T/U pharmacies do not experience significant revenue losses as a result of the transitioning of drug coverage from Medicaid to Part D for dual eligible AI/ANs.

Comment: Several commenters noted that many small I/T/U pharmacies and dispensaries carry a limited stock of drugs, and that an exemption from formulary requirements (and the ability to use permissible substitutes) is necessary in order to accommodate the fact. In addition, these commenters note that another factor in whether I/T/U pharmacies will stock a particular drug is whether it is available from the Federal Supply Schedule or 340B program, which are the principal sources of drugs purchased by I/T/U pharmacies. Thus, a Part D plan may choose one particular cholesterol-lowering agent on its formulary because it is able to negotiate a greater discount for that particular Part D drug. However, I/T/U pharmacies may be able to access a different medication for a similar, or perhaps lower, price and therefore include that drug on its formulary.

Response: We are aware that most Tribes and Tribal Organizations (operating under health programs pursuant to contracts under the Indian Self-Determination Education and Assistance Act, Public Law 93–638) and all IHS facilities use the Department of Veterans Affairs Pharmaceutical Prime Vendor (PPV) for purchasing their pharmaceuticals. By ordering through the PPV, IHS and Tribes (but not Urban programs) are able to access FSS Contract, National Standardization Contract, and Blanket Purchasing Agreement pricing for pharmaceuticals. In addition to FSS pricing, Tribes and Urban programs that have been designated as Federally Qualified Health Centers (FQHCs) and have been approved by the Health Resources and Services Administration (HRSA) are eligible for HRSA 340B drug pricing. Since I/T/U facilities have access to different pricing than commercial health plans, their formulary selections reflect the drugs for which this pricing is available. As previously mentioned, we are requiring Part D plans to include a special addendum to their standard contracting terms and conditions in order to account for the differences between retail and I/T/U pharmacies and therefore facilitate contracting with these pharmacies. We will work with major stakeholders to develop a model special addendum that will take the special circumstances of I/T/U pharmacies into account, including the limited stocking of drugs at these facilities.

Comment: Several commenters said that the any willing pharmacy rule should apply to mail order as well as retail pharmacies, and that Part D plans should not be able to exclusively use a plan-owned mail order facility.

Response: We agree that the any willing pharmacy requirement at section 1860D–4(b)(1)(A) of the Act applies to all pharmacies—including non-retail pharmacies such as mail-order pharmacies—notwithstanding a Part D plan's ability to designate certain of its network pharmacies as preferred pharmacies with lower cost-sharing, or to negotiate terms better than those in its standard terms and conditions with certain pharmacies. We clarify that a Part D plan could have standard terms and conditions for retail pharmacies and a second, separate set of standard terms and conditions for mail order pharmacies in light of those pharmacies' different characteristics. For example, a plan's contracting terms and conditions for mail-order pharmacies could reflect the full cost of adding another mail-order vendor, as well as the differential costs of strong data controls involved with having multiple network mail-order pharmacies.

Comment: One commenter said it was not clear how the any willing pharmacy rule applies to facilities that are owned and operated by a Part D plan. The commenter said such plans should be permitted to maintain a limited network of contract pharmacies for purposes of meeting the access standard in order to maximize cost savings.

Response: We agree with this commenter that the any willing pharmacy requirement makes little sense in the context of Part D plans that own and operate their own pharmacies particularly since the pharmacy access rules in § 423.120(a)(1) of our final rule will be waived for MA-PD plans and cost plans that can demonstrate comparable pharmacy access under § 422.112. As provided in § 423.458(b) of our final rule, we may waive any Part D provision as applied to an MA-PD plan if it duplicates, or is in conflict with, provisions otherwise applicable to the MA organization or MA-PD plan under Part C of Medicare, or if waiver of a Part D provision is necessary in order to improve coordination of benefits under Part D with those offered under Part C. Similarly, § 423.458(d) provides that we may waive any Part D provision as applied to a cost plan if it duplicates, or is in conflict with, provisions otherwise applicable to the cost plan under section 1876 of the Act, or if waiver of a Part D provision is necessary in order to improve coordination of benefits under Part D with those offered by the cost plans. We will consider waiving this requirement for Part D plans that own and operate their own pharmacies to the extent that they request such waiver as provided in § 423.458(b)(2) and § 423.458(d) of our final rule.

Comment: We sought comment on whether, in order to guarantee that any pharmacy willing to meet a Part D sponsor's contracting terms and conditions could participate in a Part D plan's pharmacy network, we should require that a Part D sponsor make available to all pharmacies a standard contract for participation in their Part D plans' networks.

A number of commenters thought that Part D plans should be required to have a standard or model contract for use with all pharmacies. Other comments said that we should not require a standard contract. Alternatively, several commenters said that even with a standard contract, Part D plans should have maximum flexibility to vary their contracting terms and conditions in order to reflect local conditions. Some questioned whether we should try to evaluate whether pharmacy contract terms are ''reasonable and relevant,'' as proposed in subpart K of our proposed rule.

Response: We concur with the majority of commenters on this issue and will require, under § 423.505(b)(18) of our final rule that Part D plans offer pharmacies reasonable and relevant

standard terms and conditions for network participation. We do not intend to define ''reasonable and relevant'' in order to provide Part D plans with maximum flexibility to structure their standard terms and conditions.

However, it is unreasonable to assume—the any willing pharmacist requirement notwithstanding—that a Part D plan could establish a network using a uniform set of terms and conditions throughout a service area because it will likely need to modify contracting terms and conditions to ensure access to certain pharmacies (for example, rural and long-term care pharmacies). We clarify that standard terms and conditions particularly for payment terms may vary to accommodate geographic areas or types of pharmacies) and that this is acceptable, provided that all similarly situated pharmacies are offered the same standard terms and conditions. Thus, for example, provided Part D plans offer all mail-order pharmacies in a particular area with the same standard terms and conditions, they may offer separate standard terms and conditions to mail-order pharmacies. With standard terms and conditions as a ''floor'' of minimum requirements that all similarly situated pharmacies must abide by, Part D plans may modify some of their standard terms and conditions to encourage participation by particular pharmacies.

Comment: Many commenters disagreed with our interpretation of the ''any willing pharmacy'' provision, specifically with allowing Part D plans to construct networks of preferred and non-preferred pharmacies that have different requirements for beneficiary cost sharing. These commenters argued that allowing preferred networks undermines the any willing pharmacy rule and runs counter to Congressional intent. Many said that allowing Part D plans to steer beneficiaries to preferred pharmacies would impede pharmacy access and disrupt existing relationships between pharmacists and patients. Some argued that our interpretation would disadvantage small, independent, and rural pharmacies. Others said that a designation of ''non-preferred'' would carry a negative connotation about the pharmacy's quality of service.

Several other commenters concurred with the any willing pharmacy policy in our proposed rule. One commenter said that State any willing pharmacy laws should be expressly preempted, while another commenter said we should clarify that State any willing provider laws continue to apply to Part D plans' non-Medicare business. One commenter asked us to clarify the extent to which we will allow Part D plans to vary their cost sharing for preferred networks.

Response: We believe that we have correctly interpreted the two related provisions in sections 1860D–4(b)(1)(A) and (B) of the Act, which require Part D plans to allow any willing pharmacy to participate in their pharmacy networks, while also allowing Part D plans to reduce cost-sharing differentially for network pharmacies. General principles of statutory interpretation require us to reconcile two seemingly conflicting statutory provisions whenever possible, rather than allowing one provision to effectively nullify the other provision. Consequently, when a statutory provision may reasonably be interpreted in two ways, we have an obligation to adopt the interpretation that gives full effect to competing provisions of the statute. We believe that our policy of permitting cost-sharing discounts for preferred pharmacies, as codified in § 423.120(a)(9), strikes an appropriate balance between the need for broad pharmacy access and the need for Part D plans to have appropriate contracting tools to lower costs.

We note, however, that while these within network distinctions are allowed, the statute also requires that such tiered cost-sharing arrangements in no way increase our payments to Part D sponsors. Therefore, tiered cost-sharing arrangements based on within-network distinctions could be included in Part D plans' benefits subject to the same actuarial tests that apply to formulary-based tiered cost-sharing structures. Thus, a reduction in cost sharing for preferred pharmacies in a Part D plan network could be offered through higher cost sharing for non-preferred pharmacies (or as alternative prescription drug coverage). We also note that differential cost-sharing in the context of preferred and non-preferred pharmacies does not raise the cost-sharing obligation of low-income subsidy eligible enrollees above the levels specified in sections 1860D–14(a)(1) and (2) of the Act.

We recognize the possibility that Part D plans could effectively limit access in portions of their service areas by using the flexibility provided in § 423.120(a)(9) of our final rule to create a within-network subset of preferred pharmacies. In other words, in designing its network, a Part D plan could establish a differential between cost-sharing at preferred versus non-preferred pharmacies—while still meeting the access standards in § 423.120(a)(1) of our proposed rule—that is so significant as to discourage enrollees in certain areas (rural areas or inner cities, for example) from enrolling in that Part D plan. We emphasize that such a network design has the potential to substantially discourage enrollment by certain Part D enrollees, and that we have the authority under section 1860D–11(e)(2)(D) of the Act to disallow benefit designs that are discriminatory. We clarify that State any willing pharmacist laws would be preempted as applicable to plans' Part D business. This is consistent with section 1860D–12(g) of the Act, which extends the State preemption provisions under section 1856(b)(3) of the Act to Part D plans.

Comment: Several commenters thought that Part D plans should only be allowed to have differential cost sharing for preferred pharmacies if they exceed the TRICARE access standard.

Response: We see no statutory basis for such a rule. Moreover, it would be difficult to construct and operationalize such a policy.

Comment: Several commenters wrote that special needs enrollees should be exempted from higher cost sharing at non-preferred pharmacies.

Response: We see no statutory basis for such a rule, and we believe that Part D plans will provide sufficient access for all Part D enrollees under our access standards in § 423.120(a)(1). As noted in our proposed rule, we will use the authority provided under section 1860D–11(e)(2)(D) of the Act to review, as part of the bid negotiation process, how Part D plan networks make preferred and non-preferred distinctions among their network pharmacies and disallow them if such proposed network designs would substantially discourage enrollment by certain beneficiaries in any part of a Part D plan's service area. We believe that special needs enrollees will be sufficiently protected by this review. To the extent that special needs enrollees are also eligible for low-income subsidies, as indicated above, differential cost-sharing based on preferred pharmacy status does not raise the cost-sharing obligation of low-income subsidy eligible enrollees above the levels specified in the Act.

Comment: Several commenters suggested that the TRICARE access standards be applied to Part D plans' ''preferred'' networks rather than its general network. Several other commenters concurred with the regulation as drafted in the proposed rule.

Response: Section 1860D–4(b)(1)(B) of the Act clarifies that a Part D sponsor has the option of reducing cost-sharing for covered Part D drugs dispensed through network pharmacies below the level that would have otherwise applied. Because the statute provides

that such distinctions can be made within a network, we do not believe that only preferred pharmacies constitute a Part D plan's network for the purposes of meeting the access standards in § 423.120(a)(1) of our final rule. Rather, both preferred and non-preferred pharmacies form part of a Part D plan network, and plans may count both of these types of network pharmacies toward their access standards.

Comment: Several commenters recommended that beneficiaries be able to get an extended supply of drugs, greater than a 30-day supply, from network retail pharmacies and mail-order pharmacies.

Response: We clarify that section 1860D–4(b)(1)(D) of the Act, and § 423.120(a)(10) of our final rule, require Part D plans to permit enrollees to receive extended supplies (for example, 90-day supplies) of covered Part D drugs through a network retail pharmacy.

Comment: Some commenters noted that our proposed regulations would unfairly allow Part D plans to charge beneficiaries more when they obtain their prescriptions at a community pharmacy than when they use mail order. One commenter notes that seniors benefit from face-to-face interaction with a pharmacist more than other age groups, which would be precluded under mail order and would limit enrollees' ability to use the pharmacy and pharmacist of their choice.

Many commenters recommended that we specifically prohibit Part D plans from using economic incentives for beneficiaries to use mail order that could create significant differences in cost sharing for mail order versus retail pharmacy prescription, or that plans make such difference minimal. One commenter recommended that Part D plans use the same average wholesale price (AWP) basis to determine the reimbursement rate for mail order and retail pharmacies. Another commenter noted that there is substantial evidence that seniors, particularly low-income seniors, are victims of theft from their mailboxes, undermining the financial incentive of mail order. This commenter recommended that we allow beneficiaries to pay the mail order price at a retail pharmacy when they can demonstrate their mailbox is not secure.

Response: As provided in section 1860D–11(i) of the Act, we have no authority to interfere with the negotiations between Part D plans and pharmacies and therefore cannot mandate that Part D plans negotiate the same, or similar, reimbursement rates with all pharmacies. Provided Part D plans offer all pharmacies standard terms and conditions, they may modify their contracting terms—including payment provisions as necessary, as long as all similarly situated pharmacies are subject to the same minimum terms and conditions. Moreover, section 1860D–4(b)(1)(B) of the Act provides Part D plans with the authority to designate some network pharmacies, including mail-order pharmacies, as preferred pharmacies offering plan enrollees lower cost sharing.

Comment: One commenter noted that MA organizations that own and operate their own pharmacies usually have internal systems for providing prescription services by mail that are fully integrated with the overall pharmacy operation. As a result, it is difficult to provide an incentive to beneficiaries to use less costly mail services. The commenter said we should permit these organizations to establish differential benefit levels for mail delivery as opposed to in-facility pickup.

Response: As noted above, Part D plans have the flexibility to establish different cost-sharing requirements for the pharmacies in their networks consistent with section 1860D–4(b)(1)(B) of the Act. Accordingly, Part D plans have the flexibility to establish differential cost-sharing requirements for mail delivery and in-facility pickup.

Comment: One commenter recommended that we require Part D plans to contract with pharmacies that offer home delivery service, noting that same-day or next day need for medications makes mail-order an impracticable option.

Response: We do not believe there is a compelling rationale to require Part D plans to contract with pharmacies that offer home delivery service. As discussed elsewhere in this preamble, we have defined the term ''dispensing fees'' in § 423.100 of our final rule to include reasonable pharmacy costs, including delivery costs, associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee. We clarify that reasonable delivery costs include only those costs appropriate for the typical beneficiary in a particular pharmacy setting. Thus, while it would be appropriate for Part D plans to reimburse long-term care, mail-order, and home infusion pharmacies for home delivery costs via the dispensing fee, this would not be the case for retail pharmacies (where the term ''delivery'' would be limited to the transfer of a covered Part D drug from the pharmacist to the patient at the point of sale) because the typical retail customer does not require home delivery. While retail pharmacies may offer home delivery services, Part D plans may not reimburse those pharmacies for these costs, and the delivery cost must be borne by the beneficiary.

Comment: Two commenters expressed their support for our interpretation of the term ''insurance risk'' and asked that we include in our regulations a statement that the prohibition against the assumption of risk by Part D plans' network pharmacies not preclude performance-based measures of activities within the control of a pharmacy (for example, formulary compliance and generic drug substitution).

Response: We clarify that our definition of the term ''insurance risk'' in § 423.4 of the final rule specifically excludes ''payment variations designed to reflect performance-based measures of activities within the control of a pharmacy, such as formulary compliance and generic drug substitutions.''

b. Formulary Requirements

1. P&T Committee Requirements

To the extent that a Part D sponsor uses a formulary to provide qualified prescription drug coverage to Part D enrollees, it will be required to meet the requirements of section 1860D–4(b)(3)(A) of the Act to use a pharmaceutical and therapeutic (P&T) committee to develop and review that formulary.

The majority of members comprising the P&T committee will be required to be practicing physicians or practicing pharmacists. In addition, at least one practicing pharmacist and one practicing physician member will have to be experts in the care of elderly and disabled individuals. Section § 423.120(b)(1)(ii) of the proposed rule also provided that at least one practicing pharmacist and one practicing physician members on a Part D plan's P&T committee be independent experts.

When developing and reviewing the formulary, the P&T committee will be required, in accordance with section 1860D–4(b)(3)(B) of the Act, to base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature. Section § 423.120(b)(1)(viii) of our proposed rule required that any decisions made by the P&T committee regarding development or revision of a Part D plan's formulary be documented in writing.

Except as otherwise provided below, the final rule adopts the requirements related to P&T committees set forth in § 423.120(b)(1) of our proposed rule.

Comment: Many commenters thought that P&T committee decisions regarding

a Part D plan's formulary should be binding on a plan. Other commenters thought that P&T committee recommendations should be advisory, and not binding. Several others believed that only clinical decisions should be binding on the Part D plan and that the ultimate responsibility for overall formulary design should reside with the plan and ultimately involved business leaders and technical experts. One commenter stated that it was not likely that a P&T committee comprised of non-employee clinicians would be able to make coverage determination in the Part D plan's and enrollees' best interests, particularly since many benefit design decisions have a financial, as well as a clinical, component.

Response: We agree with commenters who sought to draw a distinction between clinical and overall formulary design issues. We believe that the function of a P&T committee is to provide expertise on clinical issues, and not financial or benefit design issues. We interpret the requirement in section 1860D–4(b)(3)(A) of the Act and § 423.120(b)(1) of our final rule that Part D plan formularies be developed and reviewed by a P&T committee to mean that committee recommendations regarding which drugs are placed on a plan's formulary be binding on the Part D plan. Although § 423.120(b)(vi) and (b)(vii) of our final rule envision a role for the P&T committee in reviewing policies that guide exceptions and other utilization management processes including drug utilization review, generic substitution, quantity limits, and therapeutic interchange and in evaluating and analyzing treatment protocols and procedures related to the Part D plan's formulary at least annually, P&T committee recommendations in these areas should be considered advisory and not binding. We clarify, for example, that while the P&T committee may be involved in providing clinical recommendations regarding the placement of a particular Part D drug on a formulary cost-sharing tier, the ultimate decision on such formulary design issues is the Part D plan's, and that decision weighs both clinical and non-clinical factors. Thus, a P&T committee's role in formulary cost-sharing tiers, while important, would be advisory and not binding.

Comment: Many commenters recommended that we strengthen the statutory requirement in section 1860D–4(b)(3)(A)(ii) of the Act and require that more than just one practicing physician and one practicing pharmacist are independent and free of conflict. Suggestions for new requirements included that all, a majority, two-thirds, one-half, 40 percent, and at least four (at least two practicing physicians and two practicing pharmacists) members of a Part D plan's P&T committee be independent and free of conflict in order to ensure that formulary development is in line with beneficiary and not plan or pharmaceutical manufacturer interests. One commenter supported our current requirement requiring that at least one practicing physician and one practicing pharmacist on the committee be independent and free of conflict

Response: We appreciate commenters' suggestions and agree that maintaining the impartiality and objectivity of P&T committee members is an important goal. We have retained the proposed rule requirement that at least one practicing pharmacist and one practicing physician on the P&T committee be independent and free of conflict—in § 423.120(b)(1)(ii) of our final rule, though Part D plans should view this requirement as a floor which we encourage them to exceed. To balance concerns about conflicts of interest with regard to P&T committee members, and as proposed in the draft benefit design review criteria we recently issued for public comment, we would require all P&T committee members to sign a conflict of interest statement revealing economic or other relationships with entities that could influence pharmaceutical decisions, and to disclose such conflicts to other committee members. If P&T committee discussions center around a drug that presents a conflict of interest issue for a particular committee member, he or she would recuse himself or herself from any discussions or votes associated with that drug. We believe this requirement is necessary to ensure that the P&T committee's clinical decisions regarding development and review of the formulary are based on the strength of scientific evidence and standards of practice, safety and efficacy considerations, and other such appropriate information and considerations in accordance with section 1860D–4(b)(3)(B) of the Act. In addition, this requirement is consistent with best practices in pharmacy benefit management, and we expect that Part D plans will implement disclosure of conflicts and recusal procedures consistent with standard industry practice.

Comment: Many commenters requested clarification regarding our definition of the term ''independent and free of conflict'' with respect to a Part D sponsor and a Part D plan. Several commenters asked to clarify that our regulations regarding independence and freedom from conflict not preclude individuals from serving on a P&T committee simply because they are members of a Part D plan's provider network.

Response: In our proposed rule, we interpreted the language at section 1860D–4(b)(3)(A)(ii) of the Act requiring certain members of the P&T committee to be ''independent and free of conflict'' to mean that such P&T committee members could have no stake, financial or otherwise, in formulary determinations. We believe this interpretation is still appropriate, but clarify that we believe a P&T committee member not to be free of conflict of interest if he or she has any direct or indirect financial interest in any entity—including Part D plans and pharmaceutical manufacturers—that would benefit from decisions regarding plan formularies.

Thus, Part D plan network providers may be considered to be independent and free of conflict, provided they are not plan employees or contract workers and do not otherwise have any conflicts of interests that would compromise their independence. In cases of staff model HMOs, panel providers may be determined to be independent and free of conflict to the extent that any remuneration received from a Part D plan is limited to his or her clinical responsibilities for the care of plan enrollees.

Comment: In our proposed rule, we interpreted the language at section 1860D–4(b)(3)(A)(ii) of the Act requiring certain members of the P&T committee to be ''independent and free of conflict'' to mean that such P&T committee members would be required to be independent and free of conflict not only with respect to a Part D sponsor and its Part D plan, but also for pharmaceutical manufacturers. Some commenters supported such a requirement. A few commenters opposed such a requirement, however, claiming that our interpretation imposes a more stringent requirement than is permitted under the MMA. A number of other commenters cautioned us that our interpretation could exclude a significant number of individuals who are engaged in pharmaceutical and clinical research funded by pharmaceutical manufacturers.

Response: Section 1860D–4(b)(3)(A)(ii)(I) of the Act requires that at least one practicing physician and at least one practicing pharmacist on a Part D plan's P&T committee be independent and free of conflict only with respect to a Part D sponsor and its Part D plan. However, given the requirement in section 1860D–4(b)(3)(B) of the Act that

the P&T committee base clinical decisions on the strength of scientific evidence and standards of practice, and taking into account therapeutic advantages in terms of safety and efficacy, we believe it is necessary for those committee members who are ''independent and free of conflict'' to be so with respect to pharmaceutical manufacturers as well. We agree that P&T committee members could have certain non-employee relationships with pharmaceutical manufacturers (for example, consulting, advisory, or research relationships) and still be considered independent and free of conflict, provided those relationships do not constitute significant sources of their income and they do not otherwise have any conflicts of interests that would compromise their independence. As already mentioned, our draft benefit review criteria (recently issued for public comment) would require all P&T committee members to sign a conflict of interest statement revealing economic or other relationships with entities that could influence pharmaceutical decisions. This requirement is consistent with best practices in pharmacy benefit management, and we expect that it will be met consistent with industry standards for conflict of interest disclosures.

Comment: Several commenters supported requiring that a plurality of P&T committee members be experts in the care of elderly and disabled patients. Some commenters recommended that use of the certified geriatric pharmacist credential would be an appropriate way to ensure that at least one pharmacist on the P&T committee has expertise in care of the elderly. One commenter opposed requiring that at least one practicing physician and one practicing pharmacist be experts in the care of elderly and disabled patients. Another commenter thought that at least one member of Part D plans' P&T committees should be a State Medicaid representative.

Response: As provided in § 423.120(b)(1)(iii) of our final rule, we are retaining the requirement that at least one practicing physician and one practicing pharmacist on a P&T committee have expertise in the care of elderly or disabled persons, though plans should view this requirement as a floor which they can certainly exceed. As proposed in the draft benefit design review criteria we recently issued for public comment, we would require P&T committee members to represent various clinical specialties. This requirement is consistent with best practices in pharmacy benefit management and will ensure that appropriate expertise—including in the areas of care of disabled and elderly populations—is included on Part D plans' P&T committees and that their clinical decisions are based on the strength of scientific evidence and standards of practice, and safety and efficacy considerations. We expect that P&T committee members will represent a mix of clinical specialties in order to ensure that P&T committees have the breadth of expertise necessary to adequately evaluate scientific evidence, standards of practice, and other information.

Comment: A number of commenters suggested that we should require that P&T committees include experts in certain clinical specialties (for example, nephrology, oncology, rheumatology, dermatology, mental health, long-term care, and many others) or, at the very least, that such experts serve as consultants to P&T committees.

Response: We agree that P&T committee members should represent various clinical specialties in order to provide the depth of expertise needed to develop an adequate formulary and utilization management processes for the Medicare population. As proposed in the draft benefit design review criteria we recently issued for public comment, we would require P&T committee members to represent various clinical specialties. This requirement is consistent with best practices in pharmacy benefit management. In addition, we note that, since committee members must base clinical decisions on the strength of scientific evidence and standards of practice, it is not essential that every specialty be represented—either as a P&T committee member or as a consultant. For some issues, the use of peer-reviewed medical literature—including randomized clinical trials, pharmacoeconomic studies, outcomes research data, and other such information—may be sufficient.

Comment: We received a number of comments regarding our requirements for the basis of clinical decisions by Part D plan P&T committees. One commenter supported our characterization of the appropriate role of quality and cost considerations in Part D plan formulary development. Some commenters emphasized that cost considerations should be secondary to clinical issues in formulary development and review. One commenter suggested segregating cost and clinical reviews to preserve objectivity. Several commenters specifically suggested that we require Part D plan P&T committees to use classes of data that are included in the Academy of Managed Care Pharmacy (AMCP) format for Formulary Submissions—including clinical trials, health outcomes studies, and economic and budget impact models—as well as clinical guidelines issued by medical specialty societies. Several other commenters encouraged us to require Part D plans to consider data addressing total health care costs, if available, rather than pharmacy costs, in any cost considerations used for clinical decision-making.

Response: As required in section 1860D–4(b)(3)(B) of the Act, P&T committees will be required to base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature (for example, randomized clinical trials, pharmacoeconomic studies, outcomes research data, and other such information as the committee determines appropriate). In addition, a P&T committee must take into account whether including a particular Part D drug on the Part D plan's formulary (or on a particular formulary tier) has any therapeutic advantages in terms of safety and efficacy. Where applicable, therapeutic advantage should be considered in relation to the interaction of a drug therapy regimen and the use of other health care services.

We agree with commenters who urged that Part D plans consider data addressing total health care costs, if available, rather than pharmacy costs, in any cost considerations used for clinical decision-making. Since Part D sponsors have discretion with regard to the actual information their P&T committees use, we cannot mandate that all Part D plans use pharmacoeconomic studies, for example. However, in our subsequent guidance we intend to make clear that to the extent that the Part D plan considers costs in making its decision, it will take into account total health care costs rather than just drug costs. For example, to the extent that a particular drug has been shown to be more effective in preventing the need for hospital care or better at controlling acute flare-ups requiring the use of other services, we expect P&T committees to take these things into account in their determinations of drug efficacy. Given these requirements for evidence-based decision-making, it is our expectation that committee members will balance any relevant cost considerations with clinical considerations.

Comment: Some commenters supported a role for P&T committees in designing formulary tiers and any other clinical program implemented to encourage the use of preferred drugs. One commenter supported such a role,

provided that P&T committees are not required to be engaged in other benefit design issues.

However, several commenters believed that P&T committees should have no involvement in the development of utilization management programs including development of cost-containment tools, medication therapy management programs, and quality assurance programs, as well as more specific benefit design issues such as the development of cost-sharing tiers and should instead be limited to providing Part D plans with clinical recommendations on formularies. Other commenters thought that we should provide Part D plans with flexibility to determine how utilization management programs are designed and administered.

Response: We believe that the requirement in section 1860D–3(c)(1) of the Act that Part D sponsors establish an appropriate cost-effective drug utilization management program supports a role for P&T committees in the development of formulary management practices and policies—including prior authorization, step therapy, generic substitution, quantity limits, and other drug utilization management activities that affect access to covered Part D drugs. Furthermore, section 1860D–4(b)(3)(F) of the Act and § 423.120(b)(1)(vii) of our final rule require Part D plans to periodically evaluate and analyze treatment protocols and procedures. Clinical input is critical in the development of these policies in order to ensure that formulary management decisions balance economic and clinical factors to achieve appropriate, safe, and cost-effective policies. The review by P&T committees of Part D plan policies that guide exceptions and other utilization management processes is not only an important component in ensuring that plans adopt appropriate utilization management activities consistent with the statutory requirements, but also is consistent with best practices in pharmacy management policy. However, as previously stated, we believe that the primary function of a P&T committee is to provide clinical and not financial or benefit design—expertise.

Comment: Some commenters suggested that P&T committees review formularies regularly, with some suggesting a quarterly review and others an annual review

Response: As proposed in the draft benefit design review criteria we recently issued for public comment, we expect that P&T committees will meet on a regular basis, but not less frequently than on a quarterly basis. This standard is consistent with best practices in pharmacy management policy.

Comment: One commenter urged us to specify minimum timeframes for periodic evaluation of Part D plan treatment protocols and formulary-related procedures under § 423.120(b)(4) of our proposed rule. A number of commenters recommended that protocol reviews be conducted on an ongoing basis at least quarterly, whereas some specified that such reviews be conducted at least annually.

Response: As specified in § 423.120(b)(1)(vii) of our final rule, Part D plan P&T committees will be required to evaluate and analyze treatment protocols and procedures related to the plan's formulary at least annually.

Comment: A number of commenters also asked us to require that P&T committees have processes for making formulary revisions between regularly scheduled meetings when new clinical information becomes available or the FDA approves new medications.

Response: As proposed in the draft benefit design review criteria we recently issued for public comment, we expect that P&T committees will review new Part D drugs, or drugs for which new clinical information is made available by the Food and Drug Administration, within 90 days of the availability of new information. This will allow for appropriate formulary changes to be made with all due speed and ensure that a Part D plan's formulary is based on the most recently available scientific evidence, standards of practice, and drugs' relative therapeutic advantages in terms of safety and efficacy. However, we expect that drugs pulled from the market by the FDA or manufacturers will be removed from Part D plan formularies immediately.

Comment: Many commenters suggested additional requirements for ensuring P&T committee accountability, including requiring Part D plans to have a P&T committee regardless of whether they have a formulary or not; including a patient advocate on the committee to represent interests of patients; developing an oversight mechanism similar to local Medicare carrier advisory committees; requiring P&T committee meetings to be held publicly in order for consumers and stakeholders to have an opportunity to hear committee deliberations; requiring Part D plans to include a charge ensuring that the interests of beneficiaries are protected by their benefit design decisions; requiring thorough documentation of the rationale for P&T committee decisions; and requiring P&T committee decisions to be issued to the public upon request within a reasonable period of time.

Response: These requirements are not consistent with standard practice in pharmacy benefit management. We believe that our requirements in § 423.120(b)(1) of the final rule, as well as our formulary review which will consider the structure and utilization of an organizations P&T committee will sufficiently ensure that P&T committees function as a forum for evidence-based formulary review. As an added safeguard, and as provided in § 423.120(b)(1)(viii) of our final rule, we will require Part D plan P&T committees to document in writing the basis of their decisions regarding formulary development and revision and utilization management activities.

2. Plan Formularies

As provided under section 1860D–4(b)(3)(C)(ii) of the Act, we requested that the U.S. Pharmacopoeia (USP) develop a model set of guidelines that consists of a list of drug categories and classes that may be used by Part D sponsors to develop formularies for their qualified prescription drug coverage, including their therapeutic categories and classes. For more information about the USP model guidelines and the model guidelines themselves, please consult *http://www.usp.org/drugInformation/mmg/*.

Section 1860D–4(b)(3)(C) of the Act provides, and § 423.120(b)(2) of our proposed rule required, the inclusion of drugs in each therapeutic category and class of Part D drugs in a Part D plan's formulary, although not necessarily all drugs within such categories and classes. As discussed in the proposed rule, we interpreted this provision to require coverage of at least two Part D drugs within each therapeutic category and class of Part D drugs, unless only one Part D drug existed in a particular therapeutic category and class of Part D drugs.

We sought comments on ways to balance Part D plans' flexibility to use utilization management mechanisms to maximize covered Part D drug discounts and lower enrollee premiums with the needs of certain special populations of Part D enrollees, including Part D enrollees residing in long-term care facilities.

In accordance with section 1860D–4(b)(3)(C)(iii) of the Act, Part D sponsors cannot change therapeutic categories and classes in a formulary other than at the beginning of a Part D plan year, except as we would permit to take into account new therapeutic uses and

newly approved Part D drugs. Section 423.120(b)(4) of our proposed rule specified that, in accordance with section 1860D–4(b)(3)(F) of the Act, Part D sponsors will periodically be required to evaluate and analyze treatment protocols and procedures related to their formularies to ensure that their Part D plan members were receiving the best possible care for conditions related to their use of covered Part D drugs.

In addition, section 1860D–4(b)(3)(E) of the Act requires that Part D sponsors provide ''appropriate notice'' to us, affected enrollees, authorized prescribers, pharmacists, and pharmacies regarding any decision to either: (1) remove a drug from its formulary; or (2) make any change in the preferred or tiered cost-sharing status of a drug. Section 423.120(b)(5) of our proposed rule implemented this requirement by defining appropriate notice as at least 30 days prior to such change taking effect during a given contract year.

As provided under § 423.120(b)(6) of our proposed rule, we proposed that Part D sponsors be prohibited from removing a covered Part D drug or from changing the preferred or tiered cost-sharing status of a covered Part D drug between the beginning of the annual coordinated election period described in § 423.38(b) and 30 days subsequent to the beginning of the contract year associated with that annual coordinated election period.

Each Part D sponsor will also be required to establish policies and procedures to educate and inform health care providers and enrollees about its formulary, according to the provisions of section 1860D–4(b)(3)(D) of the Act. As required under section 1860D–4(b)(3) of the Act, the requirements regarding the development and application of formularies discussed in this preamble section may be met by a Part D sponsor directly, or through contracts or other arrangements between a Part D sponsor and another entity or entities.

Except as otherwise provided below, the final rule adopts the rules for Part D plan formularies set forth in § 423.120(b) of the proposed rule.

Comment: We received a significant number of comments that directly and indirectly relate to the USP draft model guidelines issued for public comment in August 2004. In general, the USP related comments can be grouped into two categories. On one side, many comments claim that the current draft model guidelines lack the necessary detail to ensure that beneficiaries will have access to a comprehensive drug benefit, often citing specific examples of medications that are necessary for the treatment of the most frail and vulnerable populations and could be excluded from Part D plan formularies that comply with the model guidelines.

On the other hand, many comments recommended that the USP model guidelines allow Part D plans the flexibility they need to develop clinically sound formularies that offer a prescription drug benefit at the lowest possible cost. Most of these commenters believe that the draft model guidelines, while in need of some specific modifications, are closer to reasonable than unreasonable. However, these commenters claim that the minimum ''drugs'' requirements for each category and class could significantly increase benefit costs if the categories and classes increase to a level of detail that interferes with Part D plans' ability to negotiate with manufacturers.

Response: We believe that the USP model guidelines identify a reasonable number of categories and classes that balance the need for a comprehensive Part D benefit with the need to allow Part D plans flexibility to develop their own formularies and manage costs. These model guidelines will provide us with a useful, standard format as a starting point for our review of Part D plan benefit packages, since we expect many plans will adopt the model guidelines as the basis for their formulary classifications and submissions.

The model guidelines, while important in creating a template for a formulary classification system, are not the only determinant of an adequate formulary. Plans will be required to include the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines, in their formularies. Regardless of whether a Part D plan chooses to use the model guidelines or not, we will review the drugs chosen to populate plan formularies under our authority in section 1860D–11(e)(2)(D) of the Act to ensure that plan benefit design does not discourage enrollment by certain classes of Part D eligible individuals. However, formulary structure—including tiered cost-sharing structures -utilization management processes, P&T committee utilization and structure, and exceptions and appeals processes are just as important in ensuring a comprehensive benefit, and we intend to review these benefit design features as part of our comprehensive benefit package review. We discuss our benefit design review criteria in greater detail elsewhere in this preamble.

Comment: Several commenters disagreed with our interpretation of the statutory term ''drugs'' as requiring coverage of at least two Part D drugs within each therapeutic category and class of Part D drugs (unless only one Part D drug existed in a particular therapeutic category and class of Part D drugs), arguing that such an interpretation was too expansive, and requiring coverage of too many drugs in too many categories would diminish Part D plans' negotiating leverage. These commenters provided examples of drug categories for which a blanket requirement of two drugs is not appropriate, and an exception should be granted. One commenter recommended that we should allow an exception from this rule for categories and classes that only include two drugs, and allow enrollees to obtain the non-formulary drug in such categories via the exceptions process only.

In contrast, several commenters believed that requiring Part D plans to include two drugs in each therapeutic category and class of Part D drugs was not sufficient to ensure enrollee access to necessary medications. They were concerned that for some categories—including cancer treatments, rare diseases, mental illness, chronic pain, and other conditions—requiring only two drugs per drug category and class would be inadequate for Part D plans in terms of the statutory requirement that plan design not discourage enrollment.

Several commenters urged us to clarify that this minimum two-drug requirement must be met through drugs or biologicals offered on an unrestricted basis (for example, not subject to utilization management processes, such as prior authorization or step therapy, non-preferred cost-sharing tiers, or other such restrictions on access to necessary therapies), with some specifically urging us to impose restrictions on step therapy by Part D plans. Some asked us to specify that the two drugs must be distinct chemical entities. One commenter recommended that we do not allow any Part B-covered drugs to count toward the two-drug-per-category requirement.

Response: Section 1860D–4(b)(3)(C) of the Act requires that Part D plans' formularies include ''drugs within each therapeutic category and class of Part D drugs, although not necessarily all drugs within such categories and classes.'' We believe that our interpretation of ''drugs'' as ''at least two drugs'' is consistent with Congressional intent, and that it strikes an appropriate balance between providing Part D plans with the necessary leverage to negotiate with manufacturers for significant

discounts on covered Part D drugs and ensuring sufficient drug choice for beneficiaries. We have therefore retained the two-drug minimum requirement in § 423.120(b)(2)(i) of our final rule.

However, we recognize that Part D categories and classes may exist for which there are only two Part D drugs, and that including both of those drugs on a formulary may be problematic if the two drugs are vastly different in their clinical effectiveness. Given that section 1860D–4(b)(3)(C) of the Act requires that Part D plan formularies include ''drugs within each therapeutic category and class of Part D drugs, although not necessarily all drugs within such categories and classes,'' we will allow plans to request exceptions to the requirement in § 423.120(b)(2)(i) of our final rule to the extent they can demonstrate that there are only two Part D drugs available for a particular Part D drug category or class and that one of those drugs is clinically superior to the other. We have incorporated this provision at § 423.120(b)(2)(ii) of our final rule.

In response to comments that our proposed requirement is insufficient to provide adequate access to medically necessary treatments for Part D enrollees, we clarify that we will require Part D plans to adopt policies that ensure that beneficiaries have reasonable access to medically necessary drugs. Although Part D plans will not be required to include every Part D drug on their formularies, we will—as codified in § 423.120(b)(2)(iii) of our final rule—require that plans include adequate access to the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines, on plan formularies. We are establishing this requirement consistent with section 1860D–11(d)(2)(B) of the Act, which provides us with authority similar to that provided to the Director of the Office of Personnel Management for setting ''reasonable minimum standards'' for health benefits plans. We are looking to existing national standards to inform our review at the drug level, and Part D plans will be expected to accommodate national guidelines and offer complete treatment options for a variety of medical conditions, including (but not limited to) asthma, diabetes, depression, lipid disorders, hypertension, and HIV. This is necessary in order to ensure that Part D plans do not substantially discourage enrollment by certain Part D eligible individuals based on exclusions of certain classes of drugs from their formularies. In addition to examining specific drugs on Part D plan formularies, and as discussed in greater detail elsewhere in this preamble, we will review other aspects of plan benefit designs—including tiered cost-sharing formulary structures, P&T committee structure and utilization, utilization management policies and processes, and exceptions and appeals processes—to ensure that Part D plans generally meet the requirements under Part D, including the provision of an adequate benefit.

We do not agree with comments asking that the two-drug requirement be met through drugs offered on an unrestricted basis. We recognize that Part D plans may establish utilization management processes in such a way as to substantially discourage enrollment by certain beneficiaries. On the other hand, utilization management restrictions may be entirely appropriate for specific drugs or categories of drugs. Furthermore, the statute specifically allows plans to utilize tiered cost-sharing structures provided they meet certain actuarial equivalence tests. As previously mentioned, part of our benefit design review will focus not only on the specific drugs included on a Part D plan's formulary, but also on a plan's utilization management policies and procedures, to ensure that plans do not discriminate against certain enrollees.

In addition, while drugs covered under Part B cannot be covered under Part D, as provided in section 1860D–2(e)(2)(B) of the Act, this exception to Part D coverage is limited to the drugs ''as so prescribed and administered'' under Part B. Thus, the fact that a beneficiary can have a particular drug covered under Part B ''incident to'' a physician service or as part of a hospital outpatient procedure does not mean that a prescription for the same drug should be denied by a Part D plan. We will provide more guidance on this issue, but we clarify that the number of drugs that may be denied coverage under Part D on the basis of the drug itself is limited. One category of drugs that can clearly never be covered under Part D is the list of oral cancer drugs covered under Part B. Such drugs and limited number of others may not be counted toward the two-drug minimum.

Finally, we clarify that our two-drug minimum requirement must be met through the provision of two chemically distinct drugs. In other words, Part D plans may not include two dosage forms or strengths of the same drug, or a brand-name drug and a generic equivalent, in a particular category or class and meet the requirement in § 423.120(b)(2)(i) of our final rule.

Comment: One commenter recommended that Part D plans' formularies include a wide variety of available dosage forms to the extent that was feasible. Another commenter asked us to clarify that we would not allow Part D plans to count different dosages of the same active ingredient as two separate drugs for the purposes of our two drug requirement. A third commenter asked us to clarify that it is acceptable for Part D plans to favor some dosages over others on their formularies.

Response: We stated in our proposed rule that it was our expectation that the drugs included in each therapeutic category or class would include a variety of strengths and dosage forms, and we stand by that expectation in our final rule. However, we clarify that Part D plans will not have to provide equal access to all strengths and dosage forms of a particular Part D drug, although beneficiaries will have the right to pursue coverage of additional strengths and dosage forms through the appeals process. We have clarified in § 423.120(b)(2)(i) of our final rule that Part D plans must include two chemically distinct Part D drugs in each therapeutic category and class of drugs, with different strengths and doses available for each of those drugs. Thus, Part D plans may not meet this requirement by only including two or more different dosages of the same Part D drug in a particular drug category or class.

Comment: Many commenters were concerned that our regulations will create barriers to physicians prescribing the best medication for their patients, including off-label uses of medications, which are common for many conditions and are the norm for some conditions. In actuality, off-label use is critically important and may be the mainstay of medical practice for successfully managing certain conditions, such as mental illnesses, chronic pain, chronic heart failure, arthritis, Parkinson's, HIV/AIDS and dementia. The FDA recognizes that ''off-label use of drugs by prescribers is often appropriate and may represent the standard of practice.'' A number of commenters opposed our position that the USP model guidelines should not be required to include classes of drugs if there is no FDA approved drug with an on-label indication for each class, even though there are FDA-approved drugs with commonly accepted off-label uses that would fall within a class. One commenter noted that any action taken by us regarding off-label use of medications would have a ripple effect on other public and private programs.

Some commenters requested that we clarify the formulary requirements in our final rule to require Part D plans to cover medically accepted off-label use of prescription drugs. They believe this is consistent with Congressional intent and past practice under the Medicare and Medicaid programs. In addition, one commenter is concerned that by assigning a drug to a specific class for formulary purposes, a Part D plan may not cover it for other medically accepted indications. One commenter suggested formularies should be required to include off-label uses for drugs for the prevention and treatment recommended in clinical guidelines issued by government agencies and medical societies, whether on-label or off-label. Another commenter said that off-label use must be accessible through a Part D plan's exceptions process for non-formulary drugs.

Response: We recognize the value of off label prescribing, particularly with regard to certain medical conditions. As mentioned in the proposed rule, we expect that the model categories and classes developed by USP will be defined so that each includes at least one drug that is approved by the FDA for the indication(s) in the category or class. That is, no category or class will be created for which there is no FDA approved drug and which would therefore have to include a drug based on its ''off label'' indication. We expect Part D plans using alternative drug classification systems to include at least one drug that is approved by the FDA for the indication(s) in each drug category or class. However, this would not preclude physicians and other prescribers from prescribing drugs for off label indications, provided the drug is prescribed for a ''medically accepted indication,'' as defined in section 1927(k)(6) of the Act. Further, we clarify that the USP model guidelines would not preclude Part D sponsors from assigning an FDA approved drug to a category or class based on an off label use for that drug, provided the FDA has not made a determination that the drug is unsafe for that use.

We do not have the authority to require that Part D plans cover the off-label use of certain Part D drugs. However, as discussed in greater detail elsewhere in this preamble, we will thoroughly evaluate plan benefit design to ensure that Part D plans provide an adequate benefit and do not discriminate against certain classes of Part D enrollees—including a review of plan utilization management policies and processes, formulary structure, and plan exceptions and appeals processes. We believe that these safeguards will ensure Part D enrollee access to Part D drugs dispensed for medically appropriate off label indications.

Comment: Multiple commenters were concerned that it is inappropriate for physicians to be given the new burden to ''document and justify'' off-label use in their Part D enrollees' clinical records due to the administrative burden and the interference with the practice of medicine by physicians. Many commenters mentioned that the FDA has recognized the right of physicians to use approved drugs and devices as they believe appropriate and never suggested there is a need to document such use. One commenter noted this documentation requirement is unprecedented and steps beyond well-established boundaries by inserting us into an individual physician's professional decision-making. If documentation is required, one commenter asked us to clarify what constitutes sufficient documentation.

One commenter, however, noted the need for documentation on prescriptions for off label use to enable pharmacists to conduct drug utilization review. Another commenter recommended regular reviews by us and by P&T committees through drug utilization and provider interviews as is customary in commercial plans.

Many commenters urged us to mandate that Part D plans give deference and flexibility to physicians when making coverage determinations since a patient's physician has clinical expertise and intimate knowledge of patients' medical needs. One commenter suggested that we specify that Part D plans may not prohibit providers from prescribing drugs for discretionary use if such use is supported by one or more standard reference compendia or by one or more scientific studies published in peer-reviewed medical journals or by generally accepted standards of clinical care. One commenter suggested that MMA regulations should restrict the ability of Part D plans to limit physician prescribing for off-label purposes unless there is objective medical evidence that such prescribing is inefficacious or harmful to the individual patient.

Commenters noted that onerous administrative hurdles associated with medically necessary off-label use could result in barriers to patient access to essential therapies. Without specific guidance, Part D plans could simply minimize financial risk through delay tactics disguised as Federal documentation requirements. One commenter recommended that at a minimum, we should clarify that there is nothing to prevent a Part D plan from covering an off-label use that does not meet the statutory definition of ''medically accepted indication'' if, based on expert advice, the plan determines that such use is appropriate. Multiple commenters suggested that the final rule guidance for Part D drugs should be at least as flexible as the current coverage policies for drugs covered under Medicare Part B. Under Part B, the definition of a ''medically accepted indication'' includes indications published in peer-reviewed literature; current Part B coverage policy regarding off-label drug use is also consistent with these norms.

Response: By stating in the proposed rule preamble that we strongly encouraged physicians and other prescribers to clearly document and justify off-label use in their Part D enrollees' clinical records, we did not intend to establish a new documentation requirement for prescribers. We agree with commenters that physicians must have sufficient latitude to prescribe drugs as necessary based on their patients' particular medical needs and consistent with medical standards of practice, and our statement should not be interpreted as imposing new and onerous reporting requirements on prescribers. As previously mentioned, we will thoroughly review plan benefit designs to ensure that Part D plans meet all applicable requirements under Part D including the provision of an adequate benefit. We expect that onerous documentation requirements for off-label prescribing could potentially be cause for finding that a Part D plan's proposed benefit structure does not meet Part D requirements.

We note that a drug is considered to be a Part D drug only if prescribed for a ''medically accepted indication'' as defined under section 1927(k)(6) of the Act. Drugs may not be covered under Part D even if they are not prescribed for a medically accepted indication. Coverage for other than a medically accepted indication is not permitted under the statute, since such drugs would not be considered Part D drugs. Plans have the flexibility to decide how to monitor whether a drug is prescribed for a medically accepted indication, as well as to determine whether the statutory definition of ''medically accepted indication'' is met with regard to the particular use of a drug.

Comment: We received numerous comments regarding our authority under section 1860D–11(e)(2)(D)(i) of the Act to review Part D plan benefit designs including any formulary or tiered formulary structure to ensure that plans do not discriminate against certain Part

D eligible individuals. Many commenters urged us to use this authority to thoroughly, comprehensively, and judiciously review Part D plan design and benefits including formulary structure to prevent discriminatory practices. Some of these commenters were adamant that such a review not be limited only to the particular drugs included on a formulary list, but also to tiered cost-sharing (including the use of 100 percent cost-sharing tiers), and utilization management requirements (for example, appeals, prior authorization, and step therapy requirements).

Several other comments cautioned us not to be overly prescriptive in our formulary review criteria and avoid unintentionally limiting the ability of Part D plans to manage the costs of the Part D benefit. One commenter suggested that our formulary review standards should provide substantial deference to P&T committees including on cost-sharing, step-therapy, and prior authorization processes, and that we should not establish our own requirements in these areas.

Other commenters asked that greater specificity regarding our criteria for formulary review, as well as practices that would be considered discriminatory, be provided either in regulation or in separate guidance, or both. Several commenters urged us to use defined performance metrics to make formulary discrimination assessments. Several commenters encouraged us to establish a flexible and readily accessible process for dialogue with a variety of stakeholders to create appropriate formulary review criteria, and one commenter urged us to actually involve States in the review process.

Several commenters thought our formulary review process should be performed annually and that contract renewal should be contingent upon passing our review. Others thought that Part D plan formularies should be reviewed more often given plans' ability to make formulary changes mid-year.

Response: We will comprehensively review Part D plans' proposed benefit structure to ensure that they generally comply with all applicable standards under Part D. We intend to conduct a reasonable review, providing guidelines that Part D plans can use in building formularies and structuring their bids. We recently shared with the public a first draft of our benefit package review criteria and, based on public comments received on that document, will finalize and make available publicly our final review criteria in early 2005.

Consistent with the authority provided under section 1860D–11(e)(2)(D)(i) of the Act, we will review Part D plan formularies to ensure that plans do not discriminate against certain classes of Part D eligible individuals by adopting a benefit design (including any formulary or tiered formulary structure) that would substantially discourage enrollment by certain beneficiaries. Nothing in the statute would foreclose us from concluding that a Part D plan's formulary substantially discourages enrollment even if the plan's classes and categories are considered non-discriminatory (for example, because the plan uses the USP model guidelines to structure its formulary). Although Part D plans will not be required to include every Part D drug on their formularies, we will require Part D plans to offer an adequate benefit. For example, we have the discretion to find that failure to include a specific drug would substantially discourage enrollment by beneficiaries with a condition that may only be treated by that drug. We are looking to existing national standards to inform our review at the drug level, and Part D plans will be expected to accommodate these national guidelines.

We believe that other aspects of Part D plan benefit design including formulary structure (including tiered cost-sharing structures), the structure and utilization of a plan's P&T committee, a plan's utilization management policies and procedures (for example, prior authorization, step therapy, and generic substitution), and a plan's exceptions and appeals processes are as important as a plan's formulary list of drugs in ensuring that beneficiaries are offered an adequate benefit that generally complies with all applicable standards under Part D. Therefore, we intend to review these plan features as part of our comprehensive review of Part D plan benefit designs.

We will review tiered cost-sharing arrangements to ascertain that the cost sharing associated with certain drugs or classes of drugs does not discourage enrollment by certain beneficiaries for example, those with certain diseases or medical conditions. We will also review a Part D plan's P&T committee structure and processes to ensure that plans comply with the requirements of section 1860D–4(b)(3)(B) of the Act, which creates standards designed to ensure impartial, clinically-based decision-making by P&T committees.

A Part D plan's utilization management policies and processes must ensure that beneficiaries have continuous, timely, and appropriate access to Part D drugs, and that such policies are structured on evidence-based criteria that are reviewed by a Part D plan's P&T committee. Section 1860D–4(c)(1)(A) of the Act requires Part D plans to establish cost-effective drug utilization management programs (including incentives to reduce costs when medically appropriate). Our review of plan utilization management policies and processes will ensure that those policies and processes are medically appropriate and do not discriminate against certain beneficiaries.

We clarify that a non-formulary drug is not necessarily a non-covered Part D drug. The MMA provides for an exceptions process whereby enrollees and prescribers can request Part D coverage at more favorable cost sharing than for non-preferred drugs, as well as access to non-formulary drugs at formulary cost-sharing levels. As discussed elsewhere in this preamble, we interpret section 1860D–4(h)(2) of the Act as requiring Part D plans to cover a non-formulary drug on appeal when, upon review, a physician determination of medical necessity is upheld. Thus, while Part D plans are not required to approve a non-formulary Part D drug in the first instance at the point of sale, plans are required to provide access to Part D drugs, both formulary and non-formulary, on appeal, where there is a legitimate medical need. We will review Part D plans' exceptions and appeals processes to ensure that evidence-based criteria are used to ensure medically appropriate access to all Part D drugs, including those drugs that are not favorably placed on a plan's formulary or not on the formulary at all.

Section 1860D–11(d)(2)(B) of the Act provides us with authority similar to that provided to the Director of the Office of Personnel Management with respect to health benefits plans; this includes setting ''reasonable minimum standards'' for plans. As we finalize our guidelines, we will look to existing national standards and guidelines, such as those established by the Utilization Review Accreditation Commission (URAC), the National Committee for Quality Assurance (NCQA), the American Society of Health Systems Pharmacists (ASHP), and the Academy of Managed Care Pharmacy (AMCP) to develop a framework for formulary management. The principles embodied in these standards and guidelines represent commercial best practice, and we believe Part D enrollees should be granted the same rights and protections under their Part D plan as generally

available to those enrolled in commercial plans.

Comment: Many commenters supported establishing rules for special treatment, to include alternative or open formularies and other special provisions and exemptions, for certain classes of enrollees. Commenters suggested a number of classes of beneficiaries that we may want to consider ''special populations'' for the purpose of offering such special rules, including dual eligibles, institutionalized beneficiaries, individuals with certain diseases or medical conditions, and minority populations. Other commenters opposed any requirement that special populations be subject to special rules. Instead, they argued that we should provide Part D plans the flexibility to manage and design benefits consistent with their enrollees' needs. They felt that prescriptive guidance was not necessary and that our review for discrimination should be sufficient to ensure adequate access to all medically necessary drugs.

Response: We share commenters' concerns about access to all medically necessary Part D drugs by vulnerable Part D enrollees. However, after much consideration, we disagree with commenters who advocated for specific requirements in regulation that would create special rules applicable only to certain classes of Part D enrollees. We believe commenters' concerns regarding access to Part D drugs for vulnerable populations will be addressed via our review of Part D plan benefit packages.

As discussed in great detail elsewhere in this preamble, we will comprehensively review Part D plans' proposed benefit structure to ensure that they generally comply with all applicable standards under Part D—including the provision of a benefit that provides for adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines. We intend to conduct a reasonable review, providing guidelines that Part D plans can use in building formularies and structuring their bids. We recently shared with the public a first draft of our benefit package review criteria and, based on public comments received on that document, will finalize and make available publicly our final review criteria in early 2005.

Comment: A number of commenters urged us to place strict limits on Part D plans' ability to remove drugs or increase the cost sharing associated with certain formulary drugs mid-year. One commenter suggested we allow for changes only at the beginning of a contract year so that changes are announced to current and prospective enrollees prior to the open enrollment period and Part D plans are able to market their new formulary for the upcoming plan year. Another commenter recommended that we allow formulary changes only from October 1st to November 14th of a given year.

Several commenters suggested that Part D plans be required to provide justification for any decision to remove a drug from the formulary. Another commenter stated that Part D plans should be required to document any decision to remove a drug from the formulary based on detailed scientific and clinical evidence. This commenter noted that reasons for discontinuing coverage could include new clinical evidence that a drug is unsafe, contraindicated for particular indications, or a manufacturer's withdrawal from the market. Other commenters noted that Part D plans should only be allowed to remove drugs from their formulary when new information about a drug's safety becomes available.

Response: The goal of the MMA was to encourage private sector organizations who meet the law's requirements to offer a range of Part D plan options for Medicare beneficiaries by providing flexibility in plan design and management. This flexibility is modeled after the way consumers in the private sector receive drug benefits. Although the statute requires us to limit changes in the therapeutic categories and classes of a Part D plan's formulary to the beginning of each plan year (except as we permit to take into account new therapeutic uses and newly approved Part D drugs), it does not give us similar authority to preclude mid-year changes to a Part D plan's formulary list. However, as provided in section 1860D–4(b)(3)(E) of the Act, codified in § 423.120(b)(5) of our final rule, and discussed in greater detail elsewhere in this preamble, Part D plans must provide appropriate notice to affected enrollees, among others, prior to removing a drug from their formulary or changing the preferred or tier status of a formulary drug. Such notice will provide beneficiaries with ample time to transition to a covered Part D drug that meets the enrollee's needs, or to request a coverage exception.

Comment: We received a number of comments urging us to consider requirements related to the ''grandfathering,'' on the same terms as previously available, of covered Part D drugs that are either removed from Part D plan formularies, or whose cost-sharing tier or preferred status changes, mid-year. One commenter stated that patients with chronic diseases who are stabilized by a plan-covered drug at the beginning of the year should not experience a higher copayment or be denied coverage of a drug based on a formulary change.

Other commenters thought the grandfathering should apply more broadly. Some commenters said that Part D plans should be required to grandfather a drug for anyone taking the medication prior to its removal from their formulary (unless removed due to FDA safety concerns). One commenter recommended that we require Part D plans to grandfather coverage of chronic medications until the next open enrollment period. Other commenters noted that, if we do not include rules placing strict limits on formulary changes during the year, Part D plans should be required to continue coverage of the discontinued drug for the remainder of year, at the same price, for all individuals taking the drug as part of an ongoing treatment regimen. One commenter suggested that Part D plans be required to provide patients with a 72-hour supply of a drug if it has been removed from the formulary. However, some commenters also clarified that such a requirement should not be meant to prohibit a Part D plan from asking physicians to voluntarily switch patients to less costly drugs through a therapeutic substitution initiative.

Response: Although the MMA does not preclude mid-year formulary changes by Part D plans, it does require that plans provide appropriate advance notice to affected enrollees of any removal of a covered Part D drug from a formulary, or any change in the preferred or tiered cost-sharing status of a covered Part D drug. As detailed elsewhere in this preamble, we have interpreted ''appropriate notice'' to mean at least 60 days prior to such change taking effect. We believe that 60 days, which is consistent with National Association of Insurance Commissioners (NAIC) model guidelines, provides affected enrollees with ample time to either switch to a therapeutically appropriate alternative medication, or obtain a redetermination by the Part D plan, reconsideration by the independent review entity, and request an administrative law judge hearing before the change becomes effective. To the extent that Part D plans do not provide such 60-day advance notice, they will be required to provide such notice and a 60-day supply of the drug at the same terms covered previously when affected enrollees request refills of their prescriptions. Once notice is provided, enrollees will have a 60-day window to either switch to a

therapeutically appropriate alternative medication, or obtain a redetermination by the Part D plan, reconsideration by the independent review entity, and request an administrative law judge hearing before the 60-day supply is exhausted.

Comment: A number of commenters voiced support for some kind of transition period for beneficiaries, particularly full-benefit dual eligibles, transitioning to Medicare Part D from other drug coverage. These commenters argue that, under Medicaid, many beneficiaries—especially those with certain conditions (HIV/AIDS and mental illness, for example, as well as those residing in long-term care facilities)—may experience relatively unfettered access to medically necessary drugs. This may not be the case when these enrollees transition their drug coverage from Medicaid to Part D, since different Part D plans will have different formularies, cost-sharing tiers, and utilization management requirements. Commenters are concerned that vulnerable beneficiaries may elect, or may be auto-enrolled in, a Part D plan that does not cover the drugs these beneficiaries need. More generally, several commenters noted that many beneficiaries—and not just those who are considered vulnerable or special populations—could face a significant loss of continuity of care if Part D plans' formularies are substantively different from each other or from commercial plans. They advocate for an additional coverage clause for patients transitioning into or changing Part D plans in order to avoid disruptions in care.

Response: We agree with commenters that Part D plans should have processes in place to transition current enrollees from their old coverage to their new Part D plan coverage, particularly in cases where new enrollees are currently taking Part D drugs that are not included on the Part D plan's formulary at the time of enrollment. However, we envision that the need for such a transition period will be limited for several reasons.

In reviewing a Part D plan's benefit package, we have the discretion to find that failure to include a specific drug on the formulary would substantially discourage enrollment by beneficiaries with a condition that may only be treated with that drug. For example, we expect that ensuring that beneficiaries with certain conditions, such as HIV/AIDS, are not as a group substantially discouraged from enrolling in a Part D plan will require that all or substantially all drugs in a particular therapeutic class be covered. In addition, in our review of plan benefit packages and our general oversight to ensure that Part D plans comply with all applicable requirements, we will examine not only the inclusion of particular drugs on a formulary, but also the structure and utilization of a plan's P&T committee, formulary structure (including tiered cost-sharing structures), a plan's utilization management policies and procedures (for example, prior authorization, step therapy, and generic substitution), and exceptions and appeals processes and how such processes guide access to both formulary and non-formulary drugs. Given such a review of the overall benefit package, we would expect that the majority of transition concerns vis-à-vis special populations will be obviated prior to beneficiary enrollment, as Part D plans will know our benefit package review criteria in advance of the bidding process. In addition, and as described in detail elsewhere in the section of this preamble discussing exceptions and appeals, we are adopting a substantive rule requiring coverage of non-formulary drugs on appeal provided that a medical necessity determination is upheld upon review.

To address the needs of new Part D plan enrollees who are transitioning to Part D from other prescription drug coverage, and whose current drug therapies may not be included in their Part D plan's formulary despite the safeguards noted above, we are requiring—in § 423.120(b)(3) of our final rule—that Part D plans establish an appropriate transition process for new enrollees which we would review as part of our benefit package review process. Section 1860D–11(d)(2)(B) of the Act provides us with authority similar to that provided to the Director of the Office of Personnel Management (OPM) with respect to health benefits plans; as provided in 5 U.S.C. 8902(e), this includes the authority to ''prescribe reasonable minimum standards for health benefits plans.'' It is our understanding that OPM, in its contract negotiations with FEHBP plans, requires a transition policy. Furthermore, many commercial plans include transition processes for new enrollees. Failure to appropriately transition certain beneficiaries could result in aggravation of certain medical conditions including, in some cases, hospitalization which could ultimately increase costs to Medicare under Parts A and B. Thus, requiring Part D plans to establish appropriate transition policies for new enrollees appears to be consistent with our authority to prescribe reasonable minimum standards for Part D plans.

We believe that a requirement for an appropriate transition process for new enrollees prescribed Part D drugs that are not on the Part D plan's formulary appropriately balances the protection of certain vulnerable populations with flexibility for Part D plans to develop a transition process that dovetails with plans' specific benefit designs. We will provide additional guidance regarding transition process requirements as part of our benefit package review criteria. However, we expect that a Part D plan's transition process would address procedures for medical review of non-formulary drug requests and, when appropriate, a process for switching new Part D plan enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination. Such a policy should also focus on particularly vulnerable populations, including dual eligibles and individuals with certain medical conditions (for example, enrollees with HIV/AIDS, mental illness, and those with other cognitive disorders).

Comment: Some commenters requested that we establish a standard process for making formulary changes that Part D plans are required to follow, including standard policies and procedures for communicating changes to beneficiaries, pharmacists, and physicians. Another commenter suggested that we develop a standard formulary change form.

Response: As provided in section 1860D–4(b)(3)(E) of the Act, and codified in § 423.120(b)(5)(i) of our final rule, we will require that Part D plans provide appropriate notice regarding any removal of a covered Part D drug from their formulary or any change in the preferred or tiered cost-sharing status of a drug to affected enrollees and other parties. We believe that Part D plans should have the flexibility to develop formulary change notices that meet their particular needs, provided they include the information elements we specify at § 423.120(b)(5)(ii) of our final rule and discussed in greater detail elsewhere in this preamble.

Comment: One commenter suggested that notice not be required when the enrollees' cost sharing is being reduced. This commenter also suggested that notice not be required when generic competitors have dropped out of the market, leaving only one supplier, and the generic drug as a result becomes effectively treated as a single-source ''brand name'' drug. Another commenter noted that the requirement for written notice should extend beyond changes in covered medication and should also be sent when the Part D plan changes procedures for accessing a

particular medicine. Some commenters suggested we define ''appropriate notice'' differently for the expansion of a formulary versus the removal of a drug from the formulary to be consistent with the private market.

Response: Section 1860D–4(b)(3)(E) of the Act requires Part D plans to provide notice before making ''any change in the preferred or tiered cost-sharing status of a drug.'' Plans must therefore provide notice regarding any cost-sharing changes be they increases or reductions, consistent with the requirements of § 423.120(b)(5) of our final rule. The previously cited statutory language limits the provision of notice of formulary changes to the removal of a drug from a formulary or any change in the preferred or tier status of a drug, meaning that Part D plans will not be required to provide notice regarding a change in utilization management processes associated with a particular drug. However, we encourage Part D plans to do so to the extent practicable. We agree with the commenter who asks that we make a distinction between drugs added to and removed from a formulary. As provided in § 423.120(b)(5)(i) of our final rule, Part D plans will only be required to provide advance notice of formulary changes to affected beneficiaries when drugs are removed from a formulary; at their option, Part D plans may also wish to notify enrollees of new additions to their formularies.

Comment: Some commenters support the 30-day notice provision in our proposed regulation. Other comments specifically noted that there should be exceptions to the 30-day requirement in cases where there has been an FDA directive to remove a drug from the market.

However, many commenters were concerned that the 30-day notice provision in the proposed regulation would not provide the adequate time frame for enrollees to make the necessary changes in their drug treatment and ensure continuity of care particularly for enrollees with chronic conditions. Many commenters suggested a 90-day notice requirement. Several commenters suggested that beneficiaries be notified directly in writing at least 60 days before any change, and one commenter noted that NAIC model regulations for drug benefit changes require a 60-day notice.

Response: We appreciate the feedback on our interpretation of ''appropriate notice'' in the proposed rule as consisting of advance notice of at least 30 days. To ensure that Part D enrollees are provided with sufficient time either to switch to a therapeutically appropriate alternative medication, or obtain a redetermination by the Part D plan, reconsideration by the independent review entity, and request an administrative law judge hearing, we have defined appropriate notice as at least 60 days in § 423.120(b)(5)(i)(A) of our final rule. In addition to affording enrollees more time to manage the consequences of mid-year formulary changes, a 60-day requirement is consistent with the NAIC model guidelines for drug benefit changes. As provided in § 423.120(b)(5)(i)(B) of our final rule, Part D plans also have the option to the extent that they are not able to provide a 60-day advance notice to provide the notice and provide 60 days' coverage of the Part D drug, under the same terms as previously available under the Part D plan, at the time the enrollee fills his or her prescription. Once notice is provided, enrollees will have a 60-day window to either switch to a therapeutically appropriate alternative medication, or obtain a redetermination by the Part D plan, reconsideration by the independent review entity, and request an administrative law judge hearing before the 60-day supply is exhausted.

We note that, in order for the requirement regarding plan changes during the beginning of a contract year in § 423.120(b)(6) of our final rule to be consistent with the 60-day advance notice requirement in § 423.120(b)(5)(i)(A) of the final rule, we have changed the requirement in the proposed rule such that a Part D sponsor may not remove a covered Part D drug from its Part D plan's formulary, or make any change in the preferred or tiered cost-sharing status of a covered Part D drug on its plan's formulary, between the beginning of the annual coordinated election period and 60 days after the beginning of the contract year associated with that AEP. As previously mentioned, we had proposed a period of 30 days in § 423.120(b)(6) of our proposed rule.

We note that, in cases in which the FDA requires the removal of a covered Part D drugs from the market or a manufacturer pulls the drug from the market for safety reasons, 60-day advance notice will not be required, as provided in § 423.120(b)(5)(iii) of our final rule. However, Part D plans will be required to provide notice to affected enrollees (as well as to SPAPs, entities providing other prescription drug coverage, authorized prescribers, network pharmacies, pharmacists, and us) about the removal of a such a covered Part D drug from their formularies as quickly as possible after the drug is actually removed from the formulary. This notification must comply with our notification requirements in § 423.120(b)(5)(ii)(A) through (b)(5)(ii)(D).

Comment: Some commenters asked for clarification on what is considered as ''appropriate notice''. Many commenters urged us to require Part D plans provide notice in writing and mail directly to each enrollee who is affected by the change. The commenters noted that without specifying that the notice must be provided in writing, Part D plans may believe they satisfy requirement by posting this information on their plan websites. Several commenters noted that website notification is inadequate. One commenter asked that Part D plans be allowed to give notice electronically if the enrollee opts for that communication method.

Another commenter asked that Part D plans, primarily MA plans, receive more flexibility in giving notice to enrollees. One commenter noted that Part D plans should be allowed to convey certain types of formulary changes through pre- and post-enrollment materials such as sales brochures, enrollment forms, evidence of coverage, or summaries of benefits.

Response: We agree that Part D plans must provide any formulary change notice in writing, and deliver it directly to affected enrollees. This requirement is reflected in § 423.120(b)(5)(i)(A) of our final rule. As provided in § 423.128(d)(2)(iii) of the final rule, Part D sponsors must also provide this notice to all current and prospective Part D enrollees via their plan websites. However, we agree with commenters who assert that website notification, on its own, is an inadequate means of providing specific information to the enrollees who most need it. Website notification will simply be an additional way in which Part D plans may provide notice of formulary changes to affected enrollees. We therefore require Part D plans to provide this notice directly to affected beneficiaries. As an alternative to providing this notice to affected beneficiaries via U.S. mail, to the extent that plan enrollees affirmatively elect to receive such notice electronically rather than in writing, via U.S. mail, Part D plans may provide notice electronically only.

We do not believe that the formulary change notice requirements should apply any differently to MA-PD plans (or to cost plans offering qualified prescription drug coverage) than they do to prescription drug plans. In order to ensure that enrollees receive and process information about formulary changes in a timely way, we believe that

a notice of formulary changes is the most efficient way to do so, and that other materials (including pre- and post-enrollment materials such as sales brochures, enrollment forms, evidence of coverage, or summaries of benefits) are not the most appropriate mechanisms to convey such information.

Comment: Many commenters recommended requiring Part D plans to include information about enrollees' rights to request an appeal or exception with their formulary change notification. One commenter urged that if the notice of the change in formulary involves the addition of a medication, the notice should also explain how the medication will be classed, if the Part D plan uses a tiered co-pay system or step therapy system. The notice should also indicate expected cost to the beneficiary. If a medication is being removed from the formulary, the notice should indicate what medication is available for individuals who were prescribed the medication being removed.

Response: In response to the helpful public comments received on what ''appropriate notice'' of formulary changes should comprise, § 423.120(b)(5)(ii) of our final rule requires that Part D plans include the following information on their formulary changes notices: (1) the name of the affected covered Part D drug; (2) whether the plan is removing such covered Part D drug from the formulary, or changing its preferred or tiered cost-sharing status; (3) the reason why the plan is removing such covered Part D drug from the formulary, or changing its preferred or tiered cost-sharing status; (4) alternative drugs in the same therapeutic category or class or cost-sharing tier and expected cost-sharing for those drugs; and (5) the means by which enrollees may obtain a coverage determination under § 423.566 or exception under § 423.578 of our final rule. These required information elements will provide enrollees with the information they need to request an independent review or to switch to an alternative formulary drug.

Comment: Several commenters noted that advance notice of formulary changes should only be required for enrollees currently using a particular drug, per our proposal in our notice of proposed rulemaking. One commenter asked that our interpretation of the term ''affected enrollee'' be further expanded to include an enrollee who has been dispensed a drug that has been removed, or whose status has changed, within the last 90 days. Other commenters urged us to require Part D plans to provide all enrollees (not just those taking the affected drug) with advance notice of formulary changes.

Response: We interpret the statutory term ''affected enrollee'' as referring to a Part D enrollee who is currently taking a covered Part D drug that is either being removed from a Part D plan's formulary, or whose preferred or tiered cost-sharing status is changing. In other words, Part D plans will not be required to notify all enrollees regarding formulary changes during a contract year only those directly affected by changes with respect to a particular covered Part D drug. This will minimize Part D plan administrative costs while getting information to those individuals who need it. We have incorporated this definition of the term ''affected enrollee'' in § 423.100 of our final rule.

Comment: Several commenters recommended that Part D plans notify prescribers, pharmacists and pharmacies through information posted on plans' websites or through routine communication to prescribers and pharmacists rather than contacting all prescribers and pharmacies directly. More than one commenter stated that sending a mailed notification to all beneficiaries, affected physicians, and pharmacists would be an enormous undertaking and expense. This commenter believes that it is appropriate to mail notifications to those taking the medication and provide it electronically to physicians, pharmacists, and other beneficiaries via the Part D plan website and upon request.

Response: We agree with commenters that we should provide greater flexibility in terms of the mechanism by which they provide notice to parties other than affected enrollees to whom they are required to provide advance notice of formulary changes (including authorized prescribers, pharmacists, pharmacies, and us). As provided in § 423.120(b)(5)(i) of our final rule, we do not specify that written notice is required to be provided to these parties. Thus, Part D plans can determine the most effective means by which to communicate formulary change information to these parties, including electronic means.

Comment: Several commenters suggested Part D plans also notify SPAPs, State retiree plans, and State Medicaid programs of formulary changes, and another commenter suggested State Medicaid offices as well.

Response: Section 1860D–4(b)(3)(E) of the Act requires that ''appropriate notice'' of formulary changes be made specifically to the Secretary, affected enrollees, physicians, pharmacies, and pharmacists. However, we expect Part D plans to coordinate with SPAPs and other plans providing benefits that supplement the benefits available under Part D coverage to Part D enrollees. Provision of formulary change information to these health plans and programs will be important in ensuring effective coordination. Given that section 1860D–24(a)(2)(F) of the Act provides us with flexibility to establish coordination of benefits requirements regarding other administrative processes not specified in section 1860D–24(a)(2) of the Act, we believe it is reasonable to require Part D plans to notify SPAPs and other health plans and programs (as defined in § 423.454(f)(1) of our final rule) regarding formulary deletions or changes to the tiered cost-sharing status of a drug. We have incorporated this requirement into § 423.120(b)(5) of our final rule.

Comment: One commenter recommended that Part D sponsors should include in their formulary notice to us a certification that they are still meeting the statutory formulary requirements.

Response: We note that, notwithstanding any formulary changes Part D plans make mid-year, plans will still be required to meet all the formulary requirements in § 423.120(b) of our final rule, and we will review all formulary changes to ensure that this is the case.

c. Use of Standardized Technology

In accordance with the requirements of section 1860D 4(b)(2)(A) of the Act, Part D sponsors must issue (and reissue, as appropriate) a card or other technology that enrollees could use to access negotiated prices for covered part D drugs. Section 1860D–4(b)(2)(B)(i) of the Act mandates that we develop, adopt, or recognize standards relating to a standardized format for a card or other technology for accessing negotiated prices to covered Part D drugs. Section 1860D 4(b)(2)(B)(ii) of the Act requires us to consult with the National Council for Prescription Drug Programs (NCPDP) and other standard setting organizations, as appropriate, to develop these standards.

Except as otherwise provided below, the final rule adopts the rules regarding use of standardized technology set forth in § 423.120(c) of the proposed rule.

Comment: A number of commenters support our using a standardized identification card using NCPDP standards. These commenters note that a standardized card using the NCPDP format will create increased efficiencies such as reduced waiting times for dispensing medications that will benefit pharmacy providers and beneficiaries. A

few commenters suggested that we provide MA organizations with the flexibility to integrate their drug card with their medical benefits card rather than issuing a separate card if the MA organization chooses to do so and others requested clarification that MA organizations could issue a single card for both their medical and drug benefits. One commenter expressed concern about using an identification number other than the beneficiaries' Medicare Identification Number because this number is familiar and known by the beneficiaries. In certain situations, if the card were lost or stolen, beneficiaries could easily remember their drug card number.

Response: As provided under section 1860D 4(b)(2)(B)(ii) of the Act, we will consult with the National Council for Prescription Drug Programs (NCPDP) and other standard setting organizations, as appropriate, to develop these standards. Given that NCPDP is recognized as the industry standard for current prescription drug programs, and we relied on its standards in developing requirements for discount card sponsors' cards under the Medicare Prescription Drug Discount Card and Transitional Assistance Program, we expect to base our card standards on NCPDP's ''Pharmacy ID Card Standard.'' This standard is based on the American National Standards Institute ANSI INCITS 284–1997 standard titled *Identification Card—Health Care Identification Cards*, which may be ordered through the Internet at *http://www.ansi.org*. We will provide further operational guidance regarding our standards for a card (or other technology) to entities wishing to become Part D sponsors in time for these entities to use the standards (and have their cards approved for use by us) beginning January 1, 2006. We understand that Part D sponsors would like flexibility to integrate their medical and drug benefit cards and will provide Part D sponsors with that flexibility consistent with our approach under the Medicare Prescription Drug Discount Card and Transitional Assistance Program. It is our intent, however, that these standards require that Part D plans use something other than an enrollee's social security number (SSN) as an identifier on their cards given rising concern over the increasing number of cases regarding identity fraud using an individual SSNs and privacy concerns. We understand that this number is the most familiar and known to the beneficiaries but we will work to make the drug card identification number and process easy and convenient for beneficiaries.

5. Special Rules for Out-of-Network Access to Covered Part D Drugs at Pharmacies (§ 423.124)

Section 1860D–4(b)(1)(C)(iii) of the Act requires us to establish pharmacy access standards that include rules for adequate emergency access to covered Part D drugs by Part D enrollees. Given the inherent difficulties in establishing emergency access standards for covered Part D drugs, we proposed to meet the requirements of section 1860D 4(b)(1)(C)(iii) of the Act by establishing a broader out-of-network access requirement. We proposed requiring that Part D sponsors ensure that their enrollees had adequate access to drugs dispensed at out-of-network pharmacies when they could not reasonably be expected to obtain covered Part D drugs at a network pharmacy. In the proposed rule, we stated that we expected out-of-network access to be guaranteed under at least the following four scenarios:

- In cases in which a Part D enrollee meets all of the following: is traveling outside his or her Part D plan's service area; runs out of or loses his or her covered Part D drug(s) or becomes ill and needs a covered Part D drug; and cannot access a network pharmacy;
- In cases in which a Part D enrollee cannot obtain a covered Part D drug in a timely manner within his or her service area because, for example, there is no network pharmacy within a reasonable driving distance that provides 24-hour-a-day/7-day-per-week service;
- In cases in which a Part D enrollee resides in a long-term care facility and the contracted long-term care pharmacy does not participate in his or her Part D plan's pharmacy network; and
- In cases in which a Part D enrollee must fill a prescription for a covered Part D drug, and that particular covered Part D drug (for example, an orphan drug or other specialty pharmaceutical typically shipped directly from manufacturers or special vendors) is not regularly stocked at accessible network retail or mail-order pharmacies. Both the enrollee and his or her Part D plan would have been financially responsible for covered Part D drugs obtained at an out-of-network pharmacy as described. In the proposed rule, we specified that such cost-sharing would have been applied relative to the plan allowance for that covered Part D drug. We requested comments on how to further define the term ''plan allowance.''

In addition to this cost-sharing, and as provided under proposed § 423.124(b)(2), the enrollee would have been responsible for any difference in price between the out-of-network pharmacy's usual and customary (U&C) price and the plan allowance for that covered Part D drug. We requested public comments regarding our definition of usual and customary price. We also sought comments regarding our proposal that the price differential between out-of-network pharmacies' U&C costs and the plan allowance be counted as an incurred cost against the out-of-pocket threshold consistent with the definition of ''incurred cost'' in § 423.100 of the proposed rule. Finally, we requested general comments regarding our proposed payment rules for covered Part D drugs obtained at out-of-network pharmacies when enrollees cannot reasonably obtain those drugs at a network pharmacy.

Except as otherwise provided below, the final rule adopts the out-of-network access rules set forth in § 423.124 of the proposed rule.

Comment: Many commenters generally supported our proposed out-of-network pharmacy proposal and said beneficiaries—particularly those in rural areas—should not be penalized for going out-of-network when necessary. However, some commenters felt the proposal's list of situations in which access to out-of-network pharmacies would be allowed was overly broad and recommended limiting such access to emergency situations only. Some commenters expressed support for plans having the discretion to establish out-of-network access requirements, but not being given a specific list of requirements. Some expressed concern that the message to beneficiaries might be that they can go to out-of-network pharmacies at will, resulting in increased costs.

A number of commenters stated that as proposed, allowing access to out-of-network pharmacies is impractical because these pharmacies cannot determine if beneficiaries have met their deductibles, are in the coverage gap, or the amount their Part D plan would pay had they gone to a participating pharmacy. Out-of-network pharmacies do not have access to data needed to calculate payment rates other than their own usual and customary price. These commenters asked that we clarify that out-of-network pharmacies may charge beneficiaries their usual and customary price that beneficiaries must be responsible for submitting claims for out-of-network medications they purchase to their Part D plans, and that plans must accept claims submitted to them by beneficiaries once such a purchase is made. One commenter recommended Part D plans be given

time to retroactively modify claims databases to accommodate paper claims tracking, suggesting that we minimize these requirements and be specific in the timeline under which these modifications are required (for example, 60 days).

Some commenters stated that the proposal is inadequate for emergency situations and should require Part D plans to cover a temporary supply of drugs. One commenter recommended that we require Part D plans to establish a mechanism to guarantee payment for at least a 72-hour supply of any medically necessary, covered Part D drug obtained out-of-network. One commenter disagreed with the proposal entirely, stating that if the TRICARE access standards were met by a Part D plan, this should be a sufficient guarantee of adequate network access.

Response: We expect that, given our pharmacy access standards, Part D enrollees will have adequate access to network pharmacies. However, section 1860D–4(b)(1)(C)(iii) of the Act requires us to establish pharmacy access standards that include rules for adequate emergency access to covered Part D drugs by Part D enrollees. Given the inherent difficulties in establishing what constitutes an ''emergency,'' we believe it is most appropriate to establish a broader out-of-network access requirement. Section 423.124(a)(1) of our final rule clarifies that Part D plans are required to ensure that their enrollees have adequate access to drugs dispensed at out-of-network pharmacies when they cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy. Provided that such access to out-of-network pharmacies is not routine, we expect that Part D plans would guarantee out-of-network access in cases in which an enrollee: (1) is traveling outside his or her plan's service area, runs out of or loses his or her covered Part D drugs or becomes ill and needs a covered Part D drug, and cannot access a network pharmacy; (2) cannot obtain a covered Part D drug in a timely manner within his or her service area because, for example, there is no network pharmacy within a reasonable driving distance that provides 24/7 service; (3) must fill a prescription for a covered Part D drug, and that particular drug (for example, an orphan drug or other specialty pharmaceutical) is not regularly stocked at accessible network retail or mail-order pharmacies;; and (4) is provided covered Part D drugs dispensed by an out-of-network institution-based pharmacy while a patient is in an emergency department, provider-based clinic, outpatient surgery, or other outpatient setting. We are not incorporating these scenarios into our final regulations but will closely monitor out-of-network access to ensure that Part D plans are adequately meeting beneficiaries' out-of-network access needs. In addition, plans must provide coverage of drugs in physician's offices in cases in which a beneficiary is administered a vaccine covered by Part D (or another covered Part D drug that is appropriately dispensed and administered in a physician's office).

We understand commenters' concerns that routine access to out-of-network pharmacies could undermine a Part D plan's ability to achieve cost-savings for both beneficiaries and the Medicare program. For this reason, we would like to clarify that § 423.124(c) of our final rules requires Part D plans to establish reasonable rules to ensure that enrollees use out-of-network pharmacies in an appropriate manner—provided they ensure adequate access to out-of-network pharmacies on a non-routine basis when enrollees cannot reasonably access network pharmacies. For example, Part D plans may wish to limit the amount of covered Part D drugs dispensed at an out-of-network pharmacy, require that a beneficiary purchase maintenance medications via mail-order for extended out-of-area travel, or require a plan notification or authorization process for individuals who fill their prescriptions at out-of-network pharmacies. Plans will be required to disseminate information to enrollees about their out-of-network access policies as provided in § 423.128(b)(6) of our final rule.

We wish to clarify that enrollees obtaining covered Part D drugs at out-of-network pharmacies, which by virtue of not being under contract with an enrollee's Part D plan will not have access to the data needed to calculate Part D plan payment rates, will have to pay the pharmacy's U&C price at the point-of-sale, submit a paper claim to their Part D plan, and wait for reimbursement from the plan. Out-of-network pharmacies will therefore be made whole, relative to their U&C price for a covered Part D drug, at the point of sale.

Comment: One commenter stated that patients in emergency departments, provider-based clinics, outpatient surgery, or under observation are often administered drugs (self-administered drugs or insulin, for example) under physician order for medically necessary conditions. These drugs are not covered under Part A or Part B and are billed to patients as a patient liability. For safety and quality of care reasons, patients often cannot bring their own medications into hospitals or outpatient settings when they are being treated for other conditions. This commenter asked for clarification regarding whether Part D plans will cover self-administered prescription drugs dispensed by hospital pharmacies; if so, how beneficiaries will avail themselves of their Part D benefits; and, if not, whether hospitals will have to provide drug coding and other detail on billing statements for beneficiaries so they can submit those statements to their Part D plans for reimbursement.

Response: As provided elsewhere in this preamble, Part D plans may include institutional pharmacies, including hospital-based pharmacies, in their networks, although these pharmacies will not count toward the access requirements Part D plans must meet under § 423.120(a)(1) of our final rule. To the extent hospital pharmacies are included in Part D plan networks, Part D enrollees who are furnished covered Part D drugs by those pharmacies, the situations noted by the commenter will not be an issue. However, we recognize that enrollees who are provided covered Part D drugs by hospital and other institution—based pharmacies under the circumstances described by this commenter cannot reasonably be expected to obtain needed covered Part D drugs at a network pharmacy. We therefore clarify that we expect that Part D plans guarantee out-of-network access to covered Part D drugs in cases in which an enrollee is provided covered Part D drugs dispensed by an out-of-network institution-based pharmacy while a patient in an emergency department, provider-based clinic, outpatient surgery, or other outpatient setting.

Comment: Two commenters recommended that Part D plan enrollees who live in different States during the year should be allowed access to out-of-network pharmacies, as with the other four instances we proposed. One commenter further argued that restricting pharmacy access to mail order during long absences from or trips out of a Part D plan's service area violates the prohibition on exclusive use of mail order pharmacies.

Response: The statutory authority for our proposed out-of-network access policy derives from the requirement, in section 1860D–4(b)(1)(C)(iii) of the Act, that our network access rules include provisions for adequate emergency access for Part D enrollees. Given that narrow statutory authority, we do not believe that access to out-of-network pharmacies on a routine basis can be justified under our out-of-network

access rules. Through our educational efforts, we will encourage enrollees who live in different States during a year (snowbirds, for example) to enroll in national or regional Part D plans that will provide coverage in multiple areas, or in Part D plans that include out-of-area pharmacies in their networks. However, to the extent that a beneficiary is enrolled in a Part D plan that does not provide such access, plans may not allow routine out-of-network access consistent with § 423.124(a)(2) of our final rule.

Comment: Two commenters emphasized the need to allow out-of-network access for specialty medications, such as orphan drugs, that are not typically stocked in a retail pharmacy. Their argument was echoed by commenters who emphasized the need to allow for out-of-network access to home infusion therapy.

Response: We expect that Part D plans will provide out-of-network access to specialty pharmacies in cases in which specialty medications, such as orphan drugs, are not available at a network pharmacy, as this is a case in which enrollees could not reasonably be expected to access their medications at a network pharmacy. However, given that out-of-network access to covered Part D drugs may not be provided routinely, consistent with § 423.124(a)(2) of our final rule, Part D cannot not provide access to out-of-network access to a specialty pharmacy on an ongoing basis. As discussed elsewhere in this preamble, our final rule requires that Part D plans provide adequate access to home infusion pharmacies. We established this access requirement to mitigate the need for routine out-of-network access to home infusion drugs. However, in cases in which an enrollee cannot reasonably access a home infusion pharmacy in his or her Part D plan's network, we expect that plans will provide access to an out-of-network home infusion pharmacy consistent with § 423.124(a) of our final rule.

Comment: Some commenters stated that the final rule should clarify that beneficiaries residing in a long-term care facility should be allowed access to long term care pharmacies as out-of-network pharmacies, should the pharmacy contracting with the long-term care facility in which they reside not participate with their chosen Part D plan. Another commenter thought that our proposed policy vis-à-vis beneficiaries residing in long-term care facilities is inappropriate given that our authority for establishing such requirements is based on emergency access only.

Response: As noted previously, we agree with the commenter who questioned our authority for allowing access to out-of-network long-term care pharmacies on a routine basis. The statutory authority for our proposed out-of-network access policy derives from the requirement, in section 1860D–4(b)(1)(C)(iii) of the Act, that our network access rules include provisions for adequate emergency access for Part D enrollees. Given that narrow statutory authority, we do not believe that access to out-of-network pharmacies on a routine basis including in cases where a beneficiary resides in a long-term care facility whose contracted long-term care pharmacy is not in his or her Part D plan's network can be justified under our out-of-network access rules.

Comment: One commenter said that physician offices should be considered out-of-network pharmacies insofar as they supply covered Part D drugs.

Response: We note that vaccines (and other covered Part D drugs that are appropriately dispensed and administered in a physician's office) administered in a physician's office will be covered under our out-of-network access rules at § 423.124(a)(2) of our final rule, since Part D plan networks are defined as pharmacy networks only. A scenario under which a Part D enrollee must obtain a Part D-covered vaccine in a physician's office constitutes a situation in which out-of-network access would be permitted because a beneficiary could not reasonably be expected to obtain that vaccine at a network pharmacy. We expect that the application of this requirement will be limited to vaccines and a handful of drugs (for example, some injectable long-acting anti-psychotics) that are appropriately dispensed and administered in a physician's office and are not covered under Part B, and that plans may establish utilization management policies and procedures to ensure that out-of-network coverage is limited to such covered Part D drugs. Enrollees will be required to self-pay the physician for the cost of the vaccine (or other covered Part D drug appropriately dispensed and administered in a physician's office) and submit a paper claim for reimbursement by their Part D plan.

Comment: Commenters generally recommended the beneficiary pay the difference between the network price applicable to that beneficiary and the maximum price charged to any Part D plan with which the pharmacy participates. However, they argue, determining that amount would be difficult because out-of-network pharmacies do not have access to the data necessary to calculate that amount. Some commenters specified that beneficiaries purchasing drugs from an out-of-network pharmacy in an emergency situation should not be charged anything more than the network amount. Several commenters urged us to exempt low-income beneficiaries from any differential costs incurred for visiting an out-of-network pharmacy. One noted that we should monitor usage of out-of-network pharmacies by low-income beneficiaries.

Response: As provided in § 423.124(b) of our final rule, if a Part D plan offers coverage other than defined standard coverage, it may require enrollees to not only be responsible for any cost-sharing, including a deductible, that would have otherwise applied had the covered Part D drug been purchased at a network pharmacy, but also any differential between the out-of-network pharmacy's (or provider's) usual and customary (U&C) price and the enrollee's cost-sharing. However, given the cost-sharing requirements for defined standard coverage in § 423.104(d)(2)(A) of our final rule, under which the cost-sharing between the deductible and initial coverage limit must be 25 percent of the actual cost of a drug at the point of sale, Part D plans offering defined standard coverage may not offer such an out-of-network differential. Instead, a Part D plan offering defined standard coverage must simply require its enrollees to pay any deductible or cost-sharing, relative to the out-of-network pharmacy's (or provider's) usual and customary price. The Part D plan will pay the difference between the out-of-network pharmacy's (or provider's) U&C price and the enrollee's cost-sharing.

In either case, enrollees will likely be required to pay more for a covered Part D drug purchased out-of-network than one purchased at a network pharmacy, though, as explained below, any such differential will count toward an enrollee's TrOOP limit. In order to curb unnecessary out-of-network use and preserve Part D plans' ability to achieve cost-savings based on network pharmacy use, we believe it is appropriate that beneficiaries pay more for out-of-network access to covered Part D drugs.

As explained below, we will pay any out-of-network differential for appropriate non-routine use of out-of-network pharmacies (or providers) for full and other subsidy-eligible individuals as part of our low-income subsidy under subpart P of the final rule.

Comment: Some commenters asked us to clarify whether subsidy eligible

individuals who reside in long-term care facilities will have to pay any out-of-network differentials when obtaining drugs from an out-of-network long-term care pharmacy. Many recommended that we pay the out-of-network differential for institutionalized enrollees who are subsidy eligible.

Response: We agree that for full and other subsidy-eligible individuals—whether they are institutionalized or not—we should pay any out-of-network differential for appropriate non-routine use of out-of-network pharmacies. As provided in § 423.104(d)(2) of our final rule, we define enrollee cost sharing in relation to the total cost of the drug to the Part D plan and the beneficiary (actual costs). Therefore, in cases where the total payment is not limited by the plan allowable because a drug is obtained out-of-network, the cost sharing can be defined as the total paid by beneficiary, or in the case of a subsidy eligible individual, as the total cost sharing paid by both the beneficiary and by us. This approach reconciles the need to charge the OON differential and to hold the subsidy eligible individual liable for only the statutorily allowed copayment amounts ($1/$3, $2/$5, or $0 in the case of institutionalized full subsidy individuals who are full-benefit dual eligible individuals).

Comment: A few commenters argued that enrollees accessing covered Part D drugs at out-of-network FQHC, rural and I/T/U pharmacies should also be exempt from any out-of-network differentials.

Response: We do not believe there exists a compelling rationale to exempt beneficiaries who access their drugs at FQHC, rural, or I/T/U pharmacies. However, to the extent such individuals qualify as full or partial subsidy eligible individuals, they will be responsible only for the cost-sharing amounts required in subpart P.

Comment: Comments on the definition of ''U&C price'' fell into three groups. Some commenters felt that the U&C price should be defined as that amount charged to cash paying customers, excluding sales tax. Others argued that the U&C price should be the amount typically charged to senior groups or other cash customers who are directly given some sort of discount as an inducement to make a purchase from a given supplier. A third group of commenters felt that the U&C price should be the maximum the pharmacy charges any customer covered by a Part D plan. Several commenters noted that we should not allow pharmacies to manipulate their U&C prices and should check them periodically to be sure they were less than or equal to the average wholesale price.

Response: We appreciate commenters' suggestions. We believe our proposed definition of the term ''usual and customary price'' the price that a pharmacy (or provider) charges a customer who does not have any form of prescription drug coverage is adequate and are retaining it in § 423.100 of our final rule. We note, in response to several commenters' suggestions, that we do not have the authority to require out-of-network pharmacies to accept a particular price (for example, the maximum price a pharmacy charges any of its customers enrolled in Part D plans) as their U&C price. We believe that Part D plans, not CMS, should be responsible for monitoring of U&C prices for covered Part D drugs at out-of-network pharmacies, since, given that any price differential paid by a beneficiary would count toward the TrOOP threshold, they ultimately have a vested interest in limiting the costs associated with out-of-network use.

Comment: With regard to the definition of ''plan allowance,'' several commenters recommended that it be defined as ''the lowest of contractual discounts offered in a standard contract or U&C price.'' One commenter recommended defining the term in CMS guidance to permit consultation with affected parties. One commenter pressed for Part D plan flexibility so that they could ensure the lowest prices for their members.

Response: We have retained our proposed definition of ''plan allowance'' in § 423.100 of our final rule in order to provide Part D plans with maximum flexibility to establish the most appropriate plan allowance for drugs obtained out-of-network.

Comment: One commenter asked for clarification of the appeals process relating to adverse coverage decisions for out-of-network drugs.

Response: As provided under § 423.566(b)(1) of our final rule, a Part D plan's failure to pay for a covered Part D drug furnished by an out-of-network pharmacy is an action that is a coverage determination.

Comment: Another commenter wanted to be sure that out-of-network pharmacies did not advertise their services as Medicare covered so that beneficiaries would not be confused.

Response: We believe that beneficiaries should always receive accurate and clear information about their pharmacy benefits, and we believe pharmacies must ensure that out-of-network beneficiaries are not misled. However, we have no authority under the MMA to regulate pharmacies' marketing activities. Marketing activities of pharmacies may implicate other Federal or State laws, however, including, but not limited to, consumer protection laws. Pharmacies may also be subject to sanction under section 1140 of the Social Security Act if they misrepresent an affiliation with, or endorsement by the Medicare program.

6. Dissemination of Plan Information (§ 423.128)

Our proposed rule established beneficiary protection requirements concerning the dissemination of Part D information by Part D sponsors to enrollees in, and individuals eligible to enroll in, a Part D plan. Part D information disseminated by Part D sponsors to current or prospective Part D enrollees will constitute marketing materials and must be approved by us.

With the exception of the drug-specific information dissemination requirements, many of the proposed requirements duplicated information dissemination requirements contained in § 422.111 of our proposed MA rule that are applicable to all MA plans, including MA-PD plans. We proposed applying the requirements of section 1860D–4(a) of the Act to other Part D plans to ensure that all Part D eligible enrollees have access to comparable drug-specific information about Part D plans.

a. Content of Plan Description

Proposed § 423.128(a) and (b) complied with the stipulation in section 1860D–4(a)(1) of the Act that requirements for the dissemination of Part D information be similar to the information dissemination requirements for MA organizations under section 1852(c)(1) of the Act and as interpreted in § 422.111(b).

In order to ensure that individuals who are either eligible for, or enrolled in, a Part D plan receive the information they need to make informed choices about their Part D coverage options, Part D sponsors would be required to disclose, to each enrollee in a Part D plan offering qualified prescription drug coverage, a detailed description of that plan. This description must be provided in a clear, accurate, and standardized form at the time of enrollment and annually, at a minimum, after enrollment. The information provided will be similar to the information MA plans must disclose to their enrollees.

Except as otherwise provided below, the final rule adopts the requirements pertaining to plan content description set forth in § 423.128(b) of the proposed rule.

Comment: One commenter sought clarification regarding what we mean by ''standardized'' in our requirement that

Part D plans provide information to enrollees in a ''clear, accurate, and standardized form.''

Response: We expect Part D plans to provide information about their benefit packages in a manner that is consistent with marketing guidelines that we will make available to plans.

Comment: Several commenters requested that we allow Part D plans the flexibility to make plan information available through the Internet. For the convenience of beneficiaries as well as to control costs, these commenters recommend that we encourage the use of more efficient information distribution channels (for example, Internet and email) to disseminate detailed Part D plan information and thus limit the distribution of paper materials to situations in which that makes sense. Another commenter recommended that we clarify that, with the express consent of the enrollee, Part D plans may waive enrollees' right to request and receive any required information in writing and allow for the enrollee to obtain that information via a plan website or email.

Response: We agree that some beneficiaries may prefer to receive Part D plan information electronically and that the provision of plan information through electronic means has the potential to significantly reduce Part D plans' costs. However, a number of Medicare beneficiaries still do not have access to the Internet or prefer to receive their information in written formats. We have modified § 423.128(a) of our final rule to note that we may specify the manner in which plan information must be disseminated to beneficiaries. We clarify that information disseminated by Part D plans as part of a plan description under § 423.128(b), as well as information disclosed upon enrollee request under § 423.128(c), must be provided in a written format and delivered to beneficiaries via U.S. mail unless a beneficiary explicitly consents—by actively opting in—to receive information electronically or via telephone rather than by mail. The electronic provision of Part D plan information should simply be one additional mechanism for Part D plans to communicate with enrollees and potential enrollees.

Comment: One commenter recommended that Part D plans provide information regarding any prior authorization processes required for certain drugs as part of their information dissemination efforts regarding formularies.

Response: We agree with this commenter and have modified that language at § 423.128(b)(4) to clarify that Part D plans must disclose information about any utilization management procedures they may use as part of the formulary information they must disseminate to beneficiaries.

Comment: One commenter recommended that Part D plans be required to provide a list of pharmacies in their networks since the proposed rule requires information only about the types of pharmacies in plans' networks.

Response: We believe the commenter misinterpreted the provision at § 423.128(b)(5) of our proposed rule. This provision, which we have retained in our final rule, requires Part D sponsors to disseminate information about ''the number, mix, and distribution (addresses) of network pharmacies.'' We believe that requiring Part D plans to disseminate information about the addresses of network pharmacy at which an enrollee may reasonably be expected to obtain covered Part D drugs is, in fact, tantamount to requiring plans to provide a list of network pharmacies serving enrollees' service areas. We therefore clarify that Part D plans will be expected to provide enrollees with a list of network pharmacies, including addresses, as well as information about the number and mix of network pharmacies available.

Comment: One commenter requested greater detail regarding the contents of the description of quality assurance policies and procedures that Part D plans must provide under § 423.128(b)(8) of our proposed rule. Another commenter states that, as written, the provision requiring Part D plans to describe their quality assurance policies and procedures did not indicate a clear CMS-directed oversight and enforcement structure. This commenter argues that compliance monitoring and enforcement would at best be indirect, leaving us reliant on the results of deemed status arrangements as set forth in our proposed § 423.165.

Response: We expect plans to provide descriptions of their policies and procedures for concurrent drug utilization review, retrospective drug utilization review, and internal medication error identification and reduction systems. We also expect plans to provide descriptions of their medication therapy management programs, including information describing which enrollees are eligible for such services. With respect to CMS-directed oversight and enforcement, we have added reporting requirements to § 423.153(c) and § 423.153(d) of our final rule, and we will specify the details of these reporting requirements in separate guidance.

Comment: One commenter was concerned that the transition of full-benefit dual eligible individuals from Medicaid to Medicare Part D on January 1, 2006 will likely lead full-benefit dual eligible individuals to contact Medicaid agencies for more information regarding their new pharmacy benefits. This commenter recommended that we require Part D plans to include information in their enrollee materials that clarifies that State Medicaid agencies are no longer the primary providers of pharmacy benefits and cannot answer questions about the Medicare benefit, except as pertains to limited supplemental coverage that Medicaid may provide.

Response: Our education and outreach efforts will ensure that beneficiaries receive detailed information regarding their transition from Medicaid to Medicare for prescription drug coverage. Therefore, we do not believe it is necessary to require Part D plans to include this information in their materials.

b. Disclosure of Information upon Request

In addition, in accordance with section 1860D–4(a)(2) of the Act, the proposed rule at § 423.128(c) provided that a beneficiary who is eligible to enroll in a Part D sponsor's Part D plan will have the right to obtain, upon request, more detailed plan information. Except as otherwise provided below, the final rule adopts the standards set forth in § 423.128(c) of the proposed rule.

Comment: A number of commenters are supportive of the provision in the proposed rule that required Part D plans to make available information about how to obtain information about the formulary, but thought that this requirement was insufficient given that beneficiaries will need precise and detailed formulary information to make informed choices about enrollment. These commenters recommend requiring Part D plan descriptions to include a detailed formulary listing not only the drugs on the formulary, but also any formulary tiers and corresponding copayment amounts.

Response: We agree that it will be critically important for Part D enrollees and prospective enrollees to have access to complete formulary information in order to make the best possible Part D plan selection for their particular medical and prescription drug needs. For this reason, we have modified the formulary information requirements under § 423.128(b)(4) such that Part D plans will be required to include not only information about the manner in which the formulary functions (including tiering structures and any

utilization management procedures used), a process for obtaining an exception to a Part D plan's tiered cost-sharing structure or formulary, and a description of how an enrollee may obtain additional information on the formulary, but also an actual list of drugs included on the Part D plan's formulary. For each drug, this list must indicate any cost-sharing tier information applicable to that drug and whether utilization management programs apply.

Comment: Several commenters urged us to expand the requirement that Part D plans disclose, upon request, information about the number of disputes and their disposition in the aggregate to include exceptions. Another commenter noted that we appeared to have made a mistake in terms of our references to the provisions on grievances and reconsiderations in § 423.128(c)(3) of our proposed rule.

Response: We agree with these commenters. We have corrected the reference errors in § 423.128(c)(3) of our final rule and have expanded this requirement such that Part D plans must disclose, upon request, information about the number of exceptions and their disposition in the aggregate. We did not originally include a reference to exceptions in our proposed because section 1852(C)(2) of the Act, on which the requirements in our proposed § 423.128 were based, did not envision an exceptions process for the MA program.

Comment: Several commenters noted that § 423.128(c)(1)(iii) of our proposed rule required Part D plans to inform enrollees about the potential for contract termination, but only upon request. However, these commenters felt strongly that this information needed to be included in all plan descriptions and marketing materials, and not just if requested by an enrollee or prospective enrollee, particularly in light of previous experience with volatility in the Medicare+Choice market.

Response: We agree with these commenters and have moved the requirement that Part D plans disclose information about the potential for contract termination upon request only, to § 423.128(b)(10), under which plans will be required to disclose this information as part of the plan description provided at the time of enrollment and at least annually thereafter.

c. Provision of Specific Information

As required under section 1860D–4(a)(3) of the Act and proposed at § 423.128(d) of our proposed rule, Part D sponsors will be required to have in place a mechanism for providing, on a timely basis, specific information to current and prospective enrollees upon request. Such mechanisms will include:

- A toll-free customer call center;
- An Internet website; and
- Responses in writing upon beneficiary request.

As proposed at § 423.128(d)(1)(i) and (d)(1)(ii), Part D plans' customer call centers will be required to be open during usual business hours and provide customer telephone service, including to pharmacists, in accordance with standard business practices. We strongly recommended, however, that Part D plans provide some sort of 24-hour-a-day/7 day-a-week access to their toll-free customer call centers in order to provide timely responses to time-sensitive questions. In addition, we proposed requiring that Part D plans maintain websites as one means of disseminating information to current and prospective Part D enrollees that would include the detailed plan description information described in § 423.128(b) of our proposed rule. Finally, Part D plans would be required to respond to beneficiary requests for specific information in writing, upon request. This requirement was codified in § 423.128(d)(3) of our proposed rule.

Except as otherwise provided below, the final rule adopts the specific information disclosure standards set forth in § 423.128(d) of the proposed rule.

Comment: Several commenters recommended against requiring a 24-hour/7-day-a-week call center because of the high costs associated with operating a call center during off-hours. These commenters support operating a call center during normal business hours as required in the proposed regulations. One commenter suggested Part D plans consider developing a website and IVR system that allows beneficiaries to access their accounts to determine their TrOOP balance.

Other commenters recommended requiring Part D plans to operate 24/7 call centers, stating that the need for prescription drugs may arise outside of normal business hours and would necessitate timely assistance and resolution of coverage issues. These commenters noted that the implications of delayed access are potentially very serious. One commenter stated that advice hotlines should be available 24-hour/7-days a week to assist enrollees and pharmacies in understanding Part D plan formularies. Another commenter urged requiring extended service hours especially during the initial enrollment period and also ensuring that language specialists are available.

Response: We have retained our proposed requirement (in § 423.128(d)(1) of our final rule) that Part D plans maintain a toll-free customer call center that is open during usual business hours and provides customer telephone service, including to pharmacists, in accordance with standard business practices. However, Part D plans should view this requirement as a floor which they can exceed—particularly at times such as annual open enrollment periods. Access to bilingual customer service representatives may also be appropriate in certain parts of the country. Given the need for Part D plans to provide timely information on certain time-sensitive issues, however, we strongly recommend that Part D plans also provide access to 24/7 clinical advice hotlines as is customary for many health plans.

Comment: One commenter recommended that we require formulary updates to plans' websites only when actual changes are made, but no more than once per month.

Response: We agree with this commenter. We recognize the need for formulary information to be kept as current as possible to allow enrollees and prospective enrollees to make the best possible decisions regarding coverage of their particular Part D drugs. However, P&T committees typically meet quarterly, and we expect that most formulary changes recommended by a P&T committee will be implemented following regular committee meetings. We have therefore changed the requirement in § 423.128(d)(2)(ii) of our proposed rule, which required weekly updates of formulary information on Part D plan websites, to require monthly updates instead. This requirement is codified at § 423.128(d)(2)(ii) of our final rule.

Comment: One commenter asked us to clarify that formulary information will be made available through means other than plan websites.

Response: As previously stated, enrollees and prospective enrollees will be able to obtain specific Part D plan information, including formulary information, upon request via telephone and in writing. In addition, we have revised our final rule at § 423.128(b)(4) to require Part D plans to provide enrollees with an actual list of drugs included on the plan's formulary.

Comment: One commenter requested clarification that our requirement that formulary information be posted on a Part D plan website be limited to including only a list of formulary drugs and not the full range of clinical information associated with those drugs.

Response: Plans will only be required to include a list of drugs included on their formularies—and not the clinical information associated with those drugs—under our information dissemination requirements.

d. Claims Information

In accordance with the requirements of section 1860D-(4)(a)(4) of the Act, § 423.128(e) of the proposed rule required Part D sponsors to furnish to enrollees who receive covered Part D drugs an explanation of benefits (EOB). EOBs will be required to be written in a form easily understandable to beneficiaries. In § 423.128(e)(6) of our proposed rule, we proposed that an EOB be provided at least monthly for those utilizing their prescription drug benefits in a given month.

We also proposed in § 423.128(e)(1)-(5) that Part D plans' EOBs include:

- A listing of the item or service for which payment was made, as well as the amount of such payment for each item or service;
- A notice of the individual's right to request an itemized statement;
- Information regarding the cumulative, year-to-date amount of benefits provided relative to the deductible, the initial coverage limit, and the annual out-of-pocket threshold for that year;
- A beneficiary's cumulative, year-to-date total of incurred costs (to the extent practicable); and
- Information about any applicable formulary changes.

Except as otherwise provided below, the final rule adopts the EOB standards set forth in § 423.128(e) of the proposed rule.

Comment: Some commenters supported the requirement to mail enrollees an EOB each month that the drug benefits are provided, as stated in the proposed regulations. Some commenters recommended dissemination of the EOBs quarterly and upon request of the enrollees rather than monthly when prescription drug benefits are provided.

Several commenters urged us to allow Part D plans the flexibility to provide an EOB to enrollees through means other than mail, such via a plan website, electronically through email, or by telephone inquiry. One commenter noted that it is not current practice for health plans to mail enrollees an EOB monthly and that this would raise administrative costs. Some commenters expressed their objection to providing an EOB at pharmacies, stating this would be far beyond pharmacies' technological capabilities, and that provision of the EOB via mail or electronically should be plans' responsibility.

Some commenters expressed that the EOBs should also include information about appeals right and processes, information about formulary information and plan terminations, and information regarding whether the deductible and out-of-pocket thresholds have been met. Another commenter stated that the EOB should be modified to be applicable to beneficiaries who are subsidy eligible individuals due to the differences in the deductibles and cumulative spending limits for these individuals.

Response: We appreciate commenters' feedback regarding our proposed EOB requirements. As provided in § 423.128(e)(6) of our final rule, we are retaining our proposed requirement that an EOB be provided at least monthly for those enrollees utilizing their prescription drug benefits in a given month. This requirement is consistent with our policy regarding the Medicare Summary Notice, which is provided monthly for beneficiaries with Part A or Part B utilization.

We believe it is most appropriate for enrollees to receive a written EOB, via U.S. mail, and have provided for this under § 423.128(e) of our final rule. Plans may offer additional mechanisms for the provision of such information—for example, via a website or call center. Plans may provide the EOB through alternative means electronically via email, for example only to the extent that enrollees affirmatively elect to receive their EOBs in such a manner. In the preamble, we suggested that Part D plans might explore provision of EOBs at the point-of-sale, but that statement was in no way intended to impose a requirement on pharmacies to provide Part D plan information in the absence of the technological capacity to do so.

We do not believe that the EOB is the most appropriate mechanism for provision of information about appeals rights and processes or information about plan terminations; this information will be provided through other mechanisms. We clarify, however, that EOBs will be required to include information regarding the cumulative, year-to-date amount of benefits provided relative to the deductible, the initial coverage limit, and the annual out-of-pocket threshold for that year, as well as information about any upcoming formulary changes. For low-income beneficiaries, the information about the cumulative, year-to-date total of incurred costs provided by the Part D plan in the EOB will include CMS subsidy amounts that count toward incurred costs.

7. Public Disclosure of Pharmaceutical Prices for Equivalent Drugs (§ 423.132)

Under section 1860D–4(k)(1) of the Act, Part D sponsors will be required to ensure that pharmacies inform enrollees of any differential between the price of a covered Part D drug to an enrollee and the price of the lowest priced generic version of that drug and available under the Part D plan at that pharmacy. As stipulated in our proposed rule, this information will have to be provided at the time the plan enrollee purchases the drug, or in the case of drugs purchased by mail order, at the time of delivery of that drug. Disclosure of this information will not be necessary, however, if the particular covered Part D drug purchased by an enrollee was the lowest-priced generic version of that drug available at a particular pharmacy.

As provided under section 1860D–4(k)(2)(B) of the Act, we are permitted to waive the requirement that information on differential prices between a covered Part D drug and generic equivalent covered Part D drugs be made available to Part D plan enrollees at the point of sale (or at the time of delivery of a drug purchased through a mail-order pharmacy). Accordingly, we proposed waiving the requirement that information on lowest-priced generic drug equivalents be provided to enrollees for covered Part D drugs purchased by Part D plan enrollees when those covered Part D drugs are purchased at:

- Any pharmacy, when the individual is enrolled in an MA private fee-for-service plan that offers qualified prescription drug coverage and provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies, and does not charge additional cost-sharing for access to covered Part D drugs dispensed at all pharmacies;
- Out-of-network pharmacies;
- I/T/U network pharmacies; and
- Network pharmacies located in any of the U.S. territories (American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands). We requested comments on the appropriateness of the circumstances we proposed for waiver of the requirements in § 423.132(c) of our proposed rule, as well as any additional circumstances we may wish to consider.

We also proposed waiving the requirement that information on differential prices between a covered Part D drug and generic equivalent covered Part D drugs be made available to Part D plan enrollees at the point of

sale when Part D plan enrollees obtain covered Part D drugs in long-term care pharmacies. We requested comments regarding appropriate standards with regard to the timing of disclosure of generic price differentials to institutionalized Part D enrollees.

Except as otherwise provided below, the final rule adopts the standards for public disclosure of pharmaceutical prices for equivalent drugs set forth in § 423.132 of the proposed rule.

Comment: One commenter was concerned about the administrative burden the disclosure requirement would impose at the community pharmacy level and believed it was essential for us to develop appropriate guidance to minimize potential problems. The commenter noted that the administrative burden required to calculate cost-sharing differences should cause us to consider compliance with the requirements to be impracticable in all pharmacy settings because while many community pharmacies' prescription processing systems currently compare retail prices for brand-name and generic medications, the systems are not equipped to compare the discount price calculated by a Part D plan with the potential discount price by a plan for a generic drug. According to this commenter, obtaining this discounted generic price would require the pharmacy to process and submit a second prescription transaction for the generic, and then require the pharmacy to calculate the difference between the two prescriptions; the need to compare the enrollee's cost-sharing under the two scenarios would add more challenges. Other commenters assured us that this requirement is not burdensome for retail pharmacies.

Response: As provided in section 1860D–4(k) of the Act, Part D plans must provide that each pharmacy in their networks with the exceptions that we note in § 423.132(c) of our final rule complies with the requirement to disclose to beneficiaries information about less expensive therapeutically equivalent and bioequivalent covered Part D drugs. Given this statutory requirement, we cannot waive it wholesale for all community pharmacies. We do not expect this requirement will be burdensome for community pharmacists since, given that, under § 423.132(b) of our final rule, we are requiring disclosure of generic differential information after a claim has been adjudicated and for informational purposes only. We clarify that we do not expect pharmacies to become involved in substituting a generic equivalent in order for Part D plans to comply with the disclosure requirement in § 423.132(a) of our final rule. We expect that Part D plans will work with their network pharmacies to operationalize this requirement, but we do not expect that it will be burdensome to the pharmacy industry given the prevalence of generic substitution and information programs established by private plans in the market today.

Comment: One commenter asked that we define ''lowest price'' as determined by the Part D plan at the point of sale. Another commenter asked that we clarify that ''price'' is defined as what the enrollee would pay at the pharmacy subject to the applicable cost sharing. Two commenters recommended that pricing comparison should be between the brand name drug and the Maximum Allowable Cost (MAC) established by the Part D plan for the generic equivalent to the branded drug. Another commenter suggested allowing an estimated price differential between brand and non-MAC generics to be made available to enrollees rather than the exact cost differential between the price of a covered Part D drug and the lowest priced generic version because of the technical limitations of plans (for example, plans do not have a record of generics in stock at all network pharmacies). This commenter claims that, otherwise, this requirement would involve enormous administrative efforts and costs for Part D plans. This commenter suggested a reasonable alternative would be allowing plans to utilize historical dispensing patterns and costs to have available relative price information in the form of an estimate of the price differential transmitted to pharmacies in the electronic claim response when a prescription is filled, and that Part D plans would contractually require pharmacies to share this information at the point-of-sale.

Response: Under section 1860D–4(k) of the Act, Part D plans must provide that each pharmacy in their networks complies with the requirement to disclose to beneficiaries information about less expensive therapeutically equivalent and bioequivalent covered Part D drugs. Specifically, Part D plans must provide information about the differential between the price of the covered Part D drug to the enrollee (factoring in any applicable cost-sharing) and the price of the lowest-priced therapeutically equivalent and bioequivalent drug available at that pharmacy. We expect that Part D plans will work with their network pharmacies to operationalize this requirement in the most efficient way possible, and in a manner that complies with our requirements under § 423.132 of our final rule.

Comment: One commenter recommended that disclosure of the generic drug price be the lowest priced generic available at that pharmacy because most pharmacies do not carry multiple generic drug options for the same generic entity.

Response: We agree with the commenter and clarify that § 423.132(a) requires pharmacies to disclose the differential between the price of a covered Part D drug and the price of the lowest-priced generic version of that drug available at that pharmacy, consistent with section 1860D–4(k)(1) of the Act.

Comment: One commenter recommended only requiring pharmacists to inform patients of price differentials if they are dispensing a high cost version of a ''multiple source'' drug that is available at that pharmacy. This commenter noted that in many cases these off-patent innovator brands, also known as ''multiple source'' drugs, are less costly than their generic counterparts (for example, some brand name version antibiotics are often equal or lower in price than their generic counterparts). Without this technical correction, these drugs may not be considered by some Part D plans as generics and the pharmacists would not inform the beneficiary that these lower cost ''multiple source'' drugs are available. Another commenter stated that generics should be further defined to include ''multiple source'' brand name drugs.

Response: Section 1860D–4(k) of the Act requires that each pharmacy that ''dispenses a covered Part D drug shall inform an enrollee of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered part D drug under the plan that is therapeutically equivalent and bioequivalent and available at such pharmacy.'' While we appreciate the commenter's point that off-patent innovator drugs may also be available to enrollees at low prices, and that this information should be disclosed at the point of sale, the statute very specifically applies the requirement to the lowest priced generic covered Part D drug available at that pharmacy. Our definition of ''generic drug'' at § 423.4 of the final rule does not encompass an off-patent innovator drug, however. In addition, given that section 1860D–2(b)(4)(A)(i)(I) of the Act specifically distinguishes between a ''generic drug'' and a ''preferred drug that is a multiple source drug,'' we do not believe it is appropriate to define a generic drug to include a ''multiple

source'' brand-name version of a drug. However, nothing in the statute would prohibit Part D plans from requiring their network pharmacies to provide pricing information about lower priced off-patent innovator drugs, and we encourage Part D plans to do so in the interest of ensuring Part D enrollees get the best prices available for their covered Part D drugs.

Comment: One commenter concerned with the burden on pharmacies to disclose pricing information stated that the disclosure requirement should be limited to cases in which an enrollee asks for this information at the pharmacy.

Response: As provided in section 1860D–4(k) of the Act, Part D plans must require network pharmacies, except for those which we have specifically exempted from the requirement, to disclose information about price differentials. We cannot limit this requirement to circumstances in which an enrollee specifically asks for the information. Furthermore, we believe such disclosure will provide enrollees—many of whom may not know that less expensive generic equivalents are available—with valuable information that will save money for beneficiaries, Part D plans, and Medicare.

Comment: One commenter recommended disclosure only when a brand name drug is prescribed and the prescriber has not stated ''Do Not Substitute.''

Response: As provided in section 1860D–4(k) of the Act, Part D plans must require network pharmacies, except for those which we have specifically exempted from the requirement, to disclose information about price differentials. We cannot limit this requirement to circumstances in which a prescriber has written a prescription for a brand name drug and has not specifically stated that the pharmacy must not substitute the brand name drug for a generic drug. We believe such disclosure will provide enrollees many of whom may not know that less expensive generic equivalents are available with valuable information that will save money for beneficiaries, Part D plans, and Medicare.

Comment: Two commenters suggested that we clarify that the lowest price generic version that is ''therapeutically equivalent and bioequivalent'' is an AB-rated generic equivalent, as AB rated drugs have been proved to be bioequivalent (rather than presumed to be bioequivalent). Another commenter suggested that we limit disclosure requirements to products with ''A'' code, as specified in the FDA Orange Book.

Response: We agree with these commenters and clarify that the disclosure requirement in § 423.132(a) of our final rule applies only with respect to AB-rated alternatives that are therapeutically equivalent and bioequivalent to the covered Part D drug in question.

Comment: A number of commenters recommended requiring mail-order pharmacies to provide price differentials before the prescription is filled and delivered rather than at the time of delivery. The commenters noted that notification by the time of delivery may be too late for beneficiaries to receive possible savings, especially since mail-order pharmacies provide a 90-day supply and generally have lower dispensing rates than retail pharmacies.

Response: We do not believe it is practicable to require a mail-order pharmacy to contact an enrollee with price differential information prior to filling and delivering their prescription. We believe such a requirement will delay the delivery of needed drugs and could potentially compromise beneficiaries' privacy given attempts by mail-order pharmacies to contact plan enrollees. In addition, such a requirement would be inconsistent with the requirement for retail pharmacies in § 423.132(b) of our final rule, which does not require that Part D plans provide price differential information before the drug is purchased. We have therefore retained our requirement, in § 423.132(b) of our final rule, that disclosure must occur at the time of delivery of the drug when a drug is dispensed by a mail-order pharmacy.

Comment: One commenter recommended that we not waive the public disclosure requirement for private fee-for-service plans offering qualified prescription drug coverage because there are many opportunities for generic savings that might not be realized in the absence of this requirement.

Response: Section 1860D–12(d)(2) of the Act specifically requires us to waive the public disclosure requirement for private fee-for-service MA plans that offer qualified prescription drug coverage and provide plan enrollees with access without charging additional cost-sharing for covered Part D drugs dispensed at all pharmacies.

Commenter: One commenter strongly urged that we waive the public disclosure requirement for I/T/U pharmacies because these pharmacies bear beneficiaries' out-of-pocket costs for covered Part D drugs, obviating the need for AI/AN Part D enrollees obtaining covered Part D drugs at these pharmacies to have this price comparison information.

Response: As provided both in our proposed rule and in our final rule at § 423.132(c)(3), we will waive the public disclosure requirement for I/T/U pharmacies.

Comment: One commenter requested that MA-PD plans be allowed to request a waiver of the public disclosure requirement.

Response: As provided in § 423.132(c)(5), we will consider waiving the public disclosure requirement under circumstances other than those specified in § 423.132(c)(1)-(4) to the extent that we deem such compliance to be impossible or impracticable. MA-PD plans seeking a waiver of the public disclosure requirement for any of their network pharmacies will therefore have to demonstrate to us that compliance with the public disclosure requirement in § 423.132(a) is impossible or impracticable. In addition we note that, as provided in section 1860D–21(c), we will waive any Part D requirement for an MA-PD plan that conflicts with or duplicates a requirement under Part C, or the waiver of which is necessary to promote coordination between benefits provided under Parts C and D.

Comment: Another commenter suggested that we specifically waive the disclosure requirement for MA-PD plans that own and operate their own pharmacies because these pharmacies may carry only one version of any particular generic drug at any one time (except when transitioning from one manufacturer's product to another).

Response: We do not believe the commenter has provided us with sufficient information to determine that the public disclosure requirement is impossible or impracticable for Part D plans that own and operate their own pharmacies and should therefore be waived in regulation. However, we note that MA-PD plans may also wish to consider seeking a waiver of the public disclosure requirement if, as provided in section 1860D–21(c) of the Act, they can demonstrate that this requirement conflicts with or duplicates a requirement under Part C, or that such waiver is necessary to promote coordination between benefits provided under Parts C and D.

Comment: Several commenters supported the applicability of disclosure requirements to long-term care pharmacies because many long-term care facility residents and their families would be interested to know if additional savings are possible. Two commenters opposed requiring price

disclosure at long-term care pharmacies because most long-term care beneficiaries do not have a choice regarding long-term care pharmacies and will likely qualify for low-income subsidies for institutionalized Part D enrollees who are full-benefit dual eligible individuals (which means they will have no out-of-pocket costs for covered Part D drugs). Thus, this information will have little effect on the drugs used by this population and will increase administrative burden for long-term care pharmacies.

Response: We agree with commenters who thought long-term care residents and their families would be interested to know if additional covered Part D drug savings are possible through the use of generic drugs, particularly since not all long-term care patients will qualify as full subsidy eligible individuals. We are therefore retaining the requirement we proposed at § 423.132(d)(1) of our proposed rule, but clarify—in § 423.132(d)(1) of our final rule—that long-term care pharmacies will have to provide information about differential price information required under § 423.132(a) of our final rule to Part D plans, which will, in turn, provide that information to their institutionalized enrollees via the explanation of benefits required under § 423.128(e) of our final rule.

8. Privacy, Confidentiality, and Accuracy of Enrollee Records (§ 423.136)

To the extent that the prescription drug plan offered by a PDP sponsor maintains medical records or other health information regarding Part D enrollees, § 423.136 of our proposed rule required the PDP sponsor to meet the same requirements regarding confidentiality and accuracy of enrollee records as MA organizations offering MA plans must currently meet under 42 CFR 422.118, according to the stipulations of section 1860D 4(i) of the Act. We clarify that the requirements of § 423.136 do not apply to PACE organizations and cost plans offering qualified prescription drug coverage, since these plans are subject to similar requirements under § 460.200(e) and § 460.210, and § 417.486, respectively.

PDP sponsors will be required to—

- Abide by all Federal and State laws regarding confidentiality and disclosure of medical records or other health and enrollment information, including the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the privacy rule promulgated under HIPAA;
- Ensure that medical information is released only in accordance with applicable Federal or State law;
- Maintain the records and information in an accurate and timely manner; and
- Ensure timely access by enrollees to records and information pertaining to them.

Prescription drug plans will be covered entities under the HIPAA Privacy Rule because they meet the definition of ''health plan,'' as defined in 45 CFR 160.103. The HHS Office for Civil Rights (OCR) is responsible for implementing and enforcing the HIPAA Privacy Rule. OCR has authority to investigate complaints, to conduct compliance reviews, and to impose civil money penalties for HIPAA Privacy Rule violations. Thus, any violations by PDP sponsor for its obligations under the Privacy Rule as a covered entity are subject to such enforcement by OCR. OCR maintains a website with frequently asked questions and other compliance guidance at *http://hhs.gov/ocr/hipaa*.

Comment: One commenter thought that we should detail the confidentiality and disclosure requirements set forth in § 423.136 of our proposed rule in the final rule, instead of simply referencing the requirements in § 422.118. This commenter believes that because of the importance of privacy protections, it is necessary that required protections are reiterated in our final rule and that PDP sponsors adequately understand their responsibilities to safeguard the health information of Medicare beneficiaries. Without privacy safeguards built directly in the regulation, beneficiaries could be vulnerable to another amendment.

Response: We agree with this commenter and have incorporated the provisions of § 422.118 directly into § 423.136 of our final rule rather than only referencing the provisions of § 422.118.

Comment: One commenter recommends that we make privacy provisions stronger for PDP sponsors, not only reiterating the protections under § 422.118, but also including specific rules regarding uses and disclosures of beneficiary information that both incorporate the provisions of important laws (such as the notice and authorization provisions of the HIPAA privacy rule) and strengthen the provisions of those laws to better protect the health information of Medicare beneficiaries.

Response: The requirements in § 423.136 of our final rule make clear that PDP sponsors must abide by all Federal and State laws regarding confidentiality and disclosure of medical records, or other health and enrollment information. This obligation includes compliance with the provisions of the HIPAA privacy rule and its specific rules regarding uses and disclosures of beneficiary information. Because section 1860d–4(i) of the Act stipulates that the privacy provisions under section 1852(h) apply to prescription drug plans in the ''same'' manner as they apply to MA plans under Medicare Part C, we do not have the statutory authority to expand upon those provisions as the commenter suggests.

Comment: One commenter recommends that we permit MA organizations and PDP sponsors to prevent pharmacies in their networks and out-of-network pharmacies from releasing prescriber data to third parties. Some MA organizations are concerned that providing data to drug manufacturers will have the negative effect of assisting manufacturers in targeting their marketing of unnecessary, expensive drugs in a more effective manner.

Response: Pharmacies that engage in electronic transactions are covered entities under HIPAA and are thus required to comply with the HIPAA Privacy Rule. As provided in 45 CFR 164.508, such pharmacies, as covered entities, would be prohibited from releasing individually identifiable health information to drug manufacturers for the purpose of the manufacturers' marketing unless a patient specifically authorizes the disclosure of his or her information for this purpose. However, the Privacy Rule protects patient information only, and is therefore not implicated regarding the sharing of information about prescribers.

D. Cost Control and Quality Improvement Requirements for Part D Plans

1. Overview (Scope) (§ 423.150)

Subpart D of part 423 implements provisions included in sections 1860D 4(c), 1860D–4(d), 1860D–4(e), 1860D–4(j), and 1860D–21(d)(3) of the Act and sections 102(b) and 109 of Title I of the MMA. This subpart sets forth the requirements related to the following:

- Drug utilization management programs, Quality assurance measures and systems, and Medication Therapy Management programs (MTMP) for Part D sponsors;
- Consumer satisfaction surveys of Part D plans;
- Electronic prescription program;

- Quality Improvement Organization (QIO) activities;
- Compliance deemed on the basis of accreditation;
- Accreditation organizations;
- Procedures for the approval of accreditation as a basis for deeming compliance.

Below we summarize the proposed provisions and respond to comments. (For a detailed discussion of our proposals, please refer to the proposed rule (69 FR 46666)).

2. Drug Utilization Management, Quality Assurance, and Medication Therapy Management Programs (MTMPs) (§ 423.153)

Proposed § 423.153(a) required each Part D sponsor to establish a drug utilization management program, quality assurance measures and systems, and a MTMP.

We combined these requirements into one section of the regulation because each of these requirements will impact the quality and cost of care provided to beneficiaries. We stated that our intent was to ensure that the prescription drug benefit was provided using state of the art cost management and quality assurance systems. We stated that we also understood the overlapping nature of these requirements and that provisions under one requirement might complement another requirement.

We also explained in the proposed rule that although these requirements were similar in their underlying goals, they could also be quite different, and that while we understood that some members of the industry use various quality assurance measures and systems for controlling utilization and reducing medication errors, less information was available regarding MTMPs.

After receiving many comments on our proposals, our final policy, generally stated, is that cost control and quality improvement requirements describe minimum standards for drug utilization management, quality assurance, and MTMP so as to provide plans with flexibility to develop, implement, and update their programs and systems to reflect changing best practices and to continue to provide beneficiaries with the best quality prescription drug benefit at the lowest possible cost. We expect plans to continuously monitor their programs and processes, identify opportunities for improvement, and develop improvement plans and strategies.

As we stated in the proposed rule, we believe that the different program and system requirements in this subpart frequently overlap and therefore, plans need flexibility to coordinate among the different requirements. Moreover, flexibility is required to ensure that plans can support forthcoming electronic prescribing standards that we envision will dramatically affect the utilization management and quality assurance landscape. Nevertheless, despite the lack of specificity in our requirements, we expect plans to continually pursue innovative improvements for their programs and systems, and maximize technological advances when appropriate.

Ultimately, the evaluation of these programs and systems needs to be based upon their impact on therapeutic outcomes. As part of our commitment to improving therapeutic outcomes through the Medicare Prescription Drug Benefit, we intend to work with industry and other stakeholders to develop a comprehensive strategy for evaluating plan performance that collectively considers multiple standards and services affecting the cost and quality of drug therapy. As industry practices evolve, including the expected expansion of electronic prescribing, we believe meaningful performance measures can be identified that will validate best practices and provide benchmarks that will spur further program and system improvements. Accordingly, we will work with industry to identify new standards for quality and performance that could eventually become plan requirements. Our goal is to ensure that the Medicare Prescription Drug Benefit will always provide beneficiaries with the highest quality prescription drug benefits at the lowest possible cost.

In addition to our efforts to work with industry and stakeholders to develop future performance measures and standards for Part D plans, we also intend to implement a plan for utilizing Medicare prescription drug data to improve the evidence on risks, benefits, and overall costs of drug therapies for the chronically ill and other Medicare beneficiaries. This plan will be developed through a public process and implemented in a manner that preserves the confidentiality of beneficiary information.

a. Drug Utilization Management

Proposed § 423.153(b) provided flexibility to Part D sponsors in their design of drug utilization management, and included minimum requirements for drug utilization management programs. These requirements were: (1) that plans maintain a program that includes incentives to reduce costs where medically appropriate; and (2) that plans maintain policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications. The proposed rule also stated that Part D sponsors must inform enrollees of program requirements, such as those involving allowable refill timeframes, in order to prevent unintended interruption in drug therapy.

In addition, the proposed rule contained a discussion about whether drug utilization management techniques should be under the direction and oversight of a P&T Committee to ensure an appropriate balance between clinical efficacy and cost effectiveness. The discussion on P&T Committees and their oversight of drug utilization management is contained in subpart C of this final rule.

We invited comments on whether there are industry standards for drug utilization management and whether we should adopt any of these standards.

Comment: We received numerous comments on our proposed standards, with several commenters supporting the flexibility we proposed and stating that there are no current, widely-accepted standards in the area of drug utilization management. Others supported additional detail in the regulations and suggested that we should further specify drug utilization management program standards. Some expressed concern that plans could use drug utilization management programs to restrict utilization inappropriately. In addition, several commenters recommended that we require plans to focus equally on over-utilization and under-utilization to ensure appropriate utilization by enrollees and to monitor plan performance in these areas.

Response: Based on a literature review by Booz-Allen-Hamilton[3], and the public comments received on this topic, we are not adopting further specifications for drug utilization management requirements in the final rule. While drug utilization management is common practice, plans appropriately employ a number of different approaches (for example, formularies, step therapy, tiered cost sharing, prior authorization) and different combinations of those approaches, and therefore, while we will consider additional standards in the future, we are adopting the flexibility we proposed in the proposed rule. As we stated in the proposed rule, we believe the competitive bidding and premium setting processes, combined with the requirements for transparency and information availability, will provide powerful incentives for plans to

[3] Booz-Allen-Hamilton. Final Report for Technical Support for the Implementation of Part D. September 15, 2004.

innovate and adopt the best techniques available.

Nevertheless, our requirement for inclusion of incentives to reduce costs when medically appropriate must be interpreted broadly to mean that all drug utilization management techniques must be medically appropriate, and § 423.153(b) requires the utilization management program established by plans to be ''reasonable and appropriate.'' As outlined in the formulary guidance that will follow this final rule, we will review plans' drug utilization management requirements to ensure that beneficiaries are given appropriate access to medically necessary drugs in a timely manner. In order to ensure that plans appropriately employ drug utilization management techniques, and to develop or adopt further drug utilization management performance measures, we agree with commenters who recommended we track plan performance in this area. Therefore, we are adding a reporting requirement at § 423.153(b)(3) and we will specify the information that we will require in separate guidance.

Comment: One commenter stated that there are no standard measures for drug utilization management and recommended that we investigate using HEDIS (Health plan Employer Data and Information Set) measures as well as a number of other specific measures. Another commenter suggested that we use total health care costs as a measure.

Response: As discussed in the previous response, we intend to develop or adopt further drug utilization management performance measures in the future. While we agree that no universally accepted performance measures currently exist, and are therefore not prepared to specify further requirements in regulation, we also understand that there are some performance measures being utilized today and that these could provide valuable information. We intend to evaluate existing measures, such as HEDIS, and could include these or similar performance measures in our formulary guidance or drug utilization management reporting guidelines that will follow publication of this rule. In general, we expect drug utilization management programs to ensure that beneficiaries have appropriate access to medically necessary drugs in a timely manner.

b. Quality Assurance

As with the proposed regulations for drug utilization management programs, the proposed rule for quality assurance measures and systems provided minimum standards for quality assurance measures and systems, while for the most part giving plans flexibility to design such measures and systems. Proposed § 423.153(c) required Part D sponsors to include quality assurance measures and systems for: (1) reducing medication errors; (2) reducing adverse drug interactions; and, (3) improving medication use. It also proposed to require plans to establish requirements for: (1) drug utilization review (DUR); (2) patient counseling; and, (3) patient information record-keeping.

In the proposed rule, we stated that the DUR, patient counseling and patient information record-keeping requirements would generally need to comply with section 4401 of the Omnibus Reconciliation Act of 1990 as codified in § 456.705 and section 1927(g)(2)(A) of the Act, and we stated that we were considering such specific requirements for the final rule. Although those regulations were written specifically for the Medicaid population, we stated that we understood that they describe currently accepted standards for contemporary pharmacy practice, and our intent was to require plans to continue to comply with contemporary standards. We solicited comment on whether the Medicaid standards were in fact industry standards, whether they are appropriate standards for part D, and if they are, how they should be adapted for use in Part D. We also stated our understanding that some members of industry use additional quality assurance measures and systems. We invited comments on whether there were additional industry standards that we might adopt. Furthermore, we proposed that Part D sponsors will be required to have systems and measures established to ensure that network pharmacy providers are complying with the plans' quality assurance requirements. We requested comments on the costs and challenges associated with these systems and measures.

Comment: Most commenters agreed that the relevant parts of OBRA 90 for DUR, patient counseling and patient information record-keeping describe widely accepted standards for pharmacy practice. While no other suggestions for widely accepted standards of pharmacy practice were offered, one commenter indicated that these requirements will not adequately cover appropriate standards for home infusion pharmacies, which the commenter recommended should also require patient interviews and clinical assessments. Alternatively, several commenters recommended that we defer to State laws and State board of pharmacy regulations regarding pharmacy practice standards instead of creating a redundant Federal standard for pharmacy practice.

Response: The overwhelming majority of comments confirmed our understanding that the relevant parts of OBRA90 for DUR, patient counseling, and patient information record-keeping generally describe widely accepted standards of pharmacy practice for both Medicaid and Non-Medicaid patients. We find that almost all of the State boards of pharmacy have adopted regulations for pharmacy practice that, at a minimum, generally reflect these relevant parts of the OBRA 90 requirements. However, upon reconsideration, since our intent was to ensure that plans provided access to network providers that are required to comply with contemporary pharmacy practice standards, and not to create a new Federal standard for pharmacy practice, we agree with commenters that recommended that we defer to existing authority for regulating pharmacy practice. In fact, this is consistent with the Department of Health and Human Service's (HHS) general position of deferring to States for regulating the practice of pharmacy. Therefore, our requirement at § 423.153(c)(1) in the final rule states that plans must provide us with representation that their network providers are required to comply with minimum standards for pharmacy practice established by the States.

While we understand that additional quality standards might apply to specific pharmacy practice-settings such as home infusion pharmacy, specialty pharmacy and long-term care pharmacy practice, we are not prepared to adopt additional, practice-setting specific Federal standards at this time. We believe that current pharmacy practice standards established by the States, whether or not a State has additional standards for specific pharmacy practice-settings, still provide applicable minimum standards for all pharmacy practice-settings. Nevertheless, we encourage plans and their network pharmacy providers to establish and agree upon additional quality assurance standards as necessary, including those required for accreditation by recognized accrediting organizations.

Comment: Several commenters stated that concurrent and retrospective drug utilization review (DUR) systems illustrate successful examples of industry practices that help prevent inappropriate drug therapy. Concurrent DUR systems are used to identify potential inappropriate drug therapy before a patient receives a prescription while retrospective DUR systems can

often identify patterns of potential inappropriate prescribing and drug utilization based upon drug claim history.

Response: Based upon these comments as well as similar information provided in the Booz-Allen-Hamilton report, we agree that concurrent and retrospective DUR must be components of the quality assurance systems and measures to be implemented by Part D plans. Accordingly, we have specified requirements for concurrent and retrospective DUR systems, policies, and procedures at § 423.153(c)(2) and § 423.153(c)(3), respectively.

In the proposed rule, we stated that elements we viewed as desirable for quality assurance systems were: (1) electronic prescribing; (2) clinical decision support systems; (3) educational interventions; (4) bar codes; (5) adverse event reporting systems; and, (6) provider and patient education.

While we did not expect Part D plans to adopt all of these elements, we stated that we expected substantial innovation and rapid development of improved quality assurance systems in the new competitive and transparent market being created by the new Part D benefit.

We invited comments on which, if any, elements of a quality assurance system should be contained in our program requirements. We were particularly interested in best practices in quality assurance, costs and benefits associated with each element, the challenges involved in implementing quality assurance measures and systems, types of data useful for reducing medication errors, associated costs and challenges with collecting this data, and how these data could best be communicated to providers and beneficiaries to improve medication use.

We noted that the MMA does not define or explain the term ''medication error.'' Nevertheless, we stated that we believe a common definition was important. Therefore, we cited the following definition as one that we might use initially in interpretive guidance, which was previously adopted by the FDA in its proposed rule requiring bar codes on human drug products:

''Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice; healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.'' (See 68 FR 12500 (March 14, 2003)).

We indicated that in the future we may require quality measures that include error reports and stated that we could use this information to evaluate plans. In addition, we indicated that we may publish this information for enrollees to use when comparing and choosing their individual plans. Therefore, we invited specific comments on how we could evaluate Part D plans based on the types of quality assurance measures and systems they have in place, on this proposed definition of ''medication error'', on how error rates can be used to compare and evaluate plans, and on how such information could best be provided to beneficiaries to assist them in making their choices among plans.

Comment: A number of commenters recommended we include all elements discussed in the proposed rule including decision support, electronic prescribing, bar codes, adverse event reports, and provider and patient education. Most of them recommended that we require adverse event and medication error tracking systems. However, many commenters recommended that these tracking systems be used internally and that reports not be sent to CMS or made public. These commenters argued that there is too much inconsistency in the definitions used in the field and that an external reporting requirement would actually be counter productive for quality improvement. While several commenters generally thought our proposed definition for ''medication error'' was accurate, these same commenters stated that such a definition would need to be narrowed to prove useful for consistent reporting among the plans.

Response: As to all the elements that we listed in the preamble, we agree with the many industry organizations that there are no well accepted industry standards to make these mandatory requirements. The Booz-Allen-Hamilton report[4] supports this finding. We continue to believe that these are desirable goals and have found that many organizations are already using them. We expect that electronic prescribing will greatly increase the availability of clinical decision support. We intend to work with various stakeholders to further develop these and other quality assurance systems enhancements.

We agree with commenters that there are inconsistencies associated with the reporting of adverse events and medication errors. Moreover, we are not convinced, based upon many of the comments received, that an external reporting requirement for medication errors, even if we provided a more specific and narrow definition of ''medication error'', will lead to improved quality of care. Therefore, instead of requiring plans to report medication errors to us, we require plans to implement internal medication error identification and reduction systems, and we have added this requirement at § 423.153(c)(4). We are also requiring plans to provide us with information concerning their quality assurance measures and systems, in accordance with guidelines published by us. In addition, we encourage plans to utilize the FDA Medwatch form for reporting adverse events, as well as educating prescribers and pharmacy providers about its availability. Finally, although we will not require external medication error reporting at this time, we maintain that our proposed definition of ''medication error'' can still serve as appropriate guidance for internal medication error identification and reduction systems.

c. Medication Therapy Management Programs (MTMPs)

Proposed § 423.153(d) required Part D sponsors to establish an MTMP described in section 1860D–4(c)(2) of the Act that is designed to optimize therapeutic outcomes for targeted beneficiaries by improving medication use and reducing adverse drug events, including adverse drug interactions, that may be furnished by a pharmacist, and that may distinguish between services in ambulatory and institutional settings. We stated that MTMPs may include elements designed to promote (for targeted beneficiaries):

- Enhanced enrollee understanding—through beneficiary education counseling, and other means that promotes the appropriate use of medications and reduces the risk of potentially adverse events associated with the use of medications.
- Increased enrollee adherence to prescription medication regimens (for example, through medication refill reminders, special packaging, compliance programs, and other appropriate means).
- Detection of adverse drug events and patterns of over-use and under-use of prescription drugs.

We proposed that in order to promote these elements and optimize therapeutic outcomes for targeted beneficiaries, we envision MTMPs potentially spanning a range of services, from simple to complex. In addition to those mentioned in the statute, services could include, but may not be limited to, performing patient health status

[4] Ibid.

assessments, formulating prescription drug treatment plans, managing high cost specialty medications, evaluating and monitoring patient response to drug therapy, providing education and training, coordinating medication therapy with other care management services, and participating in State-permitted collaborative drug therapy management.

We specifically sought comment on MTMP best practices, essential components of successful MTMPs, appropriate MTMP providers, service level requirements, quality assurance requirements for MTMPs, information on effective MTMP services that could be publicized and used by beneficiaries, and other effective steps to make valuable, proven MTMP services available to beneficiaries.

Comment: Numerous commenters recommended that we specifically define a minimum package of services that all plans must offer for MTMPs, because plans will not have the economic incentives to offer adequate MTMP services otherwise, or because different plans will offer such different services that the quality of services provided will vary significantly. Although comments suggested a wide variety of possible MTMP services, common elements identified in several best practice examples provided in the comments included: (1) Initial assessment/patient interview; (2) Development of a drug plan identifying goals for therapy; and, (3) Monitoring and evaluation of therapy. Nevertheless, a number of commenters recommended that we maintain the level of specificity contained in the proposed rule. These commenters stated that no widely accepted MTMP standards exist and plans need flexibility to develop and implement MTMPs that can best meet the needs of their specific patient populations and therefore, achieve the best outcomes.

Response: After reviewing extensive comments and conducting additional research, we believe that insufficient standards and performance measures exist to support further specification for MTMP services and service level requirements, and therefore we are adopting the flexibility proposed in the proposed rule. Although best practice examples identified some common elements, neither the Booz-Allen-Hamilton report, nor any comments submitted to us, showed that these MTMPs reflected widely accepted standards of practice. In fact, until the Pharmacist Provider Coalition's recent publication of their definition of MTMP, no widely agreed upon definition of MTMP existed, let alone standards and measures. While we understand the concern with potential disincentives for part D plans to develop robust MTMPs, we are not adopting additional regulatory requirements at this time because it us unclear which specific, additional requirements would enhance MTMPs, and ultimately improve therapeutic outcomes for part D beneficiaries.

We continue to believe that MTMPs can and must offer appropriate services for targeted beneficiaries. However, we are concerned that further premature regulatory requirements at this time might not only fail to improve MTMPs, but could negatively impact their development. Requiring a universal set of minimum services and service levels, without fully understanding how they could effectively be implemented on a much larger platform than illustrated in best practice examples, could result in MTMPs becoming perfunctory services offered just to satisfy regulatory requirements as opposed to patient focused services aimed at improving therapeutic outcomes. For example, several of the best practice examples stressed the importance of collaboration with prescribers to ensure that MTMP is successful. However, simply requiring specific services and service delivery mechanisms will not do anything to ensure successful collaboration. Therefore, we believe that at the outset of the Medicare Prescription Drug Benefit, plans must have maximum flexibility to develop MTMPs that can achieve the statutory goal of improving therapeutic outcomes.

Notwithstanding the lack of current MTMP standards and performance measures, we believe that MTMP must evolve and become a cornerstone of the Medicare Prescription Drug Benefit. With an understanding that the introduction of MTMP requirements can significantly impact the current practice of pharmacy, we intend to utilize the Medicare Prescription Drug Benefit as a platform for driving the quality improvement of prescription drug therapy. We require plans to report details on their respective MTMPs, and we intend to collaborate further with industry to develop measures that can be used to evaluate programs and establish appropriate standards. Our goal is to evaluate MTMPs within the context of an overall strategy that evaluates not only MTMP, but also other quality of care programs, standards, and services, such as drug utilization management, drug utilization review, chronic care improvement programs, and the role of QIOs. In so doing, we believe that we will identify best practices that will evolve into industry practice standards and could eventually be adopted as our standards.

Comment: Several commenters recommended that we require plans to allow beneficiaries to receive MTMP services from their network/non-network provider of choice. In addition, several commenters recommend that we require plans to offer MTMPs that favor face-to-face consultations over other forms of intervention.

Response: Consistent with our overall approach to MTMPs, at this time we believe plans need the discretion to decide on which methods and which providers are best for providing MTMP services available under their specific MTMP. We assume that such providers will include some network pharmacy providers, but plans are not obligated to use any specific providers as long as those providing services for the plan are qualified to provide such services. Furthermore, although we indicated in the proposed rule that we believe pharmacists will be the primary providers of these services, and that we believe beneficiary choice and on-going beneficiary-provider relationships should play a role in determining the appropriate providers, we recognize that such determinations must be made in the context of the specific, overall program design. Moreover, while we understand that face-to-face consultations can offer advantages over other methods of service delivery, it is still but one component of a successful MTMP. Successful MTMPs will need to consider and coordinate not only the method of communication and the providers of services, but also other components such as the content of the service, the qualifications of the providers, the identification of targeted beneficiaries, and the documentation requirements associated with services performed. Because plans are responsible for designing the programs to improve therapeutic outcomes, plans will be in position to make the determinations that will maximize overall MTMP effectiveness, taking into account all factors that influence successful MTMP.

In addition, while section1860D–4(b)(1)(C)(iii) of the Act requires us to establish pharmacy access standards that include rules for adequate emergency access to covered part D drugs, we do not believe the same authority applies to out of network access for MTMP services. Unlike situations when patients face an urgent need for covered Part D drugs but do not have access to a network provider, we do not believe this urgent need rationale reasonably applies to MTMP. In addition, the Congress clearly knows

how to require out-of-network access and did so specifically for Part D drugs in emergency situations. Accordingly, we can not require plans to offer MTMP services through out-of-network pharmacies.

Comment: One commenter noted that MTMP services will fall under the consideration of State boards of pharmacy and how States have defined the practice of pharmacy and scope of services which pharmacists are legally able to provide to patients. Therefore, this commenter requested that we work with States and their boards of pharmacy to prevent conflicts between MTMP under the Medicare Prescription Drug Benefit and State definitions of pharmacy practice and scope of allowable pharmacist activities.

Response: Generally, unless there is a conflict with Federal law, we will defer to State laws and regulations pertaining to the practice of pharmacy. We do not believe our current MTMP requirements pose any conflicts with State laws and therefore, plans need to develop MTMPs that comply with State laws and regulations.

Comment: Several commenters recommended that we clarify that providers can offer MTMP to non-targeted beneficiaries and bill the beneficiaries for these services.

Response: We agree that providers can offer MTMP services to non-targeted beneficiaries because MTMP in these circumstances is not part of the Medicare Prescription Drug Benefit. Providers need to notify beneficiaries receiving these services that the services are not offered as part of the Medicare Prescription Drug Benefit and therefore, the beneficiary is responsible for all of the cost of the MTMP.

Similarly, if plans choose to offer MTMP to non-targeted beneficiaries, beneficiaries must be notified that they are responsible for 100 percent of the cost. Moreover, the costs for these services fall entirely outside the Part D cost sharing structure and do not count for purposes of tracking beneficiaries' total costs, out-of-pocket costs, or for purposes of reinsurance and risk sharing with Medicare.

Comment: Several commenters recommended that we prohibit plans from implementing MTMPs as a utilization management tool geared towards shifting market share as opposed to improving therapeutic outcomes.

Response: We agree that MTMPs are more than utilization management programs focused on shifting market-share. Part D plans must implement MTMPs designed to optimize therapeutic outcomes by improving medication use and reducing the risk of adverse drug events, including adverse drug interactions. Plan sponsors will need to coordinate their MTMPs and utilization management strategies to improve therapeutic outcomes at the lowest possible costs.

In the proposed rule, we proposed that MTMP fees be treated as administrative fees and incorporated into the premium, rather than being billed to the beneficiary on a case-by-case basis. We noted that while section 1860D–4(c)(2)(E) of the Act specifies that the time and resources necessary to implement the MTMPs must be taken into account when establishing fees, it does not specify how these fees should be paid. We stated our belief that fees associated with provision of MTMP services are separate and distinct from dispensing fees discussed in § 423.100. Although section 1860D–4(c)(2)(E) of the Act states that Part D sponsors must disclose to the Secretary the amount of ''any such management or dispensing fees'', it merely governs disclosure and does not require that MTMP be included in the dispensing fee (indeed the Act distinguishes management fees from dispensing fees that are part of individual prescriptions).

Comment: Most commenters agreed with our interpretation that MTMP should be considered an administrative cost as opposed to a benefit, thereby preventing direct beneficiary cost sharing for MTMP services.

Response: We agree that direct beneficiary cost sharing for MTMP services could negatively impact targeted beneficiary participation and therefore, our final policy is to consider MTMP as an administrative cost (included in the plan bid), incident to appropriate drug therapy, and not an additional benefit.

Comment: Many commenters recommended that we include reporting requirements in the final regulation, specifying, for example, that plans provide detailed policies and procedures for implementing their MTMPs and associated performance measures for evaluating the impact on therapeutic outcomes.

Response: We agree with these commenters that we must include a reporting requirement for MTMPs. As we work with industry and other stakeholders to improve the therapeutic outcomes by optimizing prescription drug therapy, we will need detailed information about each MTMP. Therefore, we are adding a reporting requirement at § 423.153(d)(6) and we will specify the information that we will require in separate guidance.

Comment: Several commenters suggested that we specifically involve QIOs with the collecting and analyzing of data from MTMPs and establish a mechanism for QIOs to secure information from medical claims to identify targets.

Response: We believe that QIOs could play a significant role with MTMPs and this will be reflected in our contracts with the QIOs. Specific technical assistance could include collecting and analyzing MTMP data.

Comment: Several commenters responded to our request for incentives that would help drive the creation and evolution of significant MTMPs by suggesting pay-for-performance incentives and minimum renewal criteria, both based upon mutually agreed upon thresholds of patient care.

Response: We have a more complete discussion of pay-for-performance in the quality improvement section of the preamble to the final Title II rule. We are conducting several demonstrations to test this approach and we are very interested in studying this direction for plans. Plans are free to develop such arrangements with their providers, and we encourage them to do so. Such arrangements have existed for a number of years in the Medicare Advantage program. Plans will need to be mindful of any restrictions imposed by the anti-kickback statute, and those needing further clarification may want to use the OIG's advisory opinion process to obtain guidance relating to specific transactions and arrangements.

Comment: CMS should clarify that MTMP services are voluntary and that targeted beneficiaries are under no obligation to participate with programs in order to receive prescription drug benefits.

Response: We agree that beneficiaries must not be obligated to participate in MTMPs. While we hope that beneficiaries will participate to improve their therapeutic outcomes, beneficiaries must not be denied access to prescription drugs based upon failure to participate in MTMPs.

Comment: One commenter recommended that we require Part D plans to separate MTMP services agreements with providers from standard network provider contracts to reduce potential conflict of interest.

Response: Since we do not know who will be providing MTMP services, it is premature for us to require specific terms and conditions for such contracts. While MTMP service providers will likely include some network pharmacy providers, Part D plans will need to specify, in their applications, their approach to determining MTMP fees

which accounts for the time and resources necessary to perform the services. In addition, plans need to comply with any restrictions imposed by the anti-kickback statute.

Comment: One commenter recommended that we change the language at § 423.153(d)(1)(i) from ''must assure'' to ''must have processes in place so that.''

Response: Upon review of the proposed language, we agree that § 423.153(d)(1)(i) must be changed. We have changed ''must assure'' to ''is designed to ensure.'' We believe this language does not impact the intent but better reflects what is required of MTMPs.

Section 1860D–4(c)(2)(A)(ii) of the Act describes targeted beneficiaries as Part D individuals who: (1) have multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure); (2) are taking multiple covered part D drugs; and (3) are identified as likely to incur annual costs for covered Part D drugs that exceed a level specified by the Secretary, and we codified this requirement at proposed § 423.153(d)(2).

We invited comment on further defining ''multiple chronic diseases'' and ''multiple covered Part D drugs,'' and whether we should add further specifications or leave such determinations to the plans. Furthermore, we invited comment on whether we should set the cost threshold for determining targeted beneficiaries or if this determination could also be left up to the plans. Generally, we invited comment on disease, drug and cost issues that we should consider in further refining the definition of targeted beneficiary.

Comment: Many commenters recommended that we specify which chronic diseases, the number of chronic diseases, and the number of covered part D drugs that will qualify a beneficiary for MTMP services. Moreover, several commenters suggested that specific patient populations, such as beneficiaries in long term care, should automatically be considered eligible for MTMP services in all plans. Alternatively, many commenters suggested that such determinations are best left to the individual plans for designing their plan specific MTMPs.

Response: At this time, we believe these determinations must be left to the plans. Although we are not adding further specific requirements for chronic disease and multiple drugs, we do recommend that plans take notice of the statutory examples of chronic diseases when developing MTMPs. We plan to monitor the programs developed by the plans to learn from them as to whether or not further guidance is desirable.

Comment: Many commenters provided recommendations on the level of annual costs for Part D drugs likely to be incurred by a beneficiary that should be used as a threshold for MTMP eligibility. Some commenters argued that any cost threshold is inappropriate because it does not indicate those that could benefit from MTMP and in fact, could exclude beneficiaries that would benefit most. Others recommended various cost thresholds including specific dollar amounts and percentage based thresholds (for example, top 5 percent). Most comments suggested that we should make this determination and not delegate it to the plans.

Response: Despite our discussion in the proposed rule about leaving this determination to the plans, we do not believe we have the authority to delegate the cost threshold determination to plans and therefore, we will set a cost threshold. While cost might not the be best proxy for identifying patients that could benefit most from MTMP, the statute requires us to set a threshold and our goal is to identify a manageable target population so that plans offer truly valuable services to beneficiaries that will benefit from such services. Factors we will consider include typical costs associated with the most common chronic diseases and co-morbidities for Medicare beneficiaries, the relationship between cost and the number of medications a beneficiary is taking, the impact specific cost thresholds have on the size of the target population, and the alignment of incentives for providing MTMP services within the standard part D benefit structure. We intend to provide the specific cost threshold in separate guidance.

Comment: Several commenters recommended that we should require plans to allow providers and beneficiaries (self-referral) to identify appropriate MTMP targets in addition to plans utilizing system edits to identify eligible MTMP targets.

Response: The identification of targeted beneficiaries will be determined by individual plan policies. Therefore, plans will decide if and how providers and beneficiaries can participate with identifying targets. Once again, we believe that successful MTMPs must be coordinated and that plans need to develop appropriate mechanisms for notifying and identifying targeted beneficiaries that are eligible for MTMP services.

Section 1860D–4(c)(2)(C) of the Act requires Part D sponsors to develop their MTMPs in cooperation with licensed and practicing pharmacists and physicians, and we codified this requirement at § 423.153(d)(3).

Comment: Several commenters recommended that we specify that practicing pharmacists and physicians must be licensed in the United States.

Response: Part D sponsors must comply with State licensure requirements for pharmacy practice, and therefore, we believe further specific licensure requirements are not warranted.

Section 1860D–4(c)(2)(D) of the Act requires us to establish guidelines for the coordination of MTMPs with chronic care improvement programs established under section 1807 of the Act for targeted beneficiaries, and we codified this requirement at § 423.153(d)(4).

The Chronic Care Improvement Program (CCIP) is a new program established by section 721 of the MMA, which added a new section, section 1807, to the Act. The new section 1807 creates a method for us to assist beneficiaries with multiple chronic conditions in managing their care. The program is targeted only to beneficiaries in original fee-for-service Medicare not beneficiaries enrolled in MA plans.

We invited comment on how services provided through CCIP could be effectively coordinated with MTMP services provided by PDPs. We also sought comment on how to integrate MTMP services and financial incentives into the CCIP under section 721 of the Act.

Comment: Several commenters recommended that we share CCIP enrollment information with PDPs so that these individuals will be excluded from MTMP services. In addition, several other commenters recommended that we require PDPs to share their drug data with CCIPs.

Response: We agree that Part D plans need to share drug data with CCIPs and have specified this requirement in our regulation text at § 423.153(d)(4). CCIPs need this valuable data in order to provide the comprehensive care management that is intended under the CCIP. However, plans must determine, in conjunction with CCIPs, whether or not it is desirable to offer MTMP services to persons participating in CCIPs. We note that in sharing the data, both the CCIP and the Part D sponsor will need to abide by the HIPAA privacy rules including transmitting only the minimum data necessary. We strongly encourage Part D plans to consult with their privacy counsel to ensure that the

transmission of data complied with all aspects of the HIPAA privacy rules.

In the proposed rule we also discussed the requirement in section 1860D–4(c)(2)(E) of the Act specifying that the time and resources necessary to implement MTMP be taken into account when establishing fees for pharmacists or others providing MTMP services under the plan. We stated that to implement this section, in evaluating the administrative component of a Part D plan's bid, we will ask a Part D sponsor to disclose the fees it pays to pharmacists or others, including an explanation of those fees attributable to MTMP services. The fee information provided to us under this authority will be protected under the confidentiality provisions of section 1927(b)(3)(D) of the Act. Under those provisions, we are prohibited from disclosing the specific fees in a manner that links the fees to the particular pharmacy or other provider providing the MTMP services except to the extent necessary to administer the Part D program, to permit the Comptroller General to review the information, or to permit the Director of the CBO to review the information. If we were to discover situations in which plans systematically did not pay the fees described in their applications-and, if those errors were not corrected upon notification, we might, at our discretion, employ the broad ranges of intermediate sanctions or termination provisions available under subparts K and O of the regulations.

We stated, however, that while we expected to perform the due diligence described above through application review and potentially following up on any complaints, we did not believe we have the authority to mandate that Part D sponsors pay pharmacists or other providers a certain amount for MTMP services. We also stated that we will not adjudicate any specific disputes between Part D and pharmacists or other providers regarding the specific fees due for MTMP services.

Comment: Many commenters recommended that we provide further requirements for MTMP fees, including establishing a fee schedule, identifying a particular documentation and billing mechanism, and requiring plans to reimburse for MTMP services provided by out of network providers.

Response: These details are up to the plans and their arrangements with pharmacists and other providers. We do not believe the MMA provides us with the authority to establish fee schedules or interfere with the contracts between plans and providers. While we are familiar with the recommendation and accompanying efforts to pursue a CPT coding mechanism for MTMP services, which would provide for common billing and documentation procedures, the American Medical Association's (AMA) Current Procedural Terminology (CPT) Editorial Panel will make that determination and it does not directly involve us. Therefore, in the final rule, we are adopting our proposed policy to require sponsors to discuss their MTMP fees in their applications, but neither to mandate any specific MTMP fees nor become involved in payment disputes regarding MTMP between pharmacies and sponsors.

Section 423.153(e) in the proposed rule discussed fraud, waste and abuse programs required by section 1860D–4(c)(1)(D) of the Act. In an effort to consolidate, the requirements and preamble discussion pertaining to fraud, waste and abuse programs, we moved § 423.504(b)(4)(vi)(H) to subpart K, and included as a component of a Part D sponsor's general compliance plan.

d. Exception for Private Fee for Service Plans

Proposed § 423.153(f) implemented section 1860D–21(d)(3) of the Act by exempting private fee for-service MA plans that offer qualified prescription drug coverage from the requirement to establish a drug utilization management program and a MTMP; however, these private fee-for-service MA plans are still required to establish quality assurance measures and systems and a program to control fraud, waste and abuse as described in § 423.153(c) and § 423.504(b)(4)(vi)(H), respectively.

We did not receive any comments on these provisions and they have been adopted in the final rule at § 423.153(e).

3. Consumer Satisfaction Surveys (§ 423.156)

As proposed under § 423.156, we will conduct consumer satisfaction surveys of enrollees of Part D plans in order to provide comparative information about qualified prescription drug coverage to enrollees as part of our information dissemination efforts. Section 1860D 4(d) of the Act specifies that these surveys be conducted in a manner similar to how they are conducted under § 422.152(b) for MA plans by using the Consumer Assessment of Health Plans (CAHPs).

In the proposed rule, we stated that we believed a CAHPs-like instrument (or perhaps a modification of CAHPs for MA organizations offering MA-PD plans) will most likely be the vehicle used to collect this information. In addition, we stated that we anticipated working with the Agency for Healthcare Research and Quality (AHRQ) to develop a survey measuring the experience of beneficiaries with their qualified prescription drug coverage, a sampling strategy, and an implementation strategy. We also indicated that we will provide further information regarding this survey as it is developed.

Comment: Commenters had several suggestions and questions regarding the design and implementation of the survey, including the following: CMS and CAHPs should provide draft models of the survey instruments to the Part D plans for input prior to final draft and distribution; CAHPs/AHRQ should differentiate satisfaction with the benefit versus the service provided by the network pharmacy; if all plans are actuarially equivalent as approved by CMS, how will we differentiate consumer satisfaction; the first surveys should be conducted starting in 2006 with the results available before the fall open season; consumers must be included in the survey design process; and, surveys should be sent and the results analyzed by CMS, prior to the annual May notification to plans about whether or not their contracts will be renewed.

Response: We plan to have a public comment process in the development of the survey, and solicit input from key stakeholders. We expect that consumers will be included in the design process through focus groups, cognitive interviews and testing of the instrument. The purpose of the satisfaction survey is to provide information in a timely manner for purposes of beneficiary plan choice which occurs during the fall of the year. We are still determining the timing for survey administration. One major constraint is pilot testing of the survey cannot begin until early in 2006.

Since the purpose of the survey is to help consumers choose among the plan options, during the development process we will try our best to focus on things that may vary across plans versus satisfaction with the overall benefit. Although the plans are actuarially equivalent, there will be differences in formularies, customer service, informational materials, etc.

Comment: Additional comments focused on the fact that fully integrated MA organizations, unlike other MA organizations and PDP sponsors, own and operate their own pharmacies. As a result, survey instruments may be confusing to beneficiaries enrolled in these organizations if the instrument is designed only for network model plans. In addition, to the extent that survey instruments do not reflect satisfaction ratings with retail pharmacies under contract to network model plans, comparisons between network plans

and integrated organizations will be unlikely to result in apples-to-apples comparisons. In addition, consumer satisfaction ratings in health care are notoriously suspect to regional variation. In reporting satisfaction levels, we should attempt to adjust for these variations.

Response: We agree that making appropriate comparisons and adjustments will be essential to take into account certain factors that may impact satisfaction but are not under the control of the Part D plans. In the development work, we will be exploring what are the appropriate adjusters for this survey.

4. Electronic Prescription Program (§ 423.159)

Section 1860D–4(e) of the Act contains provisions for electronic prescription programs. The statute contains specific provisions on when voluntary initial standards may be adopted (not later than September 1, 2005), and when final standards must be published (not later than April 1, 2008) and then effective (not later than 1 year after the date of promulgation of final standards).

While we included a fairly long discussion of electronic prescribing in the proposed rule, shortly we will issue another proposed rule devoted to the standards that will be used for electronic prescribing and have reserved § 423.159(a) and § 423.159(b) of this final rule for such electronic prescribing standards. Therefore, the proposals we made for such standards are not being addressed in this final rule. Moreover, comments received in response to such proposals may be considered in the electronic prescribing-specific proposed rule. In addition, commenters who wish to provide additional comments on electronic prescribing will be permitted to do so after publication of the electronic prescribing proposed rule.

One standard we are finalizing is the requirement that Part D sponsors have the capacity to support electronic prescribing, once final standards are in effect, including any standards that are established before the drug benefit begins in 2006. We proposed such language at § 423.159(a) of the proposed rule. Since Part D sponsors will in fact have to support electronic prescribing, once standards are in place, we have modified the language in § 423.159(c) to make clear that Part D sponsors must not just have the capacity to support electronic prescribing but will actually have to support it. We received no comments on this proposal and are adopting it at § 423.159(c).

We also proposed at § 423.159(b) to allow an MA-PD plan to provide a separate or differential payment to a participating physician who prescribes covered Part D drugs in accordance with electronic prescription standards. (Note that this provision only applies to MA-PD plans and not to PDPs) Section 102(b) of the MMA makes it clear that this differential payment may occur when a participating physician prescribes drugs in accordance with an electronic prescription program that meets standards established under section 1860D–4(e) of the Act. We solicited comments on the differential payments provision described in § 423.159(b) of the proposed rule as it relates to the application of various legal authorities including ''the physician self-referral prohibition at § 1877 of the Act'' and the Federal anti-kickback provisions at section 1128B(b) of the Act. In order to facilitate electronic prescribing by a Part D sponsor, we also invited public comment on additional steps to spur adoption of electronic prescribing, overcome implementation challenges, and improve Medicare operations.

Comment: Many commenters supported the provision of a separate or differential payment to a participating physician that prescribes covered Part D drugs in accordance with electronic prescription standards.

Response: We agree that participating physicians have a substantial role in electronic prescribing and will have upfront and on-going costs of implementation. For this reason, the regulation permits an MA organization offering an MA-PD to provide a separate or differential payment to a participating physician that prescribes covered Part D drugs in accordance with electronic prescription standards, including both voluntary standards promulgated by HHS and final standards established by HHS once final standards are effective.

Comment: Many commenters also encouraged us to allow MA-PD plans to make similar incentive payments to participating pharmacies and pharmacists.

Response: We agree that pharmacies and pharmacists have a substantial role in electronic prescribing and will have upfront and on-going costs of implementation. The MMA statute provided for such incentives directly to physicians; however MA plans could in compliance with the Federal anti-kickback and Stark self-referral statutes offer incentives to pharmacies and pharmacists through individual plan contract agreements. HHS may consider this issue when developing the pilot programs.

Comment: One comment stated that differential payments should also be permissible by PDPs. While ''PDPs sponsors will not have network contracts with physicians in the way that MA organizations will, PDPs may have service contracts with physicians to provide MTMP services.'' The commenter noted that we have the authority to permit such payments under section 1860D–4(c)(1)(B) of the Act as part of a quality assurance program.

Response: We disagree. The MMA statute was specific in the use of incentives by MA-PD plans to participating physicians that prescribe covered Part D drugs in accordance with an electronic prescription program that meet the standards established under section 1860D–4(e) of the Act.

Comment: Many commenters expressed concern that separate or differential payments should not inappropriately influence physician prescribing behavior or restrict provider choice or decision making. Many also suggested that we provide guidance to plans to guarantee that such incentives do not impact prescribing judgment and that any incentives utilized in e-prescribing programs focus on rewarding improvements in patient safety and quality.

Response: We agree with the commenters that incentives must not inappropriately influence physician prescribing patterns. We will be providing guidance to plans on physician incentives.

Comment: Many commenters agreed that any differential payments provision must be in compliance with other Federal and State laws including the physician self-referral prohibition at section 1877 of the Act and the Federal anti-kickback provisions at section 1128B(b) of the Act. They urged the Secretary to consider extending the applicability of the safe harbor provisions beyond Part D programs and to include monetary and non-monetary remuneration.

Response: As outlined in the preamble in the proposed rule, we are sharing any comments regarding the anti-kickback statute with the OIG. Additionally, in response to comments we have added language at § 423.159(d) that such payments be subject to compliance with applicable Federal and State laws and regulations related to fraud and abuse.

In the proposed rule, we also sought comment on measures of MA-PD plan quality related to the use of electronic prescribing and other MA-PD quality

measures that reflect effective electronic prescribing systems.

We invited comments on the challenges and on possible Federal activities that will promote the effective use of electronic prescribing by providers, including publishing best practices, and making technical information on electronic prescribing products available. In addition, receptivity to the use of electronic prescribing by consumers is not well understood especially among the elderly and disadvantaged populations. We requested additional information on how those populations may view electronic prescribing and what steps may be taken to get them to use this modality and, thus, take advantage of the safety and quality benefits it offers.

We also invited comments on how to promote the use of electronic prescribing by providers, health plans and pharmacies and other entities involved in the provision and payment of health care to Medicare beneficiaries. Beyond the differential payments authorized in § 423.159, we invited comments on what incentives could be used to spur more widespread adoption, especially for early implementers. We also invited comments on what educational efforts or data analyses might be undertaken to help health practitioners understand, or empirically confirm, and ultimately realize, the benefits of electronic prescribing. Lastly, we sought public input on the ways electronic prescribing can further reduce costs to the Medicare program and promote quality of care to beneficiaries.

We received numerous comments in response to our requests.

Comment: HHS received universal support from all those who commented on § 423.159 regarding the establishment of electronic prescribing standards and its potential for improved quality of care through reduced medication errors, better therapeutic compliance and better process and cost efficiencies.

Response: We agree with the commenters that electronic prescribing has great potential to improve the health of Medicare beneficiaries and reduce medication errors.

Comment: Many commenters suggested that HHS should evaluate how electronic prescribing may improve patient compliance, clinical outcomes and patient safety and facilitate other electronic prescribing processes. Additionally commenters provided a variety of areas to focus educational efforts and data analyses.

Response: We agree with the commenters that MA-PD plan quality, related to electronic prescribing, must be evaluated to further promote quality of care for beneficiaries. We will take these suggested areas under consideration as we develop quality measures for MA-PD plans. Furthermore, for quality improvement purposes, we will make any plan information on electronic prescribing available to our QIOs either directly from the Part D plans or through us.

Comment: Many commenters stated that HHS should publish best practices and make technical information on electronic prescribing products available so that providers can make informed comparisons. Many agreed that these efforts will also spur effective adoption and use of electronic prescribing.

Response: HHS appreciates these thoughtful comments and will take them into consideration as we implement electronic prescribing.

Comment: A few commenters responded that electronic prescribing will result in procedural and behavioral changes by beneficiaries. They suggested that HHS work to ensure patients are aware of and comfortable with the new prescribing method and should disseminate information and educate enrollees on the changes resulting from electronic prescribing.

Response: We agree that electronic prescribing will result in procedural and behavioral changes in our beneficiaries. We will consider these suggestions as we work with the Part D sponsors on information dissemination and outreach.

Comment: One commenter stated that HHS should work with National Center for Vital and Health Statistics (NCVHS) to study the use of reduced malpractice insurance premiums as a financial incentive to promote the adoption of electronic prescribing.

Response: HHS will share this comment with the NCVHS.

Comment: Many commenters provided a variety of areas to focus educational efforts and data analyses to spur more widespread adoption.

Response: We will take these suggested areas for data analyses under consideration as we develop our educational efforts and quality improvement strategies by making such information on electronic prescribing available to our QIOs either directly from the Part D plans or through us.

Comment: Many commenters stated that developing standards for electronic prescribing will reduce costs to the Medicare program. Many commenters stated that the primary benefits of electronic prescribing are increased quality of care, reductions in the use of medical resources, and improved patient safety, specifically in the areas of reduced adverse events. Additionally, many stated that electronic prescribing improves the efficiency of processing prescriptions.

Response: We agree with the commenters that these electronic prescribing areas have great potential to reduce costs to the Medicare program.

5. Quality Improvement Organizations (QIO) Activities (§ 423.162)

Section 109 of the MMA expands the work of QIOs to include Part C and Part D. This provision explicitly covers the full range of Part C organizations. QIOs are required to offer providers, practitioners, and Part D sponsors quality improvement assistance pertaining to health care services, including those related to prescription drug therapy.

In the proposed rule, we stated the QIOs will need access to data from transactions between pharmacies and Part D plans. We offered examples of the types of data that would likely be required by QIOs and also discussed our role in potentially aggregating and distributing the data. Finally, we proposed that any information collected by the QIOs will be subject to confidentiality requirements in part 480 of our regulations. For purposes of applying these confidentiality regulations, we also proposed that Part D sponsors fall within the definition of health care facilities and that part 480 would apply in the same manner as that Part applies to institutions.

As the QIOs activities under Part D are developed within the 8th Scope of Work, and basic decisions are made about the collection, storage and use of Part D claims data, CMS will work with QIOs and Part D plans to develop a strategy to provide QIOs with data necessary to accomplish their task and safeguard patient confidentiality.

Comment: One commenter believes that PDPs may need additional data to identify enrollees to be targeted for MTMP services. They believe QIOs could provide that data to plans using information from medical claims submissions.

Response: QIOs cannot share with Part D plans beneficiary-specific identifiable data that it has acquired as part of its function as a QIO, but we could provide the data necessary to identify enrollees to be targeted for MTMP services to the Part D plans if appropriate. QIOs can provide other types of technical assistance to Part D plans.

Comment: One commenter recommends that serious evaluations be

designed to compare the effectiveness of different MTMP services, delivery, and payment methodologies. Another commenter wrote that QIOs could potentially perform a valuable role in collecting and analyzing the data to be made available to plans for use in establishing or revising their MTMP services.

Response: Once Title I has been implemented, we expect that outcome measures will be developed to allow the QIOs to assess the effectiveness of the MTMP services. We expect that both plans and pharmacies will be able to request technical assistance from QIOs to improve their MTMPs.

Comment: One commenter recommended that the last sentence of § 423.162(b) be deleted. [''PDP sponsors and MA plans offering MA-PD plans are required to provide specified information to CMS for distribution to the QIOs as well as directly to QIOs''] They support the voluntary nature in terms of whether a Part D plan must contract with a QIO. They are concerned about the submission of undefined information to CMS for passing through to QIOs as well as directly to QIOs regardless as to whether a Part D plan works with a QIO. In addition, it is unclear to which QIO such information will be provided, particularly since some drug plans may serve more than one State. Another commenter stated QIOs must have access to pharmacy and medical claims for quality improvement projects and oversight of the PDPs.

Response: We do not believe that the last sentence of § 423.162(b) must be deleted. QIOs need, and have the authority under section 1154 of the Act and section 109 of the MMA, to access specified data from the transactions between pharmacies and Part D plans providing the Part D benefit. However, the determination of what actual data, if any, that will be made available to QIOs will be made in subsequent guidance after QIOs activities under Part D are developed within the 8th Scope of Work, and basic decisions are made about the collection, storage and use of Part D claims data. We could provide specific data to QIOs to use for quality monitoring and extract these data from data already required by us for other administrative functions of the Title I program, thus not increasing the Part D plans' burden. We could also make data available to a QIO from plans that do not contract with the QIO but are directly related to the QIO's responsibilities as negotiated with us under its 8th scope of work. QIOs may also have access to additional data provided by plans working directly with a QIO.

Other QIO Activities

Comment: While PBMs have processes in place to monitor pharmacy dispensing and alert a pharmacy in cases where dispensing a medication may not be safe for a particular patient, it is critical the PBM or drug plan not be held accountable or responsible for activities that are beyond its control. Drug plans can be evaluated for having such process measures in place but should not be held accountable for problems outside their control, such as physician, pharmacist or manufacturer errors.

Response: We expect that the QIOs will work with physicians, pharmacists, and plans to improve the quality of beneficiaries' medication therapies. The QIOs' goal is to improve quality of care, not to assign blame. They can assist each of these players to design systems to facilitate the delivery of quality of care.

Comment: One commenter stated that QIOs should establish educational programs to assist drug plans and prescribers in the implementation of best practice guidelines through treatment algorithms.

Response: The QIOs' scope of work is being described in their contracts rather than in the regulation. The contracting mechanism allows flexibility to adjust the QIOs' tasks to be responsive for the need for quality improvement. The QIOs' activities will address quality improvement for both prescribers and plans.

Comment: The confidentiality of information collected by QIOs should be protected, as CMS has proposed.

Response: The QIOs will protect the confidentiality of the collected information, as specified in part 480. We have clarified § 423.162(c) in this final rule to make clear that the provisions of part 480 apply in the same manner as they apply to institutions.

Comment: There were several commenters who expressed concern regarding how QIOs will handle beneficiaries' complaints about the quality of care in Part D. The final rule in § 423.153(c) needs to state clearly that the QIOs will review quality of care complaints and lack of access complaints to requested services, as well as to clarify how this traditional QIO function will be carried out in the unique environment of Part D plans.

Response: Section 423.564(c), not § 423.153(c), states that QIOs must review enrollees' written complaints about the quality of services they have received under the Medicare program, as specified in section 1154(a)(14) of the Act. For any complaint submitted to a QIO, the Part D sponsor must cooperate with the QIO in resolving the complaint. For further discussion, please refer to the preamble to subpart M.

Comment: The final regulation should reflect the information contained in the summary of the 8th scope of work (SOW) for QIOs. The commenter added the regulation should specify that quality improvement projects will be performed by the QIO or by a third party (independent of the Part D plan) contracted by the QIO.

Response: This information is typically conveyed in the SOW of the contract between each QIO and us rather than in the regulation because a contract allows us the flexibility to modify the QIOs' activities without modifying the regulation. The contract is an effective way to ensure that these important tasks are accomplished.

Comment: Educational interventions are best done by QIOs or a third party independent of the Part D plan contracted by the QIO.

Response: QIOs will likely do educational interventions either with their own staff or with subcontractors, but we do not want to exclude other entities from also providing objective, evidence-based educational interventions.

Comment: Oversight of formulary decisions and subsequent review of Part D sponsors' formulary decisions could be key components necessary for QIO's to assess quality, especially in the dual-eligible long term care patients.

Response: We believe that decisions concerning which medications are on a plan's formulary are administrative decisions of the plan. These do not fall within the quality review functions of the QIO. The QIO will review beneficiary complaints that the plan's rules were not executed correctly. We will conduct reviews of plans' applications to ensure that formularies are not discriminatory, as well as review through program monitoring.

Comment: MA organizations delivering benefits through their owned and operated pharmacies are likely to rely on specialized pharmacy information systems that differ from the systems designed for PDP sponsors to communicate with their contract network pharmacies. As a result, it is possible that pharmacy data may be misinterpreted by a QIO. If QIOs will be using data from integrated MA organizations to assess quality, it will be important to work closely with the organizations to understand the data, or to develop more efficient methods to achieve the same result-an appropriate assessment of quality performance.

Response: We expect that QIOs will work cooperatively with plans. Because

QIOs work with identified organizations, they will have the opportunity to understand the context of the data they are analyzing.

Comment: One commenter suggests that QIOs examine the prescription drug claims submitted to the plan, specifically looking at the number of claims that are rejected and appealed.

Response: QIOs' activities focus on quality improvement. The number of claims rejected is an administrative function, and we do not expect the QIOs to be active in this area. It is likely the administrative performance of plans will be assessed by our program monitoring.

6. Treatment of Accreditation (§ 423.165, § 423.168, and § 423.171)

Section 1860D–4(j) of the Act requires that the provisions of section 1852(e)(4) of the Act relating to the treatment of accreditation will apply to Part D sponsors for:

- Access to covered Part D drugs including the pharmacy access requirements and the use of standardized technology and formulary requirements;
- Drug utilization management, Quality assurance, Medication Therapy Management, and a program to control fraud, waste and abuse as described in subpart K § 423.504(b)(4)(vi)(H);
- Confidentiality and accuracy of enrollee records.

Thus, the requirements in § 423.165, § 423.168, and § 423.171 are similar to the requirements found in § 422.156, § 422.157, and § 422.158 for the MA program, except for subject areas that are deemed.

Proposed § 423.165 provided the conditions under which a Part D sponsor may be deemed to meet our requirements permitted under paragraph (b) of that section. We stated that the first condition will be that the plan be fully accredited (and periodically reaccredited) by a private, national accreditation organization (AO) that we approve. The second condition will be that the plan be accredited using the standards that we approved for the purposes of assessing compliance with Medicare requirements.

Consistent with our approach in the MA program, in the proposed rule we proposed that we will analyze on a standard-by-standard basis whether an AO applies and enforces requirements that are no less stringent than those in part 423 for the standard at issue. We proposed that we will determine the scope of the AO's approval (and, thus, the extent to which Part D plans accredited by the organization are deemed to meet our requirements) based on a comparison of the AO's standards and its procedures for assessing compliance with our deemable requirements and our own decision-making standards. We stated that we will make those determinations on the basis of the application materials submitted by AOs seeking our approval in accordance with § 423.168. We also proposed to conduct surveys to validate the AO's enforcement on a standard-by-standard basis.

Proposed § 423.165(d) established the obligations of deemed Part D sponsors. A Part D sponsor will be required to submit to our surveys. We stated that the proposed surveys were intended to validate an AO's process and authorize the AO to release to us a copy of its most current accreditation survey, together with any information related to the survey that we may require (including corrective action plans and summaries of our unmet requirements). We stated that such activities will be part of our ongoing oversight strategy for ensuring that the AO applies and enforces its accreditation standards in a manner comparable to ours.

Proposed § 423.165(e) addressed removal of deemed status and proposed § 423.165(f) explained that we retain the authority to initiate enforcement action against any Part D sponsor that we determine, on the basis of our own survey or the results of the accreditation survey, no longer meets the Medicare requirements for which deemed status was granted. We stated that we expected the AO to have a system in place for enforcing compliance with our standards (such as sanctions for motivating correction of deficiencies), but we also stated that we could not delegate to the AO the authority to impose the intermediate sanctions established by section 1860D–12 of the Act or termination of the contract.

In the proposed rule, we acknowledged that deeming applies only to our enforcement of this regulation, and neither our enforcement of this regulation nor accreditation by an accrediting body undercuts the Office for Civil Rights enforcement of the HIPAA privacy rule.

Proposed § 423.168 discussed the three conditions for our approval of an AO if the organization applies and enforces standards for Part D sponsors that are at least as stringent as Medicare requirements and, if the organization complies with the application and reapplication procedures proposed in § 423.171.

Proposed § 423.168(c) established ongoing AO responsibilities. These responsibilities largely parallel those currently imposed upon accreditors under original Medicare. One exception was the proposed requirement that an AO notify us in writing within three days of identifying, for an accredited Part D sponsor, a deficiency that poses immediate jeopardy to the Part D sponsor's enrollees or to the general public.

Proposed § 423.168(d) established specific criteria and procedures for continuing oversight and for withdrawing approval of an AO. Oversight consists of equivalency review, validation review, and onsite observation.

In the proposed rule, we stated that we could withdraw our approval of an AO at any time if we determine that deeming based on accreditation no longer guarantees that the Part D plan meets the Medicare requirements, that failure to meet those requirements could jeopardize the health or safety of Medicare enrollees or constitute a significant hazard to the public health, or that the AO has failed to meet its obligations under § 423.165 through § 423.171.

Proposed § 423.171 addressed the procedures for approval of accreditation as a basis for deeming compliance. As mentioned, the process that we stated will be used to deem compliance with Part D requirements is virtually identical to the process that is being used for deeming compliance with fee-for-service requirements. One requirement proposed in § 423.171, and which also appeared in regulations governing MA plans at § 422.158(a)(11), but did not appear in regulations governing original Medicare, is the requirement that an AO applying for approval of deeming authority submit the name and address of each person with an ownership or control interest in the AO. We proposed that we will use this information to determine whether the AO is controlled by the organizations it accredits for the purposes of § 423.168. Section 423.171 further provided for reconsideration of adverse determinations of accreditation applications.

Comment: Several consumer groups oppose deeming because they believe it will diminish beneficiary protections. Several different types of organizations, such as pharmacy organizations, and others want to have input into the process, and asked who will be the AOs, how will they operate, and what standards will be used. They also commented that AOs will not be in place prior to the initiation of the program.

Response: Section 1860D–4(j) of Act provides for accreditation. We have

successfully administered accreditation programs in:

- Hospital settings, for example, JCAHCO;
- Home health, for example, JCAHCO, NLN; and
- Nursing homes and managed care, for example, NCQA, JCAHCO.

The advantages of AOs is that they eliminate duplication of efforts between us and AOs, since many private purchasers require AOs. Furthermore, it reduces the burden on government oversight.

AOs must demonstrate that their standards are at least as stringent as those in part 423 of our final regulations. Given that the regulations can only be finalized upon publication of this final rule, we agree with the commenters that AOs cannot be in place before the bids and contract applications for 2006 are due. Thus, at least in the first year of the program, applicants will have to determine on their own that they meet all of our standards. Once these rules are in effect, we can begin to consider applications for AOs; however, other program priorities will influence when we will be able to issue a public notice requesting applications. Currently, we do not believe that any AOs can meet our standards. Furthermore, it must be noted that in the Medicare Advantage program, it was several years before any AOs were accredited.

As to giving stakeholders a chance to comment, our regulation at § 423.168(b) provides that we publish a notice in the **Federal Register** whenever we are considering an AO's application. The public then has 30 days to comment.

We will be glad to meet with stakeholders to discuss these issues. The AOs must meet or exceed each of our standards. They can pass one or all standards, but will only be allowed to administer those standards for which they are approved.

The final rule has adopted the proposed rules on accreditation.

F. Submission of Bids and Monthly Beneficiary Premiums: Plan Approved

1. Overview

Subpart F will implement most of the provisions in sections 1860D–11 and 1860D–13 of the Act, as well as sections 1860D–12(b)(2)(on limitation on entities offering fallback plans), 1860D–15(c)(2)(on geographic adjustment of the national average monthly bid amount), 1860D–21(d) (on special rules for private fee-for-service (PFFS) plans), 1860D–21 (e)(3) (on cost contractors), and 1860D–21 (f)(3)(on PACE) of the Act. In this section we address submission, review, negotiation, and approval of bids for prescription drug plans and MA-PD plans; the calculation of the national average bid amount; and determination and collection of enrollee premiums. References to 42 CFR part 422 of our regulations are to the new MA rules. See Subpart T for additional information on PACE. Bidding is to be distinguished from the application process discussed in subpart K.

Although in this preamble we use the terminology, prescription drug plans and MA-PD plans, the regulations extend to all Part D sponsors (including PACE organizations and cost-based HMOs and CMPs) as these entities—just like PDP sponsors—will be required to submit bids for the prescription drug coverage they plan to offer. Therefore, we have changed the accompanying regulation text to use the terminology, ''Part D sponsor,'' throughout. We have also indicated in the regulation where separate rules would apply to fallback entities.

As discussed in subpart C, the statute provides a framework for the provision of subsidized prescription drug coverage. Within this framework, PDP sponsors and MA organizations have some flexibility to design coverage that is different from defined standard coverage to meet the needs of Part D-eligible Medicare beneficiaries. This framework plays a critical role in bid submissions, and the actuarial evaluation and approval of bids.

As part of our discussion we specify the actuarial equivalency tests plan sponsors will have to meet when offering coverage other than defined standard coverage. Please note that the coverage definitions are discussed in detail in subpart C of the preamble. In order to determine actuarial equivalency, plan sponsors will compare their plans to the defined standard coverage baseline to assess the various tests of actuarial equivalency that we discuss in detail in the sections below.

2. Requirements for Submission of Bids and Related Information

As provided under section 1860D–11(b) of the Act, each applicant to become a PDP sponsor or MA organization will be required to submit a bid for prescription drug coverage for each plan it intends to offer. Most bids will be expected to represent full risk plans, meaning that the prescription drug plan is not a limited risk plan or a fallback prescription drug plan, and is not asking for any modification of the statutory risk sharing arrangements. A bid from a full risk plan may be referred to as a full risk bid. PDP sponsors may choose to participate as limited risk plans, meaning that they provide basic prescription drug coverage and request a modification of risk level (as described in § 423.265(d)) in its bid submitted for the plan. A bid with a modified level of risk is referred to as a limited risk bid. This term does not include a fallback prescription drug plan. Bids will be due to us no later than the first Monday in June for each plan to be offered in the subsequent calendar year. This date stems from the requirement in section 1860D–11(b) of the Act that bid data from potential PDP sponsors be submitted at the same time and in a similar manner as the information described in section 1854(a)(6) of the Act for MA plans. Since section 1854(a)(1) of the Act requires initial data to be submitted on the first Monday of June of each year after 2004, we have also incorporated this date into our regulations. In the case of MA-PD plans, the prescription drug bid will be a component of the unified MA bid described in § 422.254(b)(1) with benefits beyond basic coverage (if any) incorporated into the supplemental benefits portion of the prescription drug benefit bid.

We are clarifying that this bid will represent the expected monthly average cost (including reasonable administrative costs) to be incurred by the plan applicant for qualified prescription drug coverage in the applicable area for a Part D eligible individual with a national average risk profile for the factors described in section 1860D 15(c)(1)(A) of the Act and in § 423.329(b)(1) of this rule. We plan to develop and publish the risk adjustment factors and identify the characteristics of an average individual no later than the date of the 45-day notice for the announcement of 2006 rates, which is February 18, 2005. Any modifications to these characteristics for subsequent years will be announced by the date of the annual 45-day notice. (For further discussion of prescription drug risk adjustment, see subpart G of this preamble.) In the August 2004 proposed rule we solicited comment on the nature of any additional information needed to prepare bids and suggestions for any other methods that the bid submission process could be structured to provide for later pricing data submission.

The costs represented in each plan bid must be those for which the plan will actually be responsible. Given the structure of qualified prescription drug coverage, these costs will not include payments made by the enrollee for deductible, coinsurance (including 100 percent coinsurance between the initial

coverage limit and the out of-pocket threshold), copayments, or payments for the difference between a plan's allowance and an out-of-network pharmacy's usual and customary charge (as discussed in § 423.124(b). It also does not include costs reimbursed by us through the reinsurance subsidy. However, we require the separate identification, calculation, and reporting of costs assumed to be reimbursed by us through reinsurance. For standard coverage, defined or actuarial equivalent, these costs will include the plan's share of costs above the deductible and up to the initial coverage limit, as well as the plan's share of costs above the annual out of pocket limit. If enhanced alternative coverage is provided, the plan costs for supplemental benefits will be distinguished from those for basic coverage. The costs attributable only to basic coverage, once approved, are known as the standardized bid amount.

In § 423.265(c) we will require that, with the exception of potential employer group waivers under section 1860D–22(b) of the Act and section 1857(i) of the Act, late enrollment penalties and low-income premium and cost sharing subsidies, the bid represents a uniform benefit package based upon a uniform level of premium and cost sharing among all beneficiaries enrolled in the plan. This means that all enrollees in a given PDP or MA-PD plan will be subject to the same cost sharing structure and will be charged the same premium for benefits the PDP sponsor or MA organization chose to offer.

We note that while benefits are required to be uniform for all enrollees under the drug benefit, this is not the case for enrollees under a prescription drug discount card program. To avoid any confusion between these related programs, we would like to make this distinction clear. Because of the limited low-income assistance under the card program, card sponsors have been permitted to negotiate lower prices for low-income members. Also, in some cases there may be reduced cost sharing sponsored by manufacturers for low-income members after the $600 in transitional assistance is used that does not apply to other card members. Under the Part D prescription drug program, however, both the negotiated prices and the benefit structure will be the same for all enrollees in a given PDP or MA PD plan. While the low-income subsidies will result in low-income beneficiaries' actual out of pocket costs being lower than for beneficiaries who do not qualify for this assistance, the benefit structure to which the subsidies apply is the same for all enrollees in a plan.

Comment: Two commenters suggested that we assist bidders by making accessible relevant drug utilization data from sources such as Tricare, PBMs, the National Association of Chain Drug Stores and current Medicare Advantage plans with drug benefits.

Response: We either does not have access to such data or does not have the authority for public release. Most of the data suggested by the commenters would be considered proprietary. There are other data sets that are being used to meet industry's requests that we share information from public data sets that could help potential drug plan bidders to better understand or estimate the eligible Medicare beneficiary population's utilization of prescription drugs. They include: 1) data for Federal retirees 65+, enrolled in the Federal Employee Health Benefit national Blue Cross Blue Shield plan; 2) data from the Medicare Current Beneficiary Survey; and 3) Medicaid Pharmacy Benefit Use and Reimbursement in 1999 Statistical Compendium. The latter is prepared from Medicaid Analytic eXtract (MAX) files for calendar year 1999. For more information, or to download these data see *http://www.cms.hhs.gov/pdps/default.asp*.

Comment: Several comments urged that bids be rejected from PDPs that are owned or financially controlled by a drug manufacturer or group of manufactures.

Response: We note the concern that many stakeholders have had over manufacturer acquisition of PBMs in the 1990's. However, the Federal Trade Commission's response by imposing restrictions on manufacturers acquiring PBMs (for example, offer open formularies, include drugs that compete with the parent company's products, etc) has generally led manufacturers to divest from PBMs, or to alter their behaviors in order to prevent antitrust enforcement actions (see Christopher Sroka's November, 2000 report ''Pharmacy benefit managers'' for the Congressional Research Service and Regina Johnson's 2002 piece ''PBMs: Ripe for regulation'' in Volume 57, Issue 2 of the Food and Drug Law Journal). Regardless of future industry activity in this area, the statute does not give us the authority to implement a ban as suggested by the commenters.

Comment: One commenter indicated that Part D plans are required to submit bids no later than the first Monday in June to be offered in the subsequent calendar year. This is not sufficient time for SPAPs that need to coordinate benefits. SPAPs will need to know by June of 2005 what plans will be qualified sponsors and operating in their States.

Response: Section 1854 of the Act amended by the MMA sets the bid submission date as no later than the first Monday of June. PDP sponsors and MA organizations with MA-PDs need the maximum amount of time to put together a bid. PDPs and MA-PDs will need to keep SPAPs informed in order to complete the bid process, so communication between these entities should not be an issue.

Comment: One commenter suggested that plans should be required to provide for coverage of services to residents of Long Term Care facilities that are required by OBRA 1987 and under OBRA 1990. They recommended that this be added to the included costs in § 423.265(b)(1) under submission of bids. The commenter went on to state that Part D plans should not be exempt from providing the same services required under Medicare Part A or Medicaid to nursing facility residents and recommended that we require plans to incorporate the costs of paying for such services into their bid submissions, and that plans state clearly how they intend to pay qualified pharmacists for providing such services.

Response: Part D plans are only obligated to pay the negotiated price for covered part D drugs, which consists of the ingredient cost of the drug and a ''dispensing fee'' and that take into account any discounts, direct or indirect subsidies, rebates or other price concessions received by the Part D plan). The fee will include only those activities related to the transfer of possession of the covered Part D drug from the pharmacy to the beneficiary, including charges associated with mixing drugs, delivery, and overhead. The dispensing fee will not include any activities beyond the point of sale (that is, pharmacy follow-up phone calls) or any activities for entities other than the pharmacy. The dispensing fee does not include any charges associated with administering the drug once the drug has already been transferred to the beneficiary. This means that the pharmaceutical services listed under 1819(b)(4)(A)(iii) are included within the negotiated prices for covered part D drugs only if the term ''dispensing fee'' as defined in § 423.100 captures such services.

Comment: Several commenters asked for guidance regarding the costs that we view as administrative.

Response: Administrative costs are not clinical services unless part of a Medication Therapy Management Program. Administrative costs include such costs as: 1) crossover fees paid to

obtain information from other payors in order to calculate TROOP (True Out-of-Pocket); 2) Medication Therapy Management Program expenses; 3) Marketing & Sales; 4) Direct Administration (for example, customer service, billing and claims administration); 5) Indirect Administration (for example, corporate services, such as accounting operations, actuarial, legal and human resources); 6) Net Cost of Private Reinsurance (that is, reinsurance premium less projected reinsurance recoveries); 7) Medicare User Fees; 8)Uncollected Enrollee Premium; and 9) return on investment. Additional guidance on administrative costs will be given with the release of the bid submission tool. Instructions for the tool will include more detail defining administrative costs and guidance on how they are to be indicated in the bid submission.

Comment: One comment urged us to modify the timeline to permit bidders to submit a bid for approval before June 6, 2005.

Response: While bids can be submitted before the first Monday in June (June 6 in 2005), they cannot be approved before that date because they are reviewed collectively.

Comment: Several commenters urged that the bid submission process use electronic methods and be parsimonious for data requirements.

Response: We agree with the commenters that electronic methods are preferable. Accordingly, bid submitters will upload an electronic Plan Benefit Package (PBP) and bid submission pricing tool to the Health Plan Management System (HPMS). The bid is to represent the expected monthly average cost to be incurred by a plan applicant providing qualified prescription drug coverage in an applicable area for a Part D eligible beneficiary with a national average risk profile. We are cognizant of plan burden and therefore required submission data will be limited to what is absolutely necessary for us to fulfill its bid review, payment, and negotiation obligations.

Comment: One commenter asked if plans will get the rebates from manufacturers for drugs covered by SPAP wrap around.

Response: CMS does not have the authority to dictate how manufacturers pay rebates to plans. However, we would expect that drugs covered by secondary payers would still be subject to rebates.

3. General CMS Guidelines for Actuarial Valuation of Prescription Drug Coverage

As directed by section 1860D–11(c) of the Act, we will develop processes and methods using generally accepted actuarial principles and methodologies for determining the actuarial valuation of prescription drug coverage. Although we plan to provide additional information in the future in the form of interpretive guidance on these processes, we intend on using the following processes and methods for calculating ''actuarial valuation'' and ''actuarial equivalence'' in the context of risk bids:

- Sponsors offering standard coverage with cost-sharing variants either to the 25 percent coinsurance (before the initial coverage limit) or the greater of 5 percent coinsurance or $2 generic/preferred/$5 any other drug (after the out-of-pocket threshold is met) will be required to demonstrate the actuarial equivalence of their variations.
- Sponsors offering basic or enhanced alternative prescription drug coverage will be required to demonstrate that—
  + The actuarial value of total or gross plan coverage of their alternative is at least equal to the actuarial value of total or gross coverage of the defined standard benefit.
  + The actuarial value of unsubsidized coverage of their alternative is at least equal to the actuarial value of the unsubsidized portion of defined standard coverage; and
  + The plan payout at the dollar value of the initial coverage limit under standard coverage, for individuals whose total spending exceeds that limit, is at least equal to that provided under defined standard coverage.
- All sponsors will determine the actuarial value of the defined standard benefit, either because it is—
  + Offered to the beneficiaries;
  + Used as a comparison for either of the following:
    - Standard coverage with actuarially equivalent cost-sharing variants.
    - Alternative coverage; or
  + Used to determine the basic component in enhanced alternative coverage.
- Sponsors that offer enhanced alternative coverage will also be required to determine the actuarial value of coverage beyond basic coverage.
- We will further specify in additional guidelines the data sources, methodologies, assumptions, and other techniques in accordance with generally accepted actuarial principles as either recommended or required in further guidance. We will also specify the data elements (including format) to be sent to us for evaluation. We will then evaluate the analysis and assumptions for compliance and reasonableness. For example, we will evaluate the source, size, and timeframe of data on which assumptions are based, the demographic characteristics of enrollees, the distribution of risk levels, the average costs in each cost-sharing tier, and the update factors used, among other considerations.
- We will also require the separate identification of administrative costs. Since the level of the bid will directly affect the premium paid by the beneficiary and the attractiveness of the plan, we expect that plans will have a strong incentive to keep administrative costs and return on investment at reasonable levels. Any review of administrative costs will likely focus primarily on outliers from the competitive range identified in the bids received. All proposals will contain a description of how certain costs are included in the calculations. Processes and methods for determining actuarial valuation will take into account the effect that providing actuarially equivalent standard coverage or alternative prescription drug coverage (rather than defined standard coverage) has on drug utilization. This includes utilization effects attributable to different benefit structures, such as from tiered cost sharing, as well as those attributable to supplemental benefits. The utilization effect of supplemental benefits on basic benefits will have to be loaded into the supplemental portion of the bid. In other words, since the existence of supplemental coverage will increase total average per capita spending, that increase over the average spending (if coverage were limited to basic coverage) will be included in the portion of the bid attributable to supplemental coverage. Section 1860D–11(c)(1)(D) of the Act specifies ''the use of generally accepted actuarial principles and methodologies.'' We are interpreting this to require that a qualified actuary certify the plan's actuarial valuation (which may be prepared by others under his or her direction or review). Actuarial certification will give better assurance that the actuarial values in the bid were prepared in conformance with actuarial standards and methodologies.
- Section 1860D–11(c)(3)(B) of the Act specifies that PDP sponsors or MA organizations offering MA-PD plans may use qualified independent actuaries in certifying the actuarial values in their bids. (The actuarial valuation may be prepared by others under the direction or review of a qualified actuary). We interpret this provision as requiring PDP sponsors and MA organizations that do

not employ qualified actuaries, to use outside actuaries in their processes. We proposed in the August proposed rule to specify that a qualified actuary is an individual who is a member of the American Academy of Actuaries because members of the Academy must meet not only educational and experience requirements, but also a code of professional conduct and standards of practice. These standards create a common ground for actuarial analysis. Furthermore, a member of the Academy is subject to its disciplinary action for violations of the code and standards. This same requirement is specified in the SCHIP legislation at section 2103(c)(4)(A) of the Act. Moreover, the National Association of Insurance Commissioners (NAIC) imposes significantly stricter requirements on actuaries preparing the financial statements of insurance companies.

Comment: Several commenters asked for flexibility in the actuarial standards. One commenter specifically asked for flexibility in the use of methods and actuarial assumptions by permitting the use of internal data or normative claims databases.

Response: Section 1860D–11(c)(1) of the Act instructs the Secretary to ''establish processes and methods for determining the actuarial valuation of prescription drug coverage including.the use of generally accepted actuarial principles and methodologies''. To the extent it is possible under this paradigm to be flexible, we will be. Use of internal data or normative claims databases is not only acceptable, but encouraged. We will however, review the assumptions and results of your analysis for reasonableness and appropriateness.

Comment: One commenter asserted that being a member of the American Academy of Actuaries should be a requirement, but should not be sufficient by itself.

Response: Our policy position is to require that an actuary have the skills and experience to perform the actuarial certification required. Accordingly, in § 423.265(c)(3) we state that a ''qualified actuary must certify the plan's actuarial valuation, and must be a member of the American Academy of Actuaries to be deemed qualified.'' By requiring membership in the American Academy of Actuaries we are both requiring a minimal standard, and providing an additional assurance that the actuary will be qualified. For the latter comment, the Code of Professional Conduct for Actuaries states ''an Actuary shall perform Actuarial Services only when the Actuary is qualified to do so on the basis of basic and continuing education and experience.''

Comment: Two commenters expressed that there could be problems with the proposal that the costs associated with any increased utilization in the Part D basic benefit arising from enhanced alternative coverage would be included in the supplemental benefit portion of the bid. They assert that the application of this policy as it applies to the Part D program could be problematic because in many instances an enrollee will have supplemental coverage arising from another source that would not be part of enhanced alternative coverage of the sponsor or organization. One commenter gave the example of a beneficiary who may elect basic prescription drug coverage under a PDP or MA-PD plan and may also receive coverage under an employer/union group plan that wraps around the Part D benefit. They argue that in this case, if no supplemental benefits were included in the MA-PD plan or PDP, there would be no way to take into account in the bid the impact of any increased utilization unless it can be reflected in the bid for the basic benefit. This problem could be greater for special needs plans serving dually eligible beneficiaries who are eligible for substantial subsidies under the Part D program. In this instance, if no supplemental benefits are included in the MA-PD or PDP plan, the only avenue for taking increased utilization the may result from the subsidy into account would be the bid for the basic benefit. However, this could result in a bid above the benchmark that would produce a premium higher than the low-income premium subsidy resulting in an increase in the premium obligation for dual eligible enrollees. This situation could threaten the viability of a special needs plan.

Response: Plan bids will take into account the anticipated impact of induced utilization due to the structure of the plan benefit, other insurance coverage, and the low income subsidy. The impact of induced utilization will be addressed directly in the bid for enhanced alternative coverage. Note that this is for Part D only and is different from what is discussed for Part C in the Title II regulation. There are three major mechanisms for adjusting payment to account for the utilization of the actual enrolled population in any given plan, these are risk adjustment, reinsurance, and risk corridors. One intention of risk adjustment is to take into account the utilization of dual eligibles and adjust payment appropriately for the level of utilization in this population. For all bids, the anticipated impact of other insurance coverage on the bid and its effect on reinsurance will be taken into account. Risk corridors will serve to decrease the exposure of plans where allowed costs exceed plan payments for the basic Part D benefit.

4. Determining Actuarial Equivalency for Variants of Standard Coverage and for Alternative Coverage.

When considering the specific requirements for actuarial equivalence and valuation in the Act, we are aware that there is no official definition of actuarial equivalence. Moreover, the concept of actuarial equivalence is applied in multiple contexts. We must address actuarial equivalence requirements regarding cost sharing, expected benefits, and bid submissions. Thus, we are using interpretive guidance to further explain the process and methodology for determining actuarial equivalence and valuation. The processes and methods for determining actuarial equivalence and valuation would be in keeping with generally accepted actuarial principles. We would require prospective PDP sponsors and MA organizations wishing to offer MA-PD plans to include all of the requirements discussed in the following sections in the information submitted with the bid, when applicable. The MMA contains some specific requirements for actuarial equivalence or valuation. These actuarial equivalence tests are discussed below.

a. Actuarial Equivalence as Applied to Actuarially Equivalent Standard Coverage-Cost-Sharing

As required in section 1860D–2(b)(2)(A) of the Act, standard prescription drug coverage must have ''coinsurance for costs above the annual deductible . . . and up to the initial coverage limit that is equal to 25 percent; or is actuarially equivalent . . . to an average expected payment of 25 percent of such costs.'' We interpret this to mean that sponsors would be required to demonstrate that the actuarial value of their alternative cost-sharing as a percent of the actuarial value of both cost-sharing and plan payments for claims up to the initial coverage limit is the same percentage as for 25 percent coinsurance under defined standard coverage. In calculating these percentages, sponsors would reflect the utilization impacts of the two structures, but hold constant formulary (drug list), drug pricing (except to the extent that the plan incorporated differential pricing and cost sharing based on participation

status within the plan's network), and the group whose utilization is modeled. This would allow plans to have variable co-payments or coinsurance, including tiered structures for preferred and non-preferred drugs, in the initial coverage interval as long as the actuarial equivalence test is met. As a simple example, a plan could have a tiered coinsurance benefit with coinsurance higher than 25 percent for brand name drugs and lower than 25 percent for generics. Some beneficiaries with expenses between the deductible and the initial coverage limit would be expected to pay more than 25 percent, and others to pay less, depending on their usage of brand versus generic drugs. Overall, however, the total coinsurance would have to be actuarially equivalent to an average of 25 percent for all beneficiaries with expenses in this interval, even if the total expenditures beneath the initial coverage limit ($2,250 in 2006) are lower than would be expected under defined standard coverage (due to increased use of generics, for example).

If sponsors wanted to provide a variant on defined standard cost sharing after the out-of-pocket threshold is met, an actuarial test similar to that described above for variants on the 25 percent coinsurance would apply. In this case, based on the group of individuals projected to exceed the out-of-pocket threshold, the sponsor would compute total cost sharing once the true out-of-pocket (TROOP) threshold has been met as a percentage of the sum of that cost sharing plus the comparable plan payout. This percentage would have to equal the percentage computed in the same manner using the defined standard benefit (that is, the greater of $2/$5 or 5 percent). We note that any variant in cost sharing could not lead to discrimination against certain beneficiaries, for example, by increasing the cost sharing of a drug used for a particular illness well above the cost sharing for other drugs.

b. Tests for Alternative Coverage

As required by section 1860D–2(c) of the Act, sponsors offering alternative coverage, that is, benefit structures different from standard coverage, must satisfy five tests (three of the five are actuarial equivalency tests). As discussed in subpart C, alternative coverage would include coverage actuarially equivalent to defined standard coverage (basic alternative coverage) or coverage that would include supplemental coverage (enhanced alternative coverage). All alternative coverage would have to meet all five of the coverage standards or tests discussed in section b.1–5 of this preamble. Tests one through three were established by the Congress to ensure that alternative coverage would be at least actuarially equivalent to standard coverage. Tests four and five are additional tests imposed by the Congress through section 1860D–2(c) of the Act.

(1) Test for Assuring at Least Equivalent Value of Total Coverage

As required in section 1860D–2(c)(1)(A) of the Act, a plan could offer alternative prescription drug coverage as long as the actuarial value of total or gross coverage is at least equal to total or gross coverage provided under standard coverage. Based on a typical distribution of enrollee utilization, the average plan payout (including costs reimbursed by Medicare through the reinsurance subsidy) would have to be at least equal to the sponsor's estimate of the payout under defined standard coverage (holding various factors constant as described above under section 4.a.).

Alternative benefit structures, such as a decrease in the deductible with an increase in coinsurance below the initial coverage limit, or a lower initial coverage limit with a corresponding decrease in coinsurance, or a lower initial coverage limit with a corresponding decrease in deductible, could be accommodated as basic alternative coverage as long as the actuarial value of this coverage equaled that of defined standard coverage. Alternative structures could not increase the deductible or provide less than the protection offered against high out-of-pocket expenditures described in section 1860D–2(b)(4) of the Act. To the extent that the alternative coverage exceeds the value of defined standard coverage, the plan would be offering enhanced alternative coverage, that is, alternative coverage that includes supplemental benefits (as discussed in subpart C).

(2) Test for Assuring Equivalent Unsubsidized Value of Coverage

In section 1860D–2(c)(1)(B) of Act, a plan could offer alternative coverage as long as the unsubsidized value of coverage (the value of the coverage exceeding subsidy payments) is at least equal to the sponsor's estimate of unsubsidized value under defined standard coverage (holding various factors constant as described above section 4.a.). We interpret the unsubsidized value of coverage to mean the value of the benefit attributable to the beneficiary share of the premium.

There is a basic question about how this test could be applied during the plan review and approval process. In order to determine the unsubsidized value of coverage, one would have to know the projected reinsurance payments, and the value of the direct subsidy. While the projected reinsurance payments would be known at the time of the submission (since the actuarial value of the benefit is reduced by projected reinsurance payments to produce the bid), the value of the direct subsidy would not be known (since it would require computing the national weighted average bid and bids have not yet been approved). In the face of this problem, one approach could be to remove reinsurance payments as estimated by the sponsor and to use an estimate of the direct subsidy that we would provide. For instance, in the first year we might provide the estimate used for budgeting purposes, and in subsequent years, an estimate based on prior years' actual experience updated for trend. Additional guidance will be released concerning this matter.

Comment: Two commenters suggested that we should waive the second test of actuarial equivalence because if a plan meets all of the other tests the second test would be redundant, and without knowing the true value of direct subsidy the second test would be difficult to conduct.

Response: The second actuarial equivalence test for alternative coverage ensures the equivalent unsubsidized value of coverage. As we are defining this test, the beneficiary premium for alternative coverage must be greater than or equal to the beneficiary premium for standard coverage. Since beneficiary premiums will not be determinable until after all bids have submitted and applied against the national average bid, we interpret the application of this provision to be that the total Part D bid for alternative coverage must be greater than or equal to the sponsor's bid for defined standard coverage. We note that the first test of actuarial equivalence guarantees that the total value (including reinsurance) of coverage for the basic alternative benefit must be equal to the total value of coverage of the standard benefit. The second test then precludes a basic alternative benefit structure that increases government reinsurance costs relative to define standard coverage. We note that the test imposes no additional burden beyond the first test (that is, if you constructed a bid and shown that you meet test #1, you would already have all the information available to show whether you meet test #2). Given that the program is just beginning and we have no practical experience to show that the second test adds no value beyond the first test, we see no basis for waiving this test at this time.

(3) Test for Assuring Standard Payment for Costs at Initial Coverage Limit

Under section 1860D–2(c)(1)(C) of the Act, sponsors are to determine the average payout ''for costs incurred that are equal to the initial coverage limit'' for ''an actuarially representative pattern of utilization.'' This projected payout is compared to a dollar amount that is equal to what defined standard coverage would pay for someone with costs equal to the initial coverage limit. Given the comparison, this raises the question of what represents ''an actuarially representative pattern of utilization.'' As with the other tests, we believe that it would be reasonable for plans to use either anticipated plan utilization or a typical utilization pattern based on the Medicare population. However, given the implicit comparison to payout under defined standard for someone with costs equal to the initial coverage limit, it would not be valid to include individuals with expenses below the value of the initial coverage limit. After excluding individuals with total expenses below the value of the initial coverage limit, the plan would compute the actuarial value of plan payout at the point where total expenses are equal to the initial coverage limit under standard coverage. Under this interpretation, a plan could offer alternative coverage as long as the coverage is designed to provide an actuarial value of plan payout that is equal to at least 75 percent of costs between the standard deductible and initial coverage limit ($1,500 in 2006). In other words, considering only plan enrollees with expected expenses greater than or equal to the dollar value of the standard initial coverage limit, the plan would have to demonstrate that the expected plan payout associated with expenses equal to that dollar value would be at least 75 percent of benefit costs between the deductible and initial coverage limit (75 percent of $2,000 per beneficiary in CY 2006) including taking into account their expected behavioral response to the different benefit structure. This test, combined with the prohibition on increasing the deductible under alternative coverage (described below), would ensure that the benefit below the dollar level of the standard initial coverage limit is always actuarially equivalent to standard coverage. As a result, it is not permissible to trade off benefits above the initial coverage limit for benefits below.

(4) Test for Assuring the Deductible Does not Exceed the Standard Deductible

In keeping with the requirements of section 1860D 2(c)(2) of the Act, alternative coverage could not be structured so that the deductible is any higher than what it is in standard coverage ($250 in 2006).

(5) Test for Assuring the Same Protection Against High Out of-Pocket Costs

As specified by section 1860D–2(c)(3) of the Act, any alternative coverage must provide ''the coverage'' specified for costs above the catastrophic limit in standard coverage. We interpret this to mean that both enhanced and basic alternative coverage would have to offer at least the coverage available above the catastrophic limit through defined standard coverage. We would apply this test in the same way that we do for standard coverage with a variant of cost sharing above the catastrophic limit. That is, examining the group of individuals the sponsor projects would exceed the out-of-pocket threshold, total cost sharing once TROOP has been met, as a percentage of the sum of such cost sharing plus comparable plan payout, must be less than or equal to the percentage computed using the defined standard benefit (that is, the greater of $2/$5 or 5 percent). Again, we note that any variant in cost sharing could not lead to discrimination against certain beneficiaries, for example, by increasing the cost sharing of a drug used for a particular illness well above the cost sharing for other drugs.

c. Value of Qualified Coverage

In accordance with section 1860D–11(b)(2)(B) of the Act, with the bid, each PDP sponsor and MA organization offering an MA-PD plan must submit the actuarial value of qualified coverage in the region for the Part D eligible individual with a national average risk profile for the factors described in section 1860D–15(c)(1)(A) of the Act. We interpret this to mean that the weighted average of the plan's expected risk-standardized costs will represent the plan's cost for the theoretical national average-risk Part D individual. Any increase in costs attributable to increased utilization as the result of enhanced alternative coverage must be excluded from this calculation. Any alternative coverage that does not include supplemental coverage would be, by definition, actuarially equivalent to standard coverage. Any utilization effect that supplemental coverage has on the basic benefit should be priced into the supplemental portion of the bid.

Comment: One commenter wants to ensure that they have the ability to establish flat copayments rather than the 25 percent coinsurance of the standard design. We should permit Part D providers to round flat copayments to the nearest $5 dollar level, as these are the benefit designs commonly offered in the market place.

Response: Any copayment structure must meet the test for either actuarially equivalent standard coverage or for alternative coverage. These tests are available to allow for flexibility in benefit design including use of copays rather than coinsurance. While we would anticipate that some rounding would be consistent with these tests, rounding to the nearest $5 dollar level may create too great a difference between rounded and unrounded values.

Comment: One commenter stated that the regulation text should allow for the value of any enhanced benefit design to reflect both the potential impact of utilization changes and mix shifts to less expensive drugs. Any test of benefit value should also take into account the impact of utilization management, which may increase utilization, but have a favorable impact on total costs.

Response: To the extent that a benefit design other than that of defined standard coverage will have a projected impact on the mix of drugs, this impact will be included in the pricing of that proposed design. We anticipate that utilization management will be held constant in the pricing of defined standard and the proposed design, as well as the population modeled; drug formulary; and drug pricing (except to the extent that the proposed design incorporates differential pricing and cost sharing based on participation status within the plan's network). These issues will be fully discussed in our guidance on ''processes and methods using generally accepted actuarial principles and methodologies''.

5. Information Included with the Bid

a. Bid Format

The exact format for the bid submission is detailed in separate CMS guidelines with the bid submission tool. Section 1860D–11(c)(1)(D) of the Act specifies ''the use of generally accepted actuarial principles and methodologies.'' We require that an actuary (a member of the American Academy of Actuaries) certify the actuarial valuation, which may be prepared by others under his or her direction or review. Actuarial certification would give better assurance that the actuarial values in the bid were prepared in conformance with actuarial standards and methodologies. Section 1860D 11(c)(3)(B) of the Act permits use of outside qualified independent actuaries. We expect that plans would use outside actuaries, especially if they did not have qualified in-house actuaries.

As provided in section 1860D 11(b)(3) of the Act, we have developed (see Draft PDP Bid Instructions and Pricing Tool *http://www.cms.hhs.gov/pdps/*) the bid submission format to facilitate the submission of bids for multiple regions and in all regions, and we have taken this into account in process development. This approach would need to ensure that separate bids were provided for each region in order to calculate the national average monthly bid amount and any geographic adjustment required. Our overall approach would be to increase our flexibility to develop appropriate methodologies in response to program changes, while minimizing burden, rather than codifying these processes in regulation. We believe that we would have the authority to develop these methodologies through interpretive guidance because our regulations state that sponsors provide the actuarial value of their plans in accordance with generally accepted actuarial principles and methodologies.

In most cases the information included with the bid would be sufficient for our review of the acceptability of a proposed plan based on actuarial principles and for negotiation of terms and conditions of an entity's participation in the provision of Part D benefits. However, we may require additional information during the review to support the assumptions and methods accompanying the bid. As provided in section 1860D–11(b)(2) of Act and § 423.265(d) of this rule, the information that would accompany the bid submission would, at a minimum, include the following:

- Information on the prescription drug coverage to be provided, including the structure of the benefit, including deductibles, coinsurance (including any tiers), initial (or subsequent) coverage limits at which coinsurance levels change, and out-of-pocket thresholds. This would also include the plan's formulary, utilization management techniques, and any drugs, or types of drugs, excluded from coverage, and all documents provided to beneficiaries explaining the benefit, including the Evidence of Coverage, and would be certified by an officer of the plan. We solicit comments on the best way to obtain clear information on what drugs are included in the formulary.
- The actuarial value of the qualified prescription drug coverage in the region for a beneficiary with a national average risk profile certified by a qualified actuary.
- The portion of the bid attributable to basic benefits.
- The portion of the bid attributable to supplemental benefits, if applicable.
- The actuarial basis for the portion of the bid attributable to basic coverage and to supplemental benefits, if applicable, certified by a qualified actuary.
- The assumptions regarding reinsurance subsidy payments.
- The assumptions regarding administrative expenses.
- The plan's service area and the plan's network of pharmacies serving that service area.
- (For PDP sponsors only) the level of risk assumed in the bid, including whether the sponsor requires a modification of risk level (see discussion below) and, if so, the extent of the modification. Although our procedures may subsequently seek this information, we may only review it to the extent that the initial submission of bids does not yield the statutory minimum number of full risk bidders in each region and area. Our goal in designing the bidding process will be to maximize the level of risk borne by contracting plans and to minimize the need for fallback plans; and
- Any other information that we would require.

Response to public comment

Comment: Several comments were received concerning privacy protections for information submitted during the bidding process. Two manufacturers urged adoption of the ''restriction on use of information'' standard in § 423.322(b) for bidding information. Moreover, they believe that the Trade Secrets Act (18 USC § 1905) should apply and be inserted into the regulation to cover manufacturer pricing information. Three additional comments were received suggesting that we should limit our requests concerning specific pricing and cost information. These commenters while not referring to the Trade Secrets Act, did seek protection of any information submitted. Additionally, one pharmacy benefits manager and one health insurer expressed concern that bidding information will not be protected from disclosure under the Freedom of Information Act (FOIA).

Response: We believe that information submitted with the bid that is used to pay plans (such as estimations of reinsurance or administrative costs) would be protected under § 423.322(b) and sections 1860D–15(d)(2)(B) and 1860D–15(f)(2) of the Act. These sections protect information that is submitted to us for the purposes of carrying out section 1860D–15 of the Act. Because the direct subsidy in section 1860D–15(a) of the Act is based upon the plan's standardized bid amount, we believe that the portion of the standardized bid which is used in calculating that subsidy would be protected. On the other hand, information submitted with the bid that is not used in calculating the direct subsidy (such as the structure of the formulary or the utilization management techniques to be used by the applicant) would not be protected under sections 1860D–15(d)(2)(B) and 1860D–15(f)(2) of the Act. However, bidders can always seek to protect their information under the Freedom of Information Act and label truly proprietary information ''confidential'' or ''proprietary.'' When information is so labeled, the bidder is required to explain the applicability of the FOIA exemption they are claiming. When there is a request for information that is designated by the submitter as confidential or that could reasonably be considered exempt under Exemption 4, the Department is required by its FOIA regulation at 45 C.F.R. § 5.65(d) and by Executive Order 12,600 to give the submitter notice before the information is disclosed. To determine whether the submitter's information is protected by Exemption 4, the submitter must show that- (1) disclosure of the information is likely to impair the government's ability to obtain necessary information in the future; (2) disclosure of the information is likely to cause substantial harm to the competitive position of the submitter; or (3) the records are considered valuable commodities in the marketplace which, once released through the FOIA, would result in a substantial loss of their market value. Consistent with our approach under the Part C program, we would not release information under the Part D program that would be considered proprietary in nature or that would tend to stifle the availability of discounts or rebates from pharmaceutical manufacturers negotiated by Part D plans.

Bidders may identify trade secrets and confidential business information (CBI) with their submission. However, if they have not we will give them another chance when a FOIA request has been made on their records. In this case we will notify the business submitters that we are in receipt of FOIA requests for their records. We will then provide the business submitters with instructions and ask them to identify any trade secret or CBI in order to justify our application of Exemption 4. We will then review their justifications and highlighted information against FOIA case law to see if we can support their requested redactions. Under Executive Order 12600, if the business submitters

disagree with our Exemption 4 analysis (which includes their justification) of their identified trade secret or CBI, they are provided the opportunity to seek a restraining order or injunction in Federal court prohibiting us from releasing their records under FOIA.

Comment: One commenter suggested that Pharmacy Benefit Managers be required to disclose all rebate arrangements with manufacturers.

Response: It is unclear to whom the commenter wants rebate disclosed to and in what context. The comment was made in reference to bidding and in this case information on rebates will generally be limited to the aggregate level. However, per § 423.272 more detailed information may be reviewed if necessary to ensure the reasonableness and appropriateness of the bid. Uniform requirements for detailed rebate information would unnecessarily increase the burden of the bidder. Detailed rebate information will be collected for reasons other than the bid.

b. Risk Adjustment of Supplemental Premium

The portion of the bid attributable to supplemental benefits (part of enhanced alternative coverage defined in § 423.104(g)) represents the supplemental premium for a beneficiary with a national average risk profile. The payment process provided in section 1860D–15 of the Act will only address risk adjustment of the basic portion of the bid, and there are no other provisions for risk adjusting the supplemental benefit portion of the bid. If not addressed, this would result in plans with average risk scores above 1.0 being under-compensated by enrollees for supplemental benefits, and plans with average risk scores below 1.0 being over-compensated, as illustrated below.

TABLE F–1
SUPPLEMENTAL PREMIUM RISK ADJUSTMENT

	Plan A	*Plan B*	*Plan C*
Plan Average Risk Profile	0.80	1.00	1.10
1.0 Supplemental Premium	100	100	100
Supplemental Premium if Risk-Adjusted	80	100	110
Over or (under) compensation	$20.00	$0.00	$(10.00)

Table F–1 illustrates the case of three equally efficient plans that each estimate the cost of the same supplemental benefits at $100. Plan B has an average risk profile, that is, the arithmetic average of the risk scores of all of its enrollees is equal to 1.0. Plan A and Plan C, however, have healthier and sicker than average risk pools, with enrollee risk scores averaging .80 and 1.10, respectively. Plan A only needs an average risk-adjusted premium of $80 to meet the revenue requirements of providing those supplemental benefits to its healthier enrollees, but would receive $20 more on average from enrollees if it collects the whole $100 unadjusted premium. In contrast, Plan C needs to collect $10 more than it would receive from the unadjusted (1.0) premium to fully fund the expected needs of its sicker enrollees. Consequently, we will require additional information on the projected risk profiles of projected enrollees for accurate valuation of the supplemental portion of the bid with the bid submission. We intend, through the negotiation process, to reach agreement on a supplemental premium based on the bid submission that would account for the risk profile of enrollees and, thus, meet the plan's revenue requirements. Our goal is to maintain a level playing field that would facilitate the fair competition envisioned in the MMA. Review and approval of this information is discussed in section F.3. of this preamble.

c. Modification of Risk in PDP Bids

As provided under section 1860D–11(b)(2)(E) of Act and in § 423.265(d)(4), PDP sponsors may request a modification of certain risk sharing arrangements provided under section 1860D–15(e) of the Act, thus, becoming a limited risk plan. Modification of risk could include an increase in the Federal percentage assumed in the risk corridors or a decrease in the size of the risk corridors. Any modification of risk will have to apply to all PDP plans offered by a PDP sponsor in a region.

Section 1860D–11(b)(2)(E)(i) of the Act states that modification of risk will not be available to MA-PD plans. Therefore, in discussing the possibility of including in the bid a request for a modification of risk, we include only PDP sponsors. Limited risk plans will only be accepted if the access requirements in section 1860D–3(a) of the Act could not otherwise be met through the approval of a sufficient number of full risk plans. These requirements call for at least two qualifying plans offered by different entities, one of which must be a stand-alone prescription drug plan. If other bidders meet these requirements, a bid from a limited risk plan could not be approved and might not be reviewed.

Comment: The proposed rule offers no guidance as to what we view as ''minimal risk.''

Response: While the statute allows ''limited risk'' arrangements to be accepted in order to ensure that the access requirements are met, such arrangements must provide for more than a ''de minimis'' level of risk. We would generally consider anything below 10 percent risk as ''de minimis''. Any proposal for a level of risk above the ''de minimis'' but less than the standard full risk contract will be considered if there was a need to accept a ''limited risk'' arrangement.''

Comment: One commenter suggested that we should allow PDPs who wish to enroll low income subsidy beneficiaries to apply for limited risk, but be treated as a full risk plan.

Response: While it is unclear what the commenter meant by being ''treated as a full risk plan,'' while being limited risk, full risk plans get priority and we will only approve limited risk plans when there are not a sufficient number

of full risk plans to meet the access requirements of section 1860D–3(a). Also, per section 1860D–11(f)(1), approval of a limited risk plan is conditioned on not being able to meet the access requirements but for the approval of such a limited risk plan. Thus, if there are sufficient full risk plans, we will not approve limited risk plans regardless of whether the PDP wishes to specifically enroll low income subsidy beneficiaries.

Comment: One commenter expressed confusion over how the low-income cost sharing amounts enter into the bid ''calculation'' since these amounts help to satisfy revenue needs already identified by the plans as part of the bid. The commenter went on to state that during the early years of the program it will be difficult for plans to estimate the number of low-income beneficiaries expected to enroll and the amounts that would be paid on their behalf. They requested that we recognize that these estimates are likely to be subject to error and include statement in the preamble to the final rules that a good faith standard will apply to these estimates.

Response: The commenter is correct that the low-income subsidy is not part of the bid since it represents a subsidy for enrollee cost-sharing liability rather than plan liability. We ask for PDP sponsors' or MA-PD plans' estimate of their low-income subsidy to assist us in determining an interim payment for this subsidy, which is separate from the direct and reinsurance subsidies. Their actual low-income subsidy payment will be based on the actual experience for this group. Estimates will be reviewed for reasonableness and appropriateness using ''generally accepted actuarial principles and methodologies'' as instructed by 1860D–11(c)(1)(D) of the Act.

Comment: One commenter urged that bids include information on how plans will coordinate with SPAPs for Part D wraparounds at the point of sale.

Response: Specific information elements included in the bid submission tool are not part of the regulatory text and will be released in separate additional guidance on the bidding process.

Comment: One commenter urged us to specify that bids must include information on specific drugs in each formulary tier and their corresponding co-pays, in addition to any prior authorization requirements.

Response: Specific details concerning the response fields will be released with the guidance materials accompanying the bid pricing tool and the Plan Benefit Package; however, formulary tiering structures and prior authorizations requirements will be information that we will review.

Comment: One comment stated that we should provide a sample actuarial pricing form that illustrates the type of information desired.

Response: Additional guidance on actuarial pricing will be made available in a timely manner.

6. Review and Negotiation of Bid and Approval of Plans

a. Authority to Review Bids

We will review the information filed by the PDP sponsor or MA organization in order to conduct negotiations on the terms and conditions proposed in the bid. In addition to general authority to negotiate terms and conditions of the proposed bid submitted and other terms and conditions of a proposed plan, the MMA grants use of the authority to negotiate bids and benefits ''similar to'' the statutory authority given the Office of Personnel Management (OPM) in negotiating health benefits plans under the FEHBP program. We believe that the Congress used ''similar to'' in the statute because of the differences between the two programs. For example, while the OPM authority applies to level of benefits, standard Part D drug coverage is defined. With regard to rates, in some cases the context for FEHBP negotiations is not applicable to Part D. For example, the rates for community-rated plans under FEHBP are related to the rate the entity provides to similarly sized groups, and there is no comparable concept in Part D. Arguably the degree of competition among plans, and price signaling through premium and benefits, might be significantly greater in Part D than in FEHBP. Although these differences do exist there are also similarities. OPM is concerned about trend factors used to establish the premium for experience-rated plans, and we will have similar concerns about the reasonableness of a sponsor's trend assumptions. OPM is concerned about cost-sharing changes proposed by plans, and we will have similar concerns with regard to supplemental benefits. OPM wants to maintain high member satisfaction and ensure top quality service by plans, and we will have similar interests.

Chapter 89 of title 5 USC gives OPM broad discretion to negotiate prices and levels of benefits. For example, 5 USC 8902(i) states that OPM may negotiate with carriers if it believes the rates charged do not ''reasonably and equitably'' reflect the cost of the benefits provided. In addition, OPM has broad authority to negotiate the level of benefits, including the ability to prescribe ''reasonable minimum standards for health benefits plans.'' (See 5 USC 8902(e).) Notwithstanding our broad negotiating authority and our negotiating authority ''similar to'' that of OPM, to the maximum extent feasible and consistent with the appropriate discharge of our responsibilities, we prefer to rely on competition rather than negotiation.

We note that the bid requirements will be negotiated and a denial of a contract based on a failure to come to an agreement on the bid will not be appealable under the administrative procedures for appealing a contract denial beginning with reconsideration in § 423.645. Only the application requirements, which are separate and distinct from bid negotiation, can be appealed as detailed in subpart N.

Comment: One commenter urged that we conduct a thorough review of Part D providers' estimates of reinsurance to ensure a ''level playing field.''

Response: We will review estimates of reinsurance. Per section 1860D–11(c)(1) of the Act ''an actuarial valuation of the reinsurance subsidy payments'' will be conducted. Moreover, section 1860D–11(d) and (e) require a review of the entire bid including the estimates of reinsurance. Additional detail for this review will be released in documentation supporting the bid submission process.

b. Bid and Benefit Package Review

We have the authority to negotiate in four broad areas: (1) administrative costs; (2) aggregate costs; (3) benefit structure; and, (4) plan management, if dissatisfied with some or all aspects of bid submissions. We will evaluate administrative costs for reasonableness in comparison to other bidders and in comparison to a PDP sponsor's other lines of business. We will examine aggregate costs to determine whether the revenue requirements for qualified prescription drug coverage are reasonable and equitable. We will be interested in steps that the sponsor is taking to control costs, such as through various programs to encourage use of generic drugs. We will examine and discuss any proposed benefit changes. Finally, we will discuss indicators and any identified issues with regard to plan management, such as customer service.

In addition to the negotiation process, we will ensure that bids and plan designs meet statutory and regulatory requirements. In general, we will examine bids to determine whether the bid meets the standard of providing qualified prescription drug coverage, as described in § 423.104(b) of this rule and in subpart C of this preamble. We will examine the actuarial analysis accompanying the bid to ensure that it

has been prepared in accordance with our actuarial guidelines and properly certified. We will examine bids to determine whether the revenue requirements for qualified prescription drug coverage are accurate and reasonable, and that the requirements relating to actuarial determinations are met. We note that section 1860D–11(e)(2)(c) of the Act requires that the portion of the bid attributable to basic prescription drug coverage must be supported by the actuarial basis and reasonably and equitably reflect revenue requirements for benefits provided under the plan, less the sum of the actuarial value of reinsurance payments. We will also review the structure of premiums, deductibles, copayments, and coinsurance charged to beneficiaries and other features of the benefit plan design to ensure that it is not discriminatory. We will review cost sharing both above and below the out-of-pocket threshold with regard to its impact on groups of beneficiaries. We will also look to see that there is no differential impact on groups of beneficiaries by geographical location within the plan's region or service area attributable to different levels of cost sharing between preferred and non-preferred network providers.

As required under section 1860D–11(e)(2)(D)(i) of the Act and in § 423.272(b)(2), the structure of the benefit design (including cost sharing provisions and formulary design) must not be discriminatory; that is, it must not discourage enrollment by any Part D eligible enrollee on the basis of health status, including medical condition (related to mental as well as physical illness), claims experience, receipt of health care, medical history, genetic information, evidence of insurability, and disability. In general, this means that we will review benefit plans for features that, when applied, have differential impacts on beneficiaries with particular medical conditions. Factors we will consider in determining whether a benefit structure is discriminatory include, but are not limited to: (1) the benefit design—including the initial coverage limit, the tiered cost-sharing, the use of categories and classes in a formulary, and the choice of drugs provided in each category. (For example, if the tiered cost-sharing for drugs used to treat HIV is much higher than the cost-sharing for other types of drugs, we will view this benefit structure to be discriminatory); (2) the use of any discriminatory limits such as 90-day limits or requirements for pre authorization; and (3) supplemental benefits such as supplemental coverage of drugs that will encourage a healthier population to join the PDP. As provided in section 1860D–11(e)(2)(D)(ii) of the Act, plans using formulary designs based on categories and classes that are consistent with the guidelines established by the U.S.P. as discussed in subpart C, will be recognized as satisfying the non-discrimination design related to formulary structure as it pertains to categories and classes. However, adopting the USP model categories and classes will not prohibit us from reviewing other aspects, including the use of any limits or tiers, as discussed above.

c. Approval of the Supplemental Premium

As provided under section 1860D–11(e)(2)(C)(ii) of the Act, we will determine that the portion of the bid attributable to supplemental benefits reasonably and equitably reflects the revenue requirements for that coverage under the plan. Unless the supplemental portion of the bid (which is paid by the enrollee in the form of the supplemental premium) is risk adjusted for the average level of risk among enrollees, plans with average risk scores above or below 1.0 will be over compensated or under compensated by enrollees for supplemental benefits. Therefore, on the basis of this authority, we will require additional information, consisting of estimates of the projected risk scores of the plan's enrollees in the subsequent year, to be submitted by each plan for purposes of negotiating the appropriate risk adjustment of the supplemental portion of the bid. We will review and negotiate that information, and will approve a uniform supplemental premium reflecting the average risk factor for the plan's expected enrollment.

d. Rebate Reallocation for MA-PD plans

The negotiation process for MA-PD plans could include the resubmission of modified benefit structures (other than changes in that portion of their supplemental benefits related to drugs) once we know the outcome of the national average monthly bid calculation and its impact on beneficiary premiums. Part D drug benefits, including benefits offered through supplemental Part D coverage) could not be changed during this process because any changes will have an impact on government reinsurance payments and, therefore, on the portion of the bid related to basic drug benefits. The MMA requires that all MA bid and benefit package submissions be provided to us no later than the first Monday in June. In the prescription drug program enrollee premiums must be based on a percentage of the national average monthly bid amount that can only be calculated once all bids have been received, if not actually approved. (While the enrollment weights are determined from the previous year's reference month, the bid amounts are not.) Therefore, the prescription drug portion of benefit packages submitted by MA-PD plans will be based on estimates of monthly beneficiary premiums. Some of these MA-PD plans will have allocated portions of their Part C rebates to buy-down of the Part D premium. Once the final national average monthly bid amount and the base beneficiary premium have been calculated, some of these rebate allocations in the bids could be either excessive or insufficient to achieve the desired premium level.

Excessive rebate allocation will result in a portion of the rebate that is not provided to the beneficiary as required by law, since a premium of less than zero is not permitted. Compliance with the statute will require a reallocation of the excessive portion of the rebate credit back to other allowed uses of the Part C rebate, that is, to supplemental benefits (including reduced cost sharing other than cost sharing for Part D drugs) or to credits to the Part B or supplemental premiums. On the other hand, insufficient rebate allocation may result in minimal premiums that may be seen as burdensome by plans, enrollees, and the financial institutions managing electronic funds transfer.

The statute does not address this situation, but section 1860D–11 of the Act does grant us broad authority to negotiate the terms and conditions of the proposed bids and benefit plans. Our regulatory approach will be to allow the negotiation process for MA-PD plans to include the resubmission of modified benefit structures once the outcome of the premium finalization process is known. MA PD plans will be able to redistribute their Part C rebates to correct for the difference between the projected and final national average monthly bid amounts and to achieve the previously proposed level of Part D premiums. Under no circumstances could plans submit modified bids.

For example, an MA-PD organization submitted its bid and benefit package based on the assumption that the levels of the national average monthly bid amount and its prescription drug standardized bid will result in a $35.00 monthly beneficiary premium for basic coverage, and that it will use $35.00 of its Part C rebate to completely buy down the Part D premium. If the national average monthly bid amount is determined to be higher than expected, the plan's bid will end up below the

benchmark and its base beneficiary premium will be adjusted by subtracting the difference between the bid and national average monthly bid amount. Therefore, the plan's monthly beneficiary premium will be less than the projected premium, for instance, $34.00, and the $35.00 amount allocated from the Part C rebate for Part D premium buy-down will be excessive. In that case, we will require the MA organization to amend its benefit package to reallocate the excessive $1.00 of the Part C rebate credit to additional supplemental benefits (other than for Part D drugs) or to Part B or supplemental premium credits. These adjustments will be mandatory in order to ensure that the entire amount of the rebate was provided to the beneficiary in some form.

Under an alternative scenario, the national average monthly bid amount is determined to be lower than expected and the plan's bid ends up above the benchmark. In this case, the plan's base beneficiary premium will be adjusted by adding the difference between the bid and national average monthly bid amount. Therefore, the plan's monthly beneficiary premium will be higher than projected, for instance $36.00, and the $35.00 amount allocated from the Part C rebate for Part D premium buy-down will no longer be sufficient to eliminate the Part D premium as planned. In that case, we will allow the MA organization to amend its benefit package to reallocate an additional $1.00 of the Part C rebate credit from additional supplemental benefits (other than for Part D drugs) or from Part B or supplemental premium credits to eliminate the Part D premium. These adjustments will be optional since the Part C rebate has already been provided to the enrollee. We will not permit an MA organization to simply eliminate a minimal premium instead of reallocating the rebate because doing so will mean that the cost of providing the prescription drug benefit had been overstated. However, the MA organization could elect to charge the new increased premium and to amend its benefit package submission accordingly.

Comment: One comment suggested that we should also allow reallocation of rebate dollars to round off premiums and to support to support the availability of MA-PD plans to dual eligibles.

Response: Title II MA-PD rebate dollars (note this is to be distinguished from manufacturer rebates) could certainly be used to round off premiums (§ 422.266(b)(2)), and as stated our regulatory approach will be to have a negotiation process for MA-PD plans to include the resubmission of modified benefit structures once the outcome of the premium finalization process is known. Such a reduction in the Part D premium will, however, have to be uniform for all plan enrollees.

e. Private Sector Price Negotiation and Formulary Design

The Act envisions that most price negotiation including discounts, rebates, or other direct or indirect subsidies or remunerations will take place between PDP sponsors or MA organizations (or their subcontractors) and pharmacies and pharmaceutical manufacturers. We believe the Congress used the terms direct and indirect to be all inclusive in defining subsidies. Section 1860D–11(i) of the Act precludes us from interfering with negotiations between drug manufacturers and pharmacies, or PDP sponsors, or requiring a particular formulary or pricing structure. In other words, price negotiation with manufacturers will be conducted by the private drug benefit managers and plans that are already familiar with negotiating prices of prescription drugs on a local, regional or national basis. Moreover, we expect that providing information on discounted drug prices to beneficiaries will encourage further competition on lower prices. Because beneficiaries will choose a drug plan based on drug prices and formulary coverage, the plans have strong incentives to negotiate lower prices on drugs that beneficiaries use just as private benefit managers currently do on behalf of the Federal government, State governments, and employer and retiree plans. We expect that in addition to price levels for drugs, these negotiations will also include such terms as prohibitions on substitutions of drugs if the net result will be higher costs for patients or the plans. The nature of the negotiations that we will conduct with bidders is discussed later for full-risk and limited-risk bids, and in subpart Q of this preamble for fallback plans.

We expect that the private negotiations between PDP sponsors and drug manufacturers will achieve comparable or better savings than direct negotiation between the government and manufacturers, as well as coverage options that better reflect beneficiary preferences. This expectation reflects the strong incentives to obtain low prices and pass on the savings to beneficiaries resulting from competition, relevant price and quality information, Medicare oversight, and beneficiary assistance in choosing a drug plan that meets their needs. This is similar to the conclusion of other analyses, for example, CBO's recent statement that ''Most single-source drugs face competition from other drugs that are therapeutic alternatives. CBO believes that there is little, if any, potential savings from negotiations involving those single-source drugs. We expect that risk-bearing private plans will have strong incentives to negotiate price discounts for such drugs and that the Secretary would not be able to negotiate prices that further reduce Federal spending to a significant degree. ''In accordance with the Medicaid best price exemption provided under section 1860D–2(d)(1)(c) of the Act and codified in § 423.104(h)(2) of our rule, drug plans may even be able to negotiate better prices than those paid under Medicaid. It also reflects Medicare's recent experience with drug price regulation for currently-covered drugs, in which regulated prices for many drugs have significantly exceeded market averages.

By not allowing us to require any particular formulary, the statute ensures that the Pharmacy and Therapeutics committees of prescription drug plans and MA PD plans have the flexibility to make changes in their classifications and lists of preferred drugs based on the most current evidence-based information (subject to the limitations of § 423.120(b)). Additional CMS guidelines on formulary review will be made available. However, in summary we will evaluate plan formulary categories and classes in comparison to the model guidelines developed by U.S.P. In addition to evaluating any discriminatory features, as discussed above, we have the authority to develop minimum standards and to negotiate the terms and conditions of the bid under section 1860D–11(d) of the Act. We also have the authority to promulgate additional contract terms (section 1860D–12(b)(3)(D) of the Act). Finally, we believe the structure of the Part D benefit, as laid out in section 1860D–2 of the Act, with a requirement for catastrophic coverage, anticipates a structure where beneficiaries receive coverage for medically necessary drugs. Therefore, we will evaluate the number of categories in formularies that do not meet the model guidelines and the choice of drugs available in those categories for meeting the needs of the Medicare population. After the initial year of the program, we will also review the history of plan formulary appeals to identify issues with the plan's formulary. We will conduct additional research on evaluating formularies and drug benefit designs and we would welcome comments on evaluation. As noted previously, we may also review plan cost sharing (that is, tiers). Our

formulary review will follow four important principles:

1. Rely On Existing Best Practices: Our review will rely on widely recognized best practices for existing drug benefits serving millions of seniors and people with disabilities to ensure non-discriminating, appropriate access;

2. Provide Access to Medically Necessary Drugs: We will require that drug plans provide access to medically necessary treatments for all and do not discriminate against any particular types of beneficiaries based on their expected drug costs;

3. Flexibility: We will allow plans to be flexible in their benefit designs to promote real beneficiary choice while protecting beneficiaries from discrimination; and

4. Administrative Efficiency: We will set up a process to conduct effective reviews of plan offerings within a compressed period of time.

Comment: Several comments were made regarding formulary structures that are likely to substantially discourage enrollment, with the majority merely expressing support for our regulatory text. Ten comments were received expressing concern over the definition of ''substantially discourage'', three of which called for dropping the word ''substantially'' from the regulation. One commenter specifically argued that step therapy for psychopharmacology should be considered as substantially discouraging. Another commenter simply stated that step therapy should be reviewed for discriminatory impact.

Response: The term ''substantially'' comes directly from the statute in section 1860D–11(e)(2)(D)(i) of the Act and therefore we do not believe it should be eliminated as some commenters recommended. According to research conducted for the Agency by Booz Allen Hamilton (''Drug Utilization Management and Quality Assurance Best Practices and Standards''), step therapy is one method of benefit design currently used by industry for the purpose of managing costs by requiring more cost effective drugs to be used before more expensive options are prescribed. Other research indicated the widespread use of this technique. For example, in its June 2004 ''Drug Trend Report,'' Express Scripts, a large pharmacy benefits manager, stated that the use of step therapy had risen from 4.5 million to 9.8 million lives between 2002 and 2004 for their members. Moreover, they report that step therapy with psychotropics, in particular antidepressants, is common among these members. Step therapy is also common among State Medicaid programs. Indeed, a 2003 report by the Georgetown University Health Policy Institute on behalf of the Kaiser Commission on Medicaid and the Uninsured found that 28 Medicaid agencies in 2003 used step therapy in their drug programs. The review process will examine the use of step therapy as a utilization control, but a categorical ban would be inconsistent with Congressional intent in Section 1860D–4(c)(1(A) of the Act, which calls on PDPs to have ''a cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate.'' As we have outlined, step therapy is one common method of drug utilization management. The Congress was aware that utilization management included step therapy, and they were also aware of that some stakeholders have objections to it as evidenced by the testimony given during the Subcommittee on Health of the Committee on Energy and Commerce hearing ''Designing a Twenty-First Century Medicare Prescription Drug Benefit'' on April 8, 2003. We will review step therapy and other formulary structures to ensure that they are not substantially discouraging. Accordingly, we will rigorously review formularies in a number of ways as part of the bid negotiation process. This review will include, but not be limited to: (1) reviewing the classes and categories in relation to the USP model; (2) reviewing the formulary to make sure that all appropriate treatments are available for certain complex diseases such as HIV; (3) where possible and appropriate, comparing the formularies and utilization management programs (including step therapies) to applicable treatment guidelines to make sure they support current treatment standards; and (4) comparing formularies between plans to identify outlier practices, which will include comparing plans for amount and specific drugs that they are including in step therapy, quantity limits and prior authorization.

Comment: One commenter indicated concern that SPAPs will incur significant costs if PDP sponsors' formularies are inadequate. We should establish a formulary evaluation criterion that would trigger a detailed evaluation of the adequacy for the formulary.

Response: Formularies will be evaluated according to the provisions of the statute. Regardless of the impact of specific plan formularies, we have estimated that Part D will save SPAPs approximately $3 billion between 2006—2010 (see the regulatory impact statement for more detail).

f. Bid Level Negotiation

The FEHBP standard in 5 USC 8902(i) requires us to ascertain that the bid ''reasonably and equitably reflects the costs of benefits provided.'' In addition, we note that section 1860D–11(e)(2)(c) of the Act requires that the portion of the bid attributable to basic prescription drug coverage must ''reasonably and equitably'' reflect revenue requirements . . . for benefits provided under that plan, less the sum ... of the actuarial value of reinsurance payments.'' Analogous to the manner in which FEHBP views its management responsibilities, we see this requirement as imposing the fiduciary responsibility to evaluate the appropriateness of the overall bid amount.

In general, we will evaluate the reasonableness of bids submitted by at-risk plans by means of the actuarial valuation analysis. This would require evaluating the plan's assumptions regarding the expected distribution of costs, including average utilization and cost by drug coverage tier, for example, in the case of standard coverage: (1) those with no claims; (2) those with claims up to deductible; (3) those with claims between the deductible and the initial coverage limit; (4) those with claims between the initial coverage limit and the catastrophic limit; and (5) those with claims in excess of the catastrophic limit. We could test these assumptions for reasonableness through actuarial analysis and comparison to industry standards and other comparable bids. Bid negotiation could take the form of negotiating changes upward or downward in the utilization and cost per script assumptions underlying the bid's actuarial basis.

Arguably, appropriate assurance that plan bids reasonably and equitably reflect the revenue requirements associated with providing the Part D benefit requires knowing the final drug price levels the plans are paying that are implicit in their bids. Consequently, in addition to looking at final aggregate prices, if we found that a plan's data differed significantly from its peers without any indication as to the factors accounting for this result, we could also ask bidders to provide information about rebates and discounts they are receiving from manufacturers and others, in order to ensure that they are negotiating as vigorously as possible. Section 1860D 11(b)(1)(C) of the Act allows us to ask for necessary ''information on the bid''. In other words, we will be able to inquire as to the ''net cost'' of drugs since this is the key dollar value we will need to make accurate ''apples to apples'' comparisons on drug prices between

PDPs. Under this approach, if the particular bids appear to be unusually high (or low), we could go back to the bidders and request that they explain their pricing structure, the nature of their arrangements with manufacturers, and we might ask further questions and take further action to perform due diligence to ensure that there is no conflict of interest leading to higher bids. For instance, we will look at certain indicators, such as unit costs or growth rates in the bid amounts to see if they are in keeping with private market experience to the extent feasible for a comparable population (for example, retirees). (In this case, we will be using the authority in 5 USC section 8902(i) to negotiate bids that are ''consistent with the group health benefit plans issued to large employers''.) If the overall bids were unjustifiably high, we will have the authority to negotiate the bids down to a level that is more in keeping with bids from other sponsors. We could exercise our authority to deny a bid if we do not believe that the bid and its underlying drug prices reflect market rates. Our strong expectation, however, is that we will be able to rely on the incentives provided by competitive bidding, and we will use our authority under this part only on the rare occasion we find that a plan's data differs significantly from its peers without any indication as to the factors accounting for this result.

Comment: Several comments were received on the MMA provision of ''authority similar to the authority of the Director of the Office of Personnel Management'' for the Federal Employee Health Benefits Program (FEHBP) when negotiating bids for Part D. One commenter referenced that in the preamble of the proposed rule, we stated that we were considering regulations similar to those used by Office of Personnel Management (OPM) in 48 CFR Chapter 16, which they note is comprised of 24 distinct parts and due to the lack of clarity with regard to the provisions of the OPM regulations were referring to they would be unable to comment. One health insurer asked that we clarify how our intended oversight would differ from the Similarly Sized Subscriber Groups (SSSGs) requirements in the FEHBP. Another commenter asserted that OPM negotiates an annual dollar cap on administrative expenditures that can be funded through premiums and that similar negotiations with MA plans would not be appropriate given that the MMA works on a competitive model. Two commenters suggested that broad use of the OPM authority would violate the noninterference clause in the MMA and that we should not review every plan during the bidding process in detail on pricing structure and the nature of arrangements with manufacturers. One commenter agreed with the Agency's interpretation of this authority in the proposed rule noting that nothing in our interpretation would ''set the price for any individual drug or even plans if aggregate price levels for groups of drugs were higher than prices observed among peer plans''.

Response: The section 1860D–11(d)(2)(B) of the Act authority will be used to review bids and negotiate changes consistent with the statute and regulation. Specifically, we intend to evaluate the reasonableness and appropriateness of the actuarial assumptions made in the bid. We will examine bids to determine whether the revenue requirements for qualified prescription drug coverage are accurate and reasonable. We also will examine administrative costs for reasonableness. We will review profit for reasonableness and appropriateness. We also will review the structure of the benefit plan design in terms of such features as premiums, deductibles, co-payments, and coinsurance charged to beneficiaries to ensure that it is not discriminatory.

There appears to have been confusion caused by our request for comments on 48 CFR Chapter 16. These OPM regulations assume applicability of the Federal Acquisition Regulation, which is not applicable to at-risk or limited risk Part D plans. Therefore we are not adopting any of the OPM regulations at this time. We will note however that our negotiating authority ''similar to the authority...of the Office of Personnel Management'' (section 1860D–11(d)(2)(B) of the Act) is in addition to our general authority to ''negotiate the terms and conditions of the proposed bid submitted and other terms and conditions of a proposed plan'' (Section 1860D–11(d)(2)A) of the Act). We have clarified the regulations to reflect these two separate authorities.

With regard to the application of a SSSG concept to Part D, we will note that the Part D program generally relies on competition to ensure reasonable bids. There is no authority to tie a sponsor's rate methodology to that used for a SSSG as applied under FEHBP with regard to community-rated plans. Therefore, we do not believe that this type of cross product line comparison will be appropriate at this time.

One comment correctly pointed out that there is no cap on administrative costs under Part C or Part D similar to the cap in effect in FEHBP experience rated plans. It is assumed that competition among plans will generally ensure reasonable bids. The Congress, however, did not leave the determination of rates entirely to market forces. We are required to determine that the reasonable and equitable test is met and is given negotiating authority to ensure this result. The initial review will focus in part on low and high cost outliers, and on bids in areas with little competition. It must be noted however, that bid outliers are not necessarily inappropriate, nor are bids within the measure of central tendency automatically correct. Indeed, an outlier bid may be reasonable and appropriate after additional review and explanation while an ''average'' bid could be based on incorrect actuarial assumptions. In summary, all bids will be reviewed for their reasonableness whether an outlier or not.

Two commenters seemed to suggest that they believe that the bid review authority will be used as a back door price control mechanism in direct violation of the non-interference provision of section 1860D–11(i) of the Act, which directs the Secretary to not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and to not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs. In the proposed rule we interpreted the non-interference provision as prohibiting us from setting the price of any particular drug or from requiring an average discount in the aggregate on any group of drugs (such as single-source brand-name drugs, multiple-source brand name drugs, or generic drugs), but allowing us to require justification of aggregate price levels. In addition, although we are prohibited from negotiating the price levels of drugs, it is authorized to negotiate the level of the overall bid. We will evaluate the reasonableness of costs submitted by at-risk plans bids through actuarial valuation analysis, and noted that this might require information regarding the plan's assumptions about expected distribution of costs, including average utilization and price by drug coverage tier, for: (1) those with no claims; (2) those with claims up to deductible; (3) those with claims between the deductible and the initial coverage limit; (4) those with claims between the initial coverage limit and the catastrophic limit and 5) those with claims in excess of the catastrophic limit. Through actuarial analysis, these assumptions will be tested for reasonableness, and compared to industry standards and other

comparable bids. We also want to clarify that we do not intend on universally requiring plans to submit detailed information on pricing structure and the nature of arrangements with manufacturers. Requests for additional and more detailed information will only be triggered questions involving the initial bid submission. We are confident that additional bid submission guidance will limit such occurrences from happening. We believe that this interpretation ensures that we fulfill our duty to review bids for reasonableness while avoiding any direct interference in the negotiations between manufacturers, pharmacies, and PDP sponsors.

Under the previous Medicare+Choice program, we permitted Medicare+Choice organizations to waive premiums or to offer mid-year benefit enhancements to their benefit packages. However, in order to maintain the integrity of the bidding process, we believe that it is no longer appropriate to allow either MA organizations or PDP sponsors to waive premiums or offer mid-year enhancements as they will be de facto adjustments to benefit packages for which bids were submitted earlier in the year.

These adjustments would be de facto acknowledgement that the revenue requirements submitted by the plan were overstated. Allowing premium waivers or mid year benefit enhancements would render the bid meaningless. Excessive amounts included in the bid will be subject to recovery by the government in the risk corridor calculations following the coverage year.

Consequently, we interpret the statutory provisions on competitive price negotiation as prohibiting us from setting a regulated price of any particular drug or imposing by regulation an average discount in the aggregate on any group of drugs (such as single-source brand-name drugs, multiple-source brand name drugs, or generic drugs), but as allowing justification of aggregate price levels for groups of drugs. In addition, we could, under the specific circumstances previously discussed, negotiate regarding the level of the overall risk bid. This approach will allow us to exercise the authority similar to FEHBP as visualized in the MMA to ensure that per capita rates charged reasonably and equitably reflect the cost of the benefits provided, and that beneficiaries receive the full benefits of vigorous price negotiation by their drug plans.

g. Approval of Plans

After negotiations on the terms and conditions of the bid, we must approve or disapprove the bid. After negotiations, we will approve a plan only if—

- The plan is found to be in compliance with requirements specified in this regulation;
- The plan meets the actuarial valuation requirements; and
- The plan design does not discourage enrollment by certain eligible beneficiaries.

In § 423.272(c), we approve limited risk plans only if fewer than two qualifying prescription drug plans offered by different entities, one of which must be offered by a stand-alone PDP sponsor, were submitted and approved in a region. We will approve only the minimum number of limited risk plans needed to meet these access requirements and will give priority to plans bearing the highest levels of risk; however, we may take into account the level of the bids submitted by these plans. Except as authorized under section 1860D–11(g) of the Act and in § 423.863 with regard to fallback plans, we will not, under any circumstances, approve a plan that elected to bear no risk or a de minimis level of risk.

Comment: One comment urged that we should reject bids that result in only one PBM operating as a subcontractor to all the plans in a given region.

Response: The statute does not give us the authority to do this. The statute mandates that beneficiaries have the choice of at least one PDP in an area in addition to whatever MA-PD options are available. The number of PBMs that contract with the PDP sponsors and MA organizations has no bearing on the access requirements.

h. Special Rules for PFFS Plans

As provided in section 1860D–21(d) of the Act, and codified in § 423.272(d), PFFS plans that offer prescription drug coverage are exempt from review and negotiation (under sections 1860D–11(d) and (e)(2)(C) of the Act) of their prescription drug bids and premium amounts but are otherwise subject to all other requirements under this part, with the following exceptions. While we will not negotiate PFFS bids, those bids must meet the actuarial valuation requirements applicable to all risk bids. These plans are not required to negotiate discounted prices for prescription drugs. If they do negotiate, the requirements under § 423.104(h) related to negotiated prices will apply. If the plan provides coverage for drugs purchased from all pharmacies, without charging additional cost sharing, and without regard to whether they are participating pharmacies, § 423.120(a) and § 423.132 of this rule (requiring certain network access standards and the disclosure of the availability of lower cost bioequivalent generic drugs) will not apply to the plan. PFFS plans are also exempt from drug utilization management program and medication therapy management program requirements.

Finally, we note that section 1860D–21(d)(7) of the Act provides that costs incurred for off-formulary drugs will not be excluded in determining whether a beneficiary has reached the out-of-pocket threshold if a PFFS plan does not use a formulary. We believe that section 1860D 21(d)(7) of the Act is a tautology and simply states that PFFS plans without formularies, by definition, cannot have non formulary drugs to exclude from the out-of-pocket threshold calculation.

7. National Average Monthly Bid Amount

In § 423.279, we outline the calculation of the national average monthly bid amount. For each year, beginning in 2006, we will compute a national average bid based on approved bids in order to calculate the national base beneficiary premium. As a practical matter, we realize that we might need to calculate and announce the national average monthly bid amount before negotiations on all bids were completed in order to allow time for finalization of premiums and benefit packages. Therefore, we anticipate that we will identify a date by which the national average monthly bid amount will be published, and we will use the bids that had passed a certain level of approval as of that date as the basis for the calculation.

As provided in section 1860D 13(a)(4)(A) of the Act, in computing the national average monthly bid amount, we will exclude bids submitted for MA private fee-for-service (PFFS) plans, specialized MA plans for special needs individuals, PACE programs under section 1894 of the Act (pursuant to section 1860D–21(f) of the Act) and reasonable cost reimbursement contracts under section 1876(h) of the Act (according to section 1860D–21(e) of the Act). The exclusion from the calculation of bids of PFFS, cost plans, specialized MA plans, and PACE suggests that they are different from, and not comparable to, the average bid in some way. We interpret this difference to be based solely on price levels because the legislation—

- Does not define any other basis for determining these bids;
- Continues to compare these bids to the national average bid amount to determine adjustments to enrollee premiums; and

• Generally, provides for payments to such plans (including risk adjustment) in the same manner as to non-excluded plan types—except that PFFS plans receive reinsurance payments according to estimates—and not actual costs and are not eligible for risk corridor payments.

Therefore, these excluded plan types will still submit bids on the same basis as all other plans, that is, the 1.0 risk prescription drug plan beneficiary, even though these bids are not included in the national average bid amount at this time.

The national average bid amount will be equal to the weighted average of the standardized bid amounts for each PDP and for each MA-PD plan described in section 1851(a)(2)(A)(1) of the Act. The national average monthly bid amount will be a weighted average, with the weights being equal to the proportion of Part D eligible individuals enrolled in each respective plan in the reference month (as defined in § 422.258(c)(1)). For calendar year (CY) 2006, we will determine the enrollment weights on the basis of assumptions that we will develop. In the August 2004 proposed rule we outlined that one possible approach would be to use the following procedure to assign weights to individual bids for PDPs and MA-PD plans for CY 2006:

• Obtain total Medicare enrollment by region, and enrollment in each (local) MA plan that offers a drug benefit by region. These enrollments will be as of a specific date, for example, March 31, 2005.

• Assign each (local) MA-PD plan in each region a weight equal to its MA enrollment.

• Subtract the MA enrollment from the total Medicare enrollment for each region to arrive at the PDP-eligible enrollment.

• Divide the PDP-eligible enrollment for each region by the number of companies offering PDPs in each region to arrive at the weight for each company in each region.

• For each company in a region, divide the company weight by the number of plans offered by that company to arrive at the PDP weight.

• The regional average monthly bid amount will be calculated by weighting each plan's bid by its assigned weight.

• The national average monthly bid amount will be calculated by weighting each regional average monthly bid amount by the region's proportion of Part D eligible individuals (Medicare enrollment) and summing these products.

Using this methodology, after subtracting MA enrollments, each company offering PDP(s) in a region gets equal weight. An exception might occur based on capacity limits indicated by MA-PD plans. This assumes that beneficiaries will select a company, and then select a plan from that company. It also dilutes the effect of any potential artificially high bids designed solely to increase the national average monthly bid amount. If a company offers multiple plans in a region, each plan gets an equal allocated share of its company's assigned weight.

New MA-PDs will get a zero weight. This treatment is consistent with the weight assignment specified in the statute for subsequent years. Starting with the second year, all new plans will get zero weight because they have no prior year enrollment. We request comments on the ''unequal'' inclusion of plans in the calculation of the national average monthly bid. We note that many MA PDs will operate in small geographic areas with small potential enrollment, and so we believe that the impact of this approach for new local MA-PDs is likely limited. We recognize, however, that this approach is perhaps more problematic related to the treatment of the new regional MA-PD plans, as these plans in a given region are likely to have larger enrollment than local MA-PD plans. This particular approach implicitly assigns persons in new MA PD plans (both local and regional) to the PDP weights, hence giving potentially too much weight to the PDPs.

Alternatively, assigning equal weights to PDPs and new MA PD plans (even if limited to just the regional MA-PDs) could likely assign too much weight to the new regional MA PD plans, which at least in 2006 are expected to have lower enrollment. Another possible alternative would be to base weights on regional MA-PD plan projections of enrollment, subject to our assessment of reasonableness of the estimates. In this approach we would use the proportion of projected enrollment for each plan as weights. However, particularly in the first year or so, projections may be quite inaccurate, leading to a distorted and unrepresentative benchmark. In the proposed rule we requested comments on these and other alternative approaches for how to weight bids in 2006.

Note that in this methodology the assigned weights are price inelastic, that is, the recommended weight assignment methodology implies that price is not a factor in plan selection. We recognize that in reality this is not the case, but in the absence of data on which to base the relationship between price and plan choice in this population for this benefit we cannot model the effect of price variations on demand. We believe that the fairest method that is feasible for 2006 is simply to assume an equal weight for each plan.

In subsequent years, the weights for the weighted average would be calculated as a percentage with the numerator equal to the number of Part D eligible individuals enrolled in the plan in the reference month and the denominator equal to the total number of Part D eligible individuals enrolled in all plans (except for those plans whose bids are not include in the national average bid amount, as described above) in the reference month. It represents the proportion of the Part D eligible enrolled individuals in the plan. We would multiply the portion of each plan bid attributable to basic benefits by its proportion of total Part D enrolled individuals and sum each product to arrive at the national average monthly bid. In § 423.279(c), we would also establish an appropriate methodology for adjusting the national average monthly bid amount to take into account any significant differences in prices for covered Part D drugs among PDP regions. As part of carrying out the Congress' requirement that our geographic adjustment methodology be ''appropriate,'' we believe the method would first require gathering data from PDPs and MA-PDs on regional drug prices. Therefore, we may not implement a geographic adjuster for the first few years of the program unless we have acquired sufficient information on pricing to accurately characterize that variation. If we were to determine that there is significant geographic variation in prices, we anticipate that we would announce the adjustment factors in advance of the bidding process for any year in which geographic adjustment would be applied to bids in the calculation. This would be subject to notice and comment like any other change in payment methodology and therefore would be announced in the 45-day notice in advance of the bidding process for that year. If we were to determine that there is only minimal price variation, we would not implement a geographic adjuster for the national average monthly bid calculation. Additionally, we would implement any geographic adjuster in a budget neutral manner to avoid a change in aggregate payments from the total amount that would have been paid if we had not applied an adjustment.

Comment: We received five comments on the proposed weighting methodology for the first year. One health insurer suggested that any of the CMS proposals would be acceptable. Another

commenter focused on the PDP portion of the first approach, supporting the equal weighting of PDP sponsors. Another health insurer urged that all MA plans be counted, reasoning that virtually all MA plans would offer Part D. They also stated their support for giving no weight to new MA-PDs. An industry association suggested that new MA plans, including regional PPOs and PDPs, should be weighted based on their projected enrollment as suggested in the final alternative proposed in the proposed rule. Another health insurer urged that we assign MA-PD weights based on projected enrollment, but they did not comment on weighting for PDPs.

Response: Although none of the approaches outlined in the proposed rule, or by commenters, are perfect we have decided that using MA enrollment from a reference month for MA-PDs (new MA-PDs are assigned a zero weight) and assigning equal weighting to each sponsor (other than fallback entities) for the PDP-eligible enrollment in the region is the superior choice. This option most closely mimics how the enrollment weighting will be calculated in the future given that it uses reference month data for MA-PDs and assigns new MA-PDs a zero weight. The PDP portion of the method is the fairest method for 2006, given that we cannot know enrollment prior to the launch of the drug benefit program. Alternative weighting methodologies using projected enrollment are fraught with problems. How would the validity of such projections be assessed? What if the aggregate plan projections exceeded the total number of Part D eligibles in the region? No commenter offered any suggestions for dealing with such dilemmas. We note these comments suggested the need to clarify that the weighted average does not work unless restricted to Part D plans that submit bids and are included in the national average bid amount. Accordingly, we modified § 423.279 to clarify that the denominator does not include Part D eligible individuals enrolled in fallbacks, MA private fee-for-service plans, specialized MA plans for special needs individuals, PACE programs under section 1894 of the Act, and contracts under reasonable cost reimbursement contracts under section 1876(h) of the Act.

Comment: One commenter believes that MA-PDs would consistently have lower bids and including them in the benchmark would disadvantage PDPs. They suggest that MA-PDs and PDPs have separate benchmarks.

Response: Section 1860D–13(a)(4)(A) of the Act instructs the Secretary to ''compute a national average monthly bid amount equal to the average of the standardized bid amounts (as defined in paragraph (5)) for each prescription drug plan and for each MA-PD plan described in section 1851(a)(2)(A)(i) of the Act.'' Therefore we cannot have separate benchmarks for MA-PDs and PDPs.

Comment: One commenter stated that we should calculate a unique benchmark for Specialized Needs Plans in recognition of the higher prescription drug costs these plans will have in providing coverage to the high-risk population that they serve.

Response: In § 423.279(a) we state that bids from specialized MA plans for special needs individuals will not be included in the national average monthly bid amount or benchmark. However, the payments to the special needs plans as with all plans will be risk adjusted to take into account the differences in enrolled populations.

Comment: Several comments were received concerning geographic adjustment. Three health insurers urged that geographic adjustment be implemented immediately. Another health insurer suggested that geographic adjustment not be implemented until we have acquired sufficient information on pricing to accurately characterize any variation. One commenter urged us to explore other unit price data beyond the Federal Employee Health Benefits Program data from Blue Cross Blue Shield because using a single data source may misstate actual regional variations. One health insurer urged that adjustments be made both within and between regions. Another health insurer asked that regional variations in prescription drug costs be examined based on utilization, not price.

Response: Section 1860D–15(c)(2)(A) of the Act directs the Secretary to establish an appropriate methodology for adjusting the national average monthly bid amount (computed under section 1860D–13(a)(4) of the Act) to take into account differences in prices for covered Part D drugs among PDP regions.'' To meet the appropriateness standard we will not implement a geographic adjustment until we have acquired sufficient information on pricing to accurately characterize any variation. We reiterate that we will announce the adjustment factors in advance of the bidding process for any year in which geographic adjustment would be applied to bids in the calculation. We would also note that our authority for geographic adjustment is based on differences in price not utilization. Section 107(a) of the MMA requires a report and recommendations on adjusting for geographic differences in both price and utilization (not explained by the risk-adjuster). This report is due not later than January 1, 2009.

8. Rules Regarding Premiums

In § 423.286, the monthly beneficiary premium will be the result of the calculation of a national base beneficiary premium subject to certain adjustments. Congressional intent was to arrive at an average monthly beneficiary premium in CY 2006 representing a certain percentage of the average total estimated benefit provided by the drug plans on a national basis (including benefits subject to Federal reinsurance subsidies). Taking into account that projected reinsurance subsidies are excluded from plan bids, the applicable percentage becomes approximately 34 percent, which is applied to the national average monthly bid amount.

To determine the uniform plan premium, in § 423.286(d), we will adjust the base beneficiary premium for certain plan characteristics including whether the plan's bid will be above or below the national average bid, and whether the plan offers supplemental benefits. (Since the bid has to be approved and premiums established for the entire year, we are interpreting the phrase ''if for a month'' in section 1860D–13(a)(1)(B)(i) of the Act and 1860D–13(a)(1)(B) (ii) of the Act as referring to the beneficiary premium as a monthly amount.) The base premium is adjusted to reflect the full difference between the plan's standardized bid amount and the national average monthly bid amount (which may be adjusted for regional price differences if evidence for such differences exists as determined in § 423.279(c)). To the extent that the plan's standardized bid amount is below the national average monthly bid amount, the base premium is adjusted downward by the difference. To the extent that the plan's standardized bid amount is above the national average monthly bid amount, the base premium is adjusted upward by the difference. The base premium will also be adjusted by adding the premium amount approved after negotiations for risk adjustment of the supplemental benefits, if any (as discussed above). Table F–2 illustrates a calculation of the base beneficiary premium and the adjustment for the difference between the bid and the national average monthly bid amount.

TABLE F–2
PREMIUM ILLUSTRATION

Benchmark	Plans in Region	Bids	Beneficiary Premium		
National Average Monthly Bid Amount[1]	Plans	Approved Plan Bid	Amount by which Bid Exceeds Benchmark	Amount by which Bid is Below Benchmark	Applicable Percent of Nat'l Premium +/- Difference
	Plan 1	123	14.00	0.00	$51
109	Plan 2	109	0.00	0.00	$37
	Plan 3	99	0.00	(10.00)	$27
Est. Reinsurance Percentage			25.80	(Assumed)	
Applicable Percent =			0.3437	(25.5 /(100–25.80)	
Base Beneficiary Premium =			37.00	(109 * .3437)[2]	

[1] Assumes no geographic adjustment
[2] Rounded to nearest dollar

The sum of the base beneficiary premium, the adjustment for difference between the bid and the national average bid, and the supplemental benefit premium will be the monthly beneficiary premium. The monthly beneficiary premium (except for any supplemental premium) will be eliminated or reduced for low-income subsidy-eligible individuals, as described in section 1860D–14 of the Act and § 423.780. (This adjustment reflects the fact that the government will pay all or a portion of the monthly beneficiary premium for subsidy-eligible individuals.)

In § 423.286(d)(3), the monthly beneficiary premium will be increased for enrollees subject to the late enrollment penalty. The penalty amount for a Part D eligible individual for a continuous period of eligibility (as described in § 423.46) will be the greater of an amount that we determine is actuarially sound for each uncovered month in the same continuous period of eligibility; or 1 percent of the base beneficiary premium for each uncovered month in that period. The beneficiary premium amount is cumulative which means that each month the beneficiary is subject to a penalty, the penalty accumulates. Once the beneficiary enrolls in Part D, that accumulated penalty will be added to their premium amount each month. So for example, if the penalty amount is 1 percent of the estimated base beneficiary premium above, or $0.37 per month in 2004, and is subject to 12 months of this penalty, the beneficiary would pay an additional $0.37 * 12 or $4.44 per month for as long as they are enrolled in Part D. During the first several years of the program, we currently expect that we would specify the penalty amount would be 1 percent of the base beneficiary premium per month. Once we have sufficient data on experience under the program for individuals who enroll after their Initial Enrollment Periods, we would be able to determine the appropriate penalty amount, that is, either one percent or a greater amount to be adopted.

We note that achieving very high (indeed, virtually universal) access to prescription drug coverage for beneficiaries who participate in Part D was a key Congressional consideration in enacting MMA.

Except as provided with regard to any enrollment penalty, low-income assistance, or employer group waivers under section 1857(i) of the Act and section 1860D–22(b) of the Act and § 423.458(c) (as discussed in subpart J of the preamble to our rule), the monthly beneficiary premium for a prescription drug plan or MA-PD in a PDP region must be the same for all Part D eligible individuals enrolled in the plan. The monthly beneficiary premium charged under a fallback plan is discussed in § 423.867 of our rules and in subpart Q of this preamble.

Comment: Section 1860D–13(a)(1) of the Act establishes that the monthly beneficiary premium is the base beneficiary premium adjusted to reflect the differences between the plan's bid and the national average bid. Two commenters argued that the statute anticipated that Part D providers may bid so far below the national average bid as to have a negative premium. Both commenters assert that we were wrong to interpret in the August 2004 proposed rule that negative premiums were not allowable by statute. Both proposed that it would be a greater benefit to beneficiaries if CMS were to require a Part D provider with such a low bid ''to return the value of the savings'' to the beneficiary in the form of an enhanced benefit that would be covered by the enhanced direct subsidy.

Response: We agree with the commenters' textual interpretation of the formula in the statute. Factoring out the impact of risk adjustment, the direct subsidy in absolute dollars is uniform to all plans. For the negative premium plans, the proposed rule would have offered such plans less than everyone else. We agree with the commenters that highly efficient plans that bid below the benchmark should not receive less. However, it is clear that the statute did not necessarily envisage negative premiums for there are no clear directives on how the negative premium dollars should be treated. We believe that direct rebates to beneficiaries might run into Federal anti-kickback law issues, although a definitive opinion from the Office of Inspector General has not been issued. There are other

potential issues with a direct rebate. For example, it is likely that some significant portion of the plan enrollees will lose the rebate check or never cash it, thus resulting in an overpayment to the plan sponsor. Direct deposit of the rebate in the enrollee's bank would address this problem, but would generate significant administrative costs. Nevertheless, neither of the commenters argued for beneficiary remuneration. Indeed, both expressed a desire for the negative premium dollars to be allocated to supplemental benefits, a position we agree with. This would require allowing a ''renegotiation'' of the benefit package once the national average bid (and the negative premium) are known, to incorporate the negative premium as supplemental benefits for which there would be no additional enrollee premium. Any marginal effects in the basic bid would be negotiated at the same time. As supplemental benefits, the dollars must be accounted for in the benefit package, and there will be no risk sharing on the amount. The review and negotiation of bid and approval of plans submitted by potential PDP sponsors or MA organizations planning to offer MA-PD plans (§ 423.272) and the rules regarding premiums (§ 423.286) in this subpart have been amended to reflect this change.

9. Collection of Monthly Beneficiary Premiums

a. Means of Collection

In § 423.293(a), the beneficiary will have the same options on the method for premium payments as under Part C. Section 1860D–13(c)(1) of the Act applies the provisions of section 1854(d) of the Act (as amended by the MMA) to Part D premium collection. The beneficiary will have the option of having the amount withheld from his or her Social Security benefit check similar to the way Part B premiums are withheld. Beneficiary premium payments could also be paid directly to the PDP sponsor or MA organization through an electronic funds transfer mechanism (for example, an automatic charge of an account at a financial institution or a credit or debit card account). We could specify other means of payment, including payment by an employer or under employer-based retiree health coverage (as defined in section 1860D 22(c)(1) of the Act) on behalf of an employee or former employee (or dependent). All premium payments withheld from Social Security checks will be credited to the appropriate Trust Fund (or Account) and will be paid by us to the PDP sponsor or MA organization involved. Premiums from beneficiaries enrolled in fallback plans will not be collected by the plan. Instead, these premiums will be withheld from Social Security checks (or from other benefits as permitted under section 1840 of the Act). Beneficiaries who do not receive Social Security checks or otherwise have premiums deducted from other benefits or annuities will pay us directly. Failure to make premium payments could result in disenrollment as provided under section 1854(d)(1) of the Act and § 423.44(d) of our regulations.

b. Collection of Late Enrollment Penalties

Concerning collection of the late enrollment penalty calculated under § 423.286(d)(3), after the early years of the program we will estimate and specify the portion of the penalty that will be attributable to increased actuarial costs assumed by the PDP sponsor or MA organization (and not taken into account through risk adjustment provided under § 423.329(b)(1) or through reinsurance payments under § 423.329(c)) as a result of that late enrollment. When the premium is withheld from social security benefits, we will pay only the portion of the late enrollment penalty attributable to the increased actuarial costs to the PDP sponsor or MA organization. When the premium is paid directly to the plan, we will reduce payments otherwise made to the PDP sponsor or MA organization by an amount equal to the amount of the enrollment penalty not attributable to increased actuarial cost. (Fallback plans will not receive any enrollment penalties applicable to their enrollees because they are not at risk.)

At least in the initial years of the program we do not anticipate paying plans additional funds related to late enrollment individuals. In the initial years there will not be a significant number of people who can have delayed enrollment for a significant period of time. Moreover, in the initial years of the program the risk corridors are more generous and afford more protection. Consequently we do not think it is necessary to provide a portion of the enrollment penalty to plans until experience indicates that actual risk has increased.

Comment: Several States urged that § 423.293(a) include State Pharmacy Assistance Programs (SPAPs) as a payment option for premiums.

Response: Section 423.293(a) references paragraph (c) of the section, which in turn references § 422.262(f)(1). Beneficiary premiums in § 422.262(f)(1) allow premiums to be paid by the beneficiary through Social Security withholding, electronic funds transfer; or by an employer, employment-based retiree health coverage or by other third parties such as a State, which will include SPAPs. This rule is being adopted as final in the MA final rule, and will therefore have final effect for the Part D rule as well. Therefore, SPAPs will be able to pay premiums on behalf of enrollees.

Comment: One advocacy group asked that credit cards not be allowed to pay Part D premiums. It is their position that funds transfer mechanisms are error prone.

Response: Section 1860D–13(c)(1) of the Act states that the provisions of section 1854(d) of the Act apply to PDP sponsors in the same manner as they apply to MA organizations and beneficiary premiums under Part C. Section 1854(d)(2)(B) of the Act states that an MA organization ''shall permit each enrollee ... to make payment of premiums ... through an electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account).'' Given that the Congress specifically stated electronic funds transfer will include credit or debit card accounts, we cannot prohibit their use.

Comment: One commenter asked if cost plans could be allowed to have their premiums deducted from SSA checks.

Response: An enrollee of a cost plan with Part D may pay their Part D premiums through reduction of their SSA check. The statute however, does not give us the authority to mandate an SSA check payment option on the Part C side, but we are capable of permitting withholding if acceptable to concerned parties.

Comment: We received several comments concerning the late enrollment penalty. While there was universal support for having a late enrollment penalty, there were disagreements regarding the amount of the penalty. Four commenters suggested that 1 percent of the base beneficiary premium may not be sufficient to control for adverse selection, but none had a recommendation for a higher amount. By contrast, another commenter suggested that beneficiaries will likely enroll late due to confusion. They therefore concluded that the late enrollment penalty should be less than 1 percent of the base beneficiary premium. One commenter urged us to collect data as quickly as possible to calculate a penalty amount that fairly reflects any higher costs associated with beneficiaries who delay their enrollment.

Response: Although, Part D enrollment is voluntary it is sound policy to try limiting adverse selection, or the tendency for persons with high utilization or risk to enroll in health insurance while healthy persons with no or low utilization do not, thus creating an unbalanced or biased population. To provide an incentive to enroll, the Congress created a late enrollment penalty in Section 1860D–13(b) of the Act, which is the greater of ''an amount that the Secretary determines is actuarially sound for each uncovered month'' or is ''1 percent of the base beneficiary premium''.

There is a paucity of relevant research in this area. Our only potentially relevant experience comes from the Part B late enrollment penalty, which is 10 percent per 12-month period. On average about 5 to 6 percent of Medicare Part A enrollees are not enrolled in Part B. It should be noted however, that a significant proportion of eligibles not enrolled in Part B are either working aged or are living overseas. Additionally, the utilization patterns and risks for Part B services and Part D drugs are different. Therefore, the Part B experience may not predict beneficiary behavior for Part D. Accordingly, we will set the late enrollment penalty at 1 percent of the base beneficiary premium and revisit the issue when appropriate data are available.

G. Payments to Part D Plan Sponsors For Qualified Prescription Drug Coverage

1. Overview (§ 423.301)

Subpart G of part 423 implements section 1860D–15 of the Act and the deductible and cost sharing provisions of section 1860D–14(a) of the Act. This section sets forth rules for the calculation and payment of our direct and reinsurance subsidies for Part D plans; the application of risk corridors and risk-sharing adjustments to payments; and retroactive adjustments and reconciliations to actual enrollment and interim payments. References to § 422 of our regulations are to the new MA rules. In general, the payment rules in this subpart do not apply to fallback plans—which are discussed in subpart Q

2. Definitions

We proposed definitions of a number of terms used in the computation of payments under this subpart, such as ''allowable reinsurance costs'', ''actually paid'' and ''coverage year'' in § 423.308 of our regulations, but discussed these separately in the appropriate sections of this preamble. We did this because these terms are complex and are best clarified in the context of the discussion of the pertinent provisions. We wish to clarify that a covered Part D drug for gross prescription drug costs means a Part D drug, as defined in § 423.100, that is included in a prescription drug plan's or MA-PD plan's formulary, or treated as being included in a plan's formulary as a result of a coverage determination or appeal under § 423.566, § 423.580, and § 423.600 of our rule.

3. General Payment Provisions (§ 423.315)

The payment provisions required by section 1860D–15 of the Act include the following four different payment mechanisms: 1) the direct subsidy; 2) reinsurance subsidies; 3) risk corridor payment adjustments; and 4) payments to cover certain premium, cost-sharing, and extended coverage subsidies for low-income subsidy eligible individuals.

The first payment mechanism involves monthly payments that (along with reinsurance subsidies) subsidize on average 74.5 percent of the value of the basic prescription drug benefit, thereby maintaining beneficiary premiums for basic coverage on average at 25.5 percent. The direct subsidy is determined based on a national bidding process. Sponsors who wish to offer plans submit bids on a standardized basis. After our review and approval, these bids become the basis for the direct subsidy that is equal to the plan's standardized bid, risk adjusted for health status as provided in § 423.329(b), minus the base beneficiary premium (as determined in § 423.286(c) and as adjusted for any difference between the standardized plan bid and the national average monthly bid amount (as described under § 423.286(d)(1))). The risk adjustment applied to the bid compensates the plan for individual enrollee differences in health status from the average beneficiary and thus reduces the impact from any adverse risk selection. Further adjustments to the direct subsidy payments will be made to account for actual enrollment and updated health status information.

The second and third payment mechanisms will substantially reduce the uncertainty and risk of participating in this new program. Since the Medicare prescription drug benefit is new, there is uncertainty surrounding the utilization, costs, and risk profiles (participation rates and characteristics) of potential enrollees. Federal reinsurance subsidies and risk corridor payment adjustments work along with the risk adjustment included in the direct subsidy to substantially reduce the uncertainty and risk of participating in this new program. Through reinsurance subsidies, in which we act as the re insurer, we will subsidize a large portion of any catastrophic expenses (defined as expenses over an individual's out-of-pocket limit) through a reinsurance subsidy. Through risk corridor arrangements, exposure to unexpected non-catastrophic expenses will be limited. These risk sharing arrangements are structured by the statute as symmetrical risk corridors, that is, agreements to share a portion of the losses or profits resulting from expenses above or below expected levels, respectively.

Finally, according to section 1860D–14 of the Act, PDP sponsors and MA organizations will receive payments to cover certain premium, cost-sharing, and extended coverage subsidies for low-income subsidy eligible individuals. With the exception of interim estimated payments of cost-sharing subsidies, these payments are discussed separately in subpart P of this preamble and in § 423.780 of our regulations.

Certain payments will be exceptions to these general payment provisions. Under private fee-for-service (PFFS) plans, reinsurance will be calculated differently and risk sharing will not be available. Reinsurance subsidies and risk sharing will not be available for fallback plans, which are paid in accordance with contractual terms related to actual costs and management fees tied to performance measures.

Comment: One commenter responded with support for immediate implementation of a reinsurance demonstration that would increase opportunities to fill in the donut hole in the Part D benefit and allow for a more predictable revenue flow that would support enhanced benefits for beneficiaries.

Response: The Conference Committee noted, ''the conditions under which the government provides reinsurance subsidies may create significant disincentives for private sector plans to provide supplemental prescription drug coverage. To address this concern, the conference agreement suggested use of the Secretary's current Medicare demonstration to ''allow private sector plans maximum flexibility to design alternative prescription drug coverage.'' CMS's authority to conduct Medicare demonstrations is provided in section 402 of the Social Security Amendments of 1967 (42 U.S.C. § 1395b–1). Under section 402(b), the Secretary is authorized to waive requirements in title XVIII that relate to reimbursement

and payment. The conferees specifically stated that CMS should demonstrate the effect of filling in the gap in coverage by reimbursing participating plans a capitated payment that is actuarially equivalent to the amount that plans would otherwise receive from the government in the form of specific reinsurance when an individual plan enrollee reaches the catastrophic attachment point ($3,600). They clarified that CMS would not be permitted to waive the minimum benefits provided by the plans. In the August proposed rule we stated in the executive summary that we were considering establishing a demonstration to evaluate possible ways of achieving extended coverage.

We intend to conduct a reinsurance demonstration that represents an alternative payment approach. We are working on the design of the budget neutral demonstration and issue separate guidance in the near future.

4. Requirement for Disclosure of Information (§ 423.322)

a. Data Submission.

As provided under sections 1860D 15(c)(1)(C), 1860D–15(d)(2) and 1860D–15(f) of the Act and in § 423.322 of our regulations, we will condition program participation and payment upon the disclosure and provision of information needed to carry out the payment provisions. Such information will encompass the quantity, type, and costs of pharmaceutical prescriptions filled by enrollees that can be linked to individual enrollee data in our systems; that is, linked to the Medicare beneficiary identification number (HIC#). In the August proposed rule we asked for comments on the content, format and optimal frequency of data feeds. We stated that more frequent feeds (that is monthly or quarterly) would allow us to identify and resolve data issues and assist the various payment processes.

We have evaluated our minimum data requirements with regard to prescription drug claims. Our goal is to have the least burdensome data submission requirements necessary to acquire the data needed for purposes of accurate payment and appropriate program oversight. Our view is that we will need at least the following data categories for 100 percent of prescription drug claims for the processes discussed below:

- Beneficiary identification (for example, HIC#, date of birth, gender, name)
- Prescription identification information (for example, RX identification number, NDC, quantity dispensed, fill number, date of service)
- Cost information (for example, ingredient cost, dispensing fee, sales tax, total gross cost)
- Payment information (beneficiary amount paid, low income cost sharing subsidy amount, secondary/other payer amount, supplemental amount)

We assume that ingredient cost and dispensing fee reflect point of sale price concessions in accordance with purchase contracts between plans (or their agents, such as PBMs) and pharmacies, but do not reflect subsequent price concessions from manufacturers, such as rebates. We will need these data on prescription drug claims for appropriate risk adjustment, reconciliation of reinsurance and low-income subsidies, calculation of risk sharing payments or savings, and program auditing. Data will also be required for assessing and improving quality of care. We asked for comments on the nature and format of data submission requirements based on the following requirements:

- The risk adjustment process will require 100 percent of drug claims in order to develop and calibrate the weights for the model for this new benefit. Consequently, PDP sponsors and MA organizations offering MA-PD plans will be required to submit 100 percent of prescription drug claims for Part D enrollees for the coverage year. Risk adjustment will require the submission of prescription drug agent identifying information, such as NDC codes and quantity, in order to allow the standardized pricing of benefits in the model. Because we will use standardized pricing in the model, cost data on each prescription is not a requirement for risk adjustment, although it is needed for other purposes.
- The reinsurance subsidy payment process will require 100 percent of claims for each enrollee for whom the plan claimed allowable reinsurance costs. (Although reconciliation of the reinsurance subsidy does not require NDC codes or quantities, it does require member, cost and date of service data.) All claims for enrollees with expenses in excess of the out-of-pocket limit will be necessary to verify that the costs are allowable because the totality and order in which the claims are incurred will define which claims will be eligible for reinsurance payments. While the start of reinsurance payments begins with claims after the out-of-pocket threshold has been reached, which is $5,100 in total spending (2006) for defined standard coverage, it may be associated with a higher dollar total spending amount under alternative coverage. Whatever the level, we will need to receive all claims by date of service including the amount of beneficiary cost sharing in order to determine the occurrence of the out-of-pocket threshold. Any plan-incurred costs for claims for supplemental benefits cannot be included in determining whether the out-of-pocket threshold has been met.
- The risk sharing process will require 100 percent of claims for all enrollees for the calculation of total allowable risk corridor costs. The plan will need to segregate costs attributable to supplemental benefits from those attributable to basic benefits since supplemental benefit costs are not subject to the risk corridor provisions. Again, all claims will be necessary to verify that the costs are allowable because the order in which the claims were incurred will help determine whether the claims were solely for basic coverage. For instance, a claim processed between a beneficiary's deductible and initial coverage limit (in standard coverage) will count towards risk sharing, but another claim (processed identically but immediately after the initial coverage limit has been reached) will not. Unlike the reinsurance subsidy, which is limited to individuals with expenses in excess of the out-of-pocket threshold, risk sharing involves costs (net of discounts, chargebacks and rebates, and administrative costs) for all enrollees for basic coverage, but only those costs that are actually paid by the sponsor or organization. Because all plans participate in risk sharing, potentially all claims for all Part D enrollees in all plans must be reviewed. Like the reinsurance reconciliation, risk sharing does not require NDC codes or quantities, but does require member, cost, and date of service data.
- The program audit process will require at least a statistically valid random sample of all Part D drug claims. We believe that several points of reference including HIC#, cost, date of service, and NDC code will be required for unique identification of individual claims in any random sample drawn from the population. If we receive 100 percent claims to support the payment processes, this sample could be drawn from our records. We believe it will be useful to obtain the prescribing physician's National Provider Identifier (NPI) number, as required by the administrative simplification provisions of HIPAA, in the elements of collected data for purposes of fraud control once it is available. (Nothing in this data collection discussion should be construed as limiting OIG authority to conduct any audits and evaluations necessary for carrying out our regulations.)

Comment: One commenter urged us to ensure that prescription transaction data, be made available to the QIOs. Without this information the commenter contends, it will be extremely difficult for QIOs to execute the direction of the Congress in section 109 of the MMA, to offer assistance to practitioners and plans for the purpose of improving the quality of pharmacotherapy received by older and disabled Americans enrolled in the Medicare outpatient drug benefit.

Response: Additional guidelines will be released dealing with QIO access to Part D data. QIOs do, however, have their own independent authority to collect claims data. Therefore, as we stated in the proposed rule, we believe we would have the authority to share claims data with QIOs if necessary.

Comment: One commenter stated that claims creation and submission for the pharmacy claims as proposed would probably be even more expensive, given the volume of data and the number of data elements. They encouraged us to be parsimonious in collecting data, with the understanding that plans would retain full data for audits.

Response: We will endeavor to reduce burden to the maximum extent possible. We will require only the data elements necessary to carry out the operations of the Part D program.

Comment: For the timeframe for data submissions, one commenter stated that unless all plans can provide information electronically, weekly data cycles would be too burdensome. Monthly or quarterly data cycles are more in line with other plan financial processes. Another commenter suggested that annual submission would be adequate with additional data submitted on a quarterly basis. A PBM commented that they have the capability of submitting drug utilization data to us on a monthly basis in any format required. They also noted that all of the data elements listed as proposed requirements in the proposed rule are available in their point-of-sale system. Two commenters recommended that data transmission use either the NCPDP or the American Society of Automation in Pharmacy (ASAP) standard formats. They reasoned that such standards are commonly used today and would have minimal impact on existing software applications.

Response: We agree that data submissions should be based on an established standardized format, and will be requiring data submissions in the NCPDP format. The data required will be from both incoming claims and the remittances to those claims. Some of the paid amounts that need to be reported are not on the NCPDP format (for example, the low income cost-sharing subsidy). Therefore, plans will be responsible for calculating and retaining these amounts while calculating appropriate payments and cost-sharing for each claim. We will require that the data related to drug claims be submitted no less frequently than monthly. Further details on data submission will be issued in separate guidance.

b. Allowable Costs

Section 1860D–15(b)(2) and 1860D–15(e)(1)(B) of the Act and § 423.308 of our regulations, specify that to determine ''allowable costs'' for purposes of both the reinsurance and risk corridor payments, only the net costs actually paid after discounts, chargebacks, and average percentage rebates, as well as administrative costs, are to be counted. In the proposed rule we discussed requiring average percentage rebates, which upon reflection would represent only a rough estimate on the part of a Part D plan. We wish to clarify that in order to carry out our responsibilities we will require reporting of aggregate (as opposed to at the beneficiary or claim level) rebates at the product level on a quarterly basis. Adequate lead time will be provided. Additional information will be provided through our payment guidelines.

In the proposed rule we noted, also for rebates, that we understand that much of the rebate accounting is not applied in the context of point of sale claims data, but rather in periodic accounting adjustments, and that rebates are frequently reported along with administrative fees paid by the manufacturer. We wish to clarify that we will expect reporting of all rebate dollars with no allowance for separate administration fees in order to prevent inaccuracies in reporting. We note that plans must require and keep accurate records on all price concessions. All cost reporting will be subject to inspection and audit (including periodic audits) by us and the OIG. Part D plans sponsors seeking to limit access to rebate information under this provision to Part D business only are advised to seek out separate contracts with manufacturers for their Part D and other lines of business. To the extent either we or the OIG discover that a sponsor has been overpaid for reinsurance or risk sharing (that is, the records do not support the payments made, or there is insufficient documentation to determine whether the payments are correct), we may recoup the overpayments. The reopening and overpayment provisions are discussed at the end of this part G.

We also wish to clarify our interpretation of allowable costs in the context of repackaged drugs. AWP is commonly used as the basis through which a plan sponsor or fallback plan calculates payments to pharmacies, and is used to when sponsors provide competitive bids for the Medicare Part D prescription program. AWP is typically published based on the NDC for a particular product, and is specific to the drug, strength, distributor and package size. However, AWP can vary between differing packages sizes of a drug and strength from a single distributor, as well as between multiple distributors that product a common drug, as in the case of generic products. AWP may not be published for some products that are repacked for a specific buyer, such as a mail-order pharmacy or a pharmacy chain. Furthermore, if a pharmacy benefit manager or managed care organization owns a pharmacy (including a mail-order, specialty, or clinic facility) and refers members to that facility, it essentially purchases product from itself. In these cases, special care must be taken to ensure that payment is made for a prescription ingredient cost that is an accurate reflection of the product that the facility purchases in terms of manufacturer, strength, and acquisition price.

The Department of Health and Human Services' Office of Inspector General issued the April 2003 report ''Compliance Program Guidance for Pharmaceutical Manufacturers'' that addresses AWP. The guidance report states that: ''... it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the ''spread'' to induce customers to purchase its product.'' We believe that the same principle of non-manipulation of AWP applies to sponsors of the Part D benefit. Any repricing or restatement of price of a pharmaceutical product is subject to audit, and potentially constitutes fraudulent behavior if the repricing or price restatement is done with the intent of increasing the profits of that sponsor or mail order facility by increasing the reimbursement due by the Federal government.

Comment: One commenter believes that administrative fees for administering rebates should not be included in the assessment of rebate fees.

Response: We disagree with the commenter. As stated in the proposed rule such accounting will be incompatible with the need to report all price concessions for purposes of determining allowable reinsurance and risk corridor costs. In the preamble to the proposed rule, we said that to the extent the administrative fees paid to

Part D plans (or their subcontractors, such as PBMs) are above the fair market value of the services rendered, this differential will be considered a price concession. Similarly, to the extent a Part D plans pays manufacturers or others administrative fees, and these fees are below fair market value, this would also be considered a price concession. In sum, as fiduciaries of the Medicare trust fund, we have a responsibility to ensure that price concessions are not masked as administrative fees, and therefore, we continue to believe that administrative fees are important in determining the reinsurance and risk-sharing payments.

Comment: One comment urged clarification of definition of ''allowable costs'' so to exclude manufacturer-sponsored compliance and appropriate use programs.

Response: Allowable costs are prescription drug costs excluding administrative costs, but including dispensing fees costs related to the dispensing of covered Part D drugs that are actually paid by the PDP sponsor. Thus any service, such as a compliance program, that is paid for in conjunction with drug costs as an administrative component of managing the drug benefit is not be considered an allowable cost for the PDP sponsor.

Comment: One commenter asked for clarification on how fair market value is to be determined.

Response: The fair market value of administrative fees paid to a Part D plan will typically be evaluated in relation to the values reported by other Part D plans. In other words, the fair market value will be the average or normal value of administrative fees within this market. However, this may not be an exclusive methodology. For example, if administrative fees paid to all plans were found to be improperly inflated they would not reflect fair market value and we would devise an alternative methodology.

Comment: One commenter requested that we require plans to attest to the accuracy of information submitted to manufacturers in order to ensure that rebates and discounts are based on accurate claims.

Response: We strongly encourage plans to attest to the accuracy of information submitted to manufacturers. However, we do not have the authority to require an attestation as the commenter suggests.

Comment: One commenter recommended the second approach to rebate accounting in the proposed rule whereby a plan would calculate a ratio of total rebate amounts to total spending and reinsurance-related spending to total spending to derive the share of rebates to be allocated to reinsurance. The commenter believes this option is administratively straightforward and would result in a reasonably accurate estimate of these discounts, chargebacks, and rebates.

Response: We will require reporting of actual rebates requested and paid down to the product level on a quarterly basis. Additional guidance will be released subsequent to publication of the final rule that specifically deals with rebate accounting rules.

c. Coverage Year

In § 423.308 the term ''coverage year'' is defined as a calendar year in which covered Part D drugs are dispensed if the claim for such drugs (and payment on such claim) is made not later than 3 months after the end of the year. In other words, drug claims paid past the close of the 3-month period will not be considered part of that coverage year (or the next), and will not be used to calculate that year's payments or in reconciling risk adjustment payments for the year.

This limit will be imposed in order to provide timely closure for payment determination processes such as reinsurance, risk corridors and employer subsidies. While the period of 3 months will be significantly less than the fee-for-service Medicare medical claims standard of 18 months, we believe that a shorter period is warranted due to the highly automated and point of sale nature of prescription drug claim processing. We understand that the vast majority of prescriptions are not filled without the claim being simultaneously processed and therefore, there is a much shorter claims lag to be considered. We believe that the number and value of drug claims that will potentially be missed will be immaterial, consisting primarily of paper claims. The 3-month close-out window will not limit the liability of the plan or its claims processing contractor for reimbursing any lagging claims, but will simply establish a timely cut-off for finalizing payments. We note that rebates for the coverage year must be credited against that coverage year's costs. Although we are closing the year for claims purposes after 3 months, the plan must account for and report to us all rebates that occur throughout the coverage year and send us all the data within 6 months after the end of the coverage year.

A shorter period for claims will allow for payment processes that are dependent on the knowledge of total allowable costs for each coverage year to be concluded on approximately the same schedule as other reconciliations involving enrollment or risk adjustment data. On this schedule, calculations of risk sharing could begin as soon as six months after the close of the payment year. If the claims submission standard were a longer period, final reconciliations will be significantly delayed. We requested comments on this timetable, specifically whether we should adopt a shorter or longer period than 3 months, and including data with which to estimate the proportion and value of drug claims that could be excluded with a 3-month close-out window.

Comment: Two commenters argued that the definition of the coverage year in § 423.308, being three months after the end of the year, would not be enough time for certain drug claims, such as those from out-of-network providers or those submitted by paper. They went on to say that claims made after the 3-month closeout should be appropriately accounted for. Another commenter stated that the majority of claims are submitted and paid within the 90 day window described in the rule. They went on to say that from a processor standpoint no more time is needed and based on observed claims patterns at least 98 percent of the drug claims are paid within 3 months. One industry association expressed support for the proposal to define coverage year to encompass drugs dispensed within a calendar year and for which claims have been paid no later than three months after the end of the calendar year. The commenter believes establishing finality in this manner is absolutely essential to promote financial stability by allowing timely determination of risk sharing amounts.

Response: According to Booz Allen Hamilton's August 2004 report ''Determination of Allowable Costs'' the industry standard is for claims to typically be submitted within a three month window period. We agree with the two latter comments that the definition of the coverage year is both logistically feasible and promotes timely payment. We also note that the coverage year is 3 months for claims run-out (§ 423.308), but plans have 6 months to submit data (§ 423.343). This gives plans the extra time necessary to compile the data necessary for retroactive reconciliation. We will adopt the definition of coverage year as proposed.

5. Determination of Payment (§ 423.329)

a. Direct Subsidies

As directed in section 1860D–15(a)(1) of the Act and codified in § 423.329(a), we will provide direct subsidies to PDP sponsors and MA organizations offering MA-PD plans. These subsidies will be in

the form of advance monthly payments. Payments will be equal to the plan's standardized bid, risk adjusted for health status as provided in § 423.329(b), minus the base beneficiary premium (as determined in § 423.286(c) and adjusted for any difference between the standardized plan bid and the national average monthly bid amount (as described under § 423.286(d)(1))). The standardized bid will be the portion of the plan's bid attributable to basic coverage. This portion will be risk adjusted by multiplying by our prescription drug risk score attributable to each enrollee. Between the government direct subsidy and the adjusted base beneficiary premium, the plan will receive its entire risk-adjusted standardized bid in advance each month. Payment for supplemental benefits will come from enrollees in the form of additional premium. By statute, the sponsor must bear all risk for such supplemental benefits. In the proposed rule we said ''We would note that a plan's total per capita payment could never exceed its bid, risk-adjusted for the beneficiary's health status. This would be the case even if the difference between the plan's bid and the national average monthly bid amount were greater than the beneficiary monthly premium, mathematically resulting in a ''negative premium'' amount. We do not believe that the statute envisions plan payments in excess of negotiated costs, since this would violate the revenue requirements provisions discussed in the subpart F of this preamble''. As outlined in detail in subpart F of this final rule, we have changed our policy. We now state that if the standardized bid amount is less than the national average monthly bid by an amount so great that it is in excess of the base beneficiary premium, the direct subsidy payment calculated above will be increased by the amount of the negative premium. We, therefore, have modified § 423.329(a)(1) to indicate that the direct subsidy payment may be increased by the excess amount of a negative premium as described in § 423.286(d)(1), if applicable.

b. Risk Adjustment

In section 1860D–15(c)(1) of the Act, we are directed to develop and publish a prescription drug risk adjustment methodology taking into account the similar methodologies under § 422.308(c)(1) to adjust payments to MA organizations for benefits under Part C on the basis of costs incurred under original Medicare. In § 423.329(c) we establish this risk adjustment methodology. We will develop and publish this risk adjustment methodology in the 45-day notice for the announcement of 2006 Medicare Advantage rates. Section 1860D–15(c)(1)(D) of the Act requires us to publish the risk adjustment for Part D at the same time we publish risk adjustment factors under section 1853(b)(1)(B)(i)(II) of the Act. Because these risk adjustment factors under subpart C can only be published after 45-day advance notice under section 1853(b)(2) of the Act, in general we will use the same notice procedures we use under Part C for risk adjustment. We believe this will promote consistency and uniformity in the process, and, especially for MA-PD plans, allow entities to review notices published on the same day for purposes of commenting on or learning about risk adjustment. As usual, the 45-day notice will solicit public comment on any change in proposed payment methodologies. We are expecting that this new prescription drug risk adjustment methodology will initially be based on the relationship of prescription drug utilization within the entire Medicare population to medical diagnoses, and that it will be applied at the individual beneficiary level. Our longer-term plan would be to refine the risk adjustment model to account for predictable risk based on both medical and drug claim data.

Section 1860D–15(c)(1)(C) of the Act and § 423.329(b)(3) of this rule authorize us to specify and require the submission of data from PDP sponsors regarding drug claims that can be linked at the individual level to part A and part B data in a form and manner similar to the Medicare Advantage process provided in § 422.310 and such other information as we determine necessary. Similarly, MA organizations that offer MA-PD plans must submit data regarding drug claims that can be linked at the individual level to other data that these organizations are required to submit to us. A primary requirement, therefore, is receiving claims linked to the Medicare beneficiary HIC#. Other data submission elements are discussed in section 4(a) of this part of the preamble. We expect to link these data at the plan level and will then require the inclusion of the PDP or Medicare Advantage contract identifier (H#) as well as the plan benefit package identifier. We will use this data to further refine our prescription drug risk adjustment factors and methodology in order to make payments that accurately reflect plan risk.

As we noted in the August proposed rule, any risk adjustment methodology we adopt must adequately account for low-income subsidy (LIS) individuals (and whether such individuals incur higher or lower-than average drug costs). We stated that our risk adjustment methodology should provide neither an incentive nor a disincentive to enrolling LIS individuals, and we requested comments on this concern and suggestions on how we might address this issue. Our particular concern has been that a risk adjustment methodology, coupled with the statutory limitation restricting LIS payments for premiums to amounts at or below the average, could systematically underpay plans with many LIS enrollees (assuming LIS enrollees have higher costs than average enrollees). As noted in the proposed rule, the initial risk adjustment system, which will be budget neutral across all Part D enrollees, must not under compensate plans for enrolling LIS beneficiaries. In fact, to the extent that an initial risk adjustor might at the margin tend to overcompensate for LIS beneficiaries, plans would have a strong incentive to disproportionately attract such beneficiaries. Plans could attract LIS beneficiaries both by designing features that are attractive to such beneficiaries and also by bidding low.

Comment: We received several comments generically expressing concern over the risk of insuring the low-income subsidy population exacerbated by the induced demand likely to be created by the low income subsidy itself. Several commenters specifically agreed with our proposal to deal with this issue via risk adjustment. No commenters rejected the proposal. All the commenters noted that it is critical for the risk adjustment methodology to pay fairly and appropriately for all enrollees, including income subsidy individuals. Commenters requested additional details about the risk adjustment methodology.

Response: We agree that the Part D risk adjuster must accurately predict the drug expenditures for various population subgroups, including low income beneficiaries. The best way to achieve this goal is to calibrate the risk adjustment model on a sample of beneficiaries that includes low income beneficiaries, which we intend on doing. We have experience in dealing with an analogous situation with the Part C risk adjustment model, where beneficiaries in long term care institutions are known to have significantly higher expenditures than community enrollees before health status is accounted for. In order to accurately risk adjust for this population, we have generated a version of the risk adjustment model that explicitly accounts both for these higher expenditures and for the different

relative costs of diseases for the long term institutionalized population compared to the community population. For induced demand, we have Federal Employee Health Benefit Program and State Medicaid program data that will permit us to model this effect. One commenter familiar with these data noted that ''it seems reasonable that the risk adjustment process be used to correct any underpayments due to LIS induced demand.'' Additional details will be provided with the guidance accompanying the release of the risk adjustment factors.

Comment: We also received comments concerning specific elements of the risk adjustment model. One health insurer asserted that medical diagnoses may not adequately predict drug utilization. A PBM commented that some drugs are a very good marker of disease, while other drugs can be used to treat a variety of conditions. A manufacturer suggested that we should use data on prior medication expenditures and include demographics and diagnoses.

Response: Work by Wrobel and colleagues (Health Care Financing Review Winter 2003–2004) using data from the Medicare Current Beneficiary Survey and Medicare claims data found a diagnostic based risk adjustment model was a powerful predictor of drug expenditures. Our current risk adjustment model does not use drugs as a marker of disease but use diseases to predict drug spending (see *www.cms.hhs.gov/pdps/riskad.zip*). A more detailed description of the elements of the Part D risk adjustment model will be provided in the Advance Notice of Payment Methodology. However, anyone interested in understanding how risk adjustment works can read ''Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model'' in the Health Care Financing Review, Volume 25, Number 4 (Summer 2004). These articles are publicly available online at *www.cms.hhs.gov/review/default.asp*.

The Part D risk adjustment model will use demographics and diagnoses. As Part D program data becomes available we will incorporate other indicators to enhance the predictive power of the model. This may include, if appropriate, indicators of prior use of medication. We will provide the usual opportunities for public comment on subsequent iterations.

c. Risk Adjustment Budget Neutrality

In accordance with section 1860D–15(c)(1)(A) of the Act and § 423.329(b)(1), our risk adjustment methodology will be implemented in a budget-neutral manner. A requirement for budget neutrality assumes that there is a known budget. We interpret the statute to require that the risk adjustment methodology must not result in a change in aggregate amounts payable in section 1860D–15(a)(1) of the Act, that is, the risk adjustment methodology must be ''budget neutral'' to some aggregate of direct subsidy payments made before risk adjustment. (Since direct subsidy payments are made only to full-risk or limited risk plans, this budget by definition will not include payments to fallback plans.)

For comparison, in the current MA program the budget for risk-adjustment budget neutrality is defined to be the aggregate government payments made to plans under the 100 percent demographic payment system. Since the health-status-risk-adjustment methodology currently results in lower aggregate payments than the demographic methodology, MA budget neutrality distributes among participating plans the difference between total payments under the 2 methodologies via a factor that allocated the difference in the same proportion as the allocation of risk-adjusted payments. However, there is no corresponding predetermined limit to aggregate payments in Title I, that is, to the aggregate government direct subsidy payments made before risk adjustment, so there is no amount to use as a basis for comparison in determining budget neutrality.

In the MA program, the reason for the difference between the total payments under the demographic methodology and total payments under health status risk adjustment is that the average health status of enrollees in MA is different than the average health status for the program as a whole (that is, MA plus original Medicare). In Part D, there is no equivalent to original Medicare since beneficiary access subsidized coverage through enrollment in private plans. The Part D risk adjustment system will be based on these enrollees. Since there is no group of beneficiaries outside the system like there is under Part C, total payments with and without risk adjustment are always equal or budget neutral. Therefore, we believe that risk adjustment as applied to Part D benefits must be budget neutral to the risk of the individuals who actually enroll without any additional adjustment. We did not receive any specific comments on this, and therefore will adopt as proposed.

d. Reinsurance Subsidies

- Allowable Reinsurance Costs

As provided in section 1860D–15(e) of the Act and § 423.329(c), we will reduce the risk of participating in this new program by providing reinsurance subsidies. Subsidies will be limited to 80 percent of allowable reinsurance costs for drug costs incurred after an enrollee has reached the annual out-of-pocket threshold. The annual out-of-pocket threshold will be $3,600 in 2006. Under standard coverage this corresponds to total gross covered prescription drug costs of $5,100, and will be increased annually as provided in section 1860D–2(b)(4)(B)(i)(II) of the Act and 1860D–2(b)(4)(B)(ii) (with regard to rounding).

In meeting the various actuarial tests required of alternative coverage, there could be instances where a sponsor wanting to provide basic alternative coverage will have to enhance plan benefits in order to meet the test of equal total actuarial value relative to defined standard coverage. This could occur with the use of a tiered co-pay benefit structure that could shift utilization to a cheaper set of drugs, thus allowing plans to lower cost sharing to achieve the same total dollar value as defined standard coverage. In these instances, since cost sharing is reduced relative to defined standard coverage, the out of pocket threshold will be associated with a higher total drug costs than the $5,100 under standard coverage in 2006. For sponsors offering enhanced alternative coverage, the out-of-pocket threshold will also be associated with higher total drug spending. In this instance, however, it will be due to fact that the plan's supplemental benefits will be displacing part of the cost sharing that enrollees will otherwise have incurred.

Allowable reinsurance costs are a subset of gross covered prescription drug costs. Gross covered prescription drug costs are those costs incurred under the plan, excluding administrative costs, but including costs related to the dispensing of covered Part D drugs during the year and costs relating to the deductible. These costs are determined whether paid by the individual or under the plan, and regardless of whether the coverage under the plan exceeds basic prescription drug coverage. Allowable reinsurance costs, on the other hand, are the subset of these costs that are attributable solely to basic or standard benefits and that are actually paid by the sponsor or organization or by (or on behalf of) an enrollee under the plan. Actually paid means that these costs must be net of any discounts, chargebacks, and average percentage rebates, and will exclude any amounts not actually incurred by the sponsor. The reinsurance payments are then calculated by determining the portion of

allowable reinsurance costs that are incurred after the enrollee has reached the out-of-pocket threshold ($3,600 out of pocket in 2006). The reinsurance subsidy will provide 80 percent of such excess amount.

• Payment of Reinsurance Subsidy

Since allowable reinsurance costs (the subset of gross covered drug costs that are attributable to basic coverage only and are actually paid by the sponsor or plan) can only be fully known after all costs have been incurred for the payment year, we proposed to make payments on an incurred basis to assist PDP sponsors and MA organizations with cash flow. We also proposed that we would consider payments of reinsurance amounts on a monthly prospective basis based on the reinsurance assumptions submitted and negotiated with each plan's approved bid. In the August proposed rule we also stated that regardless of which process we used for making reinsurance payments, as discussed below, if, at the end of the year, the data demonstrates the sponsor was overpaid through the interim payments—or if there is insufficient evidence to support the reinsurance payments claimed—we would recover the overpayments either through a lump sum recovery or by reducing future payments during the coverage year. Similarly, if the data demonstrates that the sponsor was underpaid, we would pay the sponsor.

Comment: Numerous comments were received on the methodology of reinsurance payments. There was a general consensus supporting prospective monthly payments, with some commenters suggesting that the payment be at 1/12th of the net present value of estimated allowable reinsurance costs in each month of the coverage year. One commenter urged that plans should be able to choose between incurred and prospective payment. One commenter suggested that plans should invoice daily for reinsurance costs rather than have prospective monthly retrospective payments. Another commenter supported claims payments on an incurred rather than prospective or retrospective basis, and reimbursement on a monthly basis as proposed. Only one comment was received supporting determining payment with either a plan-specific or averaging approach

Response: Based on public comment, as well as on considerations of our current systems capabilities, our initial methodology will entail making monthly prospective payments of estimated allowable reinsurance costs submitted with the bid. We will establish and calculate these payments at the plan level so that reinsurance estimates reflect individual plan risk and the impact of plan supplemental benefits (if any) on when catastrophic benefits and reinsurance payments are triggered. At the end of each calendar year, we will reconcile plans' allowable incurred reinsurance costs for the year with the year's prospective plan payments; we will then reimburse plans for any underestimation of costs or recover any agency overpayments. More details will be made available in CMS additional guidelines on the payment methodology. We have modified § 423.343(d)(1) to clarify that CMS data requirements for reconciliation will be specified in separate guidance. We note that two commenters suggested that payments should be made on an incurred basis. We believe that advancements in information systems could make this logistically feasible. We wish to clarify that we reserve the right to alter the payment methodology. Any future changes would be announced through the Advance Notice of Methodological Changes and be subject to public comment.

• Adjustments to Reflect the True Out-of-Pocket Threshold

The statute provides that the reinsurance subsidy would be paid only for the plan's share of individual expenses in excess of an enrollee's TrOOP threshold. As indicated above, if the PDP sponsor offers enhanced alternative coverage or an MA-PD plan offers benefits beyond basic coverage as part of its supplemental benefits, the plan's spending for these benefits would not count toward the TrOOP threshold. Since benefits beyond basic coverage reduce cost sharing that would otherwise be incurred, they shift the effective prescription drug catastrophic limit beyond the associated total spending under the standard benefit ($5,100 in 2006) and raise the effective reinsurance attachment point at the same time.

In addition, to the extent that plan cost sharing is paid or reimbursed by secondary insurance coverage or otherwise, that cost sharing does not count toward the out-of-pocket threshold. Beneficiaries are required to report the existence of secondary coverage or other types of coverage we identify and plans must identify these payments and ensure that true out-of-pocket spending is accounted for accurately in claims processing. This is more fully discussed in subpart C and subpart J of this preamble.

Comment: One commenter noted that claims covered under supplemental coverage do not count towards TrOOP. The commenter believes that reinsurance should be triggered at the point that each enrollee hits $5,100 rather than $3,600 in out-of-pocket because there will otherwise be a strong disincentive to offer plans with enhanced coverage.

Response: We agree that the delayed reinsurance attachment point that results from the provision of supplemental benefits is one issue that must be considered by Part D plan sponsors. However, section 1860D–15(b)(2) of the Act defines allowable reinsurance costs to be ''no more than the part of such costs that would have been paid under the plan if the prescription drug coverage under the plan were basic prescription drug coverage, or, in the case of a plan providing supplemental prescription drug coverage, if such coverage were standard prescription drug coverage.'' Therefore, by statute, claims for supplemental benefits cannot be counted toward allowable reinsurance costs and we have no discretionary authority in this area.

• Adjustments for the Insurance Effect of Supplemental Coverage

In the proposed rule we stated that supplemental benefits increase the level of total drug spending after which reinsurance payments begin (reinsurance attachment point). Assuming 2 identical groups of enrollees for utilization, one enrolled in enhanced alternative coverage and one in defined standard coverage, the total allowable reinsurance costs for the group with standard coverage would be greater than for the group with enhanced alternative coverage. Thus, one might hold that the differences in benefit packages are accounted for without the need for further adjustment. If one would examine average total spending for both groups, however, one would find that the average spending under enhanced alternative coverage would be greater than the average under defined standard coverage because of the impact of the insurance effect (or ''moral hazard'', that is, the tendency of increased coverage resulting in increased utilization due to decreased financial stake in the costs associated with utilization). All other things being equal, this higher total spending would result in higher allowable reinsurance costs than would otherwise occur if the total spending under enhanced alternative coverage were comparable to that under standard coverage. We therefore proposed requiring (in the definition of allowable reinsurance costs) that allowable reinsurance costs be adjusted to reflect the impact of this induced utilization. We would make this adjustment to comply with the

requirement in section 1860D–15(b)(2) of the Act that in no case shall the allowable reinsurance costs exceed the costs ''that would have been paid under the plan if the ... coverage ... were standard prescription drug coverage''.

Comment: One commenter responded that they were not clear that an adjustment for the insurance effect of supplemental coverage would be needed. They recommended that we consider allowing time to study this issue, both to determine if an adjustment is appropriate at all and if it is what the adjustment should be. Another commenter stated that this issue is very complex and offered to discuss it further with us. Another health insurer noted that if a health plan develops rates for a commercial group, the rate for supplemental benefits developed for that group will include the revenue needs for the supplemental benefits as well as the plan's increased revenue needs to the extent that the expected costs of providing the basic benefit are expected to increase as a result of the supplemental coverage. They inquired as to how this practice would be applied to Part D.

Response: We continue to believe that an adjustment for the insurance effect of supplemental coverage is necessary. The effect of reduced cost sharing resulting in increased demand for medical services (including drugs) is firmly established in the economics literature and has been discussed for decades (see Charles Phelps and Joseph Newhouse's seminal review in the August 1974 issue of The Review of Economics and Statistics and more recently Phelps' 1997 text ''Health Economics''). Specific to the Medicare population, Margaret Artz and colleagues report in the August 2002 issue of the American Journal of Public Health that regardless of insurance type per capita prescription drug expenditures increased as generosity of coverage increased in their analysis of data from the Medicare Current Beneficiary Survey. Accordingly, plans that offer supplemental benefits will be required to provide an induced utilization estimate with their bid, and we have adopted this provision without modification. Additional CMS guidelines will be provided on estimating the induced utilization.

• Reinsurance Subsidies to Private Fee-For-Service Plans

As provided under section 1860D–21(d)(4) of the Act and in § 423.329(c)(3), we will base reinsurance payments for PFFS plans on an alternative methodology. Rather than negotiating reinsurance assumptions submitted with the PFFS plan bid or otherwise adjusting for potential price level differences between PFFS and other MA organization bids, we will estimate the amount of reinsurance payments that will be payable if the plan were an MA-PD plan described in section 1851(a)(2)(A)(i) of the Act. In doing so we will take into account the average reinsurance payments made under § 423.329(c)(2) for basic benefits for populations of similar risk under such MA-PD plans. Estimated payments will not be subject to any reconciliation process to compare the amounts paid to the actual allowable reinsurance expenses, and will not allow for payment recoveries in the event that actual allowable reinsurance costs exceed payments.

6. Low-Income Cost-Sharing Subsidy Interim Payments

As provided under section 1860D–14 of the Act and in § 423.780 of the regulations, we will provide additional assistance for certain low-income beneficiaries in the form of premium, deductible and cost-sharing subsidies. Since actual expenses incurred by these low income beneficiaries can only be fully known after all costs have been incurred for the payment year, we proposed to make estimated payments on an interim basis to assist PDP sponsors and MA organizations with cash flow. Under § 423.329(d)(2)(i), we proposed to provide for interim payments of low-income deductible and cost-sharing amounts on a monthly prospective basis based on estimates of low-income cost sharing submitted and negotiated with each plan's approved bid.

We also noted in the August proposed rule that low-income cost sharing would not necessarily be incurred evenly throughout the coverage year and that we were considering the most appropriate methodology for distributing interim payments. Since equal payments would be most compatible with our systems, in the first two years of the program (and for the first two years of new plans thereafter) we said in the proposed rule that we were considering an approach paying 1/12th of the net present value of estimated low-income cost sharing in each month of the coverage year. This net present value would be calculated on the basis of all estimated costs due at the end of the year and discounted by the most recently available rate for one-year Treasury bills. An alternative approach outlined in the proposed rule would have required the submission of a schedule of the estimated timing of incurred low-income cost sharing along with the plan bid. For example, we might take schedules from each plan or we could propose an incremental schedule (X percent of the total in January, Y percent in February, etc.). We also noted that the prospective payment of estimated costs might create an incentive to overstate low-income cost sharing, and that we are interested in ensuring that our interim payments are not excessive. We stated in the proposed rule that we would welcome comments on these approaches and on the appropriate treatment of interest in any methodology.

Again, we proposed that any reconciliation at the end of the year would need to be based on the sponsor providing adequate information in order to determine the subsidy amounts for the year. If the sponsor could not provide such information, interim payments would be recovered. In addition, the low-income payments would be subject to the same inspection and audit provisions applying to the other payments made under section 1860D 15 of the Act.

Comment: Several commenters supported prospective monthly payments for the low-income subsidy based on estimates provided in the accepted bid submissions. Two commenters suggested that low-income subsidies should be paid to plan sponsors on an incurred basis.

Response: We will make low-income cost sharing subsidy payments on a prospective basis using estimates submitted and negotiated with the approved bid and will reconcile these payments after the end of the coverage year with claims data. We agree with the majority of commenters that this method best protects plans from cash flow problems. More information will be provided with CMS guidelines on payment methodology. We have modified § 423.343(d)(1) to clarify that our data requirements for reconciliation will be specified in separate guidance.

Comment: One PBM urged that PDPs should be compensated for premium underpayment if the low-income subsidy amount does not meet or exceed their premium.

Response: The PDP will get paid its full premium. In cases where the low-income subsidy amount is less that the plan's premium, any low-income beneficiary enrolling in the plan is responsible for making up the difference between the low-income premium subsidy and the plan's premium.

Comment: Two commenters stated that some SPAPs would want to supplement the premium subsidy so that their beneficiaries do not have to pay first and be reimbursed by the SPAP. They suggested that Section

423.329 should include a requirement for plans to implement a process, similar to the Medicare Part B buy-in process, which will allow States to pay Medicare Part D premiums on behalf of SPAP beneficiaries.

Response: Such authority already exists. Collection of monthly premiums are covered in § 423.292. Section 1860D–13(c) of the Act instructs that the provisions of 1854(d) shall apply to PDP sponsors and premiums under this part be paid in the same manner as they apply to MA under part C. Payment options under § 422.262(f)(3) include any ''other third parties such as a State''. Moreover, we are required to establish standards for effective coordination between Part D plans and SPAPs for payment of premiums and coverage, as well as payment for supplemental prescription drug benefits. Further information on these standards will be issued in separate guidance.

Comment: One commenter urged us to share all low-income subsidy payment data under § 423.315(d) directly with the SPAPs.

Response: Since nothing in the MMA addresses disclosure of data to SPAPs, we believe that FOIA rules apply to these data. Therefore, it is possible that we cannot disclose this data under exception 4 of FOIA, but such a determination would be done on a case-by-case basis following standard FOIA procedure.

7. Risk Sharing Arrangements

a. Risk Sharing Methodology and the Target Amount

As provided under section 1860D–15(e) of the Act and in § 423.336, we would establish risk corridors. Risk-sharing payments would limit exposure to unexpected expenses not already included in the reinsurance subsidy or taken into account through risk adjustment. These would be structured as symmetrical risk corridors that are agreements to share a portion of the losses or profits resulting from expenses for basic benefits either above or below expected levels, respectively. However, plans would always be at full financial risk for all spending on supplemental drug coverage. In addition, in accordance with section 1860D–21(d)(5) of the Act and section 1860D 15(g) of the Act, the risk sharing provisions are not available to PFFS and fallback plans.

The expected level of expenses for basic benefits included in the standardized bid is known as the ''target amount''. The target amount for any plan would be equal to the total amount of direct subsidy payments from us, and premium payments from enrollees to that plan for the year based upon the risk-adjusted standardized bid amount, less the administrative expenses and return on investment assumed in the standardized bid. Since the standardized bid is the portion of the accepted bid amount attributable to basic prescription drug coverage, the target amount can be thought of as ''prepayments'' of prescription drug expense for basic benefits. The standardized bid has also taken into account (and excludes) any utilization effects of offering supplemental coverage. The objective of risk sharing would be to compare total actual incurred prescription drug expenses to the prepayments, to compute the difference, and to reimburse or recover a portion of the difference.

In § 423.336(a)(2)(A), we establish risk corridors, defined as specified risk percentages above and below the target amount. For instance, in § 423.336(a)(2)(ii), for 2006 and 2007, the first risk corridor is defined as 2.5 percent above the target amount and the second as 5 percent above the target amount. This means that, for 2006 and 2007, the first risk corridor is between 100 percent and 102.5 percent of the target amount and the second risk corridor is between 102.5 percent and 105 percent of the target amount. A third risk corridor is above 105 percent of the target amount.

The term, symmetrical risk corridors—means that the same size corridors exist below the target amount as above it. The actual upper or lower limits of each corridor equal the target amount plus or minus the product of the risk percentage times the target amount.

b. Allowable Risk Corridor Costs

The costs applicable to the computation of risk sharing are known as allowable risk corridor costs. These costs are defined in section 1860D–15(e)(1)(B) of the Act and in § 423.308 as the part of costs for covered Part D drugs that are only attributable to basic benefits. Allowable risk corridor costs cannot include costs attributable to benefits outside the basic benefit. We interpret this as both the actual differences in benefits structure and the insurance effect of supplemental coverage on basic coverage. In section 1860D–15(e)(1)(B) of the Act, reference is made to section 1860D–11(c)(2) of the Act that provides for a utilization adjustment using as its reference point standard prescription drug coverage. We are interpreting this to mean the statutorily defined standard prescription drug coverage described in subpart C. Also, allowable risk corridor costs must actually be paid by the sponsor or organization under the plan and must be net of any chargebacks, discounts or average percentage rebates. The allowable risk corridor costs also do not include any administrative expenses (including return on investment) of the sponsor or organization. (Administrative expenses would not include costs directly related to dispensing of Part D drugs during the year.) Note that unlike allowable reinsurance costs, allowable risk corridor costs do not include any amount paid by the enrollee. In § 423.336(a)(1), we state that allowable risk corridor costs must be adjusted in accordance with section 1860D–15(e)(1)(A) of the Act, by subtracting expenses reimbursed through other separate payments. Thus, reinsurance payments made under § 423.329(c)(2) and the non-premium low-income subsidy payments made under § 423.782 in subpart P of these regulations to the sponsor of the plan for the year must be subtracted. The PDP sponsor or MA organization would already have received compensation for these costs, and thus they do not fall within the construct of risk corridors that are directed at limiting exposure to unexpected expenses.

If adjusted allowable risk corridor costs exceed the prepayments by a certain amount, we would reimburse a percentage of the difference to help plans with a portion of the unanticipated expenses associated with their drug coverage. On the other hand, if prepayments exceed adjusted allowable risk corridor costs, we would reduce future payments or otherwise recover a percentage of the difference to reduce the impact on the Trust Fund of excessive bids.

- In order to arrive at a value for actual risk corridor costs that can be appropriately compared to the target amount, allowable risk corridor costs would be adjusted to remove expenses reimbursed through total reinsurance payments and non-premium low income subsidy payments. The statute indicates that allowable risk corridor costs must be reduced by reinsurance payments and by the subsidy payments for low income individuals. The subsidy payments for low-income individuals under section 1860D–14 of the Act include subsidies for both premium and for cost sharing. We interpret ''the total subsidy payments made under section 1860D–14'' under section 1860D15(e)(1)(A)(ii)(II) of the Act in the context of ''costs incurred by the sponsor or organization'' in the definition of allowable risk corridor costs. Since premiums are not a cost, we limit our interpretation of ''the total subsidy payments'' to payments related to cost sharing.

We note that when adjusted allowable risk corridor costs are calculated by subtracting only non-premium subsidies the results are the same as for an identical plan without any subsidy-eligible individuals. However, if the adjusted allowable risk corridor costs are calculated by subtracting total low-income subsidies (that is, for premiums, cost sharing and coverage above the initial coverage limit), the risk sharing calculation results in lower recouped costs on the part of the plan and a different outcome from that in a plan without subsidy eligible individuals. Since there must be no difference in these amounts, the calculation subtracting only non-premium subsidies must be the appropriate one. We believe that to do otherwise would result in a major disincentive for PDP and MA-PD plans to enroll individuals eligible for the low-income subsidies, and we do not believe that this would be the logical outcome that was intended by the statute. We are adopting this provision as proposed.

c. Changes in Risk Corridor Limits and Percentages (§ 423.336(a) and (§ 423.336(b))

The risk corridors and the percentage of risk to be shared would be set at certain levels for 2006 and 2007 with flexibility for us to increase the risk sharing percentage if bids, and therefore target amounts, are off during the early years of the program by a certain percentage set by the statute in section 1860D 15(e)(2)(B)(iii) of the Act. During 2006 and 2007, plans would be at full risk for adjusted allowable risk corridor costs within 2.5 percent above or below the target. Plans with adjusted allowable costs above 102.5 percent of the target would receive increased payments. If their costs were between 102.5 percent of the target (1st threshold upper limit) and at or below 105 percent of the target (2nd threshold upper limit), they would be at risk for 25 percent of the increased amount; that is, their additional payments would equal 75 percent of adjusted allowable costs for spending in this range. If their costs were above 105 percent of the target they would be at risk for 25 percent of the costs between the first and second threshold upper limits and 20 percent of the costs above that amount. That is, their additional payments would equal 75 percent of the difference between the first and second threshold upper limits and 80 percent of the adjusted allowable costs over the second threshold upper limit. Conversely, if plan spending fell below the 97.5 percent of target, plans would share the savings with the government. They would have to refund 75 percent of the savings for any costs less than 97.5 percent of the target amount but at or above 95 percent of the target level, and 80 percent of any savings below 95 percent of the target.

In § 423.336(b)(2)(iii) the program will cover a higher percentage of the risk for costs between the 1st and 2nd upper threshold limits would apply in 2006 and 2007 if we were to determine that: (1) 60 percent of Part D plans have adjusted allowable costs that are more than the first threshold upper limit for the year; and (2) these plans represent at least 60 percent of beneficiaries enrolled in such plans. In this case, additional payments to plans would increase from 75 percent to 90 percent of adjusted allowable costs between the first and second upper threshold limits. Conversely, there would be no change in savings shared with the government if costs fell below 97.5 percent of the target level.

For 2008 to 2011, the risk corridors and the percentage of risk to be shared would be modified so that PDP and MA PD sponsors would assume an increased level of risk. Plans would be at full risk for drug spending within 5 percent above or below the target level. Plans would be at risk for 50 percent of spending exceeding 105 percent and at or below 110 percent of the target level. Additionally, they would be at risk for 20 percent of any spending exceeding 110 percent of the target level. Payments would be increased by 50 percent of adjusted allowable costs exceeding the first threshold upper limit and up to the second threshold upper limit and 80 percent for any additional costs exceeding the second threshold upper limit. Conversely, if plan spending fell below the target, plans would share the savings with the government. They would have to refund 50 percent of the savings if costs fell between 95 percent and 90 percent of the target level, and 80 percent of any amounts below 90 percent of the target.

For years after 2011, we would establish the risk threshold percentage as deemed necessary to create incentives for plans to enter the market. The only required parameters would be that the first threshold risk percentage could not be less than 5 percent and the second threshold risk percentage could not be less than 10 percent of the target amount.

d. Risk Sharing Payments or Recoveries

In § 423.336(c), we will make payments or recover savings after a coverage year after obtaining all of the information necessary to determine the amount of payment. In § 423.336(c)(1), the PDP sponsor or MA organization offering a MA-PD plan would provide us with the information necessary to calculate the risk sharing as discussed in section 3(a) of this part of the preamble within six months. This would include prior final reconciliation of reinsurance and low-income subsidies since allowable risk corridor costs must be reduced by the total reinsurance payments and non-premium low-income subsidies for the year. Once this information has been received, under § 423.336(c)(2) we would either make lump-sum payments or adjust monthly payments in the following payment year based on the relationship of the plan's adjusted allowable risk corridor costs to the predetermined risk corridor thresholds in the coverage year. We would not make payment if we did not receive the necessary information from the PDP sponsor or MA organization. In addition, as stated, below, we are considering certain corrective actions to recoup risk-sharing payments, in the event of lack of information.

Comment: One State suggested that any savings accrued to the government via risk sharing should be shared with the States.

Response: Risk sharing is symmetrical, meaning that if it were permissible to share cost savings, the States would also have to assume responsibility for the portion of the cost for specified risk percentages above the target amount. Nevertheless, the Congress intended for risk sharing to be between the Federal Government and the plans with no State involvement whatsoever.

8. Retroactive Adjustments and Reconciliation (§ 423.343)

In § 423.343(a) and § 423.343(b) retroactive adjustments are made to the aggregate monthly payments to a PDP or MA-PD for any difference between the actual number and characteristics, including health status, of enrollees and the number and characteristics on which we had based the organization's advance monthly payments. Reconciliation of actual payments made would be done as needed. In order for total payments to be properly accounted for in all steps, the order of reconciliation processes would be first, enrollment; second, risk adjustment; third, low-income cost sharing; fourth, reinsurance; and finally, risk sharing.

Under § 423.343(c) and (d), we provide for a final reconciliation process to compare the payments for reinsurance subsidies and low-income cost-sharing subsidies made during the coverage year to actual allowable reinsurance expenses and low-income cost sharing and to make additional payments or payment recoveries

accordingly. The form and manner in which actual allowable reinsurance costs would be submitted for reconciliation will be discussed in additional CMS guidelines on payment methodology. PDP sponsors and MA organizations offering a MA-PD plan would provide us with the information necessary to finalize reinsurance payments as discussed in section 3(a) of this part of the preamble within six months of the end of a coverage year. Once complete data were received for a coverage year, we would compare 80 percent of the allowable reinsurance costs attributable to that portion of gross covered prescription drug costs incurred in the coverage year after an individual has incurred costs that exceed the annual out-of-pocket threshold to the monthly reinsurance payments and compute the difference. We would then either make lump-sum payments or adjust monthly payments throughout the remainder of the payment year following the coverage year to pay out or recover this difference.

If an entity did not provide us with sufficient documentation for us to reconcile payments, we would reconcile by recovering payments for which the entity lacked documentation. For example, if we make interim payments during the year for the low-income subsidy, but at the end of the year, the PDP sponsor or MA organization cannot provide documentation demonstrating the amounts of beneficiary cost-sharing, the reconciliation process would involve recouping the interim payments for such subsidy. The need to provide sufficient documentation to support final payment determinations applies even in the event of a change of ownership. Thus, new owners of a PDP sponsor or MA organization would be responsible for obtaining the documentation necessary to support payment, and the reconciliation process would be used to recover any payments for which the new owner lacked documentation. We believe this authority stems from the direction of the Congress that each PDP sponsor and MA-PD organization ''provide the Secretary with such information as the Secretary determines is necessary to carry out this section,'' (section 1860D–15(f)(1)(A) of the Act) and that ''payments under this section . . . are conditioned upon the furnishing to the Secretary in a form and manner specified by the Secretary, of such information as may be required to carry out this section,'' (section 1860D–15(d)(2)(A) of the Act)).

In the proposed rule we discussed potential remedies that should be imposed in the event a PDP sponsor or MA organization offering an MA-PD plan fails to provide us with adequate information regarding risk-sharing arrangements. In the case of risk corridor costs, the organization or sponsor may owe the government money if, for example, prepayments exceed adjusted allowable risk corridor costs. In this case, failure to provide information could result in a shortfall to the government, since the entity would not have the information necessary for the Secretary to establish the proper amount owed. Therefore, we will assume that the sponsor's or organization's adjusted allowable risk corridor costs are 50 percent of the target amount. We will use a 50 percent threshold because we believe this threshold would constitute a lower limit; and it would be unlikely for any organization or sponsor to have costs lower than 50 percent of their total payments. Additional guidelines will detail our methodology for reconciliation for these payments.

9. Reopening (423.346)

We believe that the provision in 1860D 15(f)(1) of the Act providing the Secretary with the right to inspect and audit any books and records of a PDP sponsor or MA organization regarding costs provided to the Secretary would not be meaningful, if upon finding mistakes pursuant to such audits, the Secretary were not able to reopen final determinations made on payment. In addition, we believe that sections 1870 and 1871 of the Act provide us with the authority to reopen final determinations of payment to PDP sponsors and MA organizations. Therefore, our reopening provisions patterned after those used in Medicare claims reopening, found in Part 405 of the regulations, subparts G and H. Including reopening provisions will allow us to ensure that the discovery of any overpayments or underpayments could be rectified. Under our provisions, reopening could occur for any reason within one year of the final determination of payment, within four years for good cause, or at any time when there is fraud or similar fault. We could initiate a reopening on its own, or a sponsor or organization could request reopening, but such reopenings will be at our discretion. The Supreme Court has determined that in the context of reopening cost reports, a fiscal intermediary's decision not to reopen a final determination is not subject to judicial review, see Your Home Visiting Nurse Services, Inc. v. Shalala, 525 U.S. 449, 456 (1999), and we believe the same reasoning would apply in the context of Part D.

Good cause will be interpreted in the same manner as in Part 405 (see Medicare Carriers Manual section 12100). Thus, good cause will exist, if (a) new and material evidence, not readily available at the time of the determination, is furnished; (b) There is an error on the face of the evidence on which such determination or decision is based; or, (c) There is a clerical error in determination. In order to meet the standard under (a) the evidence could not have been available at the time the determination was made. A clerical error constitutes such errors as computational mistakes or inaccurate coding. An error on the face of the evidence exists if it is clear based upon the evidence that was before us when it reached its initial determination that the initial determination is erroneous. Thus, for example, good cause would exist in cases where it is clear from the files that rebates or administrative costs were not appropriately accounted for, where computation errors had been made, where a sponsor or organization included non-Part D drugs in their calculations, where individuals not enrolled in the plan were included in calculating payment, and in similar situations. Reopening could occur at any time in cases of fraud or similar fault, such as in cases where the sponsor or organization knew or should have known that they were claiming erroneous Medicare payment amounts.

Comment: One commenter asked for clarification on the criteria that we intend to follow in evaluating whether to reopen a determination during the first year under § 423.346.

Response: The criteria for reopening under § 423.346 is no different in the first year. Reopening could occur for any reason within one year of the final determination of payment, within four years for good cause, or at any time when there is fraud or similar fault. We could initiate a reopening on its own, or a sponsor or organization could request reopening, but such reopenings will be at our discretion. Good cause will exist, if: (1) new and material evidence, not readily available at the time of the determination, is furnished; (2) there is an error on the face of the evidence on which such determination or decision is based; or, (c) there is a clerical error in determination.

10. Payment appeals (§ 423.350)

Several commenters were concerned with resolving payment accuracy issues. Section 1860D–15(d)(1) of the Act gives broad authority to the Secretary to develop payment methods and we intend on using this authority to establish a payment appeals process to

help allay the aforementioned concerns. Accordingly, we have added § 423.350 to establish a payment appeals process whereby payment determinations involving the following may be subject to appeals:

- the reconciled health status risk adjustment of the direct subsidy as provided in § 423.343(b);
- the reconciled reinsurance payments under § 423.343(c);
- the reconciled final payments made for low-income cost sharing subsidies provided in § 423.343(d); or
- the final risk-sharing payments made under § 423.336.

We wish to clarify that the payment appeals process only applies to perceived errors in the application of the payment methodology described in this subpart and subsequent CMS guidelines. Under no circumstances may this process be used to submit new payment information after the established deadline. Part D plans are expected to submit payment information correctly and within the timelines we established.

I. Organization Compliance with State Law and Preemption by Federal Law.

1. Overview

In our proposed regulation at § 423.401 we implemented the requirements of section 1860D–12(a) of the Act that address licensing, the assumption of financial risk for unsubsidized coverage, and solvency and capital adequacy requirements for unlicensed sponsors or sponsors who are not licensed in all States in the region in which it wants to offer a PDP.

The provisions of this section specified the following:

- A sponsor must be organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State that it offers a PDP.
- There can be a waiver of the State licensure requirement for the reasons and under the conditions set forth under section 1860D 12(c) of the Act.
- To the extent an entity is at risk, it must assume financial risk on a prospective basis for covered benefits that are not covered by reinsurance. The PDP sponsor could obtain insurance or make other arrangements for the cost of coverage provided to enrollees to the extent that the sponsor is at risk for providing the coverage.

Below we summarize some of the proposals outlined in the August 2004 proposed rule, respond to public comment, and indicate any changes we have made to the final rule. For a full explanation of the proposals we refer readers to the August 2004 proposed rule.

a. Overview

We proposed at § 423.410 to implement the provisions of section 1860D–12(c) of the Act that address waiver of certain requirements to expand choice. Generally, section 1860D–12(c) of the Act specifies that in order to expand access to prescription drug plans, we may waive the State licensure requirement using many of the same standards that are permitted under Part C for provider-sponsored organizations (PSOs). The MMA also added some special rules for PDPs that are in addition to the PSO waivers available under Part C. Finally, the MMA allows for regional plan waivers under circumstances similar to those permitted under Part C for regional plans. We proposed requirements for regional plan waivers in § 423.115.

b. Waivers Incorporated from 1855(a)(2)

Section 1860D–12(c) of the Act provides that a prospective PDP sponsor may request a waiver from State licensure requirements from us under the waiver provisions at sections 1855(a)(2)(B), 1855(a)(2)(C) and 1855(a)(2)(D) of the Act. Because the Congress directed us to use many of the same grounds for approving waivers used in accordance to sections 1855(a)(2)(B), 1855(a)(2)(C), and 1855(a)(2)(D), we proposed adopting the regulatory provisions in § 422.372. These provisions allow a waiver when the State has failed to complete action on a licensing application within 90 days of receipt of a substantially complete application. This rule was adopted in proposed § 423.410(c)(1).

Proposed § 423.410(c)(2) included the standard of § 422.372(b)(2) (Denial based on discriminatory treatment). Under this proposed regulation, a waiver could be granted if a determination by CMS were made that: (1) the State denied an application based on requirements that are not generally applicable to PDP sponsors or other entities engaged in a similar business; or (2) the State required as a condition of licensure that the PDP sponsor offer any product or plan other than a prescription drug plan.

Proposed § 423.410(c)(3) incorporated the standard of § 422.372(b)(3) and stated that a waiver may be granted if the State denied an application on the basis of procedures or standards relating to solvency that are different from the solvency requirements established by us. In § 423.420, we proposed that we would use an application process in which the waiver applicant would be required to submit certain documents that indicate that the State is imposing procedures or standards relating to solvency that are different from CMS standards.

c. Additional Waivers Available under 1860D–12 of the Act.

In addition to the waivers available to PSOs under 1855(a)(2)(B), (C) and (D) of the Act, the MMA also created additional waiver opportunities for PDPs. The first of these was included in proposed § 423.410(c)(4) (implementing section 1860D–12(c)(2)(A)(ii) of the Act), which provides that we may grant a waiver when a State imposes requirements other than those required under Federal law.

The second and third of these (implementing section 1860D–12(c)(2)(B) of the Act) were included in proposed § 423.410(d) and (e). We proposed granting a waiver in the following scenarios:

- When a State does not have any licensing process for PDP sponsors.
- If a State does have a licensing process for years beginning before January 1, 2008, a waiver will be granted if the PDP sponsor merely submits its completed application for licensure to the State.
- We also proposed regional plan waivers at § 423.410(b).

d. Other Sections of the Proposed Rule.

The proposed rule also included § 423.420 (solvency standards for all entities receiving a waiver of State licensure); § 423.425 which proposed that an approved waiver does not deem the sponsor to meet other requirements for a sponsor under Part 423 of the regulations, and § 423.440, which proposed prohibiting State imposition of premium taxes and included the rules for Federal preemption of State law.

2. Waiver of Certain Requirements in Order to Expand Clhoice

The statute requires, at section 1860D–12(c)(3) of the Act, that the waivers granted under the provisions of section 1855 of the Act, as well as under section 1860D–12(c)(2)(B) of the Act, must also meet the conditions of approval established at section 1855(a)(2)(E), 1855(a)(2)(F) and 1855(a)(2)(G) of the Act. Accordingly, we implemented the procedures for approving a waiver in regulations at § 423.410(f). Please see our final regulations at § 423.415 and our discussion in section 2b of this preamble for requirements specific to entities wishing to offer a prescription drug plan in more than one State.

In proposed § 423.410(f)(1), we established that except in States without a licensing process for PDP sponsors and in the case of regional plan waivers described in proposed § 423.410(b)

(§ 423.415 in the final rule), a waiver applies only to a specific State and is effective for 36 months and cannot be renewed. In the final regulation we have made clarifying changes by adding new § 423.415 which is specific to regional plan waivers. As was proposed in § 423.410., in § 423.415(d) of the final rule we indicated that regional waivers are valid until the State has completed processing the application, but in no case can a regional plan waiver extend beyond the end of the calendar year for which it is received. We proposed implementing section 1855(a)(2)(F) of the Act at § 423.410(f)(2) by specifying that (except for regional plan waivers) we would grant or deny a waiver application under this section within 60 days after we determine that a substantially complete waiver application has been filed. We proposed that a substantially complete application would have to clearly demonstrate and document an applicant's eligibility for waiver. We also proposed, at § 423.410(f)(3) to implement 1860D–12(c)(3) by establishing that if we determine that a State does not have a licensing process for PDP sponsors, we will approve a waiver for a PDP sponsor that meets our solvency and capital adequacy standards and that this waiver would not be time limited

Comments and our responses to these waiver requirements follow.

We received several comments questioning, in general, the requirement allowing State licensure to be waived when the State applies grounds for licensure other than those required by Federal law. Below, in the comment and responses section we discuss the specific bases of these comments concerning preemption by Federal law, as well as other comments we received on the proposed requirements.

Comments: Several commenters supported limiting our interpretation of the preemption authority under State licensure requirements. One of these, from a State insurance department, stated that only non-profit organizations were eligible to apply under its State HMO licensure law. The commenter expressed concern that State licensure waivers could interfere with this State licensure requirement, since for-profit entities might be able to receive licensure waivers from CMS. Another commenter from a State insurance department expressed its hope that Federal waiver authority of State licensure would not stop a State from devising its own State approach to funding and financial management of PDPs within its jurisdiction.

Response: In the issues raised by these commenters concerning general licensing requirements we would need to evaluate a licensure waiver request using the standards specified in § 423.410 and § 423.415 of the regulations. If an applicant met one of these standards for waiver, we would grant the waiver, as the Congress required. This could mean, for example, that a for-profit entity, operating under a Federal waiver, does business in a State that offer HMO licenses only to non-profit entities. We believe allowing qualified plans to participate in a State or States is essential for establishing the new program and, among other things, ensuring access for beneficiaries to benefits and other requirements central to the prescription drug benefit.

Concerning the comment about State solvency standards, our regulations at § 423.410(b)(3)(i) and (b)(3)(ii) allow a waiver of State solvency and information requirements if the State requirements concerning these go beyond those specified by Federal law. We are finalizing our language from the proposed rule concerning these requirements as we believe that the intent of the statute is to ensure that entities wishing to offer prescription drug program in a State or States not be subjected to requirements beyond those required by Federal law.

Comment: Another organization requested that we specifically identify those PDP sponsors which are State licensed and those which have received a Federal waiver.

Response: We concur with the comment in principle that an organization that is not State licensed but under a Federal waiver be identified as such. As we develop additional guidance for the requirements of Part D, we will consider how best to convey such an identification. We do not believe, however, that it is necessary to include the identification in the requirements of this final rule.

Comment: A PBM requested that we clarify the rules for States without PDP licensure processes. The PBM proposed that if a State does not have a specific insurance license for prescription drug-only insurance plans, then this should be sufficient grounds for approval of the waiver by us.

Response: The approach that we have in adopted in § 422.372(b)(4) requires that the State licensing authority give the organization written notice that it will not accept its licensure application. Following this standard, we would require an organization to approach the State licensing authority for review and receive their decision prior to filing a request for waiver of State licensure under the provisions of this section.

Comment: A managed care organization and an alliance of cost contractors requested that we apply the licensure waiver rules to Medicare cost plans as well as to PDPs.

Response: Section 1860D–12(c) of the Act specifically addresses the waivers for prescription drug plans. We believe it would exceed our authority to extend these waivers to cost plans, which are not mentioned in section 1860D–12(c) of the Act. In addition, cost plans are governed by the licensure requirements in Part C and in part 422 of the regulations. This final rule is primarily addressed to the regulations in the new part 423 of 42 CFR. Therefore, we do not believe this final rule would be an appropriate place to adopt rules that affect part 422 and not part 423 of the regulations.

Comment: A Native American council requested that State licensure not be imposed upon a PDP that might be sponsored by the Indian Health Service or a tribal health program.

Response: We do not have the authority to add to the waivers included in section 1860D–12(c) of the Act. If a PDP sponsored by an Indian Health Service or tribal health program meets one of the waiver requirements in § 423.410, the PDP applicant should receive a waiver.

With the clarifying language noted we are, then, adopting our regulations concerning eligibility for waivers largely as proposed for § 423.401 and § 423.410.

3. Temporary Waiver for Entities Seeking to Offer a Prescription Drug Plan in more than One State in a Region § 423.115.

We implemented the regional plan waiver rule provided at section 1860D–12(c)(1)(B) of the Act in the regulations at proposed § 423.410. (In this final rule, we have created a new § 423.415 to clarify that the regional plan waivers are distinct from the single-State waivers, and often subject to different standards (for example, they endure only until the end of the contract period and not for 36 months). As we stated, this would allow us to use the proposed waiver authority at section 1858(d) of the Act and the temporary waiver would be available in the event a prospective PDP sponsor proposed that its prescription drug plan would cover a multi-State region, but was not yet licensed in all of the States. (Under those circumstances, we stated we could waive the State licensure requirement until the State had completed processing of the application.) In the interim, the PDP sponsor would be

required to comply with the solvency standards established by us. In the event the State ultimately denied the application, we stated that we could extend the waiver through the contract year as we deemed appropriate to provide for transition.

In the final rule we have clarified, with the addition the distinctions between the temporary waiver (for regional plans) and the waiver for entities seeking to offer a plan in a single State, the timeline for processing the application for the waiver and the length of the waiver itself. Thus in new § 423.415(c) we clarify that Secretary will determine the time period appropriate for the processing of the application and in new § 423.415(d), we repeat the policy of the proposed rule that in no case will the temporary waiver extend beyond the end of the calendar year.

4. Solvency Standards for Non-Licensed Entities (§ 423.420)

In proposed § 423.420, we specified that sponsors that have been granted a waiver by us must maintain reasonable financial solvency and capital adequacy.

Solvency standards have been developed after statutorily required consultation with the National Association of Insurance Commissioners. These standards are undergoing internal CMS review. We anticipate that these standards, which are required to be published by January 1, 2005 will be published on the CMS website in the near future in conjunction with the initial application forms for PDP organizations. These solvency standards will include such items as required minimum net worth and liquidity requirements as well as reporting requirements for future PDPs who have received waiver of State licensure. We are adopting the policy we proposed for reasonable financial solvency and capital adequacy in this final rule.

5. Preemption of State Laws and Prohibition of Premium Taxes (§ 423.440)

In the August 4, 2004 proposed rule, we stated that we would implement section 1860D–12(g) of the Act at proposed § 423.440(a), by specifying that to the extent there are Federal standards, those standards supersede any State Law.

We proposed that for purposes of Part D, with the exceptions of State licensing laws or State laws related to plan solvency, State laws would not apply to prescription drug plans and PDP sponsors.

The proposed rule for the Medicare Advantage program also discussed preemption of State laws, and because Part D and Part C incorporate the same preemption laws at section 1856(b)(3) of the Act, we believe it is necessary to summarize those discussions in this final rule.

In the Medicare Advantage proposed rule, we noted that prior to enactment of the MMA, section 1856(b)(3) of the Act provided for two types of preemption: general and specific. The presumption was that a State law was not preempted if it did not conflict with an M+C requirement, and did not fall into one of the four specified categories where preemption was presumed. (These four categories were: benefit requirements, including cost-sharing rules; requirements relating to the inclusion or treatment of providers; requirements concerning coverage determinations and related appeals and grievance processes; and requirements relating to marketing materials and summaries and schedules of benefits concerning M+C plans.)

We concluded that the MMA reversed this presumption and provided that State laws are presumed to be preempted unless they relate to licensure or solvency. We also referenced the Congress' intent that the MA program, as a Federal program, operate under Federal rules, and referred to the Conference Report of the MMA as making clear the Congress' intent to broaden the scope of preemption through its change to section 1856(b)(3) of the Act. See 69 FR 46866, 46904. We believe that because the Congress incorporated the same preemption standard into the Part D program, and because the Congress required the preemption rules to apply consistently in Parts C and D, this same reasoning would apply to Part D.

In addition, in the proposed rule for Part D, we stated that although the Congress included broad preemption rules in section 1856(b)(3) of the Act, we did not believe that the Congress intended for each and every State requirement applying to PDP sponsors to become null and void. Specifically, we stated:

> In areas where we have neither the expertise nor the authority to regulate, we do not believe that State laws would be superseded or preempted. For example, State environmental laws, laws governing private contracting relationships, tort law, labor law, civil rights laws, and similar areas of law would, we believe, continue in effect and PDP sponsors in such States would continue to be subject to such State laws. Rather, our Federal standards would merely preempt the State laws in the areas where the Congress intended us to regulate—such as the rules governing pharmacy access, formulary requirements for prescription drug plans, and marketing standards governing the information disseminated to beneficiaries by PDP sponsors. We believe this interpretation of our preemption authority is in keeping with principles of Federalism, and Executive Order 13132 on Federalism, which requires us to construe preemption statutes narrowly. (69 FR 46696.)

We also recognized that while the Congress specifically stated that State licensure and solvency laws would not be preempted, this did not mean that States could condition licensure on a sponsor meeting requirements unrelated to what we would consider licensure requirements. We also addressed this issue in the Medicare Advantage proposed rule, explaining:

> We believe that the exception for State laws that relate to ''State licensing'' must be limited to State requirements for becoming State licensed, and would not extend to any requirement that the State might impose on licensed health plans that-absent Federal preemption-must be met as a condition for keeping a State license. If a State requirement could be considered to relate to State licensing simply because the State could revoke a health plan's license for a failure to meet the requirement, this would mean that States could impose virtually any requirement they wished to impose without the requirement being preempted. ... Because we believe that it is clear that the Congress intended to broaden the scope of Federal preemption, not to narrow it, we also believe that the exception for laws relating to State licensing must be limited to requirements for becoming State licensed (such as filing articles of incorporation with the appropriate State agency, or satisfying State governance requirements), and not extended to rules that apply to State licensed health plans. (69 FR 46904.)

We are adopting these preemption interpretations as our final policy. We also note that in the accompanying regulation text we have replaced PDP sponsor with Part D sponsor, as we believe that the preemption of State law and the prohibition against imposition of premium taxes should operate uniformly for all Part D sponsors. We note that licensure requirements in this Part continue to apply only to PDP sponsors, as other Part D sponsors (such as MA organizations and cost-based HMOs and CMPs) are subject to their own licensing laws.

Comment: One large insurer felt that our narrow interpretation of the statutory preemption authority was contrary to the language of section 1856(b)(3) of the Act. This insurer requested that CMS consider making clear that all State laws and regulations (with the exception of State licensing and solvency laws) are preempted with respect to MA and Part D plans.

Response: As noted in the proposed rule, we do not believe that either the

principles of Federalism or the statute justify such a broad preemption interpretation. We do not believe, for example, we could preempt all State environmental or civil rights laws, nor do we believe it was the Congress' intent to do so. The preemption in section 1860D–12(g) of the Act is a preemption that operates only when CMS actually creates standards in the area regulated. To the extent we do not create any standards whatsoever in a particular area, we do not believe preemption would be warranted.

Comment: A pharmaceutical manufacturer and a pharmaceutical manufacturing association requested clarification from us that it is not our intent to preempt any State pharmacy laws dealing with the practice of therapeutic substitution.

Response: In general, we do not think we have the authority to preempt State pharmacy licensing laws dealing with the practice of therapeutic substitution and we do not intend to establish standards in this area. However, it should be noted that the forthcoming electronic prescription standards do have the potential to impact State pharmacy practices and such standards could preempt State pharmacy practice laws and regulations that conflict with them.

We are adopting the requirements of the proposed rule with the technical and clarifying changes noted throughout this preamble. We are also adopting the premium tax prohibition included in the proposed without modification. Both rules are found at § 423.440

J. Coordination Under Part D Plans with Other Prescription Drug Coverage

Proposed subpart J set forth the application of Medicare Part D rules to Medicare Part C plans; established waivers for employer-sponsored group prescription drug plans, MA-PD plans, cost plans, and PACE organizations; and established requirements for coordination of benefits with State Pharmaceutical Assistance Programs (SPAPs) and other providers of prescription drug coverage.

Below we summarize the proposed provisions of subpart J and respond to public comments. (Please refer to the August 2004 proposed rule (69 FR 46696) for a detailed discussion of our proposals.)

1. Overview and Terminology (§ 423.454)

Subpart J implemented sections 1860D–2(a)(4), 1860D–2(b)(4)(D), 1860D–11(j), 1860D–21(c), 1860D–22(b), 1860D–23(a), 1860D 3(b), 1860D–23(c), 1860D–24(a), 1860D–24(b), and 1860D–24(c) of the Act, as added to the Act by section 101(a) of the MMA. We proposed that, in general, the requirements of Part D generally apply under Part C for prescription drug coverage offered by MA-PD plans, although certain waivers are available. In addition, we implemented section 1860D–22(b) of the Act at proposed § 423.458(c) providing us the authority to waive the requirements of this part for employer-sponsored group prescription drug plans.

a. Part D Plans

Unless otherwise indicated, references to ''Part D plans'' in the proposed rule referred to any or all of MA-PD plans, prescription drug plans (PDPs) and fallback prescription drug plans. Likewise, the term ''Part D plan sponsor'' referred to MA organizations offering MA-PD plans, PDP sponsors, and eligible fallback entities offering fallback plans. We have moved the definition of ''Part D plan'' to § 423.4 of our final rule and expanded the definition such that it includes cost plans and PACE organizations offering qualified prescription drug coverage. Similarly, we have revised the definition of ''Part D sponsor'' under § 423.4 of our final rule to include cost plans and PACE organizations offering qualified prescription drug coverage.

b. Employer-sponsored Group Prescription Drug Plan

We used the term ''employer-sponsored group prescription drug plan'' to mean a prescription drug plan under a contract between a PDP sponsor or MA organization offering an MA-PD plan and employers, labor organizations, or the trustees of funds established by one or more employers or labor organizations (or combination thereof) to furnish prescription drug benefits under employment-based retiree health coverage.

c. State Pharmaceutical Assistance Program (SPAP)

We defined an SPAP, for purposes of this part, as a program operated by or under contract with a State if it:

(1) Provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals;

(2) Provides assistance to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls;

(3) Meets the benefit coordination requirements specified in this part; and

(4) Does not change or affect the primary payer status of a Part D plan.

Comment: Although one commenter supported our proposed definition of the term ''SPAP,'' several commenters urged us to allow SPAPs to endorse one or more Part D plans for SPAP enrollees. They believe that the non-discrimination criteria contained in the definition of the term SPAP should be designed to maximize the efficiency and effectiveness of offering benefits that supplement the benefits available under Part D coverage to enrollees. Some of these commenters believe that a preferred plan approach, if accomplished via a competitive bid process, supports the competitive, market-based model that the Congress envisioned. One commenter stated that such an approach would help it to ''ratchet down'' administrative costs. Another commenter asserted that the statute does not prohibit a State from providing consumer advice to its SPAP enrollees regarding which Part D plan might work best with an SPAP or offer the best value.

Commenters believe that this interpretation is consistent with the intent to establish an effective coordination mechanism between SPAPs and Part D plans. Defining non-discrimination in a way that prohibits SPAPs from designating preferred Part D plans and prohibiting auto-enrollment of SPAP beneficiaries into preferred plans would not facilitate enrollment in Part D plans and would further complicate, rather than promote, coordination between Part D plans and SPAPs.

Response: Section 1860D–23(b)(2) of the Act defines an SPAP, in part, as a program that ''in determining eligibility and the amount of assistance to Part D enrollees, provides assistance to such individuals in all Part D plans and does not discriminate based upon the Part D plan in which the individual is enrolled.'' We are interpreting the non-discrimination language in section 1860D–23(b)(2) of the Act and § 423.464(e)(1)(ii) of our final rule to mean that SPAPs, if they offer premium assistance or supplemental assistance for Part D cost sharing, must not only offer equal assistance to beneficiaries enrolled in all Part D plans available in the State, but also may not steer beneficiaries to one plan or another through benefit design or otherwise. We believe that the law intends that all Part D plans in a State be given comparable opportunities. Requiring States to coordinate with all Part D plans, without discrimination, levels the playing field for Part D plans that want to provide benefits in a particular State.

We further interpret section 1860D–23(b)(2) of the Act as prohibiting SPAPs from automatically enrolling (''auto-enrolling'') beneficiaries into a preferred

plan because this would, in effect, allow the SPAP to choose a Part D plan for the beneficiary. The non-discrimination provision is part of the definition of an SPAP. Thus, even if under State law a State is the authorized representative of its SPAP enrollees for purposes of enrolling them in a Part D plan elected by the State, if it auto-enrolls beneficiaries into a select plan, the State program will no longer meet the statutory definition of SPAP under section 1860D–23(b) of the Act.

This will jeopardize the program's special status with respect to true out-of-pocket (TrOOP) costs. That is, if a State does not meet the definition of an SPAP, its contributions to beneficiary cost sharing under a Part D plan do not count toward the TrOOP limit, after which a beneficiary is eligible for catastrophic coverage.

Section 1860D–23(d) of the Act provides for grants to SPAPs for the purpose of educating their members who are Part D eligible individuals about the options available to them under the Medicare drug benefit, including information comparing Part D plans in the State so that SPAP enrollees they can choose the Part D plan that provides them with the best value. We will reach out to SPAPs and provide them with information they can use to help their enrollees who are Part D eligible individuals better understand their Part D plan options. We will also assist SPAPs in their efforts to ensure that their members understand the manner in which the Part D plans in their State coordinate with their SPAP benefit. Our outreach to SPAPs will also include guidance on the various educational, outreach, and assistance activities SPAPs may undertake in a manner that will not discriminate among Part D plans, for example: (1) SPAPs can provide beneficiaries with objective and comparative education on all available Part D plans offered in the State; and (2) SPAPs can advise members on:

- which plans have lower beneficiary premiums than others (after application of any low-income premium subsidy under 423.782 of our final rule or premium subsidy offered by the SPAP, which must be applied uniformly without respect to which Part D plan an individual enrolls in),
- which plan formularies include the drugs currently utilized by the beneficiary,
- which plans offer the beneficiary the most favorable combination of deductibles, coinsurance, and negotiated prices for the drugs currently utilized by the beneficiary, and
- which plans' network pharmacies include the same pharmacies participating in the SPAP, and which plans (if any) include an emblem or symbol on their ID cards indicating their coordination with the SPAP to facilitate secondary payment at the point of service.

The nondiscrimination requirement also bars SPAPs from recommending Part D plans based on the SPAP's financial interest in minimizing the cost of providing benefits under the SPAP that supplement the benefits available under Part D coverage. In addition, to the extent an SPAP assists the enrollment into Part D of its members who fail to elect a Part D plan during their initial enrollment period or upon joining the SPAP, we encourage SPAPs to mirror our procedures for auto-enrollment of full-benefit dual eligible individuals into Part D plans, which will be done on a random basis.

Comment: One commenter asked us to clarify whether a hybrid SPAP with multiple components, some of which meet our definition of SPAP, and some of which do not, would render an entire SPAP ''unqualified'' under our definition.

Response: We agree that components of State programs that provide pharmaceutical assistance, provided they meet the definition of the term ''SPAP'' in § 423.454(e)(1) of our final rule, may provide benefits that supplement the benefits available under Part D coverage, and that such supplemental assistance for covered Part D drugs will count toward Part D enrollees' TrOOP limit (as defined in § 423.104(d)(5)(iii) of our final rule). Thus, for example, if an SPAP receives Federal program funding for certain enrollees (for example, HIV/AIDS patients) or for certain drugs (for example, vaccines or HIV/AIDS drugs), while the State covers drug costs for other SPAP enrollees or for other drugs, only those components of the SPAP program that receive no Federal program funds may be considered an SPAP. We do not see any reason why the existence of both qualified and non-qualified components of a SPAP would interfere with our ability to count the spending of the qualified SPAP toward TrOOP, as long as operations and funding are appropriately segregated.

Comment: Several commenters asked for clarification regarding whether State Kidney Programs, which are structurally similar to SPAPs, can be defined as SPAPs so that their benefits supplementing the benefits available under Part D coverage count toward their enrollees' TrOOP limit.

Response: Section 1860D–23(b) of the Act provides that an SPAP is a State program that provides financial assistance for the purchase or provision of prescription drugs, and we interpret this to mean that it provides assistance with State funds. Therefore, to the extent that all sources of program funding for a State Kidney Program's financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D enrollees are 100 percent non-Federal and provided a program that meets the other criteria included in the description of an SPAP in § 423.464(e)(1) of our final rule, the program will be considered an SPAP. Any benefits provided by such a program that supplement the benefits available under Part D coverage would therefore count as an incurred cost toward the calculation of a beneficiary's TrOOP threshold.

Comment: One commenter asked us to clarify that a State can use any source of funds available to it (other than Federal funds) to finance any form of assistance to SPAP enrollees.

Response: We have clarified in § 423.464(e)(1) of our final rule that the term ''SPAP'' excludes any program under which program funding is from Federal grants, awards, contracts, entitlement programs, or other Federal sources of funding. However, the statutory definition of the term SPAP does not address program funding sources. We believe that a State program may still be considered an SPAP if some or all of its program funding is from private sources (for example, from charities or independent foundations). We also clarify that the exclusion of Federal program funding does not exclude some Federal administrative funding or incidental Federal monies (for example, the Federal grants to SPAPs provided for in section 1860D–23(d) of the Act).

In addition, to ensure SPAPs are funded in a manner consistent with the Congress' intent in the statute, we clarify that a ''State program'' under § 423.454 of our final rule must provide assistance based on financial need, age, or medical condition, and cannot do so based on current or former employment status. Under section 1860D–23(b) of the MMA, an ''SPAP'' is defined as a State program which provides financial ''assistance'' for supplemental drug coverage or benefits. The term ''assistance'' is defined in Webster's II dictionary as ''help'' or ''aid.'' We therefore interpret the word ''assistance'' to mean financial help or aid provided to any individual in need of such support—specifically,

individuals in financial need, the aged, or those with certain medical conditions. Thus, as provided in § 423.454 of our final rule, a ''State program'' is one that provides financial assistance for supplemental drug coverage to individuals based on financial need, age, or medical condition, but not based on current or former employment status.

Comment: One commenter suggested that our interpretation of the MMA should allow for the continuation and renewal at State discretion of the Pharmacy Plus waivers.

Response: Pharmacy Plus programs can continue with Federal match after January 1, 2006, under certain circumstances. Any State that operates a Pharmacy Plus demonstration program must determine whether it is feasible to continue that Pharmacy Plus program by submitting a revised budget neutrality calculation for the demonstration. As required in section III (10) of the terms and conditions of approval for Pharmacy Plus programs, this calculation must account for the reduction in Medicaid drug costs and a lesser diversion of dual eligible beneficiaries into the Medicaid program due to the implementation of Part D. We will review the revised budget neutrality calculation and approve or disapprove the continuation of the demonstration for the period after Part D is implemented.

2. Application of Part D Rules to Certain Part D Plans on and after January 1, 2006 (§ 423.458)

In accordance with section 1860D–21(c)(1) of the Act, and proposed at § 423.458(a) of our notice of proposed rulemaking, the provisions of Part D pertaining to the provision of qualified prescription drug coverage apply under Part C to prescription drug coverage provided by an MA-PD plan in lieu of other Part C provisions that would apply to such coverage, unless otherwise provided. Thus, Part D requirements not related to the provision of drug coverage (for example, licensing requirements) do not apply to MA-PD plans.

We indicated that we would waive Part D provisions to the extent that we determine that they duplicate, or conflict with, provisions under Part C, or as necessary in order to improve coordination of Part D benefits with the Part C program. In addition, we indicated that we would apply our waiver authority to cost plans and PACE organizations as proposed at § 423.458(d).

Except as otherwise provided below, the final rule adopts the provisions related to the application of Part D rules to MA-PD plans, as well as waivers of Part D requirements for MA-PD plans and cost plans, set forth in § 423.458(a), (b), and (d) of the proposed rule.

Comment: Two commenters suggested that waivers of Part D rules related to formulary requirements and pharmacy and therapeutic (P&T) committee requirements should not be allowed for MA-PD plans under the waiver authority provided in section 1860D–21(c)(2) of the Act, since there are no comparable provisions under Part C with which the Part D rules could conflict. Another commenter believed that waivers of Part D rules regarding coverage determinations and appeals should not be allowed under the waiver authority provided in section 1860D–21(c)(2) of the Act. Another commenter said that Part D appeals and grievances requirements should be waived for MA-PD plans to the extent they are not identical with Part C appeals and grievances requirements.

Response: Section 1860D–21(c)(2) of the Act requires the Secretary to waive requirements under Part D to the extent the Secretary determines they duplicate or are in conflict with provisions otherwise applicable under Part C, or they are necessary to waive in order to promote coordination of Part C and Part D benefits. In our proposed rule, we proposed implementing this authority in § 423.458(b). The clear intent of this provision was to recognize that the delivery of health care services covered under the original Medicare program under Part C takes precedence over the delivery of a drug benefit under Part D. Although the Part D drug benefit will become a vital part of the health care services offered by an MA-PD plan, to the extent that the Part D rules make it impossible for an MA-PD plan to effectively deliver Part C benefits, we will exercise Part D waiver authority to ensure that Part C benefits continue to be effectively delivered under § 423.458(b) of the final rule. We agree with the commenter that the three waivers specifically mentioned related to formulary requirements, P&T committee requirements, and the Part D appeals process will not be waived for MA-PD plans insofar as there are no conflicting provisions or rules under Part C that will make these Part D requirements impossible for an MA-PD plan to implement.

Comment: One commenter requested two specific waivers related to the Part D benefit offered by MA-PD plans. Specifically, the commenter requested a waiver of the pharmacy access standards in § 423.120(a)(1) of our proposed rule under similar conditions to the waivers we have permitted for MA plans related to the Medicare Prescription Drug Discount Card and Transitional Assistance Program. The commenter also requested a waiver of the requirement that MA organizations post their negotiated prices on our website, again saying that we had approved a similar waiver for MA plans that are exclusive card sponsors under the drug discount card program.

Response: In our proposed rule, we signaled our intention to waive pharmacy network access requirements described at § 423.120(a)(3) in the case of an MA-PD plan that provides access (other than through mail order pharmacies) to qualified prescription drug coverage through pharmacies owned and operated by the MA organization to the extent we determine that the network is sufficient to provide comparable access for enrollees of the MA-PD plan. In the subpart B preamble of our proposed rule, we discussed the information resources available through the Internet at *www.medicare.gov*. Although we discussed information available to Medicare-approved discount drug cards in that section of the preamble, we did not specifically signal our intention to provide identical information related to Part D plans. Therefore, it remains unclear that the second waiver would be necessary. More importantly, to the extent we discuss the required written waiver process in § 423.458(b)(2), (c)(1) and (d)(2) of our final rule, it is more appropriate at this time to direct the commenter to those sections of the rule than it is to speculate as to what waivers would, and would not, theoretically be allowed, if they were requested by an appropriate party.

3. Application to PACE Organizations

Section 1860D–21(f) of the Act indicates that Part D provisions shall apply to PACE organizations electing to offer qualified prescription drug coverage in a manner that is similar to those of an MA-PD local plan and that a PACE organization may be deemed to be an MA-PD local plan. As discussed in detail in subpart T, PACE organizations will not be deemed as MA-PD local plans, but will be treated in a manner that is similar to MA-PD local plans for Part D requirements applicable to the offering of qualified prescription drug coverage. Proposed § 423.458(d) established regulatory authority for us to waive Part D provisions for PACE organizations to the extent the provisions duplicate or conflict with a requirement under PACE, or the waiver is necessary to promote coordination of benefits under

PACE and Part D, and indicates that PACE organizations may request waivers from us.

The final rule adopts the rules regarding waivers of Part D requirements for PACE organizations set forth in § 423.458(d) of the proposed rule.

Comment: We received various comments regarding waivers of Part D requirements for PACE organizations.

Response: Please refer to subpart T of this preamble for a detailed discussion of these comments and our responses to them.

4. Application to Employer Groups

Section 1860D–22(b) of the Act extends the waiver authority that is provided for MA organizations related to Part C under section 1857(i) of the Act and implemented at § 422.106(c) of our proposed MA rule to prescription drug plans. This waiver authority is intended to provide employment-based retiree health coverage an opportunity to furnish prescription drug benefits to its participants or beneficiaries through Part D in the most efficient and effective manner possible.

We invited comment on the process we proposed for authorizing waivers for employer-sponsored group prescription drug plans. We also asked for comment on the manner in which additional waivers should be permitted and what additional waivers, if any, we should not allow.

Except as otherwise provided below, the final rule adopts the provisions related waivers of Part D requirements for employer-sponsored group prescription drug plans set forth in § 423.458(c) of the proposed rule.

Comment: Most commenters indicated a strong desire to obtain clear non-regulatory guidance addressing key issues in the waiver process prior to the final regulations being published. Commenters also urged us to adopt a process for employer waivers that gives employers maximum flexibility while minimizing administrative burden. Several commenters stressed the importance of providing waivers to facilitate employers becoming their own PDP or MA-PD plan for their retiree population. Several employers commented that under ERISA, State licensure requirements would not apply. Commenters also suggested waivers for the areas of network access, service area, marketing, disclosure, and enrollment.

Response: We are adopting a streamlined approach for implementing employer group waivers that allows maximum flexibility for employers to retain retiree prescription drug coverage. Details on waivers that we will and will not consider will be included in separate guidance. Additional waiver requests will be addressed on a flow basis.

Comment: One commenter requested clarification as to whether we will extend to cost plans (as defined under section 1876 of the Act) its waiver authority under section 1860D–22(b) of the Act.

Response: Section 1860D–21(e)(1) of the Act provides that only those provisions of Part D (and related provisions of Part C) pertaining to the offering of qualified prescription drug coverage by a MA-PD local plan would apply to the offering of the coverage by a cost plan. Because the employer waiver authority under section 1860D–22(b) of the Act pertains to the offering of qualified prescription drug coverage, we believe section 1860D–21(e) of the Act extends this waiver authority to cost plans. This will facilitate the retention of employer sponsored retiree prescription drug coverage under cost plans. However, the provisions of Part C and D that do not relate to the offering of qualified prescription drug coverage by cost plans, including the employer waiver authority under section 1857(i) of the Act, would not apply to benefits offered under a cost plan other than any qualified prescription drug coverage. Accordingly, we do not interpret these statutory provisions as permitting us to apply our waiver authority for employer-sponsored group coverage to Part A and B benefits offered under cost plans.

Comment: One commenter stated that a PBM or other third party administrator supporting an employer should be able to elect to solely serve employer groups without also being required to open enrollment to beneficiaries also in the service area but unaffiliated with the employer.

Response: We will include details in separate guidance on waivers that we will and will not consider. Section 423.458(c) of our proposed rule did not propose interpreting section 1857(i)(2) of the Act as permitting entities other than PDP sponsors and MA organizations from requesting employer group waivers, or contracting with us to offer an employer-sponsored group prescription drug plan. However, given the commenter's request for clarification, we note that § 423.458(c) of our final rule provides that any entity seeking to offer, sponsor, or administer an employer-sponsored group prescription drug plan may request a waiver or modification of Part D requirements. We will provide separate guidance regarding what entities we will contract with, as well as how we will contract with them.

5. Medicare Secondary Payer Procedures (§ 423.462)

Section 1860D–2(a)(4) of the Act extends the Medicare secondary payer (MSP) procedures applicable to MA organizations under section 1852(a)(4) of the Act and 42 CFR 422.108 to Part D sponsors and their provision of qualified prescription drug coverage. Section 1852(a)(4) of the Act provides that an MA organization may charge or authorize a provider to seek reimbursement for services from a beneficiary or third parties to the extent that Medicare is made a secondary payer under section 1862(b)(2) of the Act. Accordingly, we proposed at § 423.462 of our proposed rule that Part D sponsors are required to follow the same rules as MA organizations regarding:

- Their responsibilities under MSP procedures;
- Collection of payment from insurers, group health plans and large group health plans, the enrollee, or other entities for covered Part D drugs; and
- The interaction of MSP rules with State laws.

Comment: One commenter notes that MSP rules will apply to Part D and that section 1860D–12(g) of the Act extends State law preemption to Part D sponsors. This commenter believes that the MSP provisions extended to Part D sponsors should also apply to cost plans offering qualified prescription drug coverage. They argue that Part D is a Federal program and should be implemented by all Part D plans in accord with the same Federal rules and without regard to any State laws except those governing licensure and solvency.

Response: Section 1860D–21(e)(1) of the Act provides that those provisions of Part D (and related provisions of Part C) pertaining to the offering of qualified prescription drug coverage by a MA-PD local plan would apply to the offering of such coverage by a cost plan. Accordingly, the MSP provisions under section 1860D–2(a)(4) of the Act and the preemption provisions under section 1860D–12(g) of the Act are extended to cost plans for offering of qualified prescription drug coverage under the plans. However, the MSP and preemption provisions of both Parts C and D would not apply to benefits offered under a cost plan providing other than any qualified prescription drug coverage. Accordingly, we do not interpret these statutory provisions as permitting us to apply these provisions to Part A and B benefits offered under

cost plans. Cost plans are thus still subject to the MSP and State law preemption provisions under § 411.172 for their Part A and B benefits.

6. Coordination of Benefits with Other Providers of Prescription Drug Coverage. (§ 423.464)

Section 1860D–23(a) of the Act authorizes us to establish procedures and requirements to promote the effective coordination of benefits between a Part D plan and an SPAP with respect to payment of premiums and coverage, and payment for supplemental prescription drug benefits. The elements to be coordinated include enrollment file sharing, claims processing, payment of premiums for both basic and supplemental drug benefits, third-party reimbursement of out-of-pocket costs, application of protection against high out-of-pocket expenditures (defined in section 1860D–2(b)(4) of the Act), and other administrative processes and requirements that we specify.

We will establish procedures and requirements for Part D plans no later than July 1, 2005, to ensure effective coordination. In addition, as specified at section 1860D–24(a) of the Act, we will apply the requirements for coordination of benefits with SPAPs to Part D plans when they coordinate with entities providing other prescription drug coverage, including Medicaid (including a plan operating under a waiver under section 1115 of the Act), insurers, group health plans, the Federal Employees Health Benefits Program (FEHBP), military coverage (including TRICARE), and other coverage that we specify.

Section 1860D–24(a)(3) of the Act permits us to impose user fees to defray the costs of Part D coordination of benefits, but not on SPAPs under any method of operation, for the transmittal of benefit coordination information under Part D. We are also provided authority to retain a portion of these user fees to offset costs we incur for determining whether enrollee out-of-pocket costs are being reimbursed by third parties and for alerting Part D plans when, in fact, they are being reimbursed. In the proposed rule, we noted that any user fees, if collected, would not be assessed until the implementation of the Part D benefit in 2006. We requested comments regarding the method we should use to impose user fees, especially concerning whether it would be advisable to impose user fees on a monthly or quarterly basis based on the volume of data exchanged and whether we should require electronic payment of user fees.

As provided in section 1860D–24(c)(1) of the Act, Part D plans may continue to use cost management tools (such as tiered or differential cost sharing) even if an SPAP or other drug plan provides benefits that supplement the benefits available under Part D coverage for individuals enrolled in the Part D plan. In the proposed rule, we requested comments on how we could ensure that supplemental benefits offered by SPAPs and plans providing other prescription drug coverage would not undermine or eliminate the cost management tools established by Part D plans. We also solicited comments on the most effective way to administer this provision without creating undue administrative burden on either Part D plans or other prescription drug coverage that supplements Part D benefits.

Except as otherwise provided below, the final rule adopts the coordination of benefit provisions set forth in § 423.464 of the proposed rule.

Comment: One commenter indicated that our policies regarding coordination of benefits should ensure that this process is as administratively simple as possible, and that coordination of benefits rules are structured in a way that does not create incentives for beneficiaries to switch Part D plans mid-year in order to obtain better basic benefits.

Response: We agree and will keep this in mind as we work to develop requirements for coordination of benefits between Part D plans and SPAPs and entities providing other prescription drug coverage. We note, as well, that Part D enrollees may only switch Part D plans mid-year under the limited circumstances triggering a Special Election Period (SEP) in accordance with § 423.38(c) of our final rule.

Comment: One commenter indicated that while section 1860D–23 of the Act requires us to establish requirements for coordination of benefits beyond the tracking of TrOOP expenditures and claims payment (for example, for premium payment with SPAPs), they believe that coordination of benefits responsibilities should be limited for now to the tracking of TrOOP expenditures and claims payment. This commenter believed that an incremental approach is in the best interests of all parties, particularly since it is still unclear how many entities will choose to participate in or provide supplemental coverage to Part D.

Response: Section 1860D–23(a)(2) of the Act requires that benefit coordination elements include, at a minimum, enrollment file sharing, processing of claims, claims payment, claims reconciliation reports, and application of the protection against high out of pocket expenditures. We must comply with these statutory requirements in establishing our coordination requirements for SPAPs and other providers of prescription drug coverage, and it is in the best interests of Part D enrollees and plans that coordination activities begin as soon as possible. We do not believe that an incremental approach will be necessary, and we will be issuing further information on our coordination requirements and processes soon.

Comment: One commenter recommended that we establish a technical advisory group with representatives from the industry, including pharmacy software vendors and switching services, to develop coordination of benefits requirements for Part D plans to ensure effective coordination with SPAPs and other providers of prescription drug coverage. Another commenter recommended that relevant stakeholders, including pharmaceutical benefit managers, be consulted as we develop our requirements.

Response: As discussed in our proposed rule, section 1823(a)(4) of the Act requires us to consult with SPAPs, MA organizations, States, pharmaceutical benefit managers, employers, representatives of Part D eligible individuals, data processing experts, pharmacists, pharmaceutical manufacturers, and other experts in establishing our coordination of benefits requirements. To date, we have not only encouraged comments on this issue in our proposed rule, but we have also held many consultation sessions with these various stakeholders and an Open Door Forum on TrOOP and coordination of benefits. We will continue to meet with these parties as we develop our coordination requirements and processes.

Comment: One commenter stated that an unintended consequence of requiring Part D plans to collect information on incurred costs for purposes of tracking of TrOOP expenditures is that confidential negotiated pricing information will be released. This commenter thought that we should require Part D plans to collect SPAP payment information on ''incurred costs'' on a monthly or other periodic basis, in an aggregate form broken out per beneficiary, or require SPAPs to report the utilization information for enrollees for whom the SPAPs make payments for benefits that supplement the benefits available under Part D coverage, and for the Part D plans to

apply the price that would have prevailed had the plan been responsible for payment.

Response: While we acknowledge the commenter's concern regarding disclosure of negotiated pricing in the sharing of claims data, we must point out that we will require Part D plans to submit point-of-sale pricing data to us for display on a Part D version of Price Compare, so this data will become publicly available information anyway. However, we emphasize that the cost and price concession information submitted on true acquisition costs in the allowable cost reconciliation processes will not be disclosed, and that cost and price concession information submitted as part of the bid submission process will be protected to the extent it is confidential commercial information.

We wish to clarify that given that section 1860D–2(b)(4)(C)(ii) of the Act allows SPAP assistance for covered Part D drugs to count toward TrOOP, we do not expect that SPAPs will need to report paid claims data. TrOOP calculation will work by counting all amounts not paid by the Part D plan, unless such amounts are paid through group health plans, insurance or otherwise, or third party payment arrangements. Financial assistance with covered Part D drug costs provided by SPAPs on behalf of beneficiaries is assumed to be equivalent to payments made by the beneficiary and automatically counts toward TrOOP.

For calculation of a beneficiary's TrOOP expenditures, the Part D plan will count the full amount left over after it pays a claim until it receives notice through the TrOOP/coordination of benefits process that some amount should not count (for example, because it was paid by a group health plan, insurance or otherwise, or a third party payment arrangement). The plan will then subtract that amount from the TrOOP total. Thus, for example, if a beneficiary with spending between the deductible and the initial coverage limit has a prescription for a covered Part D drug that costs $100, a Part D plan that offers defined standard coverage will pay $75 and count $25 toward the beneficiary's TrOOP total. If the beneficiary has insurance coverage that pays $20, the Part D plan will receive the information through the coordination of benefits process and subtract $20 from the TrOOP total. However, financial assistance provided by SPAPs will be treated as though the beneficiary paid that amount, so the Part D plan will not need to distinguish between how much an SPAP and the beneficiary paid, respectively. Thus, the entire $25 copay (even though the SPAP paid a portion of it) counts toward TrOOP, and it is not necessary for the Part D plan to know how much of it the SPAP paid.

Comment: Multiple commenters asked that we not charge user fees for Part D coordination of benefits. Their arguments were that supplemental payers, particularly employers, would be more likely to drop benefits that supplement the benefits available under Part D coverage because we would be imposing burdensome administrative costs on them. One commenter also added that Part D coordination of benefits, in particular the tracking of TrOOP expenditures, is a feature designed to lower costs to Medicare, and so the government (that is, the ultimate benefactor of the coordination of benefits) should bear the administrative cost of coordination of benefits under Part D.

Commenters varied in their responses to the methods for imposing user fees. One commenter noted that if we were to procure a TrOOP facilitation contractor but could not have it running beginning in 2006, we could charge higher user fees to offset our higher administrative costs until the contractor was up and running and then switch to a lower fee thereafter. Another commenter proposed that a flat fee be used instead of a transmission volume fee because if volume were the basis of fee amounts, the fees would be too variable and would be too complicated to audit properly.

Commenters had different ideas about how frequently user fees should be levied if indeed we charge them. One commenter said that because most health insurance fees are collected monthly, we should continue this trend and also collect its fees monthly. Another commentator preferred a quarterly collection in order to reduce overhead associated with the payment process.

Response: We appreciate all the feedback provided by commenters regarding whether, and how, to assess user fees. We believe that while third-party payers of drug claims, pharmacies, and Part D plans will all benefit from the use of a coordination of benefits system that supports the tracking of TrOOP expenditures, Part D plans are the ultimate benefactors of the TrOOP process. Therefore, we expect that we will charge a user fee of no more than $1 per beneficiary per year to Part D plans, and we may be able to charge considerably less. We will issue further guidance regarding the method we will employ for assessing such user fees on Part D plans in separate guidance.

Comment: One commenter argued that we should interpret the language in section 1860D–11(j) of the Act to mean that Part D plans may not impose unnecessary or unreasonable user fees on SPAPs even when the fees are related to coordination of benefits. This commenter added that plans should factor coordination of benefits costs into their bids and that we should bear these costs. The commenter wanted us to establish a ''nationwide baseline requirement of coordination'' and only make States bear coordination costs if the costs were ''extraordinary,'' beyond the baseline, and ''related to the State's unique situation.'' The commenter asked that in such situations we negotiate such costs with the SPAP in question before a contract with a Part D sponsor is executed.

One commenter wanted us to clarify whether the provision at section 1860D–24(a)(3)(B) of the Act—which specifies that the Secretary may not impose coordination of benefits user fees on SPAPs—meant that only we are prohibited from charging such fees, or if the prohibition extended to Part D plans as well. If Part D plans are allowed to charge coordination of benefits user fees under this provision, the commenter asked for clarification regarding the basis upon which we would allow plans to charge the fees. They specifically mentioned cost-based fees, enrollment-based fees, and flat fees. The commenter also wanted to know whether the SPAPs would be allowed to verify or audit the imposition of such fees. Another commenter asked if we would monitor Part D plans to ensure that the user fees they imposed on SPAPs were reasonable and accurate. One commenter argued that Part D plans should be required to substantiate their actual costs in determining what to charge, in order to avoid unreasonable charges. The commenter argued that Part D plans should not be able to impose unrestricted fees on SPAPs.

Response: Section 1860D–24(a)(3)(B) of the Act prohibits us from imposing user fees on SPAPs for the transmittal of third party reimbursement information necessary for the tracking of TrOOP expenditures. However, section 1860D–11(j) of the Act specifies that a Part D sponsor offering a Part D plan must allow SPAPs and other prescription drug coverage (described in sections 1860D–23 and 1860D–24, respectively) to coordinate benefits with the Part D plan. In connection with such coordination, Part D sponsors cannot impose any user fees that are unrelated to the cost of coordination on SPAPs or entities providing other prescription drug coverage. We interpret this

language to mean that Part D plans may charge user fees to SPAPs and entities providing other prescription drug coverage, but only for costs that are related to coordination of benefits between Part D plans and SPAPs or entities providing other prescription drug coverage. Any user fees imposed must be reasonable and related only to the Part D sponsor's actual coordination of benefits costs.

Comment: One commenter states that we should prevent entities providing coverage that supplements Part D benefits from removing enrollee incentives to choose cost-effective options under their Part D coverage. The commenter further stated that we should prohibit coverage that supplements the benefits available under Part D coverage from eliminating cost-sharing or otherwise reducing these to the extent that they lack any force to deter unnecessary drug expenditures. The commenter also thought that the supplemental benefits should also not be allowed to change or eliminate the tiering of drugs on a formulary.

Another commenter thought that unless we interpret section 1860D–24(c)(1) of the Act narrowly, plans could be allowed to veto many forms of cost-sharing assistance and benefits that supplement the benefits available under Part D coverage that employers, SPAPs, or others might want to provide for enrollees in order to ensure that they have at least as good drug coverage as they have today. They asked that we tightly define ''prohibited'' practices that might impair cost-management tools and make clear that plans are required to coordinate with SPAPs and other prescription drug coverage unless they utilize these prohibited practices as identified by us.

Response: Section 1860D–24(c)(1) of the Act provides that the coordination of benefits requirements contained in section 1860D–23 shall not impair a Part D plan's application of cost-management tools (such as tiered or differential cost sharing, prior authorization, step therapy, and generic substitution), even if an SPAP or other drug plan provides benefits that supplement the benefits available under Part D coverage for individuals enrolled in the Part D plan. We do not believe that section 1860D–24(c)(1) of the Act gives us the authority to override Part D enrollees' benefit rights under SPAPs and other prescription drug coverage. For example, we do not have the authority to override an employer's contractual obligation to provide its retirees generous supplemental drug benefits. Thus, while Part D plans may freely apply their cost-management tools, we cannot require these supplemental payers to modify their cost-sharing and other coverage rules in order to maximize the effectiveness of the Part D plan's cost management tools. However, we expect that supplemental payers may have some interest in applying utilization management tools as well.

a. Coordination with SPAPs

The statute envisions close coordination of benefits between SPAPs and Part D plans. SPAPs have filled a significant gap in prescription drug coverage for many Medicare beneficiaries in the absence of a Medicare drug benefit. With many States currently providing prescription drug coverage to a large number of Medicare beneficiaries, it is important to ensure that coordination between Part D plans and SPAPs occurs as efficiently and effectively as possible. However, section 1860D–23(c)(5) of the Act provides that nothing in the statute shall be construed to require that an SPAP coordinate with or provide financial assistance to beneficiaries enrolled in Part D plans.

We assume that some SPAPs will pay Part D plans' premiums on behalf of their SPAP enrollees. For SPAPs that choose to simply supplement the coverage provided under a Part D plan, and to forego subsidizing their enrollees' monthly beneficiary premiums, we expect to include SPAP enrollment information in the coordination of benefits system. In this way, pharmacies will know that a claim should be sent to the SPAP following adjudication by the Part D plan. We requested comment on this proposed approach, including the feasibility of the approach for SPAPs and the ease of administration for pharmacies. We also requested comment on whether or not SPAPs that choose to coordinate benefits on a wrap-around basis should be required to provide feedback on how much of the remainder of the claim they have actually paid.

Comment: Several commenters suggested that the information that Part D plans will be required to share with SPAPs as part of their coordination requirements needs to be specifically incorporated in our final regulations. In particular, several commenters asked for clarification regarding how we will assist States with receiving timely data exchanges from commercial insurance plans, employer-sponsored plans, Part D plans, and MA programs for cost-avoidance and recovery. Some commenters believe this information should include, among other things, the exchange of eligibility files, the exchange of claims payment files, and information concerning which drugs are on the plan formularies. Furthermore, they believed such information should be provided through a real-time point-of-sale process. One commenter provided extensive recommendations regarding the data and methods by which Part D plans should provide information to SPAPs.

Response: We appreciate the extensive number of comments we received on this issue. As specified in section 1860D–23(a)(1) of the Act, we will issue requirements by July 1, 2005, for Part D plans to ensure the effective coordination between the Part D plans and SPAPs and other entities providing prescription drug coverage for payment of premiums and coverage and payment for supplemental prescription drug benefits. These requirements will specify the specific coordination elements that Part D plans must share with SPAPs and other prescription drug coverage.

We note that, from a practical perspective, there may not be much need for coordination between Part D plans and SPAPs, since Part D plans will need information about supplemental payments that do not count toward TrOOP rather than those that do count toward TrOOP (for example, those made by SPAPs). To the extent that SPAPs are free-standing supplemental plans, there may not be much need for coordination activities that a Part D plan could charge for, since claims will be adjudicated at the point of sale. As we note elsewhere in this preamble, Part D enrollees will be required to provide their Part D plan with information about third-party coverage so that the Part D plan is aware that any supplemental coverage a beneficiary is receiving is from an SPAP and not, for example, from a group health plan, insurance or otherwise, or other third party payment arrangements.

However, we acknowledge that SPAPs and States have an interest in acquiring timely access to paid claims data on SPAP enrollees who are also enrollees of State medical assistance programs in order to use information on prescription drug utilization in their medical and case management activities. We are continuing to work on means to practically expedite the required data sharing with SPAPs. In addition, although we do not have the authority to require data exchanges between Part D plans and the States, we strongly encourage Part D plans to independently share data on these shared enrollees with State Medicaid plans, provided such disclosure is consistent with the HIPAA Privacy Rule provisions for the sharing of protected

health information with another covered entity. To the extent consistent with the applicable provisions of Title XIX, if there were a cost to the State for access to this data, we would match as an administrative cost at 50 percent.

Comment: One commenter believes that we should provide States with flexibility to provide benefits that supplement the benefits available under Part D coverage so as to ensure that SPAP beneficiaries have continuous access to covered Part D drugs, even during the coverage gap.

Response: As provided in § 423.464(a) of our final rule, Medicare Part D plans may coordinate with SPAPs in a number of ways, including coordinating on a claim-specific basis when Part D plan pays first and the SPAP is the secondary payer, and this may include providing assistance after the initial coverage limit. As provided in section 1860D–2(b)(4)(C)(ii) of the Act, SPAP payments for benefits that supplement the benefits available under Part D coverage will count toward an enrollee's TrOOP limit, which we believe provides SPAPs with an incentive to supplement Part D benefits on behalf of Part D enrollees, including paying part of a beneficiary's drug costs after the beneficiary has met the initial coverage limit (as defined at § 423.104(d)(3) of our final rule) under their Part D plan.

Comment: Several commenters were concerned that the coordination of prescription drug coverage between Part D plans and SPAPs and other prescription drug coverage will fall onto pharmacists. Pharmacists would have to file multiple claims to bill both the primary and secondary payers. They urged us to address these concerns when developing the coordination of benefits system.

Response: In consultation sessions we held with various groups, including pharmacies and companies that run pharmacies, they expressed a willingness to perform multiple transactions in order to bill both the primary and any secondary payers as necessary in order to get billing and payment right the first time. Furthermore, if the pharmacy does not perform a secondary transaction with the SPAP, the beneficiary must pay everything left after the Part D plan pays. Beneficiaries who qualify for SPAP coverage generally do so because they are low-income; thus, being required to pay up front themselves and bill the SPAP for later reimbursement is likely to be a heavy financial burden that may make it impossible for some of these enrollees to purchase their prescription drugs.

b. Coordination with Other Prescription Drug Coverage

As provided under section 1860D–24(a)(1) of the Act, Part D plans must also coordinate with the following entities providing other prescription drug coverage: (1) Medicaid programs (including a State plan operated under a waiver under section 1115 of the Act, such as a Pharmacy Plus waiver); (2) group health plans, as defined in 29 U.S.C. 1167(1); (3) the Federal Employee Health Benefits Program (FEHBP) under chapter 89 of title 5 of the United States Code, (4) Military Coverage (including TRICARE) under chapter 55 of title 10 of the United States Code; and (5) other prescription drug coverage as we specify.

In the proposed rule, we requested comments regarding situations that might involve coordination of benefits between States and Part D plans (other than situations in which a State is acting as an employer). We also invited comments on the other administrative processes and requirements that we might identify in order to facilitate coordination of benefits between Part D plans and entities offering other prescription drug coverage.

Comment: Two commenters requested that we clarify that States are prohibited from requiring pharmaceutical manufacturers to pay rebates on medications delivered to beneficiaries through Part D plans. Several other commenters thought that States should continue to be able to benefit from drug rebates related to drugs purchased by the SPAP as a supplemental benefit to SPAP enrollees enrolled in Part D plans.

Response: Given that the Medicaid rebate program does not apply to SPAPs, we do not have the authority under the MMA to regulate or impose prohibitions on drug rebate or drug pricing negotiations between SPAPs and manufacturers.

c. Coordination of Benefits

Sections 1860D–23(a)(1) and 1860D–24(a)(1) of the Act require that by July 1, 2005, we establish requirements for coordination of benefits between Part D plans and SPAPs and other insurers providing prescription drug coverage. The elements that are to be coordinated must include: enrollment file sharing; claims processing and payment; claims reconciliation reports; application of the protection against high out-of-pocket expenditures (by tracking TrOOP expenditures); and other processes we specify.

We considered whether a drug denied Part B coverage because the beneficiary fills the prescription at a pharmacy that does not have a Medicare supplier number should be considered a Part D drug (provided such drug otherwise meets the definition of a Part D drug), and requested comments on the relative likelihood of such an occurrence and on alternative means of addressing such circumstances.

For drugs potentially covered by Part B that are dispensed by a pharmacy that is not a Medicare supplier, we considered the development of automatic cross-over procedures. (Similar cross-over procedures are used today in connection with dual-eligible individuals entitled to both Medicare and Medicaid and related to coordination between Medicare and supplemental insurers.) We also mentioned a potential need for similar cross-over procedures for any physician-administered drugs that may be covered under Part B or Part D. Our proposed rule invited comments on both these issues.

Comment: Several commenters suggested that we allow drugs and biologicals that would otherwise be covered under Part B to be covered under Part D when a beneficiary obtains the drug at a pharmacy that has no Medicare supplier number. One commenter believed that our failure to do so could greatly hinder enrollee access to therapies for which Part D benefits should be available. In addition, allowing coverage of such drugs under Part D would facilitate the coordination of benefits process we have proposed. Another commenter asserted that these drugs and supplies are necessary for vulnerable populations at high risk. One commenter believed it would circumvent the Medicare statute to cover drugs only under Part B or Part D and would also impose a penalty in the form of higher out-of-pocket expenses on beneficiaries.

Response: While we understand the impact this could have on some beneficiaries, we do not believe that commenters have provided a compelling rationale for automatically covering drugs under Part D that are denied coverage under Part B because a beneficiary fills the prescription at the wrong pharmacy. Under section 1860D–2(e)(2)(B) of the Act, a drug is excluded from coverage under Part D to the extent that coverage for that drug is available to an individual under Parts A or B. In this case, coverage would have been available under Part B had the enrollee obtained the drug at a participating Medicare pharmacy.

To reduce the risk that beneficiaries do not lose Part B coverage by filling a prescription at a pharmacy that does not have a Medicare supplier number, we will: (1) encourage Part D plans to enroll pharmacies with Medicare supplier

numbers in their networks; (2) encourage Part D plans to inform beneficiaries whether their network pharmacies have a Medicare supplier number, and explain why this is important when filling prescriptions for drugs potentially covered by Part B; and (3) develop educational materials reminding pharmacies without Medicare supplier numbers that they must refund any payments collected from beneficiaries enrolled in Part B for Part B drugs unless they first notify the beneficiary (through an advanced beneficiary notice (ABN)) that Medicare likely will deny the claim.

Statutory ''refund requirements'' apply to claims for ''medical equipment and supplies'' that Medicare denies because the supplier lacked a supplier number (unless the beneficiary signed an ABN notifying him or her that Medicare will deny payment, and agreed to be personally responsible for payment), or the supplier did not know and could not reasonably have known that Medicare would deny payment. For this purpose, coverage of medical equipment and supplies includes durable medical equipment (DME), certain drugs and other supplies necessary for use of an infusion pump, oral immunosuppressive drugs and anti cancer drugs, and ''such other items as the Secretary may determine.'' (See the Medicare Claims Processing Manual, Chapter 30, sections 150.1.3 and 150.1.5.) Suppliers are presumed to know that Medicare will not pay for medical equipment and supplies furnished by a supplier that lacks a supplier number. (See section § 150.5.4 of Chapter 30 of the Medicare Claims Processing Manual.)

Comment: Several commenters urged us to provide guidance regarding how vaccines not covered under Part B will be covered under Part D, including reimbursement for their administration. One commenter encouraged us to arrange for Part B carriers to serve as the point of contact with physicians for purpose of payment by Part D plans for vaccine administration.

Response: As discussed in subpart C, vaccines (and other covered Part D drugs that are appropriately dispensed and administered in a physician's office) administered in a physician's office will be covered under our out-of-network access rules at § 423.124(a)(2) of our final rule, since Part D plan networks are defined as pharmacy networks only. A scenario under which a Part D enrollee must obtain a Part D-covered vaccine in a physician's office constitutes a situation in which out-of-network access would be permitted because a beneficiary could not reasonably be expected to obtain that vaccine at a network pharmacy.

Below, we use vaccines as an example of how out-of-network access to covered Part D drugs dispensed and administered in physician offices will work under Part D. However, it is worth noting that other covered Part D drugs that are appropriately dispensed and administered in a physician's office will be subject to the same treatment under our out-of-network access rules. As mentioned in subpart C, we expect the application of our out-of-network access rules to covered Part D drugs dispensed and administered in physician offices to be limited.

Costs directly related to vaccine administration may be included in the physician fees under Part B, since Part B pays for the medically necessary administration of non-Part B covered drugs and biologicals. However, there is currently no ready mechanism for physicians to bill Part D plans for vaccine costs. Requiring physicians who administer such Part D-covered vaccines to submit a claim to the appropriate Part B carrier would involve developing automatic cross-over procedures such that, if the carrier denies the claim under Part B, it would submit the claim to the TrOOP facilitation contractor, discussed elsewhere in this preamble, which would in turn create an electronic claim that it would send automatically to the Part D plan (or its claims processing agent) through which the enrollee has Part D coverage. The Part D plan would then pay the physician for the plan allowance for that vaccine.

While it is possible that we could eventually develop automatic cross-over procedures, we are concerned that establishing the cross-over procedures by January 1, 2006, will be onerous given many other systems and implementation challenges that must be addressed by then. Therefore, we believe that a two-step approach is the most appropriate policy. In the short-term, a Part D enrollee may self-pay the physician for the vaccine cost and submit a paper claim for reimbursement to his or her Part D plan. We note that this will not be necessary for enrollees of MA-PD plans, since medical and pharmacy benefits will be integrated. This approach is consistent with how beneficiaries accessing covered Part D drugs at an out-of-network pharmacy will be reimbursed by Part D plans for costs associated with those drugs. Once Part D is implemented, we will get a better sense for the actual volume of Part D-covered vaccines and other physician-dispensed and administered Part D drugs, and the need and most appropriate mechanisms for such automatic cross-over procedures.

We note that, to the extent that the amount charged by a physician for a Part D-covered vaccine and the plan's allowable cost for that vaccine vary, a beneficiary may be responsible (depending on the plan's out-of-network payment policy) for any out-of-network differential, as is the case with other covered Part D drugs obtained out-of-network.

d. Collection of Data on Third Party Coverage

Section 1860D–2(b)(4)(D)(ii) of the Act permits Part D plans to request information on third party insurance from beneficiaries. We expect Part D plans to update Medicare records based on the information provided by beneficiaries to reflect changes in coverage, including the primary or secondary status of the coverage relative to Medicare. Beneficiaries who materially misrepresent information about third party coverage may be disenrolled from any Part D plan for a period specified by us and may also be subject to late enrollment penalties upon subsequent enrollment in another Part D plan.

Section 1860D–2(b)(4)(D)(i) of the Act authorizes us to establish procedures for determining if costs for Part D enrollees are reimbursed by other payers, and for alerting Part D plans about such arrangements. In our proposed rule, we also considered mandating that beneficiaries enrolling in Part D plans provide third-party payment information and consent for release of data held by third parties as part of their enrollment application and which could be validated through a HIPAA-compliant beneficiary ''release'' or authorization. We clarify, however, that a HIPAA authorization to disclose protected health information to Part D plans for purposes of coordination of benefits related to reimbursement for health care for an individual is not required for third party payers that are covered entities under HIPAA, since such disclosures are considered ''payment'' disclosures under the HIPAA Privacy Rule.

Comment: One commenter believes that we should impose mandatory reporting requirements on third-party payers regarding the payment of out-of-pocket costs and that, as an incentive, the user fees charged to third-party payers could be adjusted depending on their degree of cooperation in providing TrOOP cost data. This commenter also thought we should require enrollees to provide third-party payment information in a standardized way as part of the enrollment process. Another

commenter suggested that the collection of third party enrollment data be incorporated into the application process as it is with the Medicaid eligibility determination, which requires a mandatory release of information by the beneficiary. One commenter agreed that beneficiaries must provide third-party payment information and consent to release of data held by third parties, which could be validated through a HIPAA-compliant beneficiary release or authorization.

Response: The Act does not give us an enforcement mechanism in the statute to impose mandatory reporting by third-party payers. However, as provided in § 423.32(b)(ii) of our final rule, we will require beneficiaries enrolling in or enrolled in a Part D plan to provide, in a form and manner that we will specify in separate guidance, third-party coverage information. Part D enrollees must also consent to the release of such information collected or obtained from other sources. Failure of beneficiaries to provide such information may be cause for termination of Part D coverage, as discussed in greater detail in subpart B.

We would like to clarify that in the event that a beneficiary does not disclose alternative coverage payments to the Part D plan, that plan has the authority to recover any payments made in error on the basis of incorrect assumptions about the level of TrOOP expenditures. The plan may recover these payments directly from the beneficiary on whose behalf the payments were made. We have modified § 423.464(f)(2) of our final rule and added paragraph (f)(4) to clarify this authority.

e. Tracking True Out-of-Pocket (TrOOP) Costs

In the proposed rule we considered a number of options for facilitating the exchange of data needed in order for Part D plans to track a beneficiary's TrOOP costs, and discussed alternatives around both mandatory versus voluntary reporting of claims and out-of-pocket costs, and centralized versus distributed responsibility for tracking the information in the. We considered two options for operationalizing the data exchange related to the Part D coordination of benefits system and TROOP accounting:

Option 1: The Part D plans will be solely responsible for tracking TrOOP costs.

Option 2: We will procure a TrOOP facilitation contractor to establish a single point of contact between payers, primary or secondary.

Additionally, to foster proper billing and coordination of benefits we also considered the establishment of the Medicare beneficiary eligibility and other coverage query system using the HIPAA 270/271 eligibility query and requested comments concerning the development of this system.

Comment: An overwhelming majority of commenters on the issue of tracking TrOOP costs supported Option 2—having us procure a TrOOP facilitation contractor to establish a single point of contact between primary and secondary payers. Generally, commenters thought that a single point of contact option would lead to standardization and compatible formats among payers, as well as a cost-efficient and effective means for providing accurate, consistently interpreted, and timely information to all parties involved in operationalizing Part D. One commenter stated that PBMs do not calculate this data and would therefore be forced to build a new system for performing coordination of benefits functions and tracking multiple payers. One commenter thought that exchange of data between payers and us must be administered efficiently and timely, and using technology and standard processing already well established in the pharmacy industry to promote online pharmacy benefit management. This commenter also urged us to require Part D plans to routinely provide enrollment updates to the TrOOP facilitator, including all data needed by payers to coordinate benefits, as well as to develop an oversight task force consisting of all parties involved in developing user requirements for the data system. Another commenter urged us to include community retail pharmacies in its single point of contact system, thereby considerably increasing the efficiency and effectiveness of this option for tracking TrOOP expenditures. One commenter supported our establishing a central clearinghouse similar to that used for Medicare Parts A and B, and another recommended that we streamline current coordination of benefits procedures so that they can be accommodated in a new TrOOP/coordination of benefits system.

Several commenters thought that tracking TrOOP expenditures in real time might not be feasible immediately after implementation of the Part D but should be a long or medium-range goal. One commenter thought we should limit our coordination of benefits responsibilities to tracking TrOOP and claims payment and reevaluate our options at a later date when it becomes clearer how different parties will participate in or interact with Part D. Another commenter urged us to establish interim rules that are administratively workable and do not impose compliance burdens or risks. Only one commenter thought that we should rely on Part D plans to track and report TrOOP amounts rather than involve an intermediary or TrOOP facilitation contractor.

Response: PDP and MA/PDs will be responsible for calculating TrOOP for all individuals enrolled in their plan. When a beneficiary has no supplemental coverage, TrOOP can be easily calculated. This is because the plan has all the necessary data within the claims it processes to calculate TrOOP. TrOOP is more complicated to compute when the supplemental coverage is through a ''free standing'' plan that wraps around Part D.

The overwhelming majority of responders felt that CMS must have some facilitation role in terms of TrOOP. We are considering facilitating the tracking of TrOOP in many ways, including: through the establishment of a TrOOP facilitation contractor, contractors, or blends of other suggested methods. Our goal is to facilitate the tracking of TrOOP by leveraging the existing coordination of benefit processes for Part D COB and TrOOP. This will include the collection of other payer information that can be used by Part D plans as part of the ongoing Medicare Secondary Payer processes. This process will be modified to include information as to whether these alternative payers that are primary to Medicare include coverage for prescription drugs. We will also expand the existing trading partner processes for Parts A and B supplemental wrap-around agreements to provide for the collection of supplemental drug plan information. In situations where an employer retiree wrap-around plan is currently wrapping around Medicare Part Parts A and B, this will require that a small amount of additional information be collected as part of the trading partner agreement to ensure coordination with the primary Part D plan. Under this strategy only one enrollment file would be required. (Employers, plans or payers may choose to submit separate enrollment files for Parts A and B crossover and Part D.) Only one file is required because this data will be maintained in the CMS Medicare beneficiary database.

SPAPs can choose this method of enrollment file sharing as well. Under this strategy an SPAP or employer will not have to create a separate enrollment file for each Part D plan. Data collected through these processes will be shared with the Part D plans. In addition to our data collection efforts, the Part D plan will also request information from beneficiaries on the presence of other

coverage that is primary or secondary to Part D, and will then have the ability to add, change, or delete information about other coverage in plan and CMS files.

We will also work with pharmacy providers, payers, PBMs and other affected parties to create an acceptable solution to facilitate situations where the pharmacy is lacking information in order to bill the appropriate payer. It is our hope that our solution will include, among other capabilities, an online eligibility file query function so the pharmacy may obtain information sufficient to direct a claim to the payer responsible for payment of a beneficiaries' claim.

We continue to work with industry on a solution to facilitate the TrOOP tracking process. A final decision on how best to address TrOOP process challenges will be released well before the July 1, 2005 statutory deadline. We are looking for a solution that will allow TrOOP to be calculated in as close to real time as possible.

Comment: One commenter recommended that we establish a standard for the transmission of TrOOP information since there is currently no HIPAA standard for the transmission of coordination of benefits information between payers in connection with pharmacy transactions. In addition, this commenter recommends that we establish a national identifier for payers and, with the help of the Congress, for patients as soon as possible in order for coordination of benefits to function most effectively.

Response: We intend to establish an efficient and effective process for handling coordination of benefits and tracking of TrOOP expenditures by the Part D plans in accordance with Federal laws and CMS guidelines.

Comment: Several commenters thought that Part D sponsors should be responsible for tracking TrOOP and that enrollees should not be held accountable to the extent that another plan providing prescription drug coverage does not act. Another commenter suggested that in circumstances in which the information maintained by the TrOOP facilitation contractor is not consistent with what an enrollee claims to be the case at a pharmacy, benefits should be administered based on data in the system at that time. The Part D plan should correct the errors afterwards, as it is the plan's ultimate responsibility to administer the benefit. The Part D plan could, for example, create a flag in the system noting that the enrollee believes his or her payment obligation is in error because of incorrect data; this flag would result in notification to a plan so that the potential error can be investigated and resolved. Another commenter thought that Part D plans should not be responsible for tracking TrOOP costs when the plan is not aware of a third party payer.

Response: Part D plans will always be responsible for correctly calculating TrOOP for their Part D enrollees. In the event that enrollees fail to provide information about other prescription drug coverage to their Part D plans, and the Part D plan later discovers that payments were made by a third-party payer, it must recalculate TrOOP and, if necessary, recover overpayments. We agree that, at the point-of-sale, the Part D plan's current information will always be the basis for its payment; a beneficiary's disagreement with such information can only be resolved by contacting the plan. At the pharmacy, the beneficiary must either pay the amount specified or decline to purchase the prescription until after the dispute is resolved. We note that in the course of normal operations, the status of beneficiary liability will fluctuate due to events such as failure to pick up prescriptions or corrected transactions, and that current pharmacy benefit management systems will automatically recalculate beneficiary liability after the updating of information in their systems. Consequently, any over- or under calculation of TrOOP will automatically be adjusted on the next claim once correct information has been received.

K. Application Procedures and Contracts with Part D Sponsors

1. Overview

Subpart K of part 423 implements section 1860D 12(b) of the Act. This subpart sets forth requirements for contracts with Part D plans, including application procedures, contract terms, procedures for termination of contracts, and reporting. We note that while Medicare Advantage (MA) organizations offering Part D plans are Part D plans, they follow the requirements of part 422 for MA organizations, except in cases where the requirements for the qualified prescription drug coverage involve additional requirements (for example, the fraud and abuse requirements specified in § 423.504(b)(4)(vi)(H) and the certification requirements in § 423.505(k). Although in the proposed rule we included the requirements of section 1860D–12(b)(2) prohibiting a fallback from acting as a PDP sponsor or a subcontractor to a PDP sponsor in subpart F of the regulations, we believe these requirements are more appropriately viewed as contract requirements, and not as bid requirements; therefore, we have moved those regulations to this subpart.

As in the proposed rule, this subpart sets forth the conditions necessary for an applicant to be considered qualified to contract with Medicare as a Part D sponsor, as well as contract requirements and termination procedures that would apply to Medicare-contracting Part D sponsors. The final rule specifies those procedures and requirements. Additionally, as we stated in the proposed rule, the applicable requirements and standards included in Part D of Title XVIII of the Act and our provisions under part 423, as well as the terms and conditions for payments described in regulation and in the statute, also apply to ''fallback plans'' found under subpart Q.

In this final rule, we clarify that any entity offering a Part D plan under the Medicare program is considered a Part D plan sponsor for the purposes of this subpart. In addition to PDPs that offer fallback plans, Part D plan sponsors can also include MA organizations that offer MA-PD plans, cost plans, and competitive medical plans (CMPs), as well as PACE organizations that offer Part D plans.

We clarify that entities offering Part D plans under Medicare must follow the provisions of this subpart unless requirements specifically pertaining to these entities in this final regulation include or allow for a waiver of these requirements. Similarly, we also clarify, as is the case with MA organizations and cost plans offering prescription drug plans, that these organizations follow the requirements of part 422 for MA organizations except when there are additional requirements in part 423 related solely to the prescription drug benefit component of the MA plan (In these cases, MA organizations offering the prescription drug benefit are directed by part 422 to any additional requirements in part 423.).

As further clarification of the exceptions to, or waiver of, requirements of this subpart, please note, for example, that PACE programs, though subject to part 423 if offering a prescription drug benefit, may waive several of the contract requirements under part 423. PACE programs are unique in that they have a Medicaid component and have been offering a prescription drug benefit for some time. As a result, some of the part 423 requirements are duplicative or not applicable. (Please see subpart T for discussion of the PACE program and the prescription drug benefit under Part D.)

In our definitions section at § 423.4 we include, as clarification, the entities

identified above in our definition of ''Part D plan sponsor.''

The proposed rule discussed at § 423.153(e) requirements for a program to control fraud, waste and abuse as required by Section 1860D–4(c)(1)(D) of the Act. In an effort to consolidate the requirements, we are moving them to this subpart at § 423.504(b)(4)(vi)(H) as a component of a Part D sponsor's or MA organization offering a MA-PD plan's overall compliance plan. In the preamble to this subpart, we will discuss our final provisions and the comments we received on the proposed requirements concerning fraud, waste, and abuse. For easier reference, we discuss this section at the conclusion of this preamble.

Further, as stated in the proposed rule, the MMA requires that the MA contracting provisions incorporated through section 1860D–12(b)(3) of the Act be applied to contracts with PDP sponsors in the same manner as those provisions apply to contracts with MA organizations under Part C of Title XVIII of the Act. Our overarching intent in the proposed rule, and our intent in the final rule, is to achieve a high degree of uniformity in the contract and application processes for both Part C and Part D. The maintenance of a single application and evaluation procedure, and a single set of contract requirements for both the Part C and Part D programs, brings simplicity, consistency, and reduced administrative burden for those entities managing both programs. Towards that end, the requirements under § 423.501 through § 423.516 are similar to the requirements in § 422.500 through § 422.524. We made every effort to keep the requirements in this subpart the same as those requirements for MA organizations; this effort was received without objection by any of the commenters; however, we did receive some comments asking us to clarify if certain sections were exclusive to PDP sponsors and inclusive of MA plans. In this preamble we address those and other comments.

2. Definitions (§ 423.501)

We proposed that the definitions pertaining to PDP sponsors and MA organizations offering MA-PD plans would be the same as those found in § 422.500, except in cases where the Part C definition is inapplicable (for example, in definitions that reference hospitals or hospital services). In addition, as mentioned above, we have added the definition of ''Part D plan sponsor'' to § 423.4 to clarify that we consider any entity offering a Part D benefit to be a Part D sponsor and, with the exception of requirements that may be waived. We have made nomenclature changes throughout the regulations text for this subpart as well, revising ''PDP sponsors'' in most cases to ''Part D plan sponsors'' to bring this language into line with our definition at § 423.4 and to indicate more clearly that a Part D sponsor includes any entity offering a Part D plan.

The majority of the subpart K regulations would also apply to fallback entities, since fallback entities are included in the definition of Part D sponsor. In addition, under § 423.871(a), fallback contracts are required to include the same terms of conditions as risk contracts, except as appropriate to carry out the provisions of subpart Q. We have also clarified the provisions that would not apply to fallback entities. For example, because fallback entities do not renew their 3-year contracts on a yearly basis, we have clarified that the renewal and non-renewal provisions would not apply to fallback entities. Fallback entities are also not required to be risk-bearing entities, and at this time we are not requiring that the licensure or solvency requirements of subparts I and K apply to fallback entities, although we may reconsider this issue in the future and we may use holding applicable licenses as a preferred, but not required selection criterion. We have clarified these provisions in the accompanying regulation text in § 423.504(b)(2).

We did not receive any comments regarding the proposed definitions for this subpart and will be adopting the policies proposed in the proposed rule.

3. Application Requirements (§ 423.502)

We proposed application procedures based on those included for the Part C program. Interested applicants would need to complete and submit a certified application in the form and manner required by CMS. In addition, we proposed that applicants must: (1) submit documentation of appropriate State licensure; (2) submit documentation of State certification that the entity is able to offer health insurance or health benefits coverage that meets State specified standards as discussed in the proposed subpart I; or (3) submit a Federal waiver as described in the proposed subpart I of the proposed rule. An individual authorized to act on behalf of the entity applying to become a Part D sponsor must describe thoroughly how the entity meets the requirements of the rule. We will determine if the applicant is qualified to contract with CMS as a Part D sponsor and if that entity meets the requirements of part 423. Also, we proposed that, as in the Part C program, an applicant submitting material that the applicant believes would be protected from disclosure under the Freedom of Information Act (FOIA) (5 U.S.C. § 522), or because of exceptions provided in 45 CFR Part 5 (the Department's regulations providing exceptions to disclosure), would have to label the material ''privileged'' and include an explanation of the applicability of an exception described in 45 CFR Part 5.

Comment: We received one comment stating that we were silent on the transition application requirements for current MA organizations wishing to add a prescription drug component to their MA plans.

Response: The application requirements for current MA organizations, and potential MA organizations wishing to offer MA-PD plans, will basically mirror those listed here for other Part D sponsors. In other words, MA organizations offering MA-PD plans and other entities offering Part D plans will, subject to any specified exceptions, follow the same requirements. Technically, MA organizations are following these requirements as specified at part 422, while other Part D plans are following these requirements at part 423. One difference between the requirements at part 422 and those at part 423 is the provisions for fraud and abuse which apply only to entities offering Part D benefits. In this case, the MA organization offering Part D benefits is directed at part 422 to follow the additional requirements specified in part 423 regarding its prescription drug benefits. In general, however, the application and contracting provisions in part 422 and part 423 are identical. Thus, while the MA-PD contract is separate from the PDP contract under Part 423, the requirements of this part will be incorporated, with any exceptions specified, into the contract of the MA organization offering an MA-PD plan. Specific transition guideline procedures will appear on the CMS Web site and through other CMS guidance to ensure that the transition to the prescription drug benefit under Part D works as smoothly as possible. Similar guidance will given to M+C organizations wishing to make the transitions to MA organizations.

To clarify further the transition to the MA-PD plan, for organizations interested in offering a MA-PD plan, we are, whenever practicable, keeping the contracting application and process the same for PDP sponsors and MA organizations. Medicare Advantage contractors will be required to apply for qualification to offer a Part D plan as

part of their MA application if their organization is a new participant in the MA program. If the MA organization is transitioning from a previous Medicare managed care contract, the Part D application will simply be a stand-alone submittal. MA organizations can expect the Part D portion of the MA application to be an abbreviated version of the PDP sponsor application, as the regulation and the Act at section 1860D–21(c)(2) of the Act, allow CMS to waive provisions that are duplicative of, or in conflict with, MA requirements or where a waiver would be necessary to improve coordination of Part C and Part D benefits.

Comments: In the application process under § 423.502(d), we proposed that a PDP sponsor applicant may request to have submitted material protected from public view under the Disclosure of Application Information under the Freedom of Information Act. A commenter recommended that we make it clear that an entire application of a potential PDP sponsor may not be protected in this manner. Also, the commenter requested that we set standards for when and why exemptions would be approved or provide a list of what is, and is not, protected from disclosure.

Response: The final rule, while not specifying 'how little' or 'how much' of an application may be protected, does require the applicant submitting material under FOIA to include an explanation of the applicability of an exemption specified in 45 CFR Part 5. The exemptions specified here serve as the standard for 'when' and 'why' an application in part, or whole, would be protected. Price and cost information provided by the bidders marked as ''confidential'' or ''proprietary'' will generally be protected by the Trade Secrets Act. However, FOIA requires the agency to disclose data to a requester if the information does not fall within any of the FOIA's exemptions. We would need to consider whether the pricing and cost data are covered by FOIA Exemption 4, which protects trade secrets and commercial or financial information obtained from a person that is privileged or confidential. See 5 U.S.C. § 552(b)(4). To facilitate this process, submitters of information to the Department may designate part or all of the information as exempt under FOIA Exemption 4 at the time the records are submitted or within a reasonable time thereafter. See 45 CFR 5.65(c). When there is a request for information that is designated by the submitter as confidential or that could reasonably be considered exempt under Exemption 4, the Department is required by its FOIA regulation at 45 CFR 5.65(d) and by Executive Order 12,600 to give the submitter notice before the information is disclosed. When notice is given, in order to determine whether a submitter's information is protected by Exemption 4, the submitter must show that: (1) disclosure of the information is likely to impair the government's ability to obtain necessary information in the future; (2) disclosure of the information is likely to cause substantial harm to the competitive position of the submitter; or, (3) the records are considered valuable commodities in the marketplace which, once released through the FOIA, would result in a substantial loss of their market value. (This is the general Exemption 4 legal standard used for required submissions to the government.) A submission may be ''required'' if it is necessary to get the benefits of a voluntary program (for example, applying to be a Part D plan sponsor).

4. Evaluation and Determination Procedures for Applications to Be Determined Qualified to Act as a Sponsor (§ 423.503)

Under proposed § 423.503, we established procedures to evaluate and determine an entity's application for a contract as a Part D plan sponsor. These provisions mostly mirrored the provisions applicable to MA specified at § 422.502 of our proposed requirements for MA organizations. We stated that the evaluation and determination of the application would be done on the basis of information contained in the application itself, as well as any additional information we obtained through on-site visits, publicly available information, and any other appropriate procedures. We also proposed rules regarding the timing of the application process, as well as the window for applicants to cure an incomplete or faulty application. See 69 FR 46709. Comments on these provisions are discussed below.

Comment: Several comments were received asking us to produce the final regulations as early as possible in January 2005 and to streamline our application process in a way that that does not increase administrative burden for MA organizations wishing to apply to offer MA-PD plans or for other Part D plan sponsor applicants. A commenter stated that the timing of the contracting (and bidding) and appeal process would afford too short a time frame for applicants to make the June 6 bidding deadline specified in subpart F. One commenter pointed out that the timelines for appeals by other Part D sponsors and MA organizations (that is, the timelines specified in parts 422 and 423) varied widely, and would cause unnecessary confusion and administrative burden. Two comments were received asking that we allow the contract determination process and the bid application process to run concurrently.

Response: We thank commenters for these comments and, in response, we are specifying in the final rule that we will be allowing applicants to enter into the bid process without an executed contract, and that the application and bid processes will run concurrently. Note that the bid application process will include both new bids to initially participate as a sponsor, as well as renewal bids. The contract will be pre-qualified and left unsigned until a successful bid negotiation has been approved by CMS. We will not award a Part D contract to an applicant until the applicant's bid is approved.

The contract application process and the bidding process as detailed under subpart F are separate but dependent processes. We view the bid application process as a negotiation and the contract process as a determination of an entity's qualifications to provide the Part D benefit. We have revised this final rule to make clear that the application process under subpart K determines only whether an applicant is qualified to contract as a Part D plan sponsor. However, actually signing the contract will require a successful bid negotiation as described under subpart F. Thus, although an entity may be pre-qualified to enter into a contract, a contract may not be signed if CMS and the entity cannot reach agreement on the bid.

We believe distinguishing between the bidding and the contract application processes carries out the intent of the Congress in section 1860D–11(d)(2) of the Act, under which the Congress provided the Secretary with the authority to ''negotiate the terms and conditions of the proposed bid . . . and other terms and conditions of a proposed plan'' and to exercise authority similar to that provided to the Office of Personnel Management under 5 U.S.C. Chapter 89. The bid negotiation will focus on the aspects of the bid and the benefit package to be provided by the Part D plan sponsor, while the contract application process will determine whether the entity offering the benefit package has the capability to contract with us under Part D. In addition, because the bid process is envisioned as a negotiation, only the contracting process under subpart K will be subject to the determinations and appeals process described in subpart N of these regulations. In order

to clarify the language concerning this distinction, we have revised our proposed rule to include new § 423.503(c)(2). Whether or not the entity and CMS are able to reach agreement on the bid and the benefit package will not be subject to subpart N. Indeed, we do not believe that the Congress intended for the bid to be appealable under these administrative provisions, because subjecting the bid to these appeals would frustrate our ability to calculate a national average premium in time for the annual enrollment period starting November 15 of each year. (We expect to have calculated the national average premium by at least August so that the beneficiary premiums, which are based on the national benchmark, can be published in time for open enrollment.)

Furthermore, taking bid negotiations out of the subpart N reconsideration process encourages plans to negotiate in good faith, as plans will realize that failure to negotiate will not lead to an opportunity to appeal, thereby maintaining the integrity of the negotiation process. We believe these changes to the contracting application and determination process will allow qualified candidates more time to prepare for CY 2006.

Additionally, we will be making the various timelines for appeals of determinations under subpart N of part 422 (Part C) and subpart N of part 423 (Part D) equivalent to eliminate any confusion and to shorten the contract application process.

Comment: In the proposed rule, we asked for comment on allowing 10 days for an incomplete application to be cured by an applicant from the date of the incomplete notice, and noted that the MA provision in § 422.502(a)(2)) currently provides a 30-day window for the MA program to furnish missing information. We also proposed a 10-day time frame for responding to an intent to deny. We received comments suggesting that the differing timelines between the Part D plan and MA organization appeal timelines (that is, the requirements specified in parts 422 and 423) were confusing in general and expressing concern with the relatively short timeline for the contract application process.

Response: We remain committed to providing successful applicants a reasonable time to be prepared to begin operations by the first of the year in their selected service area(s). However, we also wish to ensure all potential applicants are given every chance to contract with CMS.

In the event that we determine that an application is incomplete, we afford a means for the applicant to cure the contract application. However, the bidding process required under the MMA makes the use of the 'rolling application' system previously used under the Medicare Advantage and Medicare+Choice programs impracticable. As a result of the new bid calculation requirements for Part C and Part D, we need to process all final bids by a certain deadline each year. Therefore, we needed to apply a similar deadline to the application review process.

In order to respond to concerns that the determination application process as it was proposed could compromise a Part D plan sponsor's ability to effectively prepare for the beginning of a contract period, we are making the following modifications: We are no longer considering § 423.503(a)(2) as a separate and distinct step in the review process. If an applicant's contract is submitted and found to be both incomplete, as well as unqualified, (resulting in an intent to deny notice) the period to remedy the application will be 10 days from the date of the notice. Additionally, if after the initial review of applications, we determine that an application is missing information necessary for us to make a determination, we will make all reasonable efforts to notify the applicant that this is the case. This is not a requirement, however, and we are stating in the final rule that our procedural rule will be that applicants receiving notification that their application is incomplete, but who have not yet received an intent to deny notice, respond back to CMS with a cured application within two days of receiving the notice (instead of the ten days originally proposed). The two days are, thus, a guide; however, we are ultimately constrained by the total amount of time it will have to review applications. As a result, an applicant that takes longer than two days to remedy its incomplete application risks our issuing a notice of intent to deny before the Applicant submits the requested information. In cases where an Intent to deny notice has been issued, either as a result of missing information, information that would lead us to deny the application, or both, the applicant has ten days from the date of the notice to remedy the application. We believe that the amount of time given to applicants to furnish information is a procedural rule that is not subject to notice and comment. In addition, applicants will still receive the same 10 days included in the proposed rule to revise their applications if they fail to respond within 2 days, and then receive an intent to deny notice from us.

These changes to the application timelines mirror the changes we have included in the final rule for MA organizations. We believe that maintaining a single application and evaluation procedure and a single set of contract requirements for both the Part C and Part D programs brings simplicity, consistency, and reduced administrative burden for those entities that are managing both programs.

5. General Provisions (§ 423.504)

In the proposed rule, we stated that the requirements of § 423.504 would specify the general provisions that apply to Part D sponsor contracts. For more details on those proposals please see 69 FR 46709–11. For the most part, we stated that we planned to adopt the provisions that already applied to MA organizations through the Part 422 regulations. As part of these general provisions, we proposed mandatory self-reporting requirements and asked for comments on the provisions. Finally, we noted that we would annually audit the financial records (including, but not limited to, Medicare utilization, costs, reinsurance cost, low-income subsidy payments, and risk corridor costs) of at least one-third of the Part D plan sponsors, including fallback plans. We asked for comments on the best approach to audit fallback plans and whether they would require more frequent auditing because of their different payment arrangements. In the proposed rule, we also specified that we would use the authority of section 1857(c)(5) of the Act (incorporated through section 1860D–12(b)(3)(B) of the Act) to enter into Part D plan sponsor contracts without regard to the Federal and Departmental acquisition regulations set forth in title 48 of the CFR. We did not receive any comments regarding fallback plans audit methods, but did receive some comments on auditing in general, which are discussed in more detail below.

Comment: One commenter thought that PBMs should be prohibited from charging pharmacists a fee for submitting claims, as this has become customary in the private sector, and some PBMs have increased their fees for claims submission substantially. Some commenters said plans should not be allowed to tie Medicare business to other commercial business through an existing ''all products'' clause or passively enroll pharmacies in Medicare drug plan networks; rather, plans should be required to sign a Medicare-specific contract with each pharmacy, or at least get a written response from each

pharmacy confirming its participation. One commenter suggested that plans be allowed to set a limited sign-up period in which pharmacies can take advantage of the standard contract.

Response: Concerning the comment that PBMs not be allowed to charge pharmacists a fee for submitting claims, we believe that the intent of the statute is to let market forces prevail within the regulatory provisions outlined in the MMA and this final rule. In other words, if a PBM charges a relatively high fee to participating pharmacies to process claims, then it follows that a PBM would have difficulty securing contractual arrangements with a sufficient number of pharmacies to meet ''access'' requirements under Part D.

As to the comments concerning Medicare-specific contracts, our primary goal is to ensure access to Part D drugs for Medicare beneficiaries. To the extent a contract is reasonably construed by both parties to ensure access to Part D by Medicare beneficiaries, the contract is deemed sufficient.

Comment: As noted in the proposed rule, we proposed changing the compliance program requirements for MA organizations at § 422.501(b)(3)(vi)(G) to include provisions that would require MA organizations to report misconduct it believes may violate various criminal, civil or administrative authorities. We based the compliance program requirements for Part D plan sponsors on these new and recently proposed MA requirements. Numerous comments, both for and against, were received regarding these requirements of mandatory self-reporting of misconduct. The very large majority of the comments, however, objected that the rule as written was vague and broad, with no basis in statute. Other comments directed us to eliminate the proposal, stating that current compliance requirements were sufficient.

Response: In response to these comments, we are eliminating from this regulation an explicit requirement that Part D plan sponsors report to CMS violations of law, regulation, or other wrongdoing on the part of the organization or its employees/officers. While we are not requiring Part D plan sponsors to engage in mandatory self-reporting, we continue to believe that self-reporting of fraud and abuse is a critical element to an effective compliance plan; and we strongly encourage Part D plan sponsors to alert CMS, the OIG, or law enforcement of any potential fraud or misconduct relating to the Part D program. If after reasonable inquiry, the Part D plan sponsor has determined that the misconduct has violated or may violate criminal, civil or administrative law, the Part D plan sponsor should report the existence of the misconduct to the appropriate Government authority within a reasonable period, that is, within 60 days after the determination that a violation may have occurred.

The failure to disclose such conduct may result in adverse consequences for PDP sponsors, including criminal prosecution. For example, Title 42 U.S.C. Section 1320a–7b(a)(3) punishes as a felony the knowing failure to disclose an event affecting the initial or continued right to a benefit or payment under the Medicare program. The Federal civil False Claims Act, 31 U.S.C. Section 3729(a)(7) states that any person who knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government, is liable to the United States for a civil penalty plus trebled restitution for the damages sustained by the government. In addition, both DOJ and the OIG have longstanding policies favoring self-disclosure.

In summary, we have elected to recommend reporting fraud and abuse as part of the compliance plan required as a condition of contracting as a Part D plan sponsor. Plans that self-report violations will continue to receive the benefits of voluntary self-reporting found in the False Claims Act and Federal sentencing guidelines. In the future, we will examine mandatory self-reporting of health care fraud and abuse across all Medicare providers and contractors.

Comment: A commenter questioned the need for proposed § 423.505(h), which would require Part D plan sponsors to comply with certain specific Federal laws and rules, other laws applicable to recipients of Federal funds, and all other applicable laws and rules. The commenter argued that these requirements were on their face seemingly inconsistent with our regulatory provisions exempting Federal plans from procurement standards and preempting State laws other than those relating to licensure. Furthermore, nothing suggests a rationale for naming some laws and not others. The commenter also suggested that the provisions might more appropriately be replaced with one focused on plans committing themselves to compliance with Federal standards aimed at preventing or ameliorating waste, fraud, and abuse.

Response: We agree that our efforts are best focused on requirements to prevent fraud, waste, and abuse in the Part D program and on issues for which we are responsible to enforce (for example, the HIPAA Administrative Simplification rules).. We have, therefore, made the suggested changes to reflect this focus. These changes are in no way meant to imply that Part D plan sponsors need not comply with other Federal laws and regulations as applicable, but rather only that the enforcement of these Federal laws and regulations is the responsibility of Federal agencies other than CMS. We have made a similar change in the Medicare Advantage regulation.

Comments: We received four comments asking that we add an annual audit to proposed § 423.504(d) (protection against fraud and beneficiary protections). Commenters requested stronger language to clarify that we will perform an annual audit as part standard oversight procedures. One commenter referred to a $1.1 million penalty imposed on a company found to be switching patients from lower priced generics to more expensive brands. Two comments requested that we add language to the final rule that reads: ''CMS must audit annually...'' (as opposed to reading ''CMS may audit annually.''). (emphasis added), not 'may.'''

Response: Section 1860D–12(b)(3)(C) of the Act requires CMS to implement the provisions of section 1857(d) in the same manner as those provisions that apply to contracts under Part C of the Medicare program. Section 1857(d)(1) of the Act specifies that the Secretary will audit ''at least one-third'' of organizations. Therefore, in this final rule, we will continue to adopt the regulations used in the MA program under which we would expect to audit one-third of contracted plans each year. If additional audits are necessary, we would have the discretionary authority to perform them as well under § 423.505(e)(2)(iii).

Comment: A commenter asked that we require plans to contract with, and provide service through, long-term care pharmacies and Indian Health Service, Tribal or Urban Indian pharmacies. Additionally, we should carefully monitor and report on access to drugs for nursing home residents and ensure equal access to prescription drugs for those residents.

Response: We are including this issue here because some readers might look for clarification in this subpart. However, we believe that this issue is more appropriately discussed in the context of pharmacy networks and therefore refer interested readers to a

discussion of this comment in subpart C of this final regulation.

Other than the above changes, we are adopting the substance of proposed § 423.504.

6. Contract Provisions (§ 423.505)

In the proposed rule we stated that, for the most part, we would be adopting the additional contract provisions for the MA program with modifications as necessary to accommodate differences between the MA program and the prescription drug program. For a full discussion of our proposals, please see 69 FR 46711–713. We noted that elsewhere in the proposed rule, we identified additional contract terms that would apply uniformly to MA organizations offering MA-PD plans and other Part D plan sponsors (for example, the requirement to support e-prescribing). These rules continue to be included in the final rule at subpart D.

Comments: In § 423.505(d), we proposed requiring record maintenance and retention for six years, stating that records should be kept ''for the current year and 6 prior years.'' This requirement mirrored the record retention requirements from the MA program. A commenter stated that this should be changed to read, ''6 prior contract periods,'' stating that this would better clarify that the retention requirements do not precede the execution of the contract. An additional request was made to clarify whether the retention periods also refer to MA-PD plans. Another commenter asked that we clarify our retention of records to include all pertinent documents (whether in paper or electronic form). That commenter also asked that our records retention policy parallel the statute of limitations that applies to False Claims Act (that is, a maximum of 10 years from the time of the violation).

Response: We agree with the commenter that our retention requirements should more closely follow the statute of limitations that applies to the False Claims Act. As a result, in the final rule at § 423.505(e)(4), we are requiring that records be maintained for 10 years from the last contracting period or audit, whichever is latest, to conform to the statute of limitations for the discovery of violations under the False Claims Act.

We recognize that 10 years is the upper limit under the False Claims Act, but we believe that this period will best enable us to have access to pertinent records should this be necessary. Also, the 10-year retention policy is in line with requirements concerning the prescription drug rebates under the Medicaid program (§ 447.534(h)). We believe, as is the case with the Medicaid rule, that in order to ensure that we have the proper oversight for investigating the complex payment and other relationships associated with the delivery of prescription drugs under a program like Part D, the 10-year retention requirement is necessary. In order to maintain uniformity between requirements for MA organizations and other Part D sponsors, we are making a similar change to the final MA regulations.

We do not agree with the commenter, however, that we specify the particular medium of records (paper or electronic, for example)that must be retained. Specifying the type of record could lead to a requirement that is unnecessary, lengthy, and confusing with CMS attempting to list every type of medium (past, present, and future) that could contain any information. We do believe, however, that all pertinent information should be maintained, including any and all electronic records.

In response to the comment requesting that ''6 prior contract periods'' be specifically identified as opposed to ''6 years'' for the record retention requirement, we continue to specify years in this final rule (though 10 years, now, to parallel the statute of limitation for the False Claims Act) as we believe there may be occasions when a Part D sponsor during a prior period was under contract with us, ceased operation, and, at a later time, contracted again with Medicare. Specifying contract periods in these cases could make for a partial record of information and prevent us from having full access to the information over the period in question.

Comment: In § 423.505(l), we proposed six certifications that would be required of PDP sponsors. Although we refer readers to the regulations for a full discussion of these certifications, generally stated, they include certifying that—

(1) All data related to payment is accurate, complete and true;

(2) Each enrollee is validly enrolled in the prescription drug plan;

(3) The claims data submitted is accurate, complete and truthful;

(4) The information in the bid submission and assumptions related to projected reinsurance and the low income subsidy is accurate, complete, truthful, and conforms with the regulations;

(5) The information provided for purposes of supporting allowable costs for purposes of calculating risk corridor and reinsurance payments is accurate, complete, truthful, and fully conforms to the regulations; and

(6) The data submitted for price comparison is accurate, complete, and truthful. These certifications were based on the certifications required under the MA program, but were modified to reflect the different payment mechanisms under the Part D program. A commenter requested that we revise these six certifications and provide general authority for requiring the certifications. The commenter requested that we remove the specific language related to the content of the certifications in order to provide CMS with flexibility in the start-up phase of MMA, and to make it easier to integrate the Part D certifications with the Part C certifications.

Response: As we have done elsewhere, we largely based the certification process for Part D on the Part C requirements for MA organizations. We do this because of the similarity in scope of both programs, as well as the familiarity many will have with the MA process. However, the Part D program differs in some payment respects from the Part C program. Thus, while the MA regulations currently require a certification of data included in the ACR, the Part D regulations similarly require a certification of the information included in the bid submission. Also, because there are additional payment mechanisms under Part D (for example, risk corridors and reinsurance) that do not exist for Part C, we believe it is appropriate to require certifications for these separate types of payment. If at the time it is found that additional, or alternate, certifications are required we have the discretion to change them through notice and comment rulemaking. The final rule requires that the CEO or CFO of a Part D sponsor, or an authorized individual, request payment of claims on a document that certifies (based on best knowledge information and belief) the accuracy, completeness and truthfulness of all data related to payment. We highly recommend that Part D sponsors collect certification from their downstream partners as well. Further, if claim data is generated by a related entity, contractor, or subcontractor of a PDP sponsor, the entity, contractor, or subcontractor would be required to similarly certify (based on best knowledge, information, and belief) that the information provided for purposes of supporting allowable costs, as defined in § 423.308, is accurate, complete and truthful, and fully conforms to the requirements in § 423.336(c) and § 423.343(c).

Comment: A commenter recommended that we explicitly state that the certification provisions of

§ 423.505(l) apply not exclusively to PDPs, but also to MA organizations offering MA-PD plans as well.

Response: We note that the certification provisions under § 423.505(l) apply to all Part D plan sponsors as defined earlier in this section and in the definitions section at § 423.4.

In § 423.505(f)(2)(vii) we have added examples of other matters where CMS may require statistical data and information from PDP sponsors to further clarify these ''other matters that CMS may require.'' For an effective oversight program, for example, CMS may require PDP sponsors to submit statistics and information regarding performance of operations in the following areas:

(a) Experience and capabilities.
(b) Licensure and solvency.
(c) Business integrity.
(d) Benefit design.
(e) Service area and regions.
(f) Pharmacy network.
(g) Enrollment and eligibility.
(h) Exceptions, appeals, and grievances.
(i) Quality assurance and utilization management.
(j) Medication Therapy Management Programs.
(k) HIPAA.
(l) Customer service and satisfaction.
(m) Coordination of Benefits (COB).
(n) Tracking Out-of-Pocket Costs (TrOOP).
(o) Marketing and beneficiary communications.
(p) Provider communications.
(q) Control of fraud, abuse, and waste.
(r) Claims processing.
(s) Other performance measures as specified in guidelines provided by CMS.

7. *Effective Date and Term of Contract (§ 423.506)*

In the proposed rule, we specified the term of non-fallback contracts (12 months) and specified that contracts could be renewed from year to year, but only in the event that we inform the Part D plan sponsor that a renewal is authorized, and only if the Part D plan sponsor does not provide us with a notice of intent not to renew. We stated that we would not require an application process for renewals, and that because of the need to establish a national average monthly bid amount from the approved bids, PDP contracts could not be effective at any time other than the first of the year. We received no comments on these provisions and are adopting the policies as stated in the proposed rule on this section. We have changed the regulations to clarify the distinction between the bidding and the application processes. As discussed previously in this subpart, the revisions indicate that the renewal process leads only to a determination that a sponsor is qualified to renew its contract and that the actual renewal of the contract will depend upon whether CMS and the sponsor are able to reach agreement on the bid.

8. Nonrenewal of Contract (§ 423.507)

In the proposed rule, we indicated provisions concerning the non-renewal of a Part D plan sponsor's contract. Under proposed § 423.507, we required that a Part D plan sponsor not renewing its contract provide us with notification in writing by the first Monday of June in the year in which the contract ends. The Part D plan sponsor would also have to notify each Medicare enrollee at least 90 days before the date on which the nonrenewal is effective. This notice would have to include a written description of alternatives available for obtaining Medicare prescription drug services within the PDP region, including MA-PD plans, and other Part D plans, and would have to receive our approval. The general public would also have to be notified at least 90 days before the end of the current calendar year by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

We proposed that if a Part D plan sponsor chose to non-renew a contract as described in § 423.507(a)(3), we would not enter into a contract with the organization for 2 years unless circumstances warranted special consideration, as determined by CMS. For purposes of this section, we stated that we may elect not to authorize renewal of a contract for any of the reasons listed in § 423.509(a)(conditions for terminating a contract) or in subpart O (including § 423.752 (bases for imposing intermediate sanctions or civil money penalties.))

We proposed providing notice of our decision whether to authorize renewal of the contract to the PDP sponsor by May 1 of the contract year. In the event we found after May 1st that a plan for whatever reason should not be renewed the following year, we stated that we retained the right to terminate the Part D plan sponsor contract at any time based on any of the reasons stated in § 423.509, regardless of whether we renewed a Part D plan sponsor contract. If we decided not to authorize a renewal of the contract, we stated we would provide notice to the Part D plan sponsor's Medicare enrollees by mail at least 90 days before the end of the current calendar year. We also stated we would notify the general public at least 90 days before the end of the current calendar year by publishing a notice in one or more newspapers of general circulation in each community or county located in the PDP sponsor's service area. We stated that we would give the Part D plan sponsor written notice of its right to appeal the decision that it was not qualified to renew its contract in accordance with proposed § 423.642(b).

We received a few comments on this section which we discuss below. In the final rule we are adopting the provisions of the proposed rule with some minor modifications (in particular to clarify that a decision to non-renew a contract constitutes a determination that a contractor is not qualified to renew its contract).

Comment: One commenter indicated that allowing for only four months (January 1st—May 1st) for us to decide whether or not to renew a Part D plan contract provides an inadequate amount of time for us to make an informed decision.

Response: We must make the determination that a contractor is not qualified to renew its contract by May so that we can know if an organization will be entering a bid, and also so that we may calculate the benchmarks for that particular area. If, after the deadline for CMS non-renewal passes, we uncover additional information causing us to question the qualifications of the contractor to continue serving as a Part D plan sponsor, we have a range of options available under this subpart, as well as under subpart O. (For example, we could impose an enrollment freeze, a termination of marketing, or terminate the contract if necessary.) In addition, even if we determine an entity is qualified to renew its contract, this does not mean the contract will necessarily be renewed. If we and the contractor cannot reach agreement on the terms of the bid, then the contract will not be renewed.

Comment: Concern was expressed by a commenter that it was unclear how a Part D plan sponsor not renewing its contract could fulfill the requirement to inform consumers of other Part D plan options in the same service area, especially if other plans are changing or leaving the area at the same time.

Response: The plan is also required to notify the public 90 days before the end of the current calendar year. If 90 days is October 1, at that point, the plan should know (or should be able to find out from CMS) what plans are likely to offer prescription drug coverage for the

upcoming annual enrollment period in the service area.

9. Modification or termination of contract by mutual consent (§ 423.508).

In proposed § 423.508, we specified that a contract could be modified or terminated at any time by written mutual consent. If the contract were terminated by mutual consent, the PDP sponsor would have to provide notice to its Medicare enrollees and the general public using a timeframe we determine is appropriate. If the contract were modified by mutual consent, the PDP sponsor would be required to notify its Medicare enrollees of any changes that we determine are appropriate for notification within timeframes specified by CMS. We received two comments concerning this section on the proposed rule.

Comment: A Part D plan sponsor not intending to renew its contract with CMS is required to provide notice by the first Monday in June in the year in which the contract ends. Several commenters believed that this was not enough lead-time to ensure a complete transfer of files. They suggested that, as a condition of participating in the Part D program or recovery of surety bonds, Part D sponsors be required to cooperate in a timely manner with regard to all file and data transfers, including in cases where the Part D sponsor is leaving the market.

Response: We agree with the commenters that we should specify that data and files must be transferred timely and are adding language at § 423.507(a)(4), § 423.508(d), § 423.509(b)(1)(iv), and § 423.510(f) to clarify that these transfers must take place in cases of non-renewal, as well as in cases where the plan is ended for other reasons..

10. Termination of Contracts by CMS (§ 423.509)

This section discusses reasons for termination by CMS of a Part D sponsor. In the proposed rule, we asked for comments on § 423.509(a)(14), which allows us to immediately terminate a plan's contract without making corrective action available. This authority would be used if we have credible evidence of false, fraudulent, or abusive activities affecting the Medicare program. For the remainder of our proposals under this section, please see 69 FR 46714–715. We received one comment on this section as discussed below and are adopting the proposed policies in this final rule.

Comment: A commenter stated that our requirements allowing plans to cease operations 90 days after a CMS termination decision, and then requiring that the terminated Part D sponsor notify enrollees at least 30 days before the termination, is an unacceptable 60-day delay in notifying beneficiaries, and may cause gaps in coverage. Additionally, the commenter asked that the regulations stipulate that plans be immediately barred from any further marketing as soon as they are notified by CMS of their termination.

Response: We must allow some time between when a termination notice is given to an entity and when enrollees are notified of the termination so that we can alert other plans in the same service area that they are going to have to be open for enrollment and so that we can determine which plans have the capacity to accept new enrollees. In the event that only one other plan is in the area, we must make every effort in a short amount of time to contract with a qualified Part D sponsor to preserve beneficiary choice.

Regarding the comment about ending marketing immediately upon termination, sponsors are afforded appeal rights. Terminated sponsors have 15 days to file a notice of appeal.

11. Termination of Contract by the Part D Plan Sponsor (§ 423.510)

The proposed requirements for termination of a contract by a Part D plan sponsor were discussed at 69 FR 46715. These proposed requirements were unchanged from the MA program. We received one comment on notifying the States of PDP sponsors that have their contract terminated. We expect to adopt this suggestion in other guidance. In this final rule, we are adopting the provisions of the proposed rule.

12. Minimum Enrollment Requirements (§ 423.512)

We discussed the minimum enrollment requirements for potential Part D plan sponsors at 69 FR 46715 in the preamble of the proposed rule. We asked for comments on whether we should retain the minimum enrollment requirements from the MA program. We received one comment, discussed below, addressing that proposal. In this final rule, we are adopting the policies of the proposed rule.

Comment: Three commenters asked that we raise the minimum enrollment amounts from the current levels of at least 5,000 individuals enrolled for the purpose of receiving prescription drug benefits, and at least 1,500 enrollees for those plans serving rural areas. Their rationale was that at these low levels, a Part D plan sponsor could not be expected to negotiate and receive adequate prescription drug discounts or provide quality customer services to its beneficiaries.

Response: Although we have the authority under section 1860D–12(b)(3)(A)(i) of the Act to increase the minimum number of enrollees for PDP sponsors, given that we are in the first phase of the new drug benefit, we believe it would be reasonable to maintain the minimum enrollment numbers that were proposed. We may, in the future, need to adjust these thresholds based on our early experience. For now, however, we believe it would be prudent to adopt the minimum enrollment thresholds already used in the MA context, as we have greater experience with that program. Given that MA organizations offer a broader range of services than will be offered by PDP sponsors, and given that the minimum enrollment requirements have not seemed to stifle negotiation in that context, we believe it is reasonable to maintain these minimum enrollment numbers for potential PDP sponsors. Additionally, it should be noted that during the first contract year for a PDP sponsor in a region, the minimum enrollment requirements are waived. In addition, our intention for the final rule is to attract as many plans as possible to contract with us, thereby ensuring beneficiary choice and price competition. If, in the future, we find that the minimum enrollment numbers are too low for plans to garner high enough discounts or to provide quality customer service, we may increase the number through another round of rulemaking.

13. Reporting Requirements (§ 423.514)

Proposed reporting requirements were discussed at pages 46715 and 46716 of the proposed rule. We received no comments on this section and will be adopting the policies proposed.

14. Prohibition of midyear implementation of significant new regulatory requirements. (§ 423.516)

Under proposed § 423.516, we stated that we could not implement, other than at the beginning of a calendar year, provisions under this section that would impose new, significant regulatory requirements on a Part D plan sponsor or a prescription drug plan. We did not receive any comments on the provision, and the policy will be adopted in the final rule.

15. Fraud, Waste and Abuse.

Section 423.153(e) of the proposed rule discussed requirements for a program to control fraud, waste and abuse as required by Section 1860D–4(c)(1)(D) of the Act. In an effort to

consolidate the various compliance requirements in the rule, the requirements (and preamble discussion) pertaining to fraud, waste, and abuse programs have been moved from subpart D to subpart K, and included at § 423.504(b)(4)(vi)(H) as a component of a Part D plan sponsor's overall compliance plan.

Fraud and abuse compliance plans (referred to in this subpart as fraud and abuse programs) have been a part of private business practices since the early 1990's with the implementation of the Federal Sentencing Guidelines for Organizations of 1991. The Guidelines provide that a corporation can mitigate its sentencing when convicted of a Federal crime if its compliance plan is effective. Additionally, prosecutors may use their discretion in pursuing potential criminal conduct for those organizations that have an effective compliance plan. The Guidelines require an organization to exercise due diligence to detect and prevent violations of law (not just criminal law), and to promote an organizational culture that encourages compliance. They also require that businesses periodically assess the risk that criminal conduct might occur notwithstanding the organization's compliance and ethics program.

With these Guidelines in mind, we developed a set of elements for Part D plans to consider including in the fraud and abuse program component of their Compliance Plan so that they may benefit from an effective plan. These elements are similar to what many companies are doing in the private industry, including what is being done in the Federal Employee Health Benefits Program (FEHBP).

The Office of Personnel Management (OPM) requires the FEHBP plans to have a fraud and abuse program that contains at a minimum these components: an anti-fraud policy statement, written plan and procedures, formal training, fraud hotlines, education, use of technology to combat fraud and abuse, security safeguards to protect member and provider information, and a mechanism to address fraud and abuse practices that become patient safety issues.

States are also beginning to develop standards that pharmaceutical companies must follow before doing business in their State. For example, on September 29, 2004 Governor Arnold Schwarzenegger of California signed a new law that requires pharmaceutical companies to implement a Comprehensive Compliance Program (CCP). This CCP requires companies that sell pharmaceuticals in the State of California to comply with the tenets of the Code on Interactions with Health Care Professionals of the Pharmaceutical Manufacturers and Researchers of America (PhRMA) and the HHS Office of Inspector General's Compliance Program Guidelines for Pharmaceutical Manufacturers. In addition, the companies must declare in writing compliance with the plan, make its CCP and written attestation accessible to the public on its Web site, and provide a toll-free number where copies of the CCP and written attestation may be obtained.

Similarly, the current M+C organizations, under § 422.501(b)(3)(vi), must have a compliance plan that consists of the following:

- Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards related to fraud and abuse.
- The designation of a compliance officer and compliance committee who are accountable to senior management.
- Effective training and education between the compliance officer and organization employees.
- Effective lines of communication between the compliance officer and the organization's employees.
- Enforcement of standards through well-publicized disciplinary guidelines.
- Provision for internal monitoring and auditing.
- Procedures for ensuring prompt response to detected offenses and development of corrective action initiatives relating to the organization's M+C contract.

With the emergence of organized criminal groups that have become involved in healthcare fraud across the country, the defrauding of Medicare and Medicaid has increased program vulnerabilities for CMS. For example, prescription drug expenditures constitute one of the fastest growing components of all Medicaid programs and amount to more than $1 billion a year in Medicaid expenditures on pharmaceuticals. Preventing inappropriate expenditures from occurring is preferable to recouping inappropriately paid claims. States have been very aggressive in responding to many of the fraud schemes used by individuals and groups to defraud Medicaid programs. States have addressed fraud and abuse by developing systems, processes, and procedures to identify and prevent fraudulent providers from entering their programs, thus avoiding patterns of payment and recovery.

As the Medicare Prescription Drug Benefit is implemented, it is crucial to the success of the Medicare program to have a fraud detection and prevention model in place. The identification and analysis of inappropriate activities that are essential aspects of the model will help Medicare to proactively combat fraudulent drug schemes.

After researching best practices currently utilized in the industry, we recommend that Part D plan sponsors consider adopting a program similar to the one used in FEHBP by including in the fraud, waste and abuse component of their overall compliance plan the following elements:

1) Written policies and procedures for detecting and preventing fraud, waste, and abuse among Part D plan sponsors, any Pharmacy Benefit Managers, pharmacies, drug manufacturers and physicians and providers with whom the sponsors and MA organizations do business. In developing these policies and procedures, sponsors and MA-PDs may also consider requiring pharmacies to adhere to the Code of Ethics of the American Pharmaceutical Association as a best practice for its standard of conduct.

2) Designation of a compliance officer and compliance committee with responsibility for developing, operating, and monitoring the Fraud and Abuse program and with authority to report directly to the board of directors, the president, or the CEO. The Part D plan sponsor or MA-PD should consider the compliance officer's scope of responsibilities, the organization's size and resources, and the complexity of the task in determining whether this compliance officer needs to be a different individual than the one required in the overall compliance plan.

3) Effective training and education on fraud, waste, and abuse, which would address pertinent laws related to fraud and abuse (for example, anti-kickback provisions and False Claims Act provisions) and include training for Part D plan sponsor staff and contracted entities on common fraudulent schemes in the pharmaceutical industry, identified by CMS, the Office of Inspector General or Department of Justice.

4) Effective lines of communication between the sponsor and the following entities: CMS and its contractors; law enforcement; Pharmaceutical Benefit Managers; pharmacies; and physicians and providers with whom the Part D plan sponsors do business, including an effective line of communication between the Part D plan's compliance officer and all employees using a process (for example, a hotline or other reporting system) to receive complaints or questions. There should also be procedures in place to protect the

anonymity of complainants and protect whistleblowers from retaliation.

5) Internal monitoring and auditing to protect the Medicare Trust Fund from Part D fraud and abuse, including regular monitoring and auditing by the Part D plan to ensure that they are in fact taking the steps necessary to comply with all Federal and State regulations related to fraud and abuse and are following their compliance plan to mitigate the potential for fraud, waste, and abuse within their organization.

6) Enforcement of standards through guidelines that are widely disseminated to employees, contractors, agents, and directors.

7) Procedures to ensure prompt responses to detected problems and to undertaking corrective action. We recommend these procedures include: (a)referral of any abusive or potentially fraudulent conduct or inappropriate utilization activities, once identified via proactive data analysis or other processes, for further investigation to CMS or its contractors; (b) procedures to cooperate with law enforcement; (c) reporting of potential violations of Federal law to the HHS Office of Inspector General or, alternatively, to appropriate law enforcement authorities; and (d) the conduct of appropriate corrective actions, including repayment of any overpayments due to the fraud or abuse and disciplinary actions against responsible employees.

The guidelines discussed above will help ensure that the Medicare Trust Fund is protected against fraud, waste, and abuse in the Part D program. These guidelines should not be misconstrued to mean that Part D plans should undertake law enforcement activities. Rather, Part D plan sponsors should implement effective fraud and abuse programs, consistent with industry standards, to detect problems, make referrals to CMS or the appropriate program integrity contractor for further investigation and follow-up, and undertake corrective action. These provisions are crucial to the success of the Medicare Part D program and to the millions of beneficiaries who rely on these benefits.

As noted in the proposed rule, we proposed changing the compliance program requirements for MA organizations at § 422.503(b)(4)(vi)(G) to include provisions that would require a MA organization to report misconduct it believes may violate various criminal, civil, or administrative authorities. We also proposed basing the compliance program requirements for Part D plan sponsors on these proposed new MA requirements. Numerous comments, both for and against, were received regarding these mandatory self-reporting of misconduct requirements. The very large majority of the comments, however, objected that the rule as written was vague and overbroad, with no basis in statute. Other comments mentioned that imposing a self-reporting requirement on only specific health providers contracting with Medicare was patently unfair, and other comments directed us to eliminate the proposal, stating that current compliance requirements were sufficient.

In response to these comments, we have eliminated the mandatory self-reporting requirements that were proposed, but we expect all Part D plan sponsors to comply with the requirement for a comprehensive fraud and abuse plan as found under § 423.504(b)(4)(vi)(H). We continue to believe that self-reporting of fraud and abuse is a critical element to an effective compliance plan, and that organizations contracting with CMS will find it in their best interests to alert CMS, the OIG, or law enforcement to any potential financial fraud or misconduct. Part D plan sponsors must continue to have a compliance plan as found under § 423.504(b)(4)(vi).

The potential for fraud, waste, and abuse exists not only in Part D plan sponsors offering prescription drug coverage, but also in the PBMs, pharmacies, physicians, and other providers with whom Part D sponsors do business. Therefore, we recommend that, as part of their ongoing screening for abusive or fraudulent activity, one of the many fraud and abuse activities that Part D sponsors should screen for is the illegal prescribing of narcotics by physicians.

We recognize that there are many possible approaches to implementing a successful waste, fraud, and abuse program, and we have given Part D plans sponsors discretion in developing this program as part of their overall compliance plan. In developing its fraud and abuse program, we recommend that Part D plan sponsors consider the previously outlined set of elements as well as other industry best practice (for example, compliance guidelines published by the Office of the Inspector General).

Comment: Commenters cautioned CMS against imposing additional administrative requirements (for example, periodic reports summarizing data analysis activities or reports on illegal prescribing practices) unless it has been proven effective in reducing fraud and abuse.

Response: Based on the comments received, respondents felt that these additional reports would be too burdensome to submit. We will not be imposing these additional reporting requirements at this time. However, while we expect that Part D plan sponsors will have policies and procedures in place to effectively screen for wasteful, fraudulent, and abusive activity, they should also be expected to produce evidence (for example, a summary of data analysis activities, tools used, resources employed, or trend analyses performed) of this activity upon CMS request.

Comment: Commenters expressed concern that we were expecting plans to be law enforcement-like entities who would take decisive action if fraud was identified. Commenters did not believe that plans or their contracted entities were in a position to take enforcement action regarding physician or patient abuse, and that they did not have the medical information necessary to track physician or patient abuse. Commenters did not believe that plans or PBMs should be tasked with taking, or judged for failing to take, enforcement actions against providers or patients.

Response: We recognize that Part D plan sponsors are not law enforcement entities and will not expect these entities to pursue fraudulent activity in the same manner that law enforcement would. However, just as other contractors who administer Medicare benefits are responsible for monitoring for wasteful, abusive, and fraudulent activities in their organizations, we have the same expectations for Part D plan sponsors. We therefore recommend that Part D plan sponsors offering prescription drug plans detect and prevent potentially fraudulent or abusive activity. For assistance in identifying what constitutes abusive or fraudulent activity, Part D plan sponsors may consult a variety of sources including relevant statutes, regulations, and case law, as well as media reports, DOJ litigation history, HHS-OIG published guidance and CMS policy manuals. Once identified, we encourage referrals be made to CMS or appropriate CMS contractors. CMS and its contractors will investigate all cases referred as potentially fraudulent and then refer them to the appropriate law enforcement agency as warranted. Likewise, we encourage Part D sponsors offering prescription drug plans to fully cooperate in any investigation that we or our law enforcement partners pursue related to fraud identified in a particular plan's area.

Comment: We give no assurance that the proposed rule provides those giving

price concessions protection from liability under fraud and abuse laws. CMS should strongly endorse the offering of price concessions as entirely consistent with the anti-kickback statute for all manufacturers or providers who: (1) identify the price concessions as such in the applicable contract; (2) do not interfere with the reporting obligations of Part D plans; and (3) contractually obligate the plan at issue to accurately report all price concessions provided.

Response: The anti-kickback statute is enforced by the OIG and the Department of Justice. Therefore we cannot respond directly to this comment. Interested entities may wish to submit a request to the OIG for an advisory opinion on these kinds of questions.

Comment: We should make clear in the final rule that Part D plan sponsors that engage in illegal practices may be subject to sanction under the False Claims Act and certify on an annual basis that sponsors will meet all of the requirements imposed.

Response: Part D plan sponsors should devise their compliance programs so that their policies and procedures are consistent with the False Claims Act. With regard to the issue of annual certification, we are not requiring Part D plan sponsors at this time to certify that they are in compliance with their fraud and abuse programs.

Comment: In responding to the proposed rule, commenters questioned whether we would develop uniform standards for all Part D plan sponsors or if each Part D plan sponsor would develop its own criteria. Additionally, commenters wanted to know whether these compliance programs would be compared against one another.

Response: Understanding that there are many approaches to a successful fraud, waste, and abuse program, we have developed a set of suggested elements for Part D plan sponsors to consider as they develop a plan for identifying and reporting fraud and abuse activity within the overall compliance plan. We will not compare fraud and abuse plans to each other, but expect Part D plan sponsors to follow through with the monitoring and compliance initiatives that are identified in their own fraud and abuse control plans.

In addition to plan efforts to control waste, fraud and abuse, we will work to develop program level performance measures using our oversight data related to costs, benefit structure, and other factors to make comparisons with the non-Medicare prescription drug benefit market and with Medicare prescription drug baseline data. We will review these comparisons as part of our normal, continual review of the Part D program. When divergent trends between the Medicare and non-Medicare markets are identified, we will take appropriate action, as necessary. In this way, we can work to ensure that the Medicare continues to reflect private sector best practices in the efficient delivery of drug benefits and that we can remove unnecessary barriers to efficient care delivery.''

Comment: Commenters expressed concern that the proposed rule identified illicit prescribing of narcotics by physicians as a primary responsibility for Part D plan sponsors.

Response: Illegal narcotic prescribing is one of many ongoing vulnerabilities we recommend that Part D sponsors should screen for in implementing a successful fraud and abuse program. As noted in the suggested guidance on developing a fraud and abuse plan, we recommend Part D plan sponsors have in place procedures to detect and prevent abusive or fraudulent activity in their organization.

Comment: Several respondents were concerned with the illegal switching of medications and drug substitution for financial gain. For instance, switching from brand to generic may be appropriate, but switching brands, for example, Lipitor to Zocor, may not be appropriate without consultation with the prescribing physician.

Response: We agree that the potential for fraud and abuse surrounding drug substitutions programs is of grave concern. We have no intention of restricting or targeting providers who are acting in the genuine best interests of the patient, but rather are concerned that such switching practices could be abused for financial gain. Therefore, we recommend that Part D plan sponsors monitor for aberrant or abusive behavior related to drug switching both within its own organization (through its fraud and abuse component of its compliance program) and with its pharmacy network (through proactive data analysis and trending capability).

Comment: Several commenters asked CMS how they should forecast fraud and abuse detection and prevention into their solicitation proposal to be a Part D plan sponsor.

Response: Part D plan sponsors should bid these costs in the same way they cost-out their current compliance and utilization control activity, as fraud and abuse is inherently a utilization control.

Comment: Some commenters asked that safe harbors be developed for Part D plans under the Anti-kickback and physician self-referral laws.

Response: The anti-kickback statute is enforced by the OIG and the Department of Justice. Therefore, we cannot respond with specific guidance to comments asking for exceptions to the anti-kickback laws. While the physician self-referral rules are under CMS jurisdiction, this final rule does not create any exceptions to these rules at this time, as nothing on this topic was proposed. However, law concerning physician self-referral is generally not implicated in many arrangements involving PDPs and MA organizations, unless the arrangement involves a referring physician.

Comment: Some commenters were concerned about unfair extrapolation policies in the Part D plan auditing process of pharmacies. It was recommended that the same standard required for Part D auditors be required of CMS; that is, ''a statistically valid random sample.''

Response: We recommend that Part D plan sponsors utilize ''a statistically valid random sample'' when auditing pharmacies; however, Part D plan sponsors and pharmacies should agree on auditing procedures in their network contracts.

Comment: Several commenters expressed concern about unfair ''bounty hunting'' practices in the Part D plan auditing process of pharmacies. It is recommended that Part D plan sponsors be prohibited from paying auditors based on the denial of reimbursement claims. Instead, they should be paid based on an objective analysis of reimbursement claims.

Response: We do not expect Part D plan sponsors to pay auditors based on the number of reimbursement claims that auditors deny; rather, Part D auditing processes should be based on an objective analysis of reimbursement claims. Specific instructions regarding Part D auditing practices will be outlined in subsequent policy guidance.

Comment: One commenter recommended that the Agency utilize the regular auditing of plans and pharmacy benefit managers (PBMs) to help control fraud, waste, and abuse.

Response: As a part of our mandated oversight responsibilities, we will regularly audit all drug sponsors involved in the Part D program as stated under § 423.504(d).

Comment: Commenters wanted to ensure that providers and pharmacies who were on State sanction lists could not participate in Part D.

Response: Part D entities such as providers, pharmacies, PBMs, and plans may be excluded from participating in

Part D under certain circumstances. The Office of the Inspector General maintains the authority to exclude individuals and entities from participating in Federal health care programs, including Medicare. Therefore, we cannot respond with specific guidance to comments asking under what circumstances providers might be excluded from participating in Part D.

Comment: The provider community indicated that they wanted to review proposed fraud and abuse plan to ensure the consistent use of fraud and abuse tools to mitigate illegal actions.

Response: Compliance plans are the property of the Part D plan sponsors and for their internal use; consequently, we do not expect plans to publish these documents for public access. Compliance plans will only be available to government and oversight entities upon request. However, CMS manuals that outline program integrity expectations are available for public access. As for the consistent application of fraud and abuse processes and procedures, we have suggested in the final rule a set of elements for a fraud and abuse control plan for Part D sponsors to consider in developing the fraud, waste and abuse component of their overall compliance plans. Any requirements in addition to this set of elements are encouraged by CMS and are at the discretion of the Part D plan sponsors.

L. Effect of Change of Ownership or Leasing of Facilities During the Term of Contract

Subpart L of part 423 describes the impact that a change of ownership (CHOW) or the lease of facilities during the term of a PDP sponsor's contract would have on the status of the organization's contractual relationship with us, as well as the procedures the Prescription Drug Plan sponsor is required to follow when a CHOW occurs. The provisions of this subpart apply to PDP sponsor organizations and are almost identical to the provisions that apply to MA organizations at subpart L of part 422. We proposed making the requirements essentially the same since we believe a single set of CHOW requirements for both MA organizations and PDP sponsors will simplify management, assure consistency, and reduce administrative burden. The requirements in § 423.551, § 423.552, and § 423.553 of this rule, which apply to PDP sponsors, are, therefore, substantially the same as the requirements found in § 422.550, § 422.552, and § 422.553, which apply to MA organizations. We received no comment on this proposal and will adopt these provisions without modification (with the exception of a slight change in wording which we will describe below).

We also sought comments regarding the potential modification of the CHOW rules. In particular, we sought comments regarding—

- The situations which constitute a CHOW;
- How these provisions should be applied to large companies with multiple business units;
- The notification requirements related to a CHOW and the novation agreement provisions; and
- The provision related to the leasing of a PDP sponsor's facilities.

We received only favorable comments on our proposal to consider that, under § 423.551(a)(2), an asset sale only occurs when there is a transfer of substantially all the assets of the sponsor to another party. We requested comments on situations where a sponsor transfers substantial assets to another party, but less than substantially all of its assets. We received a few comments describing different scenarios that commenters believe should not constitute a CHOW. The intent of the proposals under subpart L was to fashion requirements that would not unfairly burden an organization when something less than substantially all of an organization's assets were sold or transferred. When reviewing the comments, however, it became apparent that for some organizations selling or transferring their entire PDP line of business could constitute something less than substantially all of their assets. We note that we interpret the sale or transfer of an entire PDP line of business as an asset transfer. We recognize that we cannot define all possible existing business arrangements and transactions, we are, therefore, issuing these rules as a framework and will provide guidance as needed via interpretive documents (for example, FAQs,) and on a case by case basis. Contracting organizations should be aware that we will be alert to situations where organizations may be looking to avoid compliance with the CHOW provisions to evade Medicare liabilities and obligations.

In this final rule, we note that contracted PDP sponsors must adhere to the Privacy Rule on sharing protected patient health information in the course of a CHOW and the preparation of a novation agreement. PDP sponsors are not permitted to share protected health information, absent authorization from an enrollee, with a new owner that is not, or will not, become a covered entity.

We also proposed a definition of a novation agreement. A novation agreement is an agreement among the current PDP sponsor, the prospective new owner, and CMS. This agreement would have to be signed by all three parties and, to be effective, contain the provisions at § 423.552. In the agreement, we will recognize the new owner as the successor in interest to the current owner's Medicare contract. This definition has been adopted without modification.

1. General Provisions

We are adopting the provisions we proposed for this Subpart with one slight modification to § 423.551(a)(2). This paragraph is now entitled, Asset transfer rather than Asset sale.

2. Change of Ownership (§ 423.551)

We asked for comments on the various arrangements between and within companies that may, or may not, constitute a CHOW.

Comment: Commenters requested that we clarify that a CHOW does not occur when a change in the structure of an entity's business units occurs, but the same entity continues to be the PDP sponsor.

Response: The commenter did not provide, or otherwise define, what was meant by ''change of structure.'' Assuming the entity here is a unit of a multi-unit business with the PDP sponsor contract, and that the change of structure is within the company, and the same entity continues to hold, and be responsible for, the PDP sponsor contract, we would agree that a CHOW would not appear to occur in this instance. However, as mentioned above, we will be alert for any attempts by any Medicare contracted organizations to evade their responsibility to the Medicare program and its enrollees by avoiding compliance with the CHOW requirements.

Comment: We sought comments regarding how the CHOW provisions and provisions regarding the lease of a PDP sponsor's facilities should be applied to large companies with multiple business units. We received a number of similar comments regarding this issue. Commenters questioned whether the transfer of functions within a multi-State operation that centralizes functions within one entity would constitute a CHOW. One commenter recommends that the final regulation clarify that the transfer of functions within a multi-State company to an entity in another State does not constitute a CHOW.

Response: We believe that the transferring of functions within a

company consisting of multiple business units is a common practice and will in most cases be free of CHOW obligations, regardless of whether or not the transfer of functions was from one State to another, and was done in compliance with all applicable State licensure laws. What is pertinent in this instance is whether the transfer of functions does not represent substantially all assets of the organization and is truly an intra-company transfer—that is, that the same party, or parties, continues to be responsible for the PDP contract. As discussed in a previous response we will be scrupulous in ensuring that organizations contracting with the Medicare program do not evade their Medicare contract obligations. Any transfer of functions, or assets cannot result in a change of the entity responsible for the PDP contract without complying with all the CHOW provisions at § 423.551, § 423.552, and § 423.553.

Comment: A commenter requested that, given the impact a CHOW might have on SPAPs and State retirees, the final regulation provide for States to be notified of any CHOW.

Response: We will adopt the commenter's suggestion to notify States in the event of a CHOW. We will likely handle this internally and notify the appropriate State agencies.

3. Novation Agreement Requirements § 423.552

In the proposed rule, we identified the three conditions that would have to be met for approval of a novation agreement. A novation agreement is an agreement among the current PDP sponsor, the prospective owner and CMS. All three parties must sign the novation agreement for it to be in effect. Consistent with the requirements that apply to the MA program, at § 423.552(a) we proposed that three conditions would need to be met in order to obtain our approval of a novation agreement. First, the PDP sponsor would be required to give us notice at least 60 days before the effective date of a CHOW. That notice would include updated financial information and a discussion of the financial and solvency impact of the CHOW on the surviving organization. If notice were not timely, the contractor would continue to be liable for payments that we make to it on behalf of Medicare enrollees after the date of the CHOW, as described in § 423.551(c)(2). Second, the PDP sponsor would be required to submit three signed copies of the novation agreement (that contains the provisions specified in § 423.552(b)) at least 30 days before the proposed CHOW date, and submit one copy of other required documents. Third, the PDP sponsor would have to obtain our determination that—

- The new owner is in fact a successor in interest to the contract;
- Recognition of the new owner as a successor in interest is in the best interest of the Medicare program; and
- The successor organization meets the requirements to qualify as a PDP sponsor under proposed subpart K.

At § 423.552(b) we proposed that a valid novation agreement would include the following provisions:

- The new owner would assume all obligations under the Medicare contract.
- The previous owner would waive its right to reimbursement for covered services furnished during the rest of the current contract period.
- The previous owner would guarantee performance of the contract by the new owner during the contract period, or post a performance bond that is satisfactory to us;
- The previous owner would agree to make its books, records, and other necessary information available to the new owner and to us to permit an accurate determination of costs for the final settlement of the contract period.

We proposed that the new owner would become the successor in interest to the current owner's Medicare contract if the novation agreement meets all the requirements of § 423.552 and is signed by us (and the parties to that agreement).

Comment: One commenter requested that we require that enrollees of the PDP undergoing a CHOW receive detailed notification about any change, including any impact the CHOW may have on the ability of the new PDP sponsor to provide for enrollees' healthcare. This commenter also notes that we do not seem to provide for a special enrollment period to ensure continuity of care for beneficiaries in the event a novation agreement is not reached between the prior owner of the Medicare contact and the new owners, and the commenter requests that a special enrollment period be provided to ensure continuity of care.

Response: If a CHOW takes place that we believe would not be in the best interest of the beneficiaries then we will not enter into a novation agreement with the parties. Under § 423.551(3)(e), if a novation agreement is not reached, the existing contract will become invalid. However, before this occurs, we will send out notification of the pending CHOW, and will make every effort to ensure that beneficiaries are made aware of the alternate PDPs in the same service area. In the event that a novation agreement is not executed, an enrollee will be allowed to enroll during a Special Enrollment period, as provided for at § 423.36(c).

Comment: A commenter noted that it does not believe the proposed requirements are administratively burdensome. However, the commenter points to the advance notice requirement under § 423.551(c), which requires a PDP sponsor that is considering a CHOW to provide updated financial information and a discussion of the financial and solvency impact of the CHOW on the surviving organization. With respect to that requirement, the commenter suggests that administrative burden could be further reduced if the information required be equivalent to the documentation routinely submitted to State departments of insurance or similar entities.

Response: We appreciate the commenter's suggestion, but, in order to maintain uniformity, we will retain the advance notice requirement as proposed. Given that different States require different financial solvency information we believe that the advance notice requirement will best serve both our interests and the interests of our beneficiaries without being unduly burdensome for the PDP sponsors.

M. Grievances, Coverage Determinations, and Appeals

1. Introduction

Subpart M of part 423 implements sections 1860D–4(f), 1860D–4(g), and 1860D–4(h) of the Act, which sets forth the procedures PDP sponsors and MA-PDs must follow with regard to grievances, coverage determinations, and appeals. The MMA amended the Act to provide the following:

- A PDP sponsor or MA-PD must provide meaningful procedures for hearing and resolving grievances between the PDP sponsor or MA-PD (including any entity or individual through which the PDP sponsor or MA-PD provides covered benefits) and enrollees.
- A PDP sponsor's or MA-PD's procedures must meet the same requirements as those that apply to MA organizations for organization determinations and redeterminations.
- If a PDP sponsor or MA-PD has tiered cost sharing for formulary drugs, it must establish an exceptions process.
- PDP sponsors or MA-PDs must follow appeals requirements that are similar to those applicable to MA organizations regarding independent

review entity (IRE) review Administrative Law Judge (ALJ) hearings, Medicare Appeals Council (MAC) review, and judicial review, respectively.

- Appeals involving coverage of a covered part D drug that is not on a PDP's or MA-PD's formulary are permissible only if the prescribing physician determines that all covered Part D drugs, on any tier of the formulary for treatment of the same condition, will not be as effective for the individual as the non-formulary drug, would have adverse effects on the individual, or both.

We received 192 comments on subpart M in response to the August 2004 proposed rule. Below we summarize the major proposed provisions in this subpart and respond to public comments. (For a detailed discussion of our proposals, please refer to our proposed rule (69 FR 46,632).) Please note that, for the convenience of the reader, we use the term ''plan'' to connote a PDP sponsor, MA-PD, or other Part D plan sponsor throughout the discussion in this subpart.

Comment: We received several comments that we need to clarify whether all of the subpart M provisions apply to PDPs, Medicare Advantage plans that offer prescription drug benefits (MA-PDs), and Section 1876 of the Act cost plans that offer qualifying Part D coverage. Two commenters argued that we should determine which provisions in subpart M of Part 423 apply to MA organizations and cost plans and incorporate those provisions in Part 422 and Part 417 by cross-reference. Alternatively, the commenters suggested that we add language to the corresponding sections in Parts 422 and 417.

Response: We agree with the commenters, and wish to clarify that the Part D appeal provisions do apply to PDPs (including fallback plans), Medicare Advantage plans that offer prescription drug benefits (MA-PDs), and Section 1876 of the Act, cost HMOs that offer qualifying Part D coverage. Therefore, this final rule replaces all ''PDP sponsor'' references in subpart M with ''Part D plan sponsor,'' which is defined in § 423.4 as PDP sponsors (including fallback entities), MA organizations offering MA-PD plans, PACE plans offering qualified prescription drug coverage, and cost-based HMOs and CMPs.

We recognize that MA-PDs and cost-based HMOs and CMPs will be required to follow two different processes depending on whether a claim involves a request for benefits under Part 422 or Part 423. (Note that cost-based HMOs and CMPs will be required to follow Part 422 procedures no later than January 1, 2006). However, we do not believe that it is unduly burdensome for MA-PDs and cost-based HMOs and CMPs to follow two sets of rules instead of one. To the contrary, we believe that if we adopted the commenters' suggestions, the Part 422 provisions would be difficult to follow.

2. General Provisions (§ 423.560 through § 423.562)

We proposed, at § 423.560, several definitions for terms used in the subpart. These definitions were generally self-explanatory and mirror those used in subpart M of part 422 for MA, but were modified to reflect applicability to Part D drug benefits.

Proposed § 423.562, General Provisions, provided an overview of the responsibilities of plans and the rights of enrollees for grievances, coverage determinations, and appeals. In general, plans are responsible for establishing and maintaining procedures for grievances, coverage determinations, exceptions to tiered cost-sharing formulary structures, requests for formulary exceptions, and appeals. Enrollees must receive written information about the grievance and appeal procedures available to them through the plan, and about the QIO complaint process available to enrollees. If the plan delegates this task, it is still ultimately its responsibility to ensure that the requirements are met.

Section 423.562(b) of our proposed rule explained the basic rights of enrollees in relation to plans under subpart M and referenced the regulations that explain the rights.

Proposed § 423.562(c) specified that an enrollee has no appeal right when there is no payment liability, or when benefits have been provided by a non-network provider, except in those situations in which, under subpart C, the plan is obligated to cover such drugs. Finally, § 423.562(d) explained that, unless otherwise noted, the general Medicare appeals rule under part 422, subpart M, is applicable for appeals to an ALJ or the MAC. We note that since new § 423.562(c) will incorporate part 422, and since part 422 incorporates part 405, the provisions of part 405 apply to the extent that they are appropriate. This means, for example, that the provisions to implement the time and place for a hearing before an ALJ under section 1869 of the Act would apply to Part D appeals. Thus, we have added a reference to § 423.612(b) that the time and place for a hearing before an ALJ will be set in accordance with section 405.1020. Although that section has not yet been published in final form, we expect that it will be published prior to the effective date of this rule. Readers may refer to 67 FR 69311, 69331 (Nov. 15, 2002) for an explanation of the proposals and a discussion of the possibility of using video-teleconferencing in ALJ hearings. On the other hand, the ALJ and MAC provisions that are dependent upon qualified independent contractors would not apply since an independent review entity will conduct reconsiderations for Part D appeals.

Comment: We received a comment suggesting that we modify the definition of appeal in § 423.560 from ''when a delay would adversely affect the health of the enrollee'' to ''when a delay could adversely affect the health of the enrollee.'' The same commenter suggested that we must define ''delay'' in order for it to have functional meaning.

Response: We disagree with the commenter. The ''would adversely affect the health of the enrollee'' standard we proposed in the proposed rule is consistent with the language governing MA procedures, which were incorporated in the Part D regulations. In addition, we do not think the term ''delay'' needs to be defined in the regulations. The term ''delay'' simply refers to the plan not providing benefits within the applicable adjudication timeframe.

Comment: We received several comments requesting that we not prohibit an enrollee's appeal rights when the enrollee has no further financial liability for a Part D benefit. The commenters' underlying concern is, by prohibiting enrollees who have no financial liability for a medication from filing a request for appeal, we are also prohibiting State Pharmaceutical Assistance Programs (SPAPs) or other secondary payors from acting on behalf of enrollees in the appeals process.

Response: Under our proposal, an enrollee's appointed or authorized representative (which could include SPAPs or secondary payors) are able to act on behalf of enrollees in the appeals process. However, in the proposed rule we took the position that if an enrollee has no further financial liability for a medication because the secondary payor (that is also the enrollee's appointed or authorized representative) covered the enrollee's additional cost-sharing amount, neither the enrollee nor the secondary payor would be able to request an appeal. We did not intend to preclude SPAPs or other secondary payors from filing appeals with Part D plans on behalf of enrollees. Therefore, we agree with the commenters and have

deleted the proposed provision that would prohibit an enrollee's appeal rights when he or she has no further liability to pay for prescription drugs furnished through a Part D plan.

Comment: We received one comment requesting that the definition of enrollee be revised to include people who are automatically enrolled in a PDP or MA-PD.

Response: We agree with the commenter and have revised the definition of enrollee in this final rule to mean a Part D eligible individual who has elected or has been enrolled in a Part D plan.

3. Grievance Procedures (§ 423.564)

As defined in § 423.560 of our proposed rule, a grievance means any complaint or dispute, other than one that constitutes a coverage determination, expressing dissatisfaction with any aspect of a plan's operations, activities, or behavior, regardless of whether remedial action is requested. Our proposed regulations (at § 423.564) required that each plan have procedures to ensure that grievances are heard and resolved in a timely manner, but the regulations did not include prescriptive details on the procedures. The only exception to this approach was proposed under § 423.564(d) and involved certain limited situations where a plan must respond to a grievance within 24 hours.

Section 423.564(c) explained the distinction between the grievance procedures of the plan and the quality improvement organization (QIO) complaint process. This section further established that when an enrollee submits a quality of care complaint to a QIO, the plan must cooperate with the QIO in resolving the complaint.

Proposed § 423.564(e) completed the grievance procedures by proposing minimum record keeping requirements for a plan, which included recording the receipt date of a grievance, its final disposition, and the date the enrollee is notified of the disposition.

Comment: We received one comment suggesting that the QIO be utilized to respond to expedited external appeals related to drug benefits, and all complaints regarding quality of care should be forwarded to the QIO.

Response: We thank the commenter for the suggestion, and will take it into consideration when determining the entity that will perform the IRE workload. In addition, we believe that a complaint involving a quality of care issue must be processed by the QIOs since they are statutorily required to perform such reviews under section 1154(a)(14) of the Act. Although QIOs are required to review complaints involving quality of care issues, by statute, plans must establish an internal grievance procedure to resolve these types of issues as well. An enrollee may choose to file a quality of care complaint with either the plan, QIO, or both. Therefore, quality of care complaints will not be automatically forwarded to QIOs. In addition, even if the quality of care complaints were voluntarily forwarded by a plan, QIOs do not have a statutory responsibility to review such complaints. QIOs are responsible for reviewing quality of care complaints only when the complaint has been filed directly with the QIO, in writing, and by an individual (or his or her representative) who is entitled to Medicare benefits.

Comment: We received several comments indicating that the grievance procedures should be modeled after MA and include better record-keeping requirements for grievances. Other commenters suggested that we allow enrollees to appeal grievances directly to the IRE. Commenters also requested that we clarify what types of issues can be adjudicated in the grievance process, and what types of issues are subject to the appeals process. Another commenter recommended allowing enrollees to choose whether they want their complaint to be filed as an appeal or a grievance.

Response: We agree with the commenters who suggested that the Part D grievance procedures be modeled after the MA grievance procedures. Therefore, as proposed, the same grievance requirements (including who may request a grievance, the filing procedures and record-keeping procedures) that are applicable under MA are applicable under Part D. In the MA final rule, we are adopting revised grievance provisions similar to those from a January 24, 2001 Medicare+Choice proposed rule. See 66 FR 7,593. This is in response to comments we received on the August 3, 2004 proposed rule to establish the MA program. See 69 FR 46,866, 46,913. There, in response to statutory changes in the MA Federal rules governing preemption of State requirements, commenters recommended that we adopt the January 2001 proposed grievance provisions in an effort to establish uniform Federal procedures under MA. Once these regulations are in effect, MA organizations will be required to notify enrollees of their decisions as expeditiously as the case requires, but no later than 30 calendar days after receiving a complaint. An extension by up to 14 calendar days may be permitted if the enrollee requests the extension, or if the organization justifies a need for additional information and the delay is in the best interest of the enrollee. Also, grievances that are made orally may be responded to orally or in writing, unless the enrollee specifically requests a written response. Quality of care issues and written complaints must be responded to in writing. An enrollee must file a grievance no later than 60 days after the event or incident that precipitates the grievance. Because the MMA dictates that the grievance provisions of the MA program also apply to the Part D program, the final MA requirements have been included under § 423.564, and thus will apply to PDP sponsors and MA-PDs as well.

In the proposed rule, we specified the differences between grievances, coverage determinations, and appeals in proposed § 423.564, paragraphs (b) and (c). Nothing in the proposed rule prohibits an enrollee from requesting that his or her complaint be adjudicated under the process applicable for appeals or grievances. However, plans are required to maintain different processes for each and must determine which process applies when a request is received. As stated in the proposed rule, any complaint that does not involve a coverage determination or quality of care issue may be filed under the grievance process. However, if the complaint involves a coverage determination issue, plans must process it under its appeals procedures. If the complaint involves a quality of care issue, an enrollee may request the quality improvement organization or the plan to review the complaint using its procedures. When a plan makes a decision on a grievance, its resolution is final and is not subject to an appeal. We have retained these proposals in the final rule.

4. Coverage Determinations (§ 423.566 through § 423.576)

Proposed § 423.566 through § 423.576 implemented the MMA requirement that plans establish procedures for making coverage determinations and redeterminations regarding covered drug benefits that are essentially the same as those in effect for MA organizations under part 422, subpart M for MA. Therefore, for the drug benefits under Part D, we continued standard and expedited requirements for coverage determinations and redeterminations.

Section 423.566(a) of our proposed rule specified that each plan must have a procedure for making timely coverage determinations regarding the drug benefits an enrollee is entitled to receive

and the amount, if any, that an enrollee is required to pay for a benefit. The plan would be required to establish both a standard procedure for making coverage determinations and an expedited procedure for situations in which applying the standard procedure could seriously jeopardize the enrollee's life, health, or ability to regain maximum function.

As proposed in § 423.566(b), actions that constitute coverage determinations include: a plan's decision not to provide or pay for a Part D drug (including a decision not to pay because the drug is not on the plan's formulary, the drug is determined not to be medically necessary, the drug is furnished by an out-of-network pharmacy, or because the plan determines that the drug otherwise would be excluded under section 1862(a) of the Act); failure to provide a coverage determination in a timely manner that would adversely affect the health of the enrollee; decisions on the amount of cost sharing; or decisions on whether the preferred drug is appropriate for an enrollee. As proposed at § 423.566(c), only the enrollee (including his or her authorized representative) and the prescribing physician on behalf of the enrollee could request a standard coverage determination.

Similarly, those individuals who could request an expedited determination or an expedited redetermination were an enrollee (including his or her authorized representative), or the prescribing physician on behalf of the enrollee. In these situations we proposed that a prescribing physician need not be an appointed representative of the enrollee in order to assist in obtaining either a standard or an expedited coverage determination. We welcomed comments on any additional individuals or entities that should be able to request a coverage determination.

The standard timeframes and notice requirements for coverage determinations were proposed in § 423.568. These requirements, which are consistent with MA requirements and were incorporated in Part D, included making a determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after receipt of the request if the request was for prescription drug benefits. An extension of the timeframe by up to 14 calendar days would be allowed if the enrollee requests the extension, or if the plan can justify how a delay is in the interest of the enrollee. An enrollee must be notified of the reasons for the delay, and informed of the right to file an expedited grievance if the enrollee disagrees with the plan's decision to invoke an extension.

As specified at proposed § 423.568(b), which is consistent with MA requirements and was incorporated in Part D, if the request is for payment, the determination would need to be made no later than 30 calendar days after receipt of the request. This section also established, at proposed § 423.568(c), the requirement for written notice for plan denials and the form and content of the denial notices, including that the notices must explain the reason for the denial and the availability of appeal rights.

Section 423.570 and § 423.572 proposed the requirements regarding expedited coverage determinations, including how an enrollee or an enrollee's prescribing physician could make an oral or written request (§ 423.570(b)), and how the plan must process requests (§ 423.570(c)). We clarified in § 423.570(a) that requests for payment of prescription drugs already furnished for an enrollee could not be expedited.

Section 423.570(b)(2) specified that a prescribing physician may provide written or oral support for a request for expedition, and under § 423.570(c)(3)(ii), we clarified that when requests for expedition were made or supported by an enrollee's prescribing physician, the plan would grant the request if the physician indicated that applying the standard timeframe could seriously jeopardize the enrollee's life, health, or the ability to regain maximum function. Section 423.570(d) proposed actions following a denial of a request and explained that when a plan denies a request for an expedited determination, the request would be automatically transferred and processed under the standard determination procedures.

Proposed § 423.572 outlined the timeframe and notice requirements for expedited determinations. Specifically, this section proposed the following:

- The plan must make its expedited determination and notify the enrollee and the prescribing physician of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.
- The enrollee has the right to file an expedited grievance if he or she disagreed with the plan's decision to invoke an extension.
- If the plan first notified an enrollee of an adverse expedited determination orally, then it must mail written confirmation to the enrollee within 3 calendar days.
- Notice of expedited determination must contain specific information outlined by us.
- Failure to provide a timely notice would constitute an adverse coverage determination, which may be appealed.

Similar to the expedited requirements for MA under Part C, these sections proposed requiring that drug coverage determinations be made as expeditiously as the enrollee's health condition requires. Note that given the requirement that the timing of determinations (and redeterminations) be based on an enrollee's health condition, the plan would have a responsibility to ensure that an enrollee's health situation and needs are fully considered in reviewing any request (for example, if an enrollee has a chronic condition that has necessitated ongoing use of the drug in question).

Comment: Several commenters were unclear about the differences between the processes for coverage determinations, exceptions for non-formulary and non-preferred drugs, and appeals. Some commenters believed that the procedures were too complex for enrollees to navigate.

Response: We believe that it is important to clarify the process for coverage determinations, including exceptions, and appeals to ensure that enrollees, prescribing physicians, and plans understand the procedures that apply to disputes involving drug benefits. Section 1860D–4(g) of the Act addresses the procedures for coverage determinations and redeterminations of plans. In general, the MMA requires that a plan's procedures meet the same requirements as those that apply to MA organizations (under paragraphs (1) through (3) of section 1852(g) of the Act) for organization determinations and redeterminations. This includes the same requirements for expedited procedures when the standard timeframes could seriously jeopardize an enrollee's life, health, or ability to regain maximum function. In addition, section 1860D–4(g)(2) of the Act specifies that if a plan has tiered cost sharing for formulary drugs, it must establish an exceptions process. Under the exceptions process, consistent with guidelines established by the Secretary, a non-preferred drug could be covered under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual, or both.

Section 1860D–4(h) of the Act addresses appeals of a plan's coverage

determinations and redeterminations. Here, the MMA requires that the plans follow appeal requirements that are similar to those applicable to MA organizations under paragraphs (4) and (5) of section 1852(g) of the Act (regarding IRE review and ALJ hearings, respectively). In addition, section 1860D–4(h)(2) of the Act specifies that appeals, involving coverage of a covered part D drug that is not on a plan's formulary, are permissible only if the prescribing physician determines that all covered Part D drugs, on any tier of the formulary for treatment of the same condition, would not be as effective for the individual as the non-formulary drug, would have adverse effects on the individual, or both.

In light of the MMA requirements mentioned above, our final regulations at § 423.566 through § 423.630 establish a process for addressing coverage determinations and appeals that largely mirror the procedures under the MA program. The primary structural difference between the Part D requirements and the MA rules involves the unique feature whereby enrollees may request exceptions to a plan's formulary and tiered cost-sharing structure. (Note that requests for non-formulary drugs are of course part of the MA program today, but they are not addressed separately in either the statute of regulations.) We treat these exception requests as requests for coverage determinations. Put another way, requests for tiering and formulary exceptions are forms of coverage determinations. We have made several technical changes to the proposed regulations to help clarify this point.

Section 423.566(b) of this final rule specifies the actions that we consider coverage determinations. They include a plan's decision not to provide or pay for a Part D drug (including a decision not to pay because the drug is not on the plan's formulary, because the drug is determined not to be medically necessary, because the drug is furnished by an out-of-network pharmacy, or because the plan determines that the drug is otherwise excluded under section 1862(a) of the Act) that the enrollee believes may be furnished by the plan; failure to provide a coverage determination in a timely manner when a delay would adversely affect the health of the enrollee; a decision on the amount of cost sharing for a drug; and a decision on whether a drug is a preferred drug for an enrollee. Although a plan's decision to pay for or provide a Part D drug is a coverage determination, these types of determinations are not appealable and therefore are not included in the definition of a coverage determination for purposes of subpart M. We anticipate that only a fraction of all Part D claims will involve disputes subject to the appeals and grievance procedures

Cost-utilization tools employed by plans may also result in coverage determinations. For instance, a plan's denial of a request for a specific drug based on an enrollee's failure to complete step-therapy requirements constitutes a coverage determination. Similarly, a denial based on an enrollee's exceeding a plan's quantity limitation also constitutes a coverage determination. Although enrollees may appeal such determinations if they believe that the cost-utilization requirements have been satisfied or the requirements cannot be satisfied for reasons of medical necessity, enrollees may not challenge the fact that a plan has cost-utilization tools. These tools are essentially part of a plan's benefit design, which is reviewed by us as part of the plan approval process, and like other parts of the benefit design may not discourage enrollment by certain Part D eligible individuals as described in § 423.272.

Only adverse coverage determinations are subject to the appeals process. Therefore, if a plan denies an enrollee's request for an exception, this action constitutes an adverse coverage determination that may be appealed. If we did not treat a plan's decision regarding an exceptions request as a coverage determination, then any adverse decision by a plan regarding an exceptions request would not be subject to the appeals process.

All of the enrollee filing deadlines; plan decision-making timeframes, including rules on when to apply the expedited versus the standard procedures; and notice requirements apply to exceptions requests in the same manner as they apply to other coverage determinations. Thus, § 423.578(c) specifies that a plan's decision concerning an exceptions request constitutes a coverage determination under § 423.566.

Consistent with MA appeal procedures, the entity that makes the coverage determination has an opportunity to take a second look at its original determination. Thus, the first level of the appeals process is a redetermination by the plan. One or more individuals who were not involved in making the coverage determination must make the redetermination. If a lack of medical necessity formed the basis for the coverage denial, then a physician with expertise in the field of medicine appropriate for the services at issue must make the redetermination. The redetermination procedures are set forth under § 423.580 through § 423.590.

Plan redeterminations are subject to reconsideration by an IRE under § 423.600 through § 423.604. Further appeals may be made to an ALJ under § 423.610 through § 423.612, the MAC under § 423.620, and to Federal court under § 423.630. An enrollee must meet an amount in controversy threshold, as determined by the Secretary on an annual basis, for appeals at the ALJ and Federal court levels.

Comment: We received a significant number of comments indicating that the adjudication timeframes were unreasonably long. The commenters argued that if we shortened the timeframes for coverage determinations, including exceptions, and appeals, the process would be less complex. Some commenters recommended designing an expedited exceptions process for enrollees with immediate needs such as mental health issues or chronic or debilitating conditions, which requires a response within 24 hours. Many others suggested shortening the proposed 14-day deadline for exception requests to 72 hours, or 24 hours for emergencies. One commenter stated that requiring plans to respond to all exceptions requests within 72 hours would be consistent with the practice typical in private plans and would allow enrollees better access to the therapies they need. The commenter maintained that the adjudication timeframes under Part D should be shorter than the MA adjudication timeframes because the majority of Part D claims will involve prescription drugs that have not been received by enrollees, while MA claims typically relate to payment for physician and hospital benefits that enrollees have received. A few commenters supported allowing for immediate online point of sale adjudication.

Response: We agree with the commenters that the proposed adjudication timeframes are too long for making decisions involving an enrollee's access to drugs. Therefore, we have amended the adjudication timeframes for coverage determinations (which includes exception requests), redeterminations by the plan, and reconsiderations by the IRE. The NAIC created and adopted the Health Carrier Prescription Drug Benefit Management Model Act, which has been used by many States to develop laws that regulate prescription drug formularies and Pharmacy Benefit Managers (PBMs). The NAIC Model Act requires plans to make determinations within 72 hours after the date of the receipt of the request, or if required by the health

carrier, the date of the receipt of the physician's supporting statement. Many of the States that have created laws requiring plans and PBMs to make determinations within a specified time-period have adopted adjudication timeframes that are shorted than the 72-hour timeframe adopted in the NAIC Model Act. For instance, Michigan, New Jersey, Oklahoma, and Virginia requires plans and PBMs to make a determination on an exceptions request within 24 hours of receipt, while New Hampshire requires determinations on exceptions requests to be made within 48 hours of receipt. Like many States, we have relied on the adjudication timeframes adopted in the NAIC's Model Act as a benchmark for developing the Part D adjudication timeframes. We continue to maintain the requirement that all determinations be made as expeditiously as the enrollee's health condition requires, but will shorten the maximum amount of time that a plan or the IRE can take to make a determination. A plan will have 24 hours for expedited coverage determinations (including exception requests) and 72 hours for expedited redeterminations. The expedited procedures will continue to apply to situations where an enrollee's life, health, or ability to regain maximum function could be seriously jeopardized by waiting for a determination within the standard timeframe. For non-expedited matters, plans will have up to 72 hours to make standard coverage determinations (including acting on an exceptions request) and no later than 7 days for standard redeterminations. In this final rule, the adjudication timeframes begin after receipt of the request, or in the case of an exceptions request, after receipt of the physician's supporting statement. The timeframes of 72 hours for expedited cases and 7 days for non-expedited cases used for redeterminations also apply to reconsiderations by the IRE.

Although the MMA requires plans to meet the requirements for plan determinations and redeterminations for Part D in the same manner as such requirements apply to MA organizations under sections 1852(g)(1) through (3) of the Act, we believe that we have the authority under the Act to shorten the adjudication timeframes. Section 1852(g)(1)(A) of the Act does not require us to mandate a specific amount of time for MA plans to make standard coverage determinations. The Act requires only that such coverage determinations be made on a ''timely basis.'' Under MA, we interpreted ''timely basis'' to mean no more than 14 days from the date the request is received. However, we agree with many of the commenters that 14 days is not timely for determinations that involve prescription drugs. There is too much risk for an enrollee's health if determinations are not made sooner than 14 days from the date the request is received, since an enrollee often will not be able to pay out-of-pocket for a prescribed medication and thus must forgo necessary therapy until a determination is made. We agree with the commenter that the MA adjudication timeframes do not offer an appropriate standard for Part D. We anticipate that the majority of Part D requests for exceptions and appeals will involve prescription drugs that have not yet been provided to enrollees, in contrast with MA requests, which typically involve services that have already been received or are not immediately needed, such as procedures that are often scheduled weeks in advance of being performed. (Expedited determinations are the exception to this general rule.) Clearly, Part D enrollees are likely to suffer significant adverse consequences if medications are not received quickly.

Section 1852(g)(2)(A) of the Act gives the Secretary the authority to require MA organizations to make standard reconsiderations in a time period that is no later than 60 days from the date the request is received. In MA, we require MA organizations to complete standard reconsiderations in 30 days from the date it receives a request. However, in this final rule, we have established adjudication timeframes that are shorter than the 60-day maximum imposed by the Act. Under our final regulations at § 423.590(a), plans must make standard redeterminations within 7 days from the date a request is received.

Because section 1860D–4(h)(1) of the Act only requires plans to meet the requirements that apply to Part D IRE reconsiderations or higher appeals in a similar manner as they apply to MA organizations, we have the authority to revise the adjudication deadlines as appropriate. As mentioned previously, we will hold the IRE to the same timeframes as Part D plans (that is, as quickly as the beneficiary's health requires but no later than 72 hours for expedited reconsiderations and 7 days for standard reconsiderations). However, ALJ hearings and Departmental Appeals Board (DAB) reviews will follow the same timeframes and procedures under MA. The complexities associated with in-person hearings and appellate reviews make it impossible for an ALJ or the DAB to complete a decision in an abbreviated timeframe.

Section 1852(g)(3)(B)(iii) of the Act requires MA organizations to process expedited coverage determinations and reconsiderations ''under time limitations established by the Secretary, but no later than 72 hours of the time of receipt of the request or the information necessary to make the determination or reconsideration, or such longer period as the Secretary may permit in expedited cases.'' Under MA, health plans and the IRE must process expedited reviews no later than 72 hours. However, given that the final rule reduces the timeframe for making a standard coverage determination (including an exceptions request) under Part D from 14 calendar days to 72 hours, the 72-hour decision-making timeframe we initially proposed for expedited determination is unreasonable. We believe that a 24-hour deadline for expedited initial coverage determinations (including expedited exceptions requests) is more meaningful. This change is reflected under § 423.572(a). Expedited redeterminations and reconsiderations will be processed no later than 72 hours, as proposed. We note that we have removed references to 14-day extensions of the adjudication timeframes. We believe that allowing extensions is inconsistent with our rationale for shortening the adjudication timeframes.

Comment: We received many comments from the public suggesting that we require plans to provide continued coverage of a prescription drug during part or all of the coverage determination and appeals process, or provide an emergency supply in limited circumstances. Several of the commenters were concerned that the proposed timeframes for making coverage determinations were too long, which would result in lapses of coverage for enrollees.

The commenters' recommendations varied on the length of time a drug should be supplied, as well as who should bear the burden of cost. Some commenters recommended providing enrollees with a 72-hour emergency supply of the prescription, while others suggested that enrollees be provided with coverage for 45 days. A number of commenters suggested that enrollees be permitted to continue receiving a requested drug at no cost until the appeal is resolved, while others recommended providing enrollees with the requested drug at the preferred cost-sharing amount until final resolution.

Response: Although the commenters suggested different solutions, each has requested some degree of continued coverage as a means of addressing a larger concern—whether and how

enrollees can continue receiving a prescribed medication until the coverage issue is properly adjudicated. We do not believe we have the statutory authority to require plans to continue covering a drug that has been removed from the plan's formulary, or placed on a different tier during the plan year, pending the outcome of an appeal. Nevertheless, we believe that we can address the commenters' concern in this final rule by minimizing the adjudication timeframes as discussed above, and by modifying the proposed provisions related to the timelines for notices and coverage and appeals decisions. As required under subpart C of this regulation, plans must either provide notice to affected enrollees 60 days in advance of a change to its formulary or tiering structure, or provide notice regarding the change along with a 60-day supply after an enrollee's request for a refill of the drug affected by a change. As mentioned above, we have also significantly reduced the adjudication timeframes for coverage determinations, redeterminations, and reconsiderations. As a result, when a formulary changes, enrollees will have sufficient time to obtain a determination, including an independent review, before their medication runs out. Finally, beneficiaries always have the option of paying out of pocket for an initially non-covered Part D drug and then appealing to seek reimbursement.

Comment: Some commenters also suggested that we incorporate a fast-track appeals process for Part D similar to the fast-track appeals process provided in the Medicare appeals regulations as a result of the Grijalva v. Shalala settlement.

Response: The MA provisions at § 422.624 and § 422.626 apply to situations where an MA organization intends to terminate an enrollee's services in a skilled nursing facility, home health agency, or a comprehensive outpatient rehabilitation facility. The provider must deliver a notice two days in advance of the services ending, thereby affording an enrollee the ability to request an appeal by an IRE before the services end. As noted above, we have created a similar concept in Part D by shortening the maximum amount of time that a plan or the IRE can take to make a determination and requiring plans to either provide notice to affected enrollees 60 days in advance of a change to its formulary or tiering structure, or provide notice regarding the change along with a 60-day supply after an enrollee's request for a refill of the drug affected by a change. Thus, enrollees will receive notice in advance of a change to a plan's formulary, thereby affording an enrollee the ability to request an appeal by an IRE before a lapse in coverage occurs.

Comment: We received several comments from organizations arguing that the regulations proposed in subpart M fail to meet the Due Process Clause of the Fifth Amendment of the United States Constitution. Specifically, the commenters believe that the proposed rules do not afford enrollees with adequate notice explaining the reasons for a denial and right to appeal, and an adequate opportunity to a hearing with an impartial trier of fact. The commenters also noted that Medicaid enrollees whose prescription requests are not being honored currently receive a 72-hour supply of medication pending a resolution of the initial coverage request, and Medicaid appeals are completed more expeditiously than Medicare appeals. The commenters recognize that although the most efficient means of protecting enrollees, amending the MMA to provide for an appeals process similar to Medicaid, is beyond our authority, we can take steps to improve notice and the opportunity for a speedy review.

Response: As noted above, we have addressed the commenters' concerns by significantly reducing the adjudication timeframes for coverage determinations, redeterminations, and reconsiderations, and requiring plans to either deliver notice to affected enrollees 60 days in advance of a change to its formulary or tiering structure or provide notice regarding the change along with a 60-day supply after an enrollee's request for a refill of the drug affected by a change. Under § 423.568(d) and § 423.572(c), we require plans to provide enrollees with detailed written notices explaining the reason(s) for the denial, and the enrollee's right to, and conditions for, obtaining a redetermination and the rest of the appeals process. In addition, under § 423.590(g), we require plans to provide enrollees with the same type of written notices required in § 423.568(d) and § 423.572(c) when a redetermination is made. Finally, § 423.602 contains provisions governing the notice issued by an IRE upon a reconsideration. Thus, we believe that the Part D process affords enrollees with appropriate notice explaining their rights to an exceptions process, reasons for any coverage denials, and the opportunity to appeal to an independent review entity.

Comment: We received many comments that we need to clarify whether the point-of-sale transaction at the pharmacy counter constitutes a coverage determination. Some commenters suggested that the transaction should not be considered a coverage determination on the basis that it would be unrealistic to treat a pharmacy as an agent of a plan for the purpose of accepting and processing appeals, and providing information about a plan's benefit design does not constitute a denial triggering notice. Others commented that point-of-sale transactions should be considered coverage determinations because those transactions result in enrollees receiving a decision that a drug is either covered or not, and pharmacies receive real-time claims adjudication information from plans and deliver that information to enrollees.

Response: We agree with the commenters who suggested that transactions that occur at the pharmacy counter should not be considered coverage determinations. Although pharmacists will receive information from plans regarding whether to provide or pay for a covered Part D drug, the amount of cost sharing, or whether a drug is a preferred drug for the enrollee, we do not believe as a policy or practical matter that such information by itself should be considered a coverage determination. Instead, the pharmacist is conveying information regarding the plan's benefit design as it pertains to all enrollees, and is exercising no discretion on behalf of a plan. The same type of information is provided in writing by the plan to enrollees at the beginning of a new plan year, and is often made available to enrollees in other formats, for example, online.

Like MA organizations under Part C, plans must issue written notices to enrollees whenever the plans deny a drug benefit in whole or in part. The written notice must state the specific reason(s) for the denial and explain the enrollee's right to an appeal. It would be difficult for pharmacists to create and issue written notices that satisfy the coverage determination requirements given the number of customers (likely from various plans) that pharmacists assist each day. In addition, not all pharmacies have systems capable of receiving information specific enough to explain that a prescription is not on a plan's formulary or why the level of cost-sharing is higher than the enrollee expected to pay.

The DOL considered a similar issue under 29 CFR 2560.503–1, which generally applies to all claims for benefits under plans subject to the Employee Retirement Income Security Act (ERISA). Specifically, the DOL

considered whether, when a group health plan participant presents a prescription to a pharmacy to be filled at a cost to the participant determined by reference to a formula or schedule established in accordance with the terms of such plan and for which the pharmacy exercises no discretion on behalf of the plan, the regulation under § 2560.503–1 requires that the presentation of the prescription be treated as ''claim for benefits.'' The DOL is of the view that neither ERISA nor the regulation under § 2560.503–1 requires that a group health plan treat interactions between participants and preferred or network providers under such circumstances as a ''claim for benefits'' governed under § 2560.503–1. See DOL, EBSA, Benefit Claims Procedure Regulation Frequently Asked Questions and Answers, A–11, at *http://www.dol.gov/ebsa/faqs/faq_claims_proc_reg.html*. We agree with the approach taken by DOL. Under this final rule, therefore, a plan is not required to treat the presentation of a prescription as a claim for benefits; instead, enrollees must contact their plans to formally request coverage determinations. However, consistent with the DOL approach, nothing in this rule prohibits a plan from treating the presentation of the prescription as a claim for benefits if it chooses to. As under Part C, we will require PDP sponsors and MA-PDs to provide information in the enrollee's Evidence of Coverage explaining how to contact the plan to obtain a coverage determination and an appeal. We will also develop standardized notices and require plans under § 423.562(a)(3) to arrange that their pharmacy networks utilize the standardized notices to notify enrollees of the right to receive, upon request, a detailed written notice from the Part D plan sponsor regarding the enrollee's prescription drug coverage, including information about the exceptions process. The standardized notices may, for example, be posted in or disseminated by a plan's network pharmacies.

Comment: One commenter requested that we clarify § 423.566(b)(4), which specifies that a decision on whether a drug is a preferred drug for an enrollee is a coverage determination. The commenter is concerned that, as proposed, the provision allows an enrollee to challenge a plan's formulary development process, without regard to whether the enrollee actually received the drug. To remedy this problem, the commenter suggested that we ''limit the coverage determination in this case to the scope of the exception.''

Response: We agree that enrollees may not challenge a plan's formulary. The intent of § 423.566(b)(4) was to ensure that a plan's determination regarding an enrollee's request for an exception involving a non-formulary drug is considered a coverage determination. To clarify our intent, we have amended § 423.566 (b)(3) and (4) to state that a decision concerning an exceptions request under § 423.578(a), or a decision concerning an exceptions request under § 423.578(b), is a coverage determination.

Comment: One commenter requested clarification as to whether a decision made by a plan not to pay for drugs obtained at an out-of-network pharmacy is subject to appeal.

Response: If a plan decides not to pay for a drug that an enrollee obtained at out-of-network pharmacy in accordance with § 423.124(a), this action constitutes a coverage determination that is subject to appeal. Therefore, § 423.566(b)(1) requires that a plan's decision not to provide or pay for a Part D drug because the drug is furnished by an out-of-network pharmacy is a coverage determination. To avoid confusion, we deleted the limitation proposed in § 423.562(c)(2), which gave the impression that such determinations are not appealable. When a plan denies coverage for a drug obtained at an out-of-network pharmacy on the grounds that the provisions of § 423.124(a) were not satisfied, but the enrollee believes that the denial was unreasonable, for example, the enrollee obtained a drug at an out-of-network pharmacy because he or she needed the drug at midnight and the only pharmacy open at that time within a reasonable driving distance was an out-of-network pharmacy, then the enrollee can appeal the plan's determination. However, the policies that plans develop to encourage enrollees to use network pharmacies are not subject to appeal.

Comment: We received several comments expressing concern regarding the notification procedures when a plan denies a prescribed medication. Some commenters suggested that both the physician and enrollee be provided with immediate written notification, while others recommended providing the prescribing physician and the enrollee with notification within 24 hours from the time the determination is made. Several commenters requested that denials and approved requests be reported to the pharmacists, and a significant number of commenters suggested that we require pharmacists to distribute notices to enrollees at the pharmacy counter.

Response: Most commenters who suggested that the point-of-sale transaction is a coverage determination also argued that pharmacists should deliver written notification of the coverage determination to enrollees when they are not able to obtain a prescription at the pharmacy counter. Although plans are required under the regulations to deliver written notice to enrollees when plans make a coverage determination, plans are not required to deliver a notice as a result of the transaction that occurs at the pharmacy counter. As mentioned above, point-of-sale transactions are not coverage determinations and thus do not trigger the notice requirements associated with adverse determinations. However, we recognize that it would be helpful for enrollees to receive some information at the pharmacy explaining how to obtain a coverage determination or request an exception. Therefore, we will require plans under § 423.562(a)(3) to arrange that their network pharmacies notify enrollees of their right to receive, upon request, a detailed written notice from the Part D plan sponsor regarding the enrollee's prescription drug coverage, including information about the exceptions process. Plans may, for instance, require their network pharmacies to post or distribute notices that instruct enrollees on how to contact their plans to obtain a coverage determination or request an exception when enrollees disagree with the information provided by the pharmacist.

Another concern raised by the commenters involved who would receive notices from the entities offering Part D plans. Entities offering Part D plans must send written notification to enrollees whenever the plan makes any adverse coverage determination. Plans also must notify prescribing physicians of any adverse coverage determination when the physician requests standard or expedited coverage determinations, and expedited redeterminations on behalf of enrollees. Plans must notify enrollees and prescribing physicians, if the physician requested the determination, for all favorable coverage determinations. Also, when a plan denies a request that a determination or redetermination be expedited, renders an unfavorable expedited coverage determination, or affirms its unfavorable expedited coverage determination, the plan must provide oral notification within the applicable timeframe and follow-up with a written notice within three days.

A written notice of any determination must be sent to enrollees, or any individual or entity appointed by an enrollee or authorized under State or

other applicable law to act on behalf of an enrollee. We also wish to point out in this final rule that we believe it is unnecessary to require plans to provide pharmacists with formal written notice of plans' coverage determinations or appeals. Plans have established customary practices for communicating their benefit determinations with pharmacists, and we see no reason to interfere with that relationship.

Comment: We received many comments expressing concern regarding who should be considered an authorized representative. Commenters suggested that we modify the definition of authorized representative to include any licensed healthcare and social service provider caring for the beneficiary, a practitioner's agent who may act on behalf of the physician caring for the enrollee, pharmacists where State Pharmacy Acts empower collaborative practice agreements, and secondary payors, including employers, SPAPs, Medicaid agencies, and charities that provide wrap-around coverage or otherwise may pay for a drug when the plan denies coverage. One commenter suggested that we limit representatives to authorized family members and physicians.

Response: We considered the comments provided and believe that the commenters' concerns are already addressed. We do not need to add to the list of individuals or entities permitted to act on behalf of enrollees because they have the ability to appoint anyone to be their representative under this rule. In addition, individuals or entities authorized under State law may also act on behalf of enrollees. Therefore, we removed the definition of an ''authorized representative'' under § 423.560 and replaced it with ''appointed representative'' to clarify that a representative is an authorized representative, or is an individual appointed by an enrollee, or authorized under State or other applicable law, to act on behalf of the enrollee in obtaining a coverage determination or in dealing with any of the levels of the appeals process. Thus, any individual or entity (including prescribing physicians, secondary payors, charities, and pharmacists) appointed by an enrollee, or authorized under State law, may file a grievance, request a coverage determination, or appeal on behalf of enrollees. We also have clarified that the appointed representative will have all of the rights and responsibilities of an enrollee in obtaining a coverage determination or in dealing with any of the levels of the appeals process.

In proposed § 423.560, we proposed to define ''enrollee'' as a part D eligible individual or his or authorized representative. Instead, in our final rule we clarify that an enrollee is a Part D eligible individual who has elected or has been enrolled in a prescription drug plan offered by a PDP sponsor, MA organization, or other Part D plan sponsor. Although we have now clarified that an appointed representative is not an enrollee, a plan, nevertheless, has an obligation to the appointed representative to fulfill the requirements under this subpart in the same manner that it is required to do so for the enrollee.

We also disagree with the commenter who suggested that we limit authorized representatives to authorized family members and physicians. We have always provided Medicare beneficiaries with the ability to choose who may act on their behalf, and we see no reason to deviate from this practice in Part D.

Comment: We received several comments addressing permissible filing methods and locations for grievances, appeals, and exceptions. Some commenters suggested that we require enrollees to submit requests in writing only. Other commenters suggested that we require plans to accept requests electronically, or by telephone, fax, or mail. One commenter stated that accepting oral requests would be unduly burdensome, and another argued that requests only be submitted directly to the plans.

Response: As noted above, an enrollee may file a grievance either orally or in writing. Also, as previously mentioned, the MMA requires plans to meet the requirements for coverage determinations and redeterminations under Part D in the same manner as they apply to organization determinations and plan-level reconsiderations in MA. The regulations applicable to MA do not specify the method by which enrollees must file requests for standard organization determinations. However, the MA regulations require MA organizations to have procedures for accepting oral or written requests for expedited organization determinations. The MA regulations also require requests for reconsideration to be filed in writing, but permit requests for expedited reconsiderations to be filed orally or in writing. Therefore, plans must also have procedures for accepting oral or written requests for expedited coverage determinations (including exceptions) and requests for expedited redeterminations. However, plans need only accept standard requests for redetermination when they are made in writing.

Similar to the MA proposed rule, we proposed to require plans to have procedures for accepting oral (including by telephone) or written (including by fax or mail) requests for standard redeterminations. However, consistent with the MA final rule, Part D enrollees must make standard requests for redetermination in writing, unless the plan accepts oral requests. Therefore, we deleted the provision in § 423.582(a) that would have permitted enrollees to file oral requests for redetermination with plans. Although the process currently cannot accommodate electronic appeal requests, we intend to explore this as another filing option for Medicare appeals.

Comment: We received several comments related to the consequences that should apply when a plan fails to meet its adjudication deadlines or provide timely notice. Some commenters suggested that this failure should be considered a favorable determination because, under the proposed rule, plans have no incentive for making coverage determinations or redeterminations since the failure to meet the adjudication deadlines result in de facto denials. The commenters argue that, to ensure enrollee protection, there must be meaningful consequences when plans fail to meet adjudication deadlines. Still others believed that it should result in an adverse determination that may be appealed.

Response: In the proposed rule, we indicated that the failure to provide timely notice of a coverage determination or redetermination would constitute an adverse determination that may be appealed. We also proposed in § 423.578(c)(2) that when the plan fails to make a determination on an exceptions request when a drug is being removed from a formulary, the enrollee would be entitled to receive the medication in dispute until the plan notified the enrollee of its determination. We agree with the commenters who suggested that this provision provides little incentive for plans to make determinations any sooner than by the end of the adjudication deadline, especially if the plan expects to issue an unfavorable determination. Our intent, in part, was to require plans to make timely determinations as mandated by section 1852(g) of the Act. However, we also wanted to remove any barriers for enrollees to accessing needed medications as quickly as possible. We now believe that the provisions, as proposed, fall short of that policy goal. Under MA, if a plan does not provide the enrollee with timely notice of an organization determination, this failure constitutes an adverse determination that may be appealed. However, if the

MA plan fails to issue its reconsideration within the appropriate timeframe, this failure constitutes an adverse determination that must be automatically forwarded to the IRE within 24 hours of the expiration of the timeframe. Unlike under MA, however, we did not propose that Part D plans be required to automatically forward all adverse determinations to the IRE. Instead, we believe that a more effective policy under Part D is to require plans to automatically forward enrollees' requests for determination or redetermination to the IRE only when the plans fail to meet the adjudicatory timeframes for making determinations and redeterminations. As under MA, plans must forward the enrollees' requests to the IRE within 24 hours of the expiration of the adjudication timeframe.

Comment: Several commenters maintained that enrollees should be able to pursue an expedited appeal regardless of whether they already paid for the drug in dispute. Commenters believed that low income beneficiaries, in particular, would be harmed by having to wait 30 days for a plan to make a coverage determination or 60 days to render a redetermination.

Response: A determination regarding benefits is expedited when the application of the normal time frame for making a decision could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function. As proposed in Part D and like Part C, such a determination would not involve a payment request since a medical emergency does not exist for an enrollee who already obtained the medication in dispute. Nevertheless, the concern raised by the commenters regarding the length of time it takes for an enrollee to be reimbursed has been remedied by our decision to no longer distinguish between payment and service-related disputes. As a result, we have reduced the timeframe for plans to make standard coverage determinations to 72 hours in § 423.568(a), and redeterminations to 7 days in § 423.590(a). In addition to shortening the adjudication timeframes, we also reduced the effectuation timeframes for requests involving payment issues to 30 days. Thus, while plans must make a decision on whether to pay for a prescription drug within 72 hours, they must effectuate the decision within 30 days. Likewise, although a plan must make a redetermination within 7 days, it must effectuate no later than 30 days. The effectuation timeframes for requests involving payment issues are longer than the effectuation timeframes for requests for benefits because our experience is plans normally process claims in 30-day cycles. Therefore, plans must effectuate claims for payment no later than 30 days after making a favorable coverage determination or redetermination, or receiving notice of a reversal by the IRE, ALJ, MAC, or Federal court.

Comment: One commenter suggested that we delete the term ''seriously'' and add ''or maintain'' to the last sentence of § 423.566(a) so that it states ''may jeopardize the enrollee's life, health, or ability to regain or maintain maximum function, in accordance with § 423.570.'' The commenter maintained that such a modification is necessary because any amount of jeopardy to an enrollee's health or life is serious enough to warrant an expedited review, and maintenance of maximum function is just as important as regaining maximum function.

Response: The MMA requires entities that offer Part D plans to meet the requirements that apply to Part D coverage determinations and redeterminations in the same manner as they apply to MA organizations for organization determinations and reconsiderations. Section 1852(g)(3)(B) of the Act requires MA organizations to establish procedures for expediting organization determinations and reconsiderations when ''the application of the normal timeframe for making a determination...could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.'' Therefore, we are not adopting the commenter's suggestion.

Comment: We received one comment suggesting that the prescribing physician should make the determination whether to expedite an enrollee's request for a coverage determination or redetermination. The commenter maintained that the physician, not the plan, is in the best position to determine how quickly an enrollee needs a prescribed medication.

Response: We agree with the commenter. Therefore, like under MA, we require plans to automatically provide an expedited determination or redetermination when the prescribing physician indicates that applying the standard timeframe would seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

Comment: Two commenters suggested that prior authorization decisions should be included in the list of actions that constitute a coverage determination under § 423.566(b). The commenters maintain that placing a medication on a prior authorization list has the effect of limiting access to such a medication since the administrative cost and burden associated with obtaining a prior authorization may cause physicians to cease prescribing drugs that require that a prior authorization requirement be satisfied.

Response: As previously noted, information regarding a plan's benefit design as it pertains to all enrollees is not a coverage determination. We will allow plans the flexibility to determine how to structure their formularies, subject to our approval. As a result, plans are permitted to determine which medications are placed on their prior authorization lists. The decision to place a medication on a prior authorization list is not a coverage determination and is not subject to appeal. However, when a plan processes a prior authorization request, the plan's determination on whether to grant approval of a drug for an individual enrollee constitutes a coverage determination that is subject to appeal. In addition, if a plan denies a drug, because the enrollee failed to seek prior authorization, that would also constitute a coverage determination subject to appeal.

Comment: One commenter requested that we define ''State law'' where we stipulate in § 423.560 that a representative authorized under State law may act as an authorized representative on behalf of an enrollee. The commenter suggests that State law be defined as a constitution, statute, regulations, rule, common law, or other State action having the force and effect of law.

Response: We agree that ''State law'' may include a constitution, statute, regulation, rule, common law, or other State action having the force and effect of law. However, we do not believe that it is necessary to define State law under § 423.560.

Comment: We received one comment suggesting that we define the phrase ''furnished by the PDP'' in § 423.566(b)(1), which limits actions that are coverage determinations to the failure to provide or pay for a covered Part D drug that an enrollee believes may be furnished by the plan. The commenter is concerned that if an enrollee receives prescription drugs while satisfying the deductible or during the period between the initial coverage limit and the out-of-pocket threshold, a plan could determine that it did not furnish the drugs to the enrollee. As a result, enrollees who receive prescription drugs during such periods would not receive a coverage determination and would therefore be

excluded from the appeals process. The commenter maintains that enrollees should be entitled to appeal a determination that denies coverage even when a plan does not pay for the prescription drug because of the enrollee's cost-sharing obligations.

Response: Our intent in § 423.566(b)(1) was to indicate that the failure to provide or pay for a Part D drug that the enrollee believes may be covered by the plan results in a coverage determination. Rather than define what ''furnished by the PDP'' means, we replaced ''furnished'' with ''covered'' to make clear that coverage determination and appeals procedures do apply in these situations.

5. Formulary Exceptions Procedures (§ 423.578)

a. Exceptions to a Plan's Tiered Cost-Sharing Structure

The MMA specifies that an enrollee may request an exception to a plan's tiered cost-sharing structure and that plans must have a process in place to handle such requests. Under such an exception, a ''non-preferred drug *could* (emphasis added) be covered under the terms applicable for a preferred drug'' under certain conditions. At a minimum, the prescribing physician will have to determine that the preferred drug either will not be as effective for the individual, or will have adverse effects for the individual, or both. Unfavorable determinations constitute coverage denials and are subject to all the appeal rights discussed in subpart M of part 423.

We proposed under § 423.578 that a plan must establish a tiering exceptions process that addresses each of the following sets of circumstances: (1) the enrollee is using a drug and the applicable tiered cost-sharing structure changes during the year; (2) the enrollee is using a drug and the applicable tiered cost-sharing structure changes at the beginning of a new plan year; and (3) there is no pre-existing use of the drug by the enrollee.

While we thought it necessary to require plans to include certain criteria in the tiering exceptions process, we also recognized the need to avoid a situation where a plan's cost-sharing rules are effectively driven by the tiering exceptions criteria, rather than the other way around.

At proposed § 423.578(a)(2) we outlined a limited number of elements that must be included in any plan's tiering exceptions criteria: (1) a description of the process used by the plan to evaluate the physician's supporting statement; (2) consideration of the cost of the requested drug compared to that of the preferred drug; (3) consideration of whether the formulary includes a drug that is the therapeutic equivalent of the requested drug; and (4) consideration of the number of drugs on the plan's formulary that are in the same class and category as the requested drug.

Consistent with existing MA rules, we proposed that an enrollee, the enrollee's authorized representative, or the prescribing physician may request a tiering exception. The statutory requirement that the prescribing physician determine that the preferred drug either would not be as effective for the individual generally, or would have adverse effects for the individual, constitutes a minimum threshold for approving an exception request. We proposed at § 423.578(a)(4) that a plan may require a written supporting statement to that effect from the prescribing physician, as well as certain limitations on the content requirements that plans could impose for these supporting statements. We would permit plans flexibility in how this standard would be applied. For example, a plan could require that a physician certify that the preferred drug would be less effective than the non-preferred drug, or the plan could choose to apply a more stringent standard (such as requiring that the prescribing physician's supporting statement also include the enrollee's patient history or require the enrollee to first try the plan's preferred formulary drug, absent medical contraindications).

A plan's exceptions procedures will also be required to describe how a determination on an exception request will affect the enrollee's cost sharing obligations under the plan's tiering structure.

Comment: Several commenters expressed concern regarding our proposal to allow plans the flexibility to establish exceptions criteria. Some commenters opposed giving plans the flexibility to determine their own exceptions criteria because the MMA requires the Secretary to establish guidelines for the exceptions process. Other commenters stated that drug plans should establish their own criteria to determine whether a preferred drug would not be as effective or would have adverse effects for the enrollee's health condition.

Response: We agree with commenters that plans should impose some criteria for making tiering exception determinations, and in this final rule, we are requiring that plans grant exceptions when the plan determines that the lower-tier drug would not be as effective for the enrollee as the requested drug, would have adverse effects for the enrollee, or both. Other than the above requirement, however, we will not be overly prescriptive in how tiering exception criteria are designed and what criteria a plan uses to determine whether a preferred drug would not be as effective or would have adverse effects for the enrollee. Although the MMA requires plans to develop an exceptions process for requests involving a tiered cost-sharing issue that is consistent with the guidelines established by the Secretary, it does not require the Secretary to establish a comprehensive and uniform set of criteria that plans must meet when developing their exceptions processes. We have established specific requirements that plans must satisfy when processing exceptions requests that are the same as other coverage determinations. They include, for example, timeframes for decision-making; the consequences for failing to make timely decisions; expedited procedures when an enrollee's life, health, or ability to regain maximum function could be seriously jeopardized; detailed notices when exceptions are denied; the right to appeal through a 4–tiered administrative process, and if necessary, to request judicial review; and when the plan must continue benefits. However, while plans must design their exception criteria so that drugs determined by the plan to be medically appropriate for the enrollee are covered, we do not believe that we should require detailed standards that go beyond such a medical necessity requirement. This is particularly the case for the reasons previously mentioned, that is, allowing plans flexibility, and our uncertainty of how plans will develop formularies. Also, we still have ultimate authority over what the criteria will entail. Rather than exercise this authority through the establishment of specific exceptions criteria, we believe that the most appropriate policy is to review the plans' exceptions criteria as part of the approval process, to ensure that the criteria are reasonable and complete. For example, we would likely expect that a plan would establish different types of criteria for different classes of drugs. Thus, in some instances, tiering exceptions may be connected to demonstrated adverse effects based on previous use of the lower tiered drug, while in others, exceptions may be linked to predictive adverse effects based on knowledge of the enrollee's medical condition. While we are by no means dictating the establishment of separate criteria for each drug class or

category, a plan's criteria should encompass all drug classes. Thus, to the extent that the plan chooses to differentiate among drug classes, its exceptions procedures need to clearly explain which criteria apply for various types of drugs or situations. Additionally, we would not approve a plan's tiering procedures if they are unreasonable. Similarly, we would not approve a plan's procedure that would require demonstrated adverse effects in every situation. Clearly, there are situations in which enrollees would suffer significant harm if they are required to demonstrate adverse effects.

Comment: One commenter suggested that plans only be required to maintain an exceptions process for instances where an enrollee is receiving a drug that is affected by a plan's mid-year tiering change. The commenter believed that the four categories established under the proposed rule were unnecessary.

Response: We disagree with the commenter that a plan's exceptions procedures need only address instances where an enrollee is using a drug that is affected by a plan's mid-year change to its formulary tiers. We believe that a plan's exceptions procedures must encompass all types of tiering exception requests and have added language to § 423.578(a) to make clear that Part D sponsors must have complete exceptions procedures that grant exceptions when the plan determines that the factors under § 423.578(a)(4) exist (that is, the lower-tiered drug would not be as effective, would have adverse effects, or both). Nevertheless, we also recognize that the circumstances raised by the commenter involve perhaps the single most critical aspect of a plan's exceptions procedures.

To reflect and emphasize the importance of such circumstances (where a tiering structure changes mid-year and the enrollee has already been using the drug), we are modifying § 423.578(a)(1) and (b)(1) to mention only that circumstance as a situation that plans must specifically address in their exceptions procedures. By no means does this change obviate the need for complete exceptions procedures. A plan must have exceptions procedures that can be applied to all requests for exceptions. Thus, for example, plans' exceptions procedures would need to address situations where an enrollee has no pre-existing use of a drug in dispute and the tiering structure changes mid-year. However, the case of a beneficiary who has a preexisting use of a drug and where the tiering structure changes mid-year represents the only set of circumstances that needs to be addressed distinctly.

We recognize that each plan is required to notify enrollees of changes that will occur in an annual notice of coverage by October 31st each year. Since enrollees have the option of switching plans at the beginning of a new plan year, an exceptions request that has been approved may be reviewed at the end of the year. Consistent with plans notifying affected enrollees of changes to their formularies 60 days in advance under § 423.120(b)(5), a plan must also notify enrollees if the plan intends to change the cost-sharing for a drug on its formulary during the next enrollment period. Therefore, enrollees will have sufficient notice of any tiering changes made at the beginning of a plan year to either choose a new plan, or request an exception.

Comment: We received numerous comments concerning how the price for a drug will be determined when there are mid-year changes in the tiering structure and an exception is approved. Some commenters suggested that, when there is a mid-year change in the tiering structure, enrollees should be granted continued access to drugs at the price before the change. Other commenters argued that we should define who should receive continued access at the price before the change. One commenter argued that it would be impossible to manage a benefit if enrollees could obtain an exception that would permit non-preferred drugs to be priced at the generic drug level. A few commenters, however, believed that, when there is a mid-year change, we should not require plans to provide access to drugs at the price before the change.

Response: We agree that enrollees who are receiving a medication affected by a mid-year change in the tiering structure must have a method for ensuring that they are able to receive a medically necessary drug at a given cost-sharing amount when a tiering exception is granted. Consistent with section 1860D–4(g)(2) of the Act, § 423.578(c)(3) requires that where a plan grants an exception to its tiered cost-sharing structure, a non-preferred drug will be covered under the terms applicable for preferred drugs. Thus, if a plan has a generic level in its tiering structure, we would not expect the plan to provide a non-preferred drug at the generic level. In addition, if a plan has developed a tier in which it places very high cost and unique items, for example, genomic and biotech products, a plan may design its exception process so that such Part D drugs are not eligible for a tiering exception. We have added regulatory language to § 423.578 to make these two points clear.

As stated in § 423.578(c), if a tiering exception is granted, the enrollee will be approved for coverage as long as the prescribing physician continues to prescribe the drug; the drug continues to be safe for treating the enrollee's disease or medical condition; and the enrollment period has not expired.

Comment: Many commenters suggested that we develop a single well-designed exceptions process in which decisions are made based on the medical needs of the enrollee. The commenters maintained that a single process may help streamline administrative requirements and costs, and one based on the medical needs of the enrollee would address all three circumstances proposed in § 423.578, that is, where an enrollee is using a drug and the applicable tiered cost-sharing structure changes mid-year; the enrollee is using a drug and the cost sharing changes at the beginning of a new plan year; or there is no pre-existing use of the drug by the enrollee. Other commenters recommended that the certifying standard for physicians under proposed § 423.578(a)(4) be revised to comply with the statute.

Response: We partially agree with the commenters, and have added regulatory language that requires both off-formulary and tiering exceptions to be based on the medical needs of the enrollee. However, tiering exceptions are not typically offered in private industry currently. While tiering exception procedures must be reasonable, complete, and based on medical needs, as we discuss above, we do not believe that it would be appropriate at this stage to dictate a single type of tiering exception procedure that must be used by all plans.

We also agree with the commenters that the ''certifying'' standard for physicians must be revised to comply with section 1860D–4(g)(2) of the Act. Note that the statute does not use the term ''certification,'' and we believe that this term may be interpreted too formally. Therefore, we have modified § 423.578(a)(4) to require plans to obtain a ''supporting statement from the prescribing physician that the preferred drug for treatment of the same condition either would not be as effective for the enrollee, would have adverse effects for the enrollee, or both. We have made corresponding technical changes to the regulation wherever the term ''certification'' was previously used.

We also believe that a physician must be able to certify that the enrollee meets one or both of these conditions orally or

in writing. A plan may require a physician who provides an oral supporting statement to subsequently follow-up in writing, particularly where a plan decides not to grant an exception. The plan may require the prescribing physician to provide additional supporting medical documentation as part of the written follow-up. A plan may want to preserve the record in the event the enrollee or physician requests an appeal. However, we do not want to create a process whereby physicians must routinely provide written supporting statements. Otherwise, such an administrative burden could have the unintended consequence of discouraging exceptions requests when enrollees need non-preferred drugs. Finally, once a physician provides an oral or written supporting statement, the plan will review the request. The plan may obtain other evidence, including additional medical information from the prescribing physician. After performing its review, the plan must determine if the enrollee's condition can be treated with the preferred drug. We removed the content requirements for a physician's supporting statement, such as the enrollee's name, patient history, primary diagnosis related to the exceptions request, and why the non-preferred drug is needed. Again, we do not want to mandate that every exceptions request must be processed according to a listing of procedures. We believe that plans are in the best position to determine on a case-by-case basis the type of information they need to overcome the burden.

Comment: We received two comments suggesting that, instead of creating a separate definition of therapeutic equivalence in proposed § 423.578(a)(2)(iii), we should apply the same definition proposed in § 423.100.

Response: We agree with the commenter. Therefore, we have deleted the definition of therapeutic equivalence in the proposed rule and added a cross-reference to § 423.100.

Comment: A few commenters recommended that we adopt a uniform set of exceptions codes to be used by physicians and pharmacists. One commenter suggested that we work with the National Council for Prescription Drug Programs, Inc. to develop a standard claim processing field that payors and pharmacies would be required to use for purposes of communicating which tier is applied. Both commenters argued that adopting a uniform set of codes to be utilized by plans, pharmacists, enrollees, and physicians would streamline the exceptions process and make it easier to navigate.

Response: We appreciate the commenters' suggestions, but we believe the entities that provide Part D plans are in the best position to determine how to communicate with physicians and pharmacies. As we gain a better understanding of how plans intend to develop their formularies, we will work with interested parties to ensure that there are standard systems or procedures in place to make the process as simplistic as possible for pharmacists, physicians, and enrollees to navigate.

b. Exceptions and Appeals Rules for Non-Formulary Determinations

Section 1860D–4(h)(2) of the Act establishes a limitation on requests for exceptions when a particular drug is not on a plan's formulary at all. The statute specifies that an enrollee may appeal a determination not to provide coverage of a non-formulary drug ''only if the prescribing physician determines that all covered Part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the non-formulary drug, would have adverse effects for the individual, or both.''

Notably, this limitation is set forth under the ''appeals'' provisions of the statute, as opposed to under the preceding coverage determination and redetermination provisions that are discussed above for exceptions to tiered cost-sharing rules. Thus, we believe the intent of this provision is to limit appeals to cases where the prescribing physician has made the determination described by the law.

Unlike for the tiering exceptions, the statute does not specifically require that plans develop an exceptions process to review requests for exceptions for non-formulary drugs. However, the statute under section 1860D–4(h)(2) of the Act permits enrollees to appeal a determination not to provide for coverage of non-formulary drug only if the prescribing physician determines that all of the covered Part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the enrollee as the non-formulary drug, would have adverse effects, or both. As a result of the statutory requirement that enrollees obtain a physician's determination to request an appeal, we do not believe that the statute intends to preclude an enrollee from obtaining a coverage determination from a plan absent a determination by the prescribing physician, or to require that the physician's determination alone will result in a favorable coverage determination by the plan. Therefore, we proposed to require that plans also establish exceptions criteria for addressing these situations.

We stated our belief that requiring plans to use an exceptions process to review requests for coverage of non-formulary drugs would ensure that enrollees know what standards are to be applied and ensure that a plan's formulary is based on scientific evidence rather than tailored to fit exceptions and appeals rules for formulary drugs.

Under the exceptions process proposed at § 423.578(b), a plan would be required to allow enrollees to request (1) coverage of Part D drugs that are not on a plan's formulary; (2) continued coverage of a drug the plan has removed from its formulary; (3) an exception to a plan's policy regarding coverage for a step therapy; and (4) an exception to a plan's dosing limitation.

A plan's criteria would have to include a description of the criteria it would use to evaluate the prescribing physician's determination, clarify how the plan will evaluate the relative safety and efficacy of the requested drug, and describe the cost-sharing scheme that will be applied if coverage is provided. Again, an enrollee, the appointed or authorized representative, or prescribing physician could request an exception, and the plan could require a written supporting statement from the prescribing physician that the non-covered drug was medically necessary to treat the enrollee's disease or medical condition. We proposed that an enrollee would have the right to a redetermination by the plan of any unfavorable coverage determination.

Comment: One commenter suggested that we not require plans to develop and maintain an exceptions process for non-formulary drugs because it would make formulary adherence more difficult for plans to control.

Response: Although the statute does not specifically require that plans develop an exceptions process to review requests for exceptions for non-formulary drugs, we continue to believe that there is ample authority in the statute to require plans to have exception processes for off-formulary drugs. First, section 1860D–4(h) of the Act permits a beneficiary to request an appeal of an off-formulary drug if the prescribing physician determines that all covered part D drugs on any tier of the formulary under the plan for treatment of the same condition would not be as effective for the individual, would have adverse effects, or both. We do not believe that it is reasonable to require a beneficiary to wait until the appeal stage in order to receive an off-formulary drug, when the plan could

just as easily determine at the initial coverage determination stage that the on-formulary drugs are not appropriate for the beneficiary. In addition, the entire structure of the benefit, as explained in section 1860D–2 of the Act, is a structure that assumes that beneficiaries will have access to medically necessary drugs when appropriate, regardless of whether such drugs are on or off the formulary. Finally, under section 1860D–11(d)(2) of the Act we have the authority to set minimum standards for sponsors' benefit packages, and under section 1860D–12(b)(3)(D) of the Act, we have the authority to add contract terms to PDP sponsor contracts. Based on all of these authorities, we believe it is appropriate to require plans to maintain exception processes for off-formulary drugs. Requiring plans to use an exceptions process to review requests for coverage of non-formulary drugs will create a more efficient and transparent process and will ensure that enrollees know what standards are to be applied. In addition, this requirement is consistent with the industry standard where private plans allow enrollees to file exceptions to receive non-formulary medications.

Comment: Several commenters recommended that we require plans to establish additional exceptions criteria, including criteria that would preclude the use of a formulary drug where the enrollee experiences an adverse reaction from the drug previously tried and failed. Commenters believed that we should develop exceptions criteria for certain classes of drugs, namely those used by special populations such as beneficiaries with HIV/AIDS or mental health patients. Other commenters, however, believed that the exceptions criteria should be limited to whether the requested medication is appropriate for the patient, as documented by the prescribing physician.

Response: First, we agree with commenters that exceptions criteria should be designed to grant exceptions in cases where a plan determines that an off-formulary drug is medically appropriate for an enrollee and that the drug would have been covered but for the fact that the drug is off-formulary. We have added language to § 423.578(b) to this effect. As stated above, we believe the structure of the benefit under section 1860D–2 of the Act, the authority to create minimum standards and additional contract terms, and the requirement for off-formulary appeals, provide ample authority for this requirement. However, while plans must design their exception criteria so that drugs determined by the plan to be medically appropriate for the enrollee are covered, we do not believe that we should require detailed standards that go beyond such a medical necessity requirement. This is particularly the case because we do not know how plans will design their formularies. These comments illustrate the complexity of attempting to do so. Instead, the plan must establish criteria that encompass all exceptions requests and the procedural elements that must be followed to process a request. We will review these criteria as part of the plan approval process.

The primary issue that plans must address in a plan's non-formulary exceptions criteria is how it will determine medical necessity. Although plans must provide access to all Part D drugs that they determine are medically necessary (as that is described in § 423.578(b)(5)), we are not requiring prescriptive requirements for the methods that plans use to determine medical necessity. Therefore, plans will have some flexibility in creating the criteria or methods, such as prior authorization or step-therapy, to determine whether a non-formulary drug is medically necessary for an enrollee. We agree that where an enrollee's prior use of a drug has proven ineffective or caused adverse consequences to the enrollee's health, the plan must not require the use of the formulary drug as a condition in the exceptions process. This is a key component of the exceptions process, which entails a written statement from the prescribing physician that all covered Part D drugs on any tier of the formulary would not be as effective as the non-formulary drug, would have adverse effects for the enrollee, or both. Note that such a statement does not necessarily result in an automatic approval of the request. Clearly, nothing in this rule precludes a plan adopting a process whereby it grants automatic approval of a non-formulary drug upon a physician's supporting statement. However, some plans may want physicians to provide their rationale as to why, for example, the formulary drug would not be as effective for treating the enrollee's condition.

Finally, we do not believe that the statute permits us to develop unique exceptions criteria for certain classes of drugs used by special populations. Nevertheless, special populations will benefit from the rights and protections that the exceptions process affords all enrollees.

Comment: Several commenters requested us to provide an exception that would permit an enrollee to obtain a drug that is excluded from Part D.

Response: We strongly disagree with the commenters. The MMA mandates that we only provide access to Part D drugs and specifies certain categories of drugs as excluded. Therefore, we do not have the statutory authority to require plans to provide access to drugs that are excluded from Part D. As a result, we have strengthened § 423.578(e) to emphasize that nothing in the exceptions process shall be construed to allow an enrollee to use the exceptions process to request or be granted coverage for a prescription drug that is not a Part D drug. However, we note that while an enrollee cannot appeal the policy that a drug is not a Part D drug if excluded (that is, covered by Part B or otherwise excluded from the definition of Part D drug in § 423.100), the enrollee can request a coverage determination or an appeal regarding the policy as it applies to his or her set of facts. In other words, the enrollee can seek to demonstrate that the policy is not applicable in a particular instance based on the facts of his or her case. This is the same standard used in claims appeals where a beneficiary cannot appeal a national coverage determination (NCD) through the claims appeals process, but may appeal whether the NCD should apply in his or her case.

Comment: One commenter sought clarification on whether formulary use includes the type of the dosage, for example, liquid, capsule, tablet, and packaging, such as bubble wraps for long-term care facility residents. The commenter argued that ''formulary use'' includes more than just dose restriction, and § 423.578 must be revised to meet the statutory requirements that the Secretary establish guidelines for the exceptions process.

Response: We believe that an enrollee must be permitted to file an exception when he or she cannot take the dosage form of a medication that is included on a plan's formulary. If a medication is offered in tablet and liquid form but the plan only covers the tablet form on its formulary, an enrollee must be permitted to file an exception to obtain the liquid form of the medication if the prescribing physician indicates that the tablet form either would not be as effective for the enrollee, would have adverse effects, or both. For example, an elderly enrollee may not be able to swallow the tablet form. Therefore, we clarified in § 423.578(b) that ''formulary use'' includes the form of the dosage. However, we do not agree that ''formulary use'' includes packaging because the packaging of a drug, for example, bubble-wrapping, blister-cards, cassettes, does not impact the

effectiveness of a medication. In addition, activities related to the transfer of Part D drugs are included in the negotiation of the dispensing fee under section 1860D–2(d)(1)(D) of the Act.

Comment: A few commenters requested that we clarify who should make the determination as to whether a drug is no longer safe and effective for treating an enrollee's disease or medical condition. The commenters suggested that an authoritative agency or organization such as the FDA should make this type of determination.

Response: Plans may discontinue coverage of a medication for safety reasons, and in their exceptions procedures for non-formulary drugs, must include a process for comparing applicable medical and scientific evidence on the safety and effectiveness of the requested non-formulary drug with the formulary drug. Thus, in some instances, plans themselves may make an initial determination whether a drug is no longer safe and effective for the treatment of a disease or medical condition, subject to the appeals process. Plans also will rely on safety information generated by an authoritative government body such as the FDA (for example, relying on information released in an FDA Medwatch form) when discontinuing coverage of a medication for safety reasons.

c. Exceptions and Appeals Rules for a Plan's Tiered Cost-Sharing Structure and Non-Formulary Determinations

We received several comments that raise issues related to § 423.578(a) and (b). Instead of addressing the comments in each of the preamble discussions in sections 5.a. and 5.b. above, we have consolidated the comments and responses in this section since the issues are common to exceptions involving tiered cost-sharing structure and non-formulary issues.

Comment: We received numerous comments regarding the weight that plans will give a physician's supporting statement. Many commenters suggested that the physician's supporting statement carry great weight in determining whether an enrollee should receive a prescribed medication. Other commenters suggested that, if a physician prescribes a medication for an enrollee, he or she should automatically receive it. Still other commenters suggested that once a physician certifies that an enrollee should receive a prescribed medication, the burden should shift to the plan to show why the physician's supporting statement is not dispositive. The commenters argued that the burden on physicians to justify their drug selection decisions is too great under the proposed rule. In order to make the process faster and simpler for enrollees, physicians, and pharmacists, the physician's supporting statement should be the primary factor in determining whether an enrollee should receive a requested medication.

Response: As noted above, we agree with the commenters that a physician's opinion must carry great weight. However, we do not agree that a physician's supporting statement necessarily means that an enrollee must automatically receive a drug. If the Congress intended such an outcome, there would be no need for plans to develop exceptions procedures. Therefore, once a physician provides a supporting statement that an enrollee should receive a prescribed medication, the plan will review the request. The plan may obtain other evidence, including additional medical information from the prescribing physician. After performing its review, the plan must determine if the enrollee's condition can be treated with the preferred or formulary drug. We note that if an enrollee disagrees with the plan's exception determination, it can still appeal that determination through the regular appeals process.

Comment: We received several comments objecting to an option considered by us that would require an enrollee who is using a drug that is subsequently removed from the plan's formulary, or is no longer designated as the ''preferred drug,'' to try a preferred drug(s), and experience adverse effects, before being permitted to resume using the original drug.

Response: We agree with the commenters that we must not add an exceptions criterion that will require an enrollee to try a preferred drug(s) and experience adverse effects before being permitted to resume using the original drug. However, we wish to point out that nothing in this rule precludes a plan from establishing such a requirement in its exceptions process. As mentioned in our earlier response, we do not believe that an enrollee who has used a formulary or preferred drug and has already experienced adverse consequences should be required to take the same harmful drug, as certified by the prescribing physician. For instance, most clinicians find it inappropriate to change the medication of a patient stabilized on a selective serotonin reuptake inhibitor (SSRI) that was moved from a formulary, or from a lower tier to a higher tier, because the effectiveness level of SSRIs is not reached for two weeks. However, the scenario that the commenters have described is quite different. There, the situation involves a drug that has been removed from the plan's formulary or moved to a different tier, subsequent to an enrollee's use of a drug. Because the enrollee would be affected by the plan's formulary or tiering change, the plan is obligated to provide a notice to the enrollee 60 days in advance, or continue coverage of the drug as required under subpart C of this rule. Thus, this gives the enrollee sufficient time to request an exception. If the physician indicates that the formulary or preferred drug would have an adverse effect on the enrollee's health, the plan likely will not require the enrollee to take the drug. However, if the physician's supporting statement does not demonstrate that the drug would have adverse consequences or would be ineffective, we would not prohibit the plan from requiring the enrollee to try the formulary or preferred drug. For example, in many instances, a patient may be able to try a formulary alternative statin medication when their current statin medication is being removed from the formulary. However, if the enrollee experiences adverse effects after trying the drug, the plan must then grant the exception. In addition, as we state above, there may be some cases where requiring a beneficiary to try a drug and experience adverse effects would be unreasonable.

d. Treatment of Determinations Regarding Exceptions Requests

We proposed at § 423.578(c)(1) that determinations on exception requests would constitute plan coverage determinations under § 423.566 and should be completed in the same timeframes. Enrollees would then have an opportunity to request a plan redetermination. Unfavorable redetermination decisions could then be appealed to the IRE. If the IRE determines that the plan correctly applied its exceptions criteria, the plan's determination would be upheld.

Thus, we proposed that the IRE would not have any discretion regarding the validity of the plan's exceptions criteria or formulary. Instead, we would be responsible for evaluating and approving a plan's exceptions criteria and formulary as part of the annual plan approval process. In many instances, however, evaluating whether the plan had appropriately applied its own exceptions criteria for a formulary exception would necessarily involve an element of medical judgment (for example, if the plan had a rule that an enrollee would need to suffer significant adverse effects by using the Part D drug covered by the plan in order to obtain an exception, the IRE would need to

review whether such adverse effects had been experienced). In those situations, we stated the IRE's medical staff would be responsible for reviewing the plan's determination as to whether the formulary exceptions criteria had been applied properly. Because the final rule requires a Part D plan's formulary and tiering exceptions process to grant an exception when the plan determines it is medically appropriate, the IREs will likely be reviewing medical necessity in numerous cases.

Although not required by statute, we thought it important to put in place certain safeguards regarding the issuing and effect of a coverage determination made as part of the exceptions process. We believed that certain safeguards would help to ensure that the exceptions process was both fair and efficient for enrollees. First, to ensure that enrollees who file exceptions requests for drugs that are being removed from a plan's formulary are not disadvantaged by a plan's failure to issue a timely decision, we proposed in § 423.578(c)(1) and § 423.578(c)(2) that if a plan failed to issue a timely decision, the plan would be required to continue providing coverage until a decision was made on the request. Proposed § 423.578(c)(2)(i) allowed enrollees to receive up to a one-month supply of the requested drug, but a plan could adjust the supply to account for a shorter time frame. As noted above, we have revised proposed § 423.578(c)(2) to be consistent with our requirement in MA that an MA plan's failure to issue its reconsideration within the appropriate timeframe constitutes an adverse determination which must be automatically forwarded to the IRE within 24 hours of the expiration of the timeframe. We also provided, at proposed § 423.578(c)(3), that once a plan approved a drug pursuant to the exceptions process, an enrollee would be entitled to continue receiving refills of the drug at the prescribing physician's discretion.

The final safeguard implemented under proposed § 423.578 prohibited plans from assigning drugs approved under either exceptions process to a special formulary tier, co-payment, or other cost-sharing requirement. In other words, plans must employ reasonable criteria in determining the co-payments or other cost-sharing requirements of drugs approved for coverage under the exceptions process.

Comment: We received several comments regarding the level of cost-sharing that enrollees would be required to pay when an exception is approved. Some commenters suggested that all drugs be approved at the preferred level of cost-sharing. Another commenter agreed that non-preferred drugs should be approved at the cost-sharing level applicable for preferred drugs when an exception request is approved, but recommended that we clarify that non-preferred drugs can not be approved at the generic cost-sharing level.

Response: We agree with the commenters that, when an exceptions request involving a tiering issue is approved, the enrollee is entitled to the amount of cost-sharing that applies for a preferred drug, but not for a generic drug. We have clarified this under § 423.578(c)(3).

We do not agree that we must mandate the amount of cost-sharing that applies when an exception involving a non-formulary drug is approved. Section 1860D–4(h)(2) of the Act requires plans to treat non-formulary Part D drugs approved under the exceptions process as being included on the plan's formulary for purposes of determining whether an enrollee has reached the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) of the Act. However, the MMA does not mandate that plans apply the cost-sharing terms of a particular tier when plans establish tiers to manage covered Part D benefits. Therefore, we do not specify in § 423.578(c) the tier that must be applied when a plan approves an exceptions request that involves a non-formulary drug. Instead, § 423.578(b)(2)(iii) gives plans the flexibility to determine which level of cost-sharing will apply when it approves an exceptions request involving non-formulary drugs. Plans must explain in its exceptions criteria the cost-sharing scheme that will be applied. Allowing plans the flexibility to determine which level of cost-sharing will apply is consistent with section 1860D–2(b)(2) of the Act, which permits a plan to establish tiers to manage its covered Part D benefits so long as the co-payments associated with the plan's tiers meet the actuarial equivalence standard in section 1860D–2(b)(2)(A)(ii) of the Act. If we required plans to apply the cost-sharing amount that applies to covered part D drugs at a specific cost-sharing level, we would impede a plan's flexibility to develop its tiered cost-sharing structure.

We note that plans are prohibited under § 423.578(c)(4)(ii) from establishing a special formulary tier or other cost-sharing requirement that is applicable to non-formulary Part D drugs that are approved under the exceptions process. As mentioned previously, we will review all of the plans' exceptions criteria and determine if they are appropriate and meaningful. We have clarified under § 423.578(c)(3) through (4) the difference between how exceptions involving tiering and non-formulary issues must be treated after approval.

We would also like to clarify that, if a plan approves an exception for a non-formulary drug, an enrollee may not request a tiering exception for the non-formulary drug. Although, section 1860D–4(h)(2) of the Act requires plans to treat non-formulary Part D drugs approved under the exceptions process as being included on the plan's formulary, it does so only for purposes of determining whether an enrollee has reached the annual out-of-pocket threshold. Plans are not required to add a non-formulary drug to its formulary once an exception is granted. Therefore, although a non-formulary drug could be obtained at the amount of cost-sharing that applies to drugs on a plan's non-preferred tier under the exceptions process, the ''non-formulary drug'' is not a ''non-preferred drug,'' and only non-preferred drugs are subject to the exceptions process.

Comment: We received one comment recommending that we delete the requirement in proposed § 423.578(c)(3)(ii) which would prohibit plans from assigning drugs approved under an exceptions request to a special formulary tier, co-payment, or other cost-sharing requirement. The commenter acknowledges that the provision is derived from the statute, but maintains that the provision is unnecessary because the commenter believes that we have presented two options for cost-sharing (payment at the preferred and generic cost-sharing levels) that constitute a special formulary tier.

Response: We disagree with the commenter that we have created a special formulary tier. We believe that it is necessary to include in § 423.578(c)(4)(ii) a provision that will ensure that plans do not assign drugs approved under a non-formulary exceptions request to a special formulary tier, co-payment, or other cost-sharing requirement. This policy is consistent with the statute.

Comment: Several commenters contended that, when an exceptions request is approved, the approval should not be for an indefinite period of time. The commenters argued that we should include provisions for limiting indefinite exceptions based on safety or accepted clinical practice standards, including step-therapy and length of therapy edits. Some commenters suggested that plans be permitted to annually re-evaluate exceptions that

have been approved. However, other commenters believed that proposed § 423.578(c)(3) provided important beneficiary protections to the extent that the enrollee would not need to renew an exceptions request so long as the prescribing physician continues to prescribe the drug.

Response: We agree that plans must continue providing a drug that was approved under the exceptions process so long as the prescribing physician continues to prescribe the medication and the medication continues to be considered safe for treating the enrollee's condition. However, we do not believe that an approval should last indefinitely. Therefore, we have added § 423.578(c)(4) to provide that once an exceptions request is approved, the plan must provide coverage of the drug so long as the enrollee also continues to be a member of the plan, or the enrollment period has not expired, whichever is sooner. Thus, in no case will a plan be required to continue coverage beyond the plan year.

6. Appeals

a. Redeterminations (§ 423.580 through § 423.590)

Sections 423.580 through § 423.590 explain the right to a redetermination and the requirements that apply to plans for both standard and expedited redeterminations. If a decision regarding a coverage determination is unfavorable (in whole or in part) to the enrollee, the enrollee may file an oral or written request with the plan for a redetermination on the decision.

The proposed regulations did not identify Social Security Administration (SSA) field offices as possible locations for filing redetermination requests. Using any filing location other than the plan itself can significantly affect the speed with which the appeal is resolved. Moreover, given that section 931 of the MMA mandates the transfer of responsibility for Medicare appeals from SSA to DHHS by no later than October 1, 2005, we believed that an explicit regulatory reference to SSA field offices would not be appropriate.

For an expedited redetermination, an enrollee or the prescribing physician (acting on behalf of an enrollee) may submit an oral or written request for redetermination. However, requests for payment of drugs already received would not be expedited. The proposed requirements for making standard redeterminations for requests involving covered benefits in proposed § 423.590(a) specified that the plan would issue its redetermination as expeditiously as the enrollee's health condition required, but no later than 30 calendar days from the date of receipt of the request.

Under proposed § 423.590(b), for standard redeterminations involving requests for payment, the plan would be required to issue its redetermination no later than 60 calendar days from the date of receipt of the request. In the case of expedited redeterminations, § 423.590(d) specified that a plan would complete its redetermination and give the enrollee and the prescribing physician involved, as appropriate, notice of its determination as expeditiously as the enrollee's health condition required, but no later than 72 hours after receiving the request. For both the standard and expedited redetermination for covered benefits, the plan could extend the timeframe for making its determination by up to 14 calendar days if the enrollee requested the extension, or if the plan justified a need for additional information and how the delay would be in the interest of the enrollee. An extension would not be provided for redeterminations involving requests for payment. If the plan's redetermination resulted in an affirmation, in whole or in part, of its original adverse coverage determination, the plan would be required to give written notification to the enrollee and advise the enrollee of the right to file an appeal with the IRE that contracts with us.

Comment: Several commenters asked us to define ''good cause'' for extending the timeframe for filing a redetermination request in § 423.582(c).

Response: Although we have not defined ''good cause'' in the regulations applicable to either MA or prescription drug appeals, we believe that it is useful to provide examples of good cause to plans. Examples of circumstances when good cause may be found to exist include, but are not limited to, the following situations: (1) the enrollee was prevented by serious illness from contacting the plan in person, in writing, or through a friend, relative, or other person; (2) the enrollee had a death or serious illness in his or her immediate family; (3) important records were destroyed or damaged by fire or other accidental cause; (4) the plan, or its designated entity, gave the enrollee, appointed or authorized representative, or prescribing physician incorrect or incomplete information about when and how to request a redetermination; (5) the enrollee, appointed or authorized representative, or prescribing physician did not receive notice of the determination or decision; or, (6) the enrollee, appointed or authorized representative, or prescribing physician sent the request to another Government agency in good faith within the time limit and the request did not reach the correct plan until after the time period had expired. Again, these examples are not an exhaustive list, but are illustrative of the kinds of scenarios that a plan might find good cause for extending the filing deadline.

Comment: We received many comments that argued that the 30-day redetermination timeframes were unreasonably long and should be shortened.

Response: As mentioned earlier, we agree with the commenters that the proposed adjudication timeframes are too long. Therefore, redeterminations by the plan must be made as expeditiously as the enrollee's health condition requires, but no later than 72 hours for expedited cases and 7 days for standard cases. In response to the concern raised by the commenters regarding the length of time it takes for an enrollee to be reimbursed, we are no longer distinguishing between payment and service-related disputes. As previously mentioned, we reduced the timeframe for plans to make standard redeterminations to 7 days in § 423.590(a) and (b). Again, redeterminations that involve requests for payment cannot be expedited because a medical emergency does not exist for an enrollee who already obtained the medication in dispute.

Comment: Some commenters did not support the provision at § 423.586, which would require plans to have methods in place for receiving evidence in person because it is unduly burdensome for plans to receive evidence in person.

Response: We disagree that permitting enrollees or prescribing physicians to submit evidence in person is unduly burdensome. The right to present evidence in writing as well as in person is consistent with MA, and we anticipate that Part D enrollees may want to deliver evidence in person rather than mailing their materials to plans. Therefore, plans must have procedures in place for accepting evidence in person from enrollees, including, for example, the ability to accept evidence delivered by enrollees at the plan's physical location or by telephone. However, we note that this requirement is not intended to require plans to provide in-person hearings for enrollees.

b. Independent Review Entity (IRE) Reconsideration (§ 423.600 through § 423.604)

The MMA gives the Secretary the flexibility to establish an appeals process similar to that used for the MA appeals process. Thus, the proposed IRE

reconsideration process set forth at § 423.600 through § 423.604 was much like that applicable to MA organizations under Part C. Note that when the plan's redetermination affirms, in whole or in part, its adverse coverage determination, any issue remaining in dispute could be appealed by the enrollee to the IRE that contracts with us. However, unlike under the MA program, plan redeterminations involving tiering issues or coverage of a non-formulary drug would not be automatically forwarded to the IRE. Instead, an enrollee would need to request an IRE review. This proposed requirement modified the MA procedure that affords automatic referral to the IRE whenever the MA organization's original denial was upheld by the organization's redetermination.

At § 423.600, we proposed that an enrollee who was dissatisfied with the plan's redetermination could file a written request for reconsideration by the IRE. We also proposed that when an enrollee filed for an appeal, the IRE would be required to solicit the views of the prescribing physician. In order to request an off-formulary drug, the prescribing physician would be required to indicate that all covered part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the non-formulary drug, would have adverse effects for the individual, or both. To be consistent with our requirement in § 423.590(f), we added (e) to § 423.600, which requires reconsiderations to be made by a physician with expertise in the field of medicine that is appropriate for the services at issue when the issue is the denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity).

Section 423.602 proposed the requirements for the IRE reconsideration determination notice, including the requirement that if the determination were adverse, the enrollee must be informed of the right to request an ALJ hearing and the procedures that must be followed to obtain the hearing.

Section 423.604 of our proposed rule explained that a reconsideration by the IRE was final and binding on the enrollee and the plan, unless the enrollee requested an ALJ hearing.

Comment: We received a number of comments regarding automatic forwarding of redeterminations to the IRE. While a few commenters supported our decision to require enrollees to request an IRE reconsideration, many argued that cases should be automatically forwarded as provided in MA to ensure that enrollees receive an independent review of a plan's redetermination. The commenters maintained that the automatic forwarding of unfavorable redeterminations to the IRE is necessary to prevent enrollees from experiencing a lapse in coverage due to the length of time that it takes for an appeal to receive an independent review. Some commenters also disagreed that the dollar value of drug appeals would involve relatively small monetary amounts, which we reasoned that forwarding all adverse redeterminations to the IRE would be inefficient.

Response: As previously mentioned, we have streamlined the appeals process by shortening the adjudication timeframes and requiring plans to either provide notice to enrollees 60 days in advance of a change to its formulary or provide notice and a 60-day supply of a medication that is affected by a formulary change. Thus, enrollees will not be faced with any lapses in coverage of a medication they are already taking by being required to request a reconsideration with the IRE directly. In addition, even if the amount in controversy for reconsiderations is higher on average than originally anticipated by us, we do not believe that requiring enrollees to request appeals has any bearing on the process. Therefore, § 423.600 requires that an enrollee who is dissatisfied with the plan's redetermination may file a written request for reconsideration with the IRE. We note that we have eliminated the plan as an alternative filing location since the decision-making timeframe begins upon receipt of the IRE's request. This change ensures that there are no delays in enrollees receiving timely responses.

Comment: Some commenters stated that the scope of an IRE's review should not be limited to whether a plan applied its exceptions criteria correctly.

Response: We agree with the commenters that the IRE's review must not be limited to whether a plan applied its exceptions criteria correctly. As stated above, plans' exceptions procedures must include measures to grant an exception when the plan determines that an exception would be medically appropriate. Because these determinations will be subject to review by the IRE, the IRE will necessarily also review whether a drug is medically necessary. Therefore, the IRE's medical staff also must review the plan's medical necessity determination in addition to whether the plan properly applied its exceptions criteria for the individual in question. Examining the record de novo using the plan's exceptions criteria, as approved by us, and making an independent medical necessity determination will form the basis for the IRE's decision. However, the IRE is prohibited from ruling on the validity of a plan's exceptions criteria or formulary. Only we can evaluate and decide whether to approve a plan's exceptions criteria and formulary as part of the annual plan approval process.

Comment: We received several comments requesting that we specify the method under § 423.600(b) by which the IRE can solicit the views of the prescribing physician.

Response: The IRE may solicit the views of the prescribing physician either orally, or in writing. We also clarified that a written account of the prescribing physician's views (prepared by either the prescribing physician or IRE, as appropriate) must be contained in the IRE's record so that, if appealed, the ALJ, MAC, or Federal court will be able to review all of the evidence considered or disregarded by the reviewing entity.

Comment: A few commenters recommended that we require requests for IRE review to be filed directly with the IRE, as opposed to alternative locations, to avoid delays.

Response: We agree with the commenter, and as mentioned above, have modified § 423.600(a) to require enrollees to file requests for IRE review directly with the IRE instead of permitting enrollees to choose whether to file a request with the IRE or plan.

Comment: One commenter recommended that enrollees and prescribing physicians should be able to submit additional evidence to the IRE.

Response: We agree with the commenter, and like under MA, enrollees and prescribing physicians must have an opportunity to submit additional evidence to the IRE.

Comment: We received one comment suggesting that we require physician certifications to accompany all requests for reconsideration by an IRE and hearing by an ALJ. The commenter believed this requirement would ensure that the reconsiderations are focused on medical necessity rather than patient preference.

Response: We agree that supporting statements from prescribing physicians are often necessary for making proper determinations, especially when medical necessity is at issue. However, since the IRE is required to solicit the views of the prescribing physician, it is not necessary to require that supporting statements from physicians accompany all requests for IRE reconsiderations or ALJ hearings. In fact, IREs may not always be called upon to make medical

judgments. For example, the definition of a Part D drug excludes ''agents when used for anorexia, weight loss, or weight gain.'' See § 423.100 citing section 1927(d)(2) of the Act. An IRE may be called upon to review whether an agent was in fact used for anorexia, weight loss or weight gain (and therefore excluded from the definition of Part D drug), or whether it was used for some other purpose.

Comment: One commenter suggested that we require IREs to include information about an enrollee's right to an ALJ hearing, the procedure for requesting it, and the amount in controversy threshold amount required for an ALJ hearing in the notices of reconsideration.

Response: Section 423.602(b) specifies the requirements for the IRE reconsideration determination notice, including the requirement that if the determination is adverse, the enrollee must be informed of the right to request an ALJ hearing if the amount in controversy meets the requirements of § 423.610, and the procedures that must be followed to obtain the hearing.

c. Administrative Law Judge (ALJ) Hearings, Medicare Appeals Council (MAC) Appeals, and Judicial Review (§ 423.610 through § 423.630)

As stated above, section 1860D–4(h)(1) of the Act merely requires the Secretary to establish a reconsideration and appeals process that is ''similar'' to the process used for MA organizations under the authority of sections 1852(g)(4) and (5) of the Act. Although we believe the Congress gave us a good deal of discretion in designing these procedural rules under Part D, we determined as a policy matter to adopt most of the ALJ, MAC, and judicial review procedures currently used in the MA program.

Section 1852(g)(5) of the Act provides the right to a hearing and to judicial review for an enrollee dissatisfied by reason of the enrollee's failure to receive a Part D drug to which he or she believes he or she is entitled, and at no greater charge than he or she believes he or she is required to pay. Section 1852(g)(5) of the Act also specifies the amount in controversy needed to pursue a hearing and judicial review, and authorizes representatives to act on behalf of individuals that seek appeals.

As provided in proposed § 423.610, if the IRE's reconsideration determination is not fully favorable, the enrollee may request a hearing before an ALJ if the amount remaining in controversy meets the threshold requirement established annually by the Secretary. The threshold requirement will be published annually in the **Federal Register**. We note that in § 423.612 (a) of the proposed rule, we required enrollees to file their requests for ALJ review with the entity specified in § 423.582(a). However, we did not intend that requests for ALJ hearing be filed with the Part D plan sponsor. Therefore, we modified § 423.612(a) of this final rule to require enrollees to file written requests for an ALJ hearing with the entity specified in the IRE's reconsideration notice. The plan is not considered a party to the ALJ hearing, but may participate in the hearing at the discretion of the ALJ. If the ALJ hearing does not result in a fully favorable determination, the enrollee may request MAC review of the ALJ decision. Unlike under MA, the plans do not have the right to request an appeal of an ALJ decision with which the plan disagrees.

Following the administrative review process, the enrollee is entitled to judicial review of the final determination if the amount remaining in controversy meets the threshold requirement established annually by the Secretary and published in the **Federal Register**.

Comment: We received several comments expressing concern about how we will calculate the amount remaining in controversy. Many commenters noted that the proposed rule does not clearly state how ALJs and the MAC will determine whether an enrollee has met the applicable amount in controversy (AIC) threshold. One commenter recommended that calculation of the amount remaining in controversy include the projected cost of the drug at issue for at least the duration of the current calendar/plan year, including consideration of any cost sharing amount paid by the enrollee or a third-party. Additionally, commenters asked that we define the term ''projected value'' as used under § 423.610(b) of the final regulation.

Response: In order to clarify how the amount remaining in controversy will be calculated, we have adopted a modified version of the formula used in the Medicare fee-for-service program to determine the amount remaining in controversy. Therefore, the amount remaining in controversy will be calculated by subtracting any allowed amount under Part D, payments made by third parties, deductible, and coinsurance amounts applicable to the particular Part D drug at issue from either the projected value of the drug, or, where the enrollee is seeking reimbursement, the actual amount the enrollee paid for the Part D drug. Like the MA program, rather than putting this formula in regulation, we will include it in separate guidance, such as CMS manuals, in order to adjust the formula if necessary.

In response to comments we received about defining the term ''projected value,'' we have amended § 423.610(b) to state that the projected value of a Part D drug, for purposes of calculating the amount remaining in controversy, shall include any costs the enrollee could incur based on the number of refills prescribed for the drug in dispute during the plan year.

Comment: Two commenters were concerned that the aggregation of multiple enrollee appeals would limit the consideration given to individual cases. Both commenters felt strongly that the assessment of a particular prescription drug for an enrollee requires an evaluation of the enrollee's individual case, including his or her medical condition, medical history and other factors. To ensure that all enrollees' cases receive this type of consideration, the commenters recommended either reducing the AIC threshold at the ALJ level of appeal so that aggregation is almost never necessary or precluding aggregation of appeals by multiple enrollees.

Response: We first note that the ALJ AIC is a statutorily established threshold. Neither CMS nor the Secretary has discretion to alter this requirement. Nevertheless, we do not agree with the commenters' assessment of the consideration individual appeals will receive if multiple enrollees elect to aggregate their appeals for purposes of meeting the AIC threshold. Currently, in the Medicare fee-for-service program, two or more beneficiaries may combine claims to meet the AIC requirement for obtaining an ALJ hearing, so long as the claims involve common issues of law or fact. In adjudicating these appeals, ALJs often make individual medical necessity determinations for each beneficiary who received the item or service in dispute. Given the ALJ's experience in adjudicating aggregated cases, we believe that Part D appeals that are aggregated by multiple beneficiaries will receive appropriate individual consideration.

Comment: Several commenters requested that we clarify the applicable filing requirements for appeals that an enrollee wishes to aggregate for purposes of meeting the AIC threshold for requesting an ALJ hearing.

Response: We agree with the commenters' observation that the proposed rule was not clear regarding the applicable filing timeframes for appeals an enrollee wishes to aggregate. Therefore, we have to amended § 423.610(c)(1)(ii) and (2)(ii) in this final rule to specify that multiple appeals,

filed by either a single enrollee or multiple enrollees, may be aggregated to meet the AIC threshold for ALJ hearings so long as all of the appeals to be aggregated have been filed in accordance with the requirements in § 423.612(b).

Comment: One commenter suggested that we revise our proposal that plans are considered a ''party to the ALJ hearing'' for the limited purpose of participating in the hearing. The commenter believes that plans should be afforded full party status at the ALJ level so that they can defend their redetermination decisions, rather than just respond to questions asked by the ALJ. Additionally, the commenter suggested that when a plan is a party to an ALJ hearing, it should be permitted to file a request for review with the Medicare Appeals Council and the appropriate Federal court, just as MA organizations are permitted.

Response: In the proposed rule, we stated in the introduction of the preamble to § 423.610 that plans had party status for the limited purpose of participating in ALJ hearings. Part 422, subpart M gives MA organizations party status at the ALJ level. However, we do not agree with the commenter that plans should have full party status at the ALJ level as MA organizations. Section 1860D–4(h) of the Act, which requires plans to provide Part D enrollees with ALJ hearings and MAC review, allows only Part D enrollees to file appeal requests at these levels. Thus, the Congress did not grant plans with party status at the ALJ levels of the appeals process. To clarify this point, § 423.620 has been revised to state that the MAC provisions that apply to MA organizations apply to plans, to the extent applicable. Even though plans are not parties to ALJ hearings, we continue to believe that it is important to give plans the ability to participate in ALJ hearings. Therefore, plans may participate in hearings at the ALJ's discretion.

Comment: One commenter suggested that we modify the Part D regulations so that if the ALJ issues a decision that is favorable for an enrollee and the plan files an appeal with the MAC, the plan does not have to effectuate the ALJ's decision until the MAC upholds the decision favorably to the enrollee. The commenter also suggested that plans be required to effectuate ALJ decisions within 60 days after the decision has been issued if the plan does not request a review by the MAC within the 60-day timeframe. The commenter argued that adding these provisions would be consistent with the MA regulations.

Response: As indicated above, § 423.620 permits only Part D enrollees to appeal ALJ decisions. Therefore, in accordance with the requirements set out in § 423.636(c), plans are required to effectuate favorable ALJ decisions involving payment issues no later than 30 calendar days after a final decision is issued and all other cases as quickly as the enrollee's condition warrants, but no longer than 72 hours after a final decision is issued. These effectuation timeframes have been reduced from the proposed 60-day deadline in light of our decision to shorten the adjudication timeframes.

7. Effectuation of Reconsideration Determinations (§ 423.636 through § 423.638)

Section 423.636 and § 423.638 proposed the requirements for effectuation of coverage determinations reversed by the plan, redeterminations reversed by the IRE, or reversals by an ALJ or higher level of appeal. When the plan's redetermination is reversed by the IRE, § 423.636(b)(1) required that it must authorize the benefit under dispute within 72 hours from the date it received notice reversing the redetermination, or provide the benefit as expeditiously as the enrollee's health required, but no later than 14 calendar days from the date of the reversal notice. For redeterminations of requests for payment, proposed § 423.636(a)(2) required that if the plan reversed its coverage determination, it must pay for the benefit no later than 60 calendar days after the date it received the request for reconsideration. Under § 423.636(b)(2), if a plan's redetermination was reversed by the IRE, it must pay for the benefit no later than 30 calendar days from the date it received notice reversing the redetermination.

Section 423.638 proposed that for expedited redeterminations reversed by the plan or the IRE, the plan must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition required but no later than 72 hours after the date it received the request for redetermination, or in the case of reversal by the IRE, from the date it received the reversal notice.

Finally, for reversals by an ALJ or higher level of appeal, we proposed under § 423.636(c) and § 423.638(c) that the plan must pay for, authorize, or provide the benefit under dispute as expeditiously as the enrollee's health condition required, but no later than 60 calendar days from the date it received notice reversing its determination.

Comment: We received a number of comments requesting us to revise the effectuation timeframes. Several commenters recommended that plans effectuate IRE determinations within 24–48 hours, ALJ hearing decisions within 48 hours, and the MAC review decisions within 48 hours. The commenters also suggested that plans be required to authorize benefits within 72 hours after receiving notice from the IRE.

Response: As mentioned previously, we agree that the proposed adjudication timeframes were too long. As a result, we need to make corresponding changes to the effectuation timeframes in § 423.636 and § 423.638. Therefore, the effectuation timeframes for appeals involving non-payment issues are no later than 72 hours (expedited) or 7 calendar days (standard) from the date the plan receives the request for redetermination if the plan is reversing its previous determination, or no later than 24 hours (expedited) or 72 hours (standard) from the date the plan receives notice of a reversal by the IRE, ALJ, MAC, or Federal court. For payment issues, the plan must authorize payment within 7 calendar days from the date it receives the request for redetermination and make payment within 30 days from the date from the date it receives the request for redetermination if the plan is reversing its previous determination, or it must authorize payment for the benefit within 72 hours and make payment no later than 30 calendar days from the date it receives notice reversing the coverage determination by the IRE, ALJ, MAC, or Federal court.

Comment: We received a comment suggesting that we remove the term ''completely'' from § 423.638(a) when describing a plan's obligation to effectuate a coverage determination the plan reversed.

Response: We agree with the commenter. Under MA, the term ''completely'' was added to § 422.638(a) because any MA reconsideration that was not completely favorable was automatically forwarded to the IRE for reconsideration. However, under Part D, the regulations, except in limited circumstances where a Part D plan sponsor has missed its claims adjudication or redetermination deadline, do not allow automatic forwarding of unfavorable redeterminations to the IRE. Therefore, we have deleted the term ''completely'' from § 423.638(a).

8. Federal Preemption of Grievances and Appeals

Section 232(a) of the MMA amended section 1856(b)(3) of the Act so that it now reads: ''The standards under this part shall supersede any State law or regulation (other than State licensing laws or State law relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part.'' Section 1860D–12(g) of the Act then incorporates this preemption rule for plans.

We believe that the grievance procedures for the Part D Drug Program under Title I must be the same as those that apply to the MA program under Title II. In the proposed rule, we proposed continuing to defer to State law on the issue of authorized representatives of enrollees in the appeals process.

We did not believe that the Congress intended for the Secretary to regulate matters for which the Secretary was not authorized to promulgate standards (for example, spousal rights, powers of attorney, or legal guardianship). Often, authorized representative matters are non-Federal issues. However, because we do have the authority to regulate in the field of grievances, we were concerned that State grievance requirements would now be preempted, thereby requiring us to reexamine our Federal grievance requirements. We requested comments on this preemption issue and the specific State grievance requirements that should be incorporated into Federal regulatory requirements at § 423.564.

We also noted that tort law, and often contract law, are generally developed based on case law precedents established by courts, rather than by legislators through statutes or by State officials through regulations. In addition, we did not believe we would have the authority under Part D to set specific tort remedies or to govern resolution of private contracting disputes between plans and their subcontractors. We believed that the Congress did not intend for our regulations to supersede each and every State requirement applying to plans—particularly those for which the Secretary lacks expertise and authority to regulate. Thus, we did not believe, for example, that wrongful death or similar lawsuits based upon tort law would be superseded by the appeals process established in these regulations. Similarly, State contract law would continue to govern private contract disputes between plans and their subcontractors.

Under principles of Federalism, and Executive Order 13132 on Federalism, which generally require us to construe preemption narrowly, we believe that an enrollee will still have State remedies available in cases in which the legal issue before the court is independent of an issue related to the organization's status as a stand alone PDP or an MA-PD plan.

Comment: We solicited comments on whether the proposed Federal grievance procedures should preempt State grievance requirements. We received several comments on this issue, which primarily supported adopting a single set of grievance procedures to reduce enrollee confusion and plan burden. Some commenters recommended that we adopt the provisions proposed by us for Medicare+Choice organizations in a January 24, 2001 proposed rule. See 66 FR 7,593. However, one commenter opposed Federal law preempting State law where Part D appeals are concerned.

Response: We agree with the commenters that establishing a uniform set of grievance standards will reduce confusion and burden for enrollees and plans. We also believe that one set of rules will ensure better beneficiary protections and achieve consistency among plan operations. Thus, § 423.564 implements the specific guidelines for Part D grievances that we proposed in January 2001 for Medicare+Choice organizations. We disagree with the commenter that Federal provisions should not preempt State requirements for appeals. We believe that such an approach is inconsistent with § 232(a) of the MMA, which preempts State appeal and grievance requirements and which is incorporated into the Part D laws through section 1860D–12(g) of the Act.

Under the grievance requirements, plans must notify enrollees of decisions as expeditiously as the enrollee's case requires, but no later than 30 calendar days after receiving a complaint. Plans may extend the timeframe by up to 14 calendar days if the enrollee requests the extension, or if the plan justifies a need for additional information and the delay is in the interest of the enrollee. We believe that the timeframes must be according to the enrollee's case as opposed to the enrollee's health since not all grievances involve medical care. For example, an enrollee may complain that a network pharmacy does not offer convenient hours for getting prescriptions filled. In addition, we believe that most plans will be able to respond to most grievances within 30 days. If an enrollee makes a grievance orally, the plan may respond to it orally or in writing, unless the enrollee requests a written response. If an enrollee files a written grievance, then the plan must respond in writing. In addition, a plan must provide information to enrollees on their right to request a review by a Quality Improvement Organization (QIO) if the grievance involves a quality of care issue. For any complaint involving a QIO, the plan must cooperate with the QIO in resolving the complaint. Plans must establish a 72-hour expedited grievance process for complaints involving certain procedural matters in the appeals process. Finally, plans must create a system to track and maintain records on all grievances.

We note that under MMA, enrollees will still have access to various State remedies available in cases in which an issue is unrelated to the plan's status as a PDP or MA-PD plan.

9. Employer Sponsored Prescription Drug Programs and Appeals

As explained above, MA-PDs and PDPs are subject to the requirements of Part 423 for Part D benefits. In addition, when an employer, whether by contracting with an MA-PD, PDP, or otherwise, provides prescription drug benefits in addition to those covered under Part C and Part D of Title XVIII of the Act to their retirees, such employer may have established a group health plan governed by both Title I of the Employee Retirement Income Security Act of 1974, as amended (ERISA), and State law (to the extent such State law is not preempted by ERISA).

In drafting our Part C, MA rules, we consulted the Department of Labor (DOL), employer groups, and the health plan industry in trying to eliminate unnecessary Federal regulation of claims and appeals issues that impact matters within the jurisdiction of both DOL and DHHS. Based on our experience under Part C, we have reason to believe that some Medicare eligible individuals may receive integrated prescription drug benefits, that is, Part D benefits through an MA-PD or PDP and supplemental benefits through an ERISA-covered plan. For example, an ERISA-covered plan could pay all or part of the retiree's cost sharing amount (for example, deductibles and coinsurance amounts specified in subpart C of Part 423) for a covered Part D drug provided through an MA-PD or PDP. Clearly, if the enrollee had a dispute about Part D coverage, he or she could file an appeal under the provisions in subpart M of Part 423. If the enrollee's dispute involved only the amount of cost sharing paid by the ERISA plan, he or she would file an appeal in accordance with the

procedures of the ERISA covered plan. In some cases, however, the dispute might involve independent coverage decisions under both Part D and the ERISA plan; possibly necessitating parallel appeal procedures on the same case. In this regard, we solicited comments on whether, and to what extent, the application of parallel procedures in this context might be a problem for plans, employers, and eligible individuals. We also solicited suggestions for addressing problems, if any, resulting from the application of parallel procedures.

Comment: Generally, commenters supported utilizing only the Medicare appeal procedures for claims involving integrated ERISA and Part D benefits. One commenter stated that enrollees probably do not distinguish between ERISA and CMS approved benefits when they are integrated, and therefore, a single appeals process would be less confusing. Another commenter agreed, recommending that to the extent any benefits received by an individual are part of an underlying Part D plan, including benefits separately negotiated between the Part D sponsor or organization and an employer (or labor organization), those benefits should be governed by the Part D regulations rather than by two separate processes. One commenter suggested that, where possible, we make our requirements consistent with the existing DOL final rule that establishes standards for processing benefit claims under an ERISA-covered plan.

Three commenters agreed that adopting and applying a single, uniform appeals process for all benefits would be easier for the enrollee to understand. Other commenters pointed out that parallel appeal processes for enrollees with Medicare and ERISA benefits were costly, redundant, and burdensome to administer, with the potential for conflicting determinations. Only one commenter promoted Part D plans to process appeals under an employer-sponsored plan.

Response: After reviewing the public comment and conferring with representatives of DOL, we have concluded that changes (not only to our regulations but also to the DOL regulations) are needed to properly address this issue. Accordingly, we have added § 423.562(d), which is intended to give ERISA plans the option, pursuant to regulations of the Secretary of Labor, of electing the Part D process rather than the procedures under 29 CFR 2560.503–1 for claims involving supplemental benefits provided by contract with a Part D plan. In this regard, DOL has agreed to work with us to develop such regulations. We note that the language in § 423.562(d) is intended to demonstrate our commitment to make the entire Part D process available in this context. The provision in § 423.562(d) will not take effect in the absence of regulations by the Secretary of Labor.

10. Miscellaneous

Comment: Two commenters believed that there would be an additional administrative workload for physicians and their staff in light of the appeals and exceptions processes. They asked whether we would provide reimbursement for these activities, as they are not currently reflected on the physician fee schedule.

Response: We were mindful of any administrative burden that physicians might encounter as they help enrollees pursue prescription drugs through the exception and appeals processes. As a result, we eliminated the requirement that a physician's supporting statement, which the statute requires for tiering and non-formulary exceptions, be in writing. We also provide that the IRE may solicit the view of the prescribing physician orally or in writing. Thus, a prescribing physician need not in all circumstances provide a written account of the medical necessity or appropriateness of the prescription drug. We anticipate that physicians and other healthcare providers will assist enrollees with their Part D appeals to the same extent that they currently help beneficiaries with Part A, Part B, and Part C appeals. We do not pay physicians for their assistance with appeals under Part A, B, or C. Likewise, we do not expect to pay physicians under Part D for certifying and sharing their views on an enrollee's need for a medication.

Comment: Some commenters expressed concern about the lack of enrollee participation in the formulary development process. These commenters felt that we should either include enrollees in the formulary development process or alternatively, allow enrollees to challenge the formulary development process.

Response: The formulary development process is outside the scope of the grievance and appeals process. Additionally, section 1860D–4(h) of the Act does not provide a mechanism for Part D eligible individuals to challenge the formulary development process. Finally, the MMA intends for plans to compete in regards to benefit package and premium, which ensures that enrollees receive the best package for the lowest premium. The competitive model contemplated by the MMA would be undermined if enrollees are permitted to challenge the formulary development process.

We also believe that that permitting enrollees to challenge the formulary development process is not necessary. Enrollees are aware of a plan's formulary before they choose a plan. If an enrollee does not agree with a plan's formulary, he or she is free to enroll in a different plan. Once enrollees choose a plan, we have required plans to provide significant protections that will ensure that enrollees either receive the drug in dispute or are switched to an appropriate alternative medication if a plan changes its formulary during the plan year. In addition, enrollees have available to them an exceptions and appeals processes under which they may request coverage of non-formulary drugs. If enrollees continue to be unsatisfied with a plan, they are able to change plans at the end of the plan year.

Comment: Another commenter suggested that we establish a drug manufacturer appeals process to evaluate the discriminatory effect of a plan's negative formulary inclusion decision and to review negative formulary inclusion decisions.

Response: We are required by MMA to model the Part D grievance and appeals procedures after the Part C grievance and appeals procedures. Neither the MMA, nor the applicable provisions of the Act provide for the type of appeals process suggested by the commenter. As a result, we do not have the statutory authority to create an appeals process for drug manufacturers. In addition, allowing manufacturers to challenge how plans choose to place drugs on their formularies would also undermine the competitive model since it would negate any benefit that could be obtained by negotiating with plans.

Comment: We received many comments about the new notification requirements established under Part D, particularly those regarding how plans must communicate information about coverage determinations and appeals. Several commenters recommended that enrollees, physicians, and authorized representatives receive appeals notices giving the reason for denial, right to appeal, and information about accessing the appeals process. Another commenter suggested that denial notices be written at a 6th grade reading level, while another commenter suggested that plans provide notices in alternative formats (for example for the visually impaired and in different languages). Other commenters requested that detailed appeals notices, like those provided for coverage determinations,

be provided at the redetermination level.

In addition to the appeals notices, many commenters also made recommendations about other important information they felt plans ought to be required to provide to enrollees. First, many commenters requested that we require plans to provide enrollees with written information about the exceptions and grievance processes. Finally, we received one comment suggesting that we require plans to notify enrollees of their potential cost-sharing obligations if an appeal is successful.

Response: We agree with many of the suggestions offered by the commenters. Therefore, in § 423.568(g) of the final rule, we require plans to include specific types of information in denial notices, including the reason for denial, the right to appeal, and information about the appeals process. We also require denial notices to be written in a readable and understandable form. These notices will be developed or approved by us based on consumer-testing and marketing guidelines. We agree that notices must be made available in alternative formats, and expect that they will be made available in all the same formats MA notices are currently offered. We also agree that plans must include information about the potential cost-sharing obligation if an exception regarding tiering is successful. As previously mentioned, we specify that when an exception for a lower cost-sharing is approved, the enrollee is entitled to the amount of cost-sharing that applies for a preferred drug, but not for a generic drug. Finally, as mentioned earlier, plans must provide written notices to enrollees 60 days in advance when plans change their formularies. These advance notices must contain information about the exceptions process. We also require plans to provide written information about the grievance, exceptions, and appeals processes in enrollment materials.

We agree with the commenters who suggested that we require detailed notices at the redetermination level. Therefore, we added § 423.590(g) to require plans to provide detailed written notices to enrollees whenever plans make adverse redeterminations. The redetermination notices must: be written in approved language that is in a readable and understandable; state the specific reasons for the denial; inform the enrollee of his or her right to a reconsideration (including a description of the standard and expedited reconsideration processes, and the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeals process); and comply with any other notice requirements specified by us.

Finally, as previously mentioned, the final rule requires that notice of any determination be sent to enrollees or their appointed or authorized representative.

Comment: We received a few comments indicating that plans should be required to track and report denial rates for the purpose of identifying plans with high rates of inappropriate denials. One commenter suggested using the IRE to evaluate the data submitted by the plans.

Response: We appreciate the commenters' suggestions and share their desire to have plans provide information on the disposition of their decisions. We are in the process of developing an appeals system that will capture case-specific appeals data. Because appeals are generated as a result of coverage denials, we believe that the appeals information will enable us to identify potential inappropriate denials.

Comment: We received one comment suggesting that we create a special election period of 30 days during which enrollees who receive unfavorable coverage determinations or responses to exceptions requests may elect to enroll in a different plan.

Response: We strongly disagree with the commenters that enrollees should be granted a special election period (SEP) to enroll in a different plan when they receive unfavorable coverage determinations or responses to exceptions requests. Although section 1860D–1(b)(3)(C) and section 1851(e)(4) of the Act provides us with the authority to grant SEPs for exceptional circumstances, we decline to establish an SEP for enrollees who have received unfavorable determinations because we do not view this as an exceptional circumstance under the Part D program. The Congress anticipated that unfavorable determinations would be made, and therefore required us to establish an extensive appeals process. However, we do retain the authority to establish additional SEPs through operational guidance if necessary.

Comment: A few commenters suggested that we require plans to assign consumer advocates to enrollees who need assistance with the appeals process. One commenter suggested that we make available the Medicare Beneficiary Ombudsman to assist Part D enrollees, or provide the telephone number of an appropriate ombudsman in coverage determinations and appeal notices.

Response: The commenters raise a very valid point and we agree that Part D enrollees must be permitted to obtain assistance with the grievance and appeals processes, but we do not believe that we have the authority to use Trust Fund dollars to pay for consumer advocates on behalf beneficiaries accessing the appeals process.

The Medicare Ombudsman is designed to utilize most inquiry and appeals processes in place, while providing enhancements and efficiencies through monitored performance metrics, continuous quality improvement feedback, and standardized data management. Fiscal Intermediaries, Carriers, Regional Offices and SHIPs are all part of the whole Ombudsman system. These entities, in addition to others, are being trained in Part D enrollment, will handle most routine concerns, and have the ability to forward any serious concerns to the Office of the Ombudsman for resolution.

In addition to obtaining assistance from the Medicare Ombudsman, we permit Part D enrollees who are in need of assistance to select an individual or an entity to serve as their appointed representative. Additionally, we recognize individuals who are authorized under State or other applicable law to represent the enrollee. Both appointed and authorized representatives may act on behalf of Part D enrollees in obtaining coverage determinations or in dealing with any of the levels of the appeals process, subject to the rules described in part 422, subpart M.

Comment: One commenter suggested that we clarify the difference between a ''non-preferred'' drug and a ''non-formulary'' drug since there are different processes for requesting each and the differences may not be apparent to enrollees.

Response: We have required plans to establish different exceptions processes for handling exceptions requests involving tiered formulary drugs and exceptions requests involving non-formulary drugs. Under a tiered cost-sharing structure, drugs are assigned to different co-payment tiers based on cost-sharing, clinical considerations, or both. An enrollee's level of cost-sharing is based on the tier into which the prescribed drug falls. Typically, drugs fall into one of three tiers—generic drugs, preferred brand-name drugs, or non-preferred brand-name drugs. All of a plan's cost-sharing tiers make up its formulary, and an exceptions request that involves a drug covered under one of a plan's tiers must be processed in accordance with § 423.578(a). A non-

formulary drug is simply a drug that is not on a plan's formulary. An exceptions request that involves a non-formulary drug must be processed in accordance with § 423.578(b). Alternatively, if a plan organizes its drug benefits by providing coverage only for formulary drugs and requires enrollees to pay for prescriptions out-of-pocket if they are not on the formulary, the plan has established a closed formulary. A drug that is not on a plan's formulary under this type of cost-sharing arrangement is also considered a non-formulary drug and must be processed in accordance with § 423.578(b).

N. Medicare Contract Determinations and Appeals

1. Overview

Subpart N implements section 1860D–12(b)(3)(F) of the Act which directs the ''procedures for termination'' in section 1857(h) of the Act be incorporated into the requirements for PDP sponsors. As we stated in the proposed rule, to enhance the flow of the rule, we have separated the provisions of section 1857(h) of the Act into two portions and addressed the two portions in separate subparts—subpart K (Application Procedures and Contracts with PDP Sponsors) and this subpart of the preamble and regulations.

2. Provisions of the Final Rule

Subpart N establishes administrative appeals procedures available to an applicant or PDP sponsor in the event that we—

- Determine that an entity is not qualified to contract with us as a PDP sponsor under Part D of title XVIII of the Act.;
- Determine that an entity is not authorized to renew its contract as a PDP sponsor in accordance with § 423.507(b); or
- Make a determination to terminate the contract with a PDP sponsor in accordance with § 423.509.

We note that in subpart K, in response to comments, we have explained that the contract application (or renewal) process and the bid process under subpart F will run concurrently. In other words, we could review and pre-approve a contract even though the bid process was not yet complete. In this situation, the actual approval of the contract would be dependent upon us and the sponsor reaching agreement on the bid. We have revised our regulations at § 423.506(d) to reflect this change. As discussed in the subpart K preamble, we will make determinations that an entity is qualified to contract as a PDP sponsor or authorized to renew its PDP sponsor contract, and these determinations will be subject to the procedures of subpart N. However, although an entity may be determined qualified to enter into or renew its contract, the contract might not be signed if we are unable to reach agreement on the bid with the entity under subpart F. This failure to reach an agreement on the bid will not be subject to the procedures of subpart N. We revised our proposed regulation by adding § 423.502(c)(2) to subpart K in order to clarify this distinction. We refer readers to subpart K for a full discussion of the concurrent processes and an explanation of those policies.

In order to clarify the timeline for valid contracts, in the event of a redetermination, we have added new § 423.647(c) to subpart N. This provision specifies that in the case of a favorable redetermination, to include favorable decisions as the result of a hearing or Administrative review, such determination must be made by July 15 for the contract in question to be effective on January of the following year. We have made a corresponding change to the MA regulations by adding § 422.654(c).

We had proposed that a single set of procedures relating to contract determinations and appeals would apply to both MA and PDP sponsor contractors and that the requirements in § 423.641 through § 423.669 would mirror the requirements at § 422.641 through § 422.698 for the MA program. We refer readers to the preamble of the Medicare Prescription Drug Benefit proposed rule (69 FR 46723–4) for a fuller discussion of our proposals.

Comment: We received one comment on this subpart. The commenter—while acknowledging the provisions in this subpart duplicate those relating to MA contractors in part 422, subpart N—asked that we state in the final rule specifically that part 423, subpart N, applies only to PDP sponsors, not to MA plans.

Response: We do not believe it is necessary to amend the regulation text to make clear that the subpart N rules apply only to PDP sponsors, since the MA organization contracts will, by definition, be subject to the appeals procedures in part 422 and not part 423. We have, however, clarified that because fallback prescription drug plan contracts are entered into using a competitive process, except to the extent a fallback contract is terminated, fallback entities will not be subject to the procedures of subpart N. We thank the commenter for the suggestion and do acknowledge that the subpart N procedures of part 423 would apply only to PDP sponsors or PDP sponsor applicants.

With the clarifying language noted above, in this final rule we have adopted these proposed changes almost entirely without change.

O. Intermediate Sanctions (§ 423.750)

As required by 1860D–12(b)(3)(E) of the Act, Subpart O provides that the provisions governing ''intermediate sanctions'' for MA organizations, with two exceptions, will apply to contracts for Part D Plan sponsors. Specifically, we would not impose sanctions on a Part D Plan sponsor in the event it fails to enforce the limit on balance billing under a private fee for service plan, as required at § 422.216(a)(4), or fails to prohibit interference with practitioners' advice to enrollees, as required at § 422.206, since we do not believe these provisions are applicable in the context of the Part D drug benefit. We did not receive any comments regarding this proposal. We also proposed that the requirements in § 423.750 through § 423.760 would mirror the requirements at § 422.750 through § 422.760. However, we recently discovered that these requirements do not mirror each other and, further, that recent changes to the requirements at § 422.750 through § 422.760 require us to make conforming changes in this final rule. We learned that the regulation text, as proposed, did not reflect revisions made to the requirements at § 422.750 through § 422.760 in the August 22, 2003 final rule for MA plans entitled, ''Modifications to Medicare Rules'' (68 FR 50840). However, several errors were made in modifying the regulation text in the August 2003 final rule. Consequently, an interim final rule with a comment period was published on December 30, 2004 to correct this technical error. We are making changes to the provisions in Part 423 to reflect the substance of changes to the regulations at § 422.750 through § 422.760 as corrected by the interim final rule published on December 30, 2004. Additionally, we proposed, and asked, for comments on our goal to have a consistent policy on how sanctions are imposed. The MMA requires at least two qualified plans, at least one of which is a Part D Plan per region. If we were to freeze the enrollment or marketing of a Part D Plan sponsor, that is one of only two plans in a region, beneficiaries would no longer have the breadth of choice the MMA intended. If we are contemplating sanctioning a plan that is one of only two Part D Plan sponsors in a region, we may have to consider using other remedies including

civil monetary penalties (CMPs) to maintain an adequate level of choice for beneficiaries. However, we would like to have consistent policies and procedures for Part D Plan sponsors and across all regions with regard to sanctions. We received two comments asking us how we would expect to preserve beneficiary choice if the above instance should occur. In this final rule, we decided to adopt the proposed requirements as final and rely on the number and kinds of sanctions available to us under subpart O and deal with offending entities on a case-by-case basis.

While we are adopting the substance of the proposed rule as final, in reviewing and responding to comments we discovered a need for some technical revisions in the interest of clarity. Consequently, we are making the following changes in this final rule:

- At § 423.752 (Basis for imposing sanctions.), paragraph (a), we clarified our authority to impose more than one sanction at a time.
- At § 423.752, paragraph (a)(6), we added the word ''excluded'' for clarification.
- Under § 423.752, paragraph (b), we are deleting references to § 423.756(c)(1) and (c)(3) because they are listed under procedures for imposing sanctions, and replacing them with § 423.750(a)(2) and (a)(4) which fall under ''Kinds of Sanctions''. This clarifies in this final rule that we are cross-referencing the basis for sanctions with the kind of sanctions that could result and not the procedure for imposing sanctions.
- At § 423.756(f)(2) a reference to ''part 1005 of this chapter'' was incorrect. The reference should be to ''part 1003 of this chapter'' since part 1003 includes the OIG procedures for imposing sanctions, whereas part 1005 is appeal procedures.
- At § 423.756(f)(3), we have deleted a reference to ''part 1005 of this chapter,'' because this subparagraph discusses CMS' authority to impose CMPs, as opposed to the OIG's authority.
- At § 423.758, we revised the language to better clarify the basis for CMPs imposed by us.

1. Kinds of Sanctions (§ 423.750)

Comment: Several commenters requested that the final regulation clarify how the imposition of the sanction of suspension of enrollment of Medicare beneficiaries (§ 423.750(a)(1)) would impact the statutory requirement that a consumer have a choice of at least two Part D Plans. One commenter suggested that, in the event CMS imposes an enrollment freeze on a Part D Plan sponsor which results in there being only Part D Plan in a given region, that we add a fallback plan to the region.

Response: While freezing marketing or enrollments has generally been our first and most frequently used sanction authority, other kinds of sanctions are available to us under Subpart O. These include suspension of our payments to the Part D Plan sponsor and CMPs (or a combination of both). The MMA intends for beneficiary choice to be preserved and directs us to make every reasonable effort to preserve that choice. We have the option of imposing these other sanctions if the suspension of enrollment of one of only two Part D Plans in the same region would eliminate beneficiary choice.

Comment: Several commenters suggested that CMS establish a range of civil money penalties that vary according to the nature and extent of the Part D Plan sponsor's noncompliance with legal requirements.

Response: Section 423.750 allows us to impose CMPs from $10,000 to $100,000 depending on the offense.

2. Basis for Imposing Sanctions (§ 423.752)

Section 423.752(a) and (b) of this final rule lists the seven violations for which sanctions may be imposed on a Part D Plan sponsor organization. These violations are the same as those that warrant the imposition of sanctions for MA organizations, with the exception of two deletions we are proposing below. Specifically, sanctions are imposed if the Part D Plan sponsor engages in any of the following:

- Fails substantially to provide, to a Part D Plan enrollee, medically necessary services that the organization is required to provide (under law or under the contract) to a Part D Plan enrollee, and that failure adversely affects (or is substantially likely to adversely affect) the enrollee.
- Imposes, on Part D Plan enrollees, premiums in excess of the monthly basic and supplemental beneficiary premiums permitted under section 1860D of the Act and subpart F of this final rule.
- Acts to expel or refuses to reenroll a beneficiary in violation of the provisions of subpart O of this final rule.
- Engages in any practice that may reasonably be expected to have the effect of denying or discouraging enrollment of individuals whose medical condition or history indicates a need for substantial future medical services (that is, health screening or ''cherry picking'').
- Misrepresents or falsifies information furnished to us, any other entity, or individual under the Part D drug benefit program.
- Employs or contracts with an individual or entity excluded from participation in the Medicare program as specified under sections 1128 or 1128A of the Act (or with an entity that employs or contracts with an excluded individual or entity) for the provision of certain services.

Additionally, as an alternative to the sanctions listed above, we would be able to decline to authorize renewal of the organization's contract (or may elect to terminate the contract entirely in accordance with § 423.509). In addition, § 423.509(a) will provide that a Part D Plan sponsor organization may be sanctioned if it fails to carry out the terms of its contract as specified under this section.

We will not impose sanctions on a Part D Plan sponsor in the event it fails to enforce the limit on balance billing under a private-fee-for-service plan as required at § 422.216(a)(4), or fails to prohibit interference with practitioners' advice to enrollees, as required at § 422.206, since we do not believe these provisions are applicable in the context of the Part D drug benefit.

We received three comments asking us to detail our methodology for imposing sanctions. As we have noted below, we believe that since the law grants us the discretion to choose from multiple options on a case-by-case basis we should retain this approach. We received other comments asking that we explain how we determine if a Part D Plan sponsor deserves to be sanctioned. Additionally, one comment suggested that we amend § 423.752(a) to clarify that CMS may impose more than one sanction at a time. In this final rule, we clarify that one or more sanctions may be imposed by us when a sanctionable offense as described under § 423.752 has been discovered.

Comment: Several commenters asked that CMS provide a methodology as to what sanction, or sanctions, will be imposed on a Part D Plan sponsor in response to a specific set of circumstance(s). Additionally, the commenters note that it is their understanding that all of the sanctions are permissive and they believe this increases the likelihood that sanctions will not be imposed.

Response: We have intentionally retained discretion as to what sanctions will be imposed on a Part D Plan. The rule lists a variety of sanctions that may be imposed so as to permit us to tailor the sanction to the particular offense. As a condition of contracting with Medicare, we require that a Part D Plan sponsor agree to be subject to these

sanctions. This approach has been successful in the Medicare managed care program, and we believe it will also be successful in sanction actions against Part D Plan sponsors. We should not be confined to only one sanction option for a certain violation, since the law grants us the discretion to choose from multiple options on a case-by-case basis. We believe that this approach will improve the oversight of Part D Plan sponsors and the protection of Medicare beneficiaries.

Comment: Three commenters state that it is not clear from the proposed rule how CMS would determine that a Part D Plan sponsor is not in compliance with legal requirements. The commenters also suggest that CMS publicize, through press releases in the **Federal Register**, an annual report, or other statements, citations against Part D Plan sponsors and any sanctions imposed against Part D Plan sponsors.

Response: We will determine compliance by a variety of means. We will be monitoring field reports, performing random periodic audits and conducting enrollee surveys. In addition, we perform random audits annually in order to ensure that those entities contracting with us are in compliance. The corrective action plans of contractors are subject to public disclosure under the Freedom of Information Act. Therefore, we do not believe it is necessary to publicly disclose the compliance status of each contracted organization. Some organizations that have received sanctions have later become solid examples of compliant contract administration. We believe that a public listing of sanctioned Part D Plans may not portray the current level of compliance by contracted organizations and could unfairly impede business opportunities for fully compliant contractors that were sanctioned in prior years. The purpose of a sanction is to protect beneficiaries and public funds by improving the compliance of contracted organizations. When an organization resumes compliant behavior, the sanction is ended. Sanction authority is not designed to be punitive.

Comment: Two commenters recommend that we revise one of the bases for sanctions under § 423.752(a). Section 423.752(a)(1) currently states that sanctions may be imposed if a Part D Plan sponsor ''[f]ails to provide required medically necessary services with an adverse effect on the enrollee.'' (emphasis added) The commenters recommend that we remove the phrase ''adverse effect'' from this provision.

Response: The specific wording of this provision is based on the language in the statute. We have not included the phrase ''adverse effect'' in an attempt to impose an obstacle that prevents the imposition of a sanction on a Part D Plan sponsor that fails to provide a medically necessary service to an enrollee.

Comment: One commenter suggested we amend § 423.752(a) to clarify that CMS may impose more than one sanction at a time, as we stated in the preamble to the proposed rule.

Response: We do have the authority to impose more than one sanction at a time, but we have taken the commenter's suggestion and made this authority explicit under § 423.752(a).

3. Procedures for Imposing Sanctions (§ 423.756)

Section 423.756 details our procedures for imposing sanctions on Part D Plan sponsor organizations. This process would mirror that used for the MA program. A brief summary of the process is as follows:

- We must send a timely written notification of the sanction to the Part D Plan sponsor, outlining the nature and basis of the proposed sanction, and copy OIG.
- We must provide the Part D Plan sponsor with 15 days, or if an extension is granted, 30 days to respond. If requested, an uninvolved CMS official will conduct an informal reconsideration of the determination with a written decision.
- Non-monetary sanctions would be effective 15 days from the organization's receipt of a final notice of sanction and remain in effect until we determine that the violation is corrected. CMS or the OIG, depending on the basis for the sanction, may impose civil money penalties.

Comment: One commenter suggested that § 423.756(e) be expanded to allow CMS to impose civil money penalties when CMS declines to renew or terminate a Part D Plan contract.

Response: We have authority to impose CMPs under the circumstances described in § 423.758. If we make a determination under § 423.509(a) (except a determination under § 423.509(a)(4)), we may impose CMPs.

P. Premiums and Cost-Sharing Subsidies for Low-Income Individuals

Section 1860D–14 of the Act requires us to subsidize the monthly beneficiary premium and cost-sharing amounts incurred under this Part by Part D eligible individuals with lower income and resources. The regulations in this subpart and regulations published by the Social Security Administration (SSA) adding a subpart D to a new part 418 of title 20 of the Code of Federal Regulations, implement section 1860D–14 of the Act.

The statute divides subsidy eligible individuals into two different groups based on income and resources: (1) full subsidy eligible individuals; and (2) other low-income subsidy eligible individuals. The different groups are entitled to different amounts of premium assistance and reductions in cost-sharing. Full-benefit subsidy eligible individuals are entitled to further reductions if they are eligible for full benefits under both Medicare/Medicaid and have income below a certain income threshold or if they are institutionalized in medical institutions or nursing facilities for which Medicaid will make payment.

In the proposed regulation, we defined the eligibility criteria and the amounts of subsidy assistance provided. We received several hundred comments on subpart P. Below we summarize our proposed rule and respond to comments. (For a detailed discussion of our proposals, please refer to the August 2004 proposed rule.)

General

We received general comments related to delayed implementation of the Part D program for full-benefit dual eligible individuals (as defined under 423.772) as well as the transition of shifting coverage for Part D drugs from the Medicaid program to the Medicare program for full-benefit dual eligible individuals, as discussed below.

Comment: Many commenters suggested that we delay implementation of the Part D program for full-benefit dual eligible individuals by at least five or six months, and some recommended a year's delay, although the commenters recognized that such a delay would require a legislative change. The commenters also expressed concern about the feasibility of identifying, educating and enrolling the population of full-benefit dual eligible individuals in time for a smooth transition. Some commenters pointed out the need to ensure adequate time for physicians and patients to navigate administrative barriers and change medications to comply with formularies. Others expressed concern that full-benefit dual eligible individuals tend to have complex medical or mental health problems, thus reinforcing the need for an appropriate transition from coverage for Part D drugs under Medicaid to Medicare.

Response: As mentioned by the commenters themselves, such a delay requires a legislative change. Absent

such a change we cannot delay implementation of the Part D program for dual eligibles.

Comment: Many commenters also expressed concern about the transition of coverage for Part D drugs from Medicaid to Medicare for the population of full-benefit dual eligible individuals. Commenters were particularly concerned about identifying, educating, and enrolling these individuals in Part D plans in a timely and efficient manner and desire to avoid noncoverage on plan formularies of drugs currently used for this vulnerable population, particularly those with AIDS or mental illness.

Response: We recognize the special needs of the dual eligible population and those with serious medical or mental health conditions. We have addressed in Subpart B of this rule the efforts to be made to avoid any interruption in coverage for this population by auto-enrolling full-benefit dual eligible individuals in Part D plans no later than January 1, 2006. Full-benefit dual eligible individuals and those eligible for Medicare Savings Programs as QMBs, SLMBs, and QIs are automatically deemed eligible for the low-income subsidy. We are working with State Medicaid Directors to develop strategies to educate dual eligible beneficiaries about the new Medicare prescription drug benefit, how this new program impacts their coverage under Medicaid, and the process to enroll in prescription drug plans.

We note that Subpart C addresses the steps that will be taken as part of the formulary review process to provide safeguards that ensure a drug coverage transition process for new enrollees taking a drug not covered under a plan. We expect that our review of Part D plan formularies and transition plans as outlined broadly under the requirements in subpart C, and our review of the plan appeals process as described in subpart G, will ensure that all Medicare beneficiaries, including dual eligibles, have prompt access to the prescriptions they need.

1. Definitions (§ 423.772)

In the proposed rule we discussed definitions relevant to the low-income subsidy provisions of this subpart. These definitions were explained in detail in the Preamble discussion related to § 423.773 of the proposed rule. Comments related to these definitions are addressed below.

2. Eligibility for the Low-Income Subsidy (§ 423.773)

The proposed rule provided that full subsidy eligible individuals are eligible for the premium assistance and cost-sharing subsidies set forth in § 423.780 and § 423.782 of the proposed rule. We have added a definition of full subsidy at 423.772 of the final rule to mean the premium assistance and cost-sharing subsidies for which full subsidy eligible individuals are eligible for under § 423.780(a) and § 423.782(a) of the final rule.

In order to qualify as a full subsidy eligible individual, an individual must live in one of the fifty States or the District of Columbia and have countable income below 135 percent of the Federal poverty line for the individual's family size. For purposes of this section, we said in the proposed rule that ''Federal poverty line'' (FPL) has the meaning given that term in section 673(2) of the Community Services Block Grant Act (42 USC 9902(2)), including any revision required by that section.

In addition, the proposed rule provided that to be considered a full subsidy eligible individual, an individual must have resources that do not exceed three times the resource limit under section 1613 of the Act for applicants for Supplemental Security Income (SSI) under title XVI, which in 2006 is $6,000 if single, or $9,000 if married. Thereafter, this resource limit would be increased annually by the percentage increase in the Consumer Price Index (all items, U.S. city average) as of September for the year before, rounded to the nearest multiple of $10.

Individuals not eligible as full subsidy eligible individuals may be eligible as other low-income subsidy eligible individuals if they live in one of the fifty States or the District of Columbia and have income below 150 percent of the FPL for their family size, and have resources in 2006 that do not exceed $10,000 if single, or $20,000 if married. Beginning in 2007 and for each subsequent year, the resource limit would be increased annually by the percentage increase in the Consumer Price Index (all items, U.S. city average) as of September for the year before, rounded to the nearest multiple of $10. The proposed rule provided that other low-income subsidy eligible individuals are entitled to the premium assistance and cost-sharing subsidies set forth in § 423.780 and § 423.782 of the proposed rule.

Low-income Part D eligible individuals who reside in the territories are not eligible to receive premium and cost-sharing subsidies under this subpart. Subpart S of the proposed rule addressed the provision of covered Part D drugs to low-income individuals residing in the territories.

For making income and resource determinations for the low-income subsidy for Part D, the statute refers to certain sections of the SSI statute. For example, the MMA refers to income being determined in the same manner as for Qualified Medicare Beneficiaries (QMBs) under the Medicaid program, without use of the more liberal methodologies that States are permitted to use. The QMB provisions reference the SSI statutory provisions(specifically, section 1612 of the Act, which applies to determining income under the SSI program). Our proposed definition of income was consistent with the MMA in that it references SSI statutory provisions.

The MMA provides that we will compare the individual's income to the appropriate FPL applicable to ''the family of the size involved.'' As there is no reference in the MMA statute to using existing definitions of family size, we proposed to define family size to include the applicant, his or her spouse who lives in the same residence, and the number of individuals related to the applicant who live in the same residence and who depend on the applicant or the applicant's spouse for at least one-half of their financial support.

We said in the proposed rule that we considered limiting family size to 1 or 2 individuals to more closely resemble the SSI statutory provisions, where family size is not actually defined but where benefits are paid on the basis of an eligible individual or eligible couple. This is the definition we use in determining eligibility for Transitional Assistance under the Medicare-approved prescription drug card program (See 42 CFR 402.802). The decision to limit family size under the Medicare-approved prescription drug card program was based on the short duration of that program (18 months), the limited benefit ($600 a year), and the fact that we would have to rely entirely on a computer and systems-based process for determining Transitional Assistance eligibility and verifying income and other information from applicants. However, we did not believe it was the intent of the Congress to similarly limit the definition for purposes of determining eligibility for subsidies under the Part D program. Unlike the provisions authorizing the Medicare-approved drug discount card program, there are no provisions for the low-income subsidy program that give the Secretary specific authority to define family size. Instead, we believed that the term ''family of the size involved'' implies a definition that is greater than an individual or couple and that includes other dependent relatives residing in the applicant's household. In

addition, in order for the term ''family size'' to have meaning in the context of subsidy determinations, the notion of dependency needs to take into account the impact of a dependent on the relative need of the applicant or the applicant's spouse in attaining the subsidy. Accordingly, we specified that dependents included in the calculation of family size are only those relatives residing in the residence who are financially dependent on the applicant or the applicant's spouse for one-half of their support.

In determining the income to be compared to the FPL for the size of the family involved, we included income of the Medicare beneficiary and spouse, if any. Thus, if a married individual applies, both the income of the applicant and his or her spouse who lives in the same residence, regardless of whether the spouse is also an applicant, is counted and measured against the appropriate standard for the low-income subsidy.

In our view, this best comported with the statutory reference to determining income in the manner described in section 1905(p)(1)(B) of the Act (for QMBs). In making a standard QMB income determination, States would consider the income of one spouse as available to the other spouse. Moreover, since both spouses would be considered in the family size determination, it would be illogical to count a spouse's presence while not including that spouse's income. Other members who meet the one-half support test would be counted in the family size calculation, but income of these dependents will be ignored in the eligibility determination. The one-half support test ensures that a family member with sizable income is not erroneously counted as a dependent while that person's income is ignored.

Section 1860D–14(a)(3)(D) of the Act provides that resources will be determined according to section 1613 of the Act. The resource standard depends upon whether the applicant is a single individual or a member of a married couple and whether the resources will be measured against the basic or alternative resources standards. See sections 1860D–14(a)(3)(D) and (E) of the Act and H.R. Conference Report No. 108–391 at 470.) However, section 1613 of the Act does not define resources, but rather only defines what are not resources.

Sections 1860D–14(a)(3)(E)(ii) and (iii) of the Act also provides for the development of a simplified application in which applicants attest to their level of resources and submit only minimal documentation. The implication of this provision is that the Congress envisioned a simple process. In order to keep the process simple and minimize administrative cost, we intended to only consider liquid resources (that is, those that could be converted to cash within twenty days) and real estate that is not an applicant's primary residence as resources that are available to the applicant to pay for the Part D premiums, deductibles and copayments. Thus, we would not consider other non-liquid resources (for example, a second car) to be available to the applicant for this purpose.

We did not believe this policy would have a significant impact on program costs. We believed any program costs that would result from counting only liquid resources and countable real estate would be offset by the administrative savings resulting from a more simplified program. As we indicated further in this section, we are working with SSA on a quality assurance strategy that would strike an appropriate balance between administrative costs and program goals and objectives.

Under Medicaid, the term ''dual eligibles'' generally refers to low-income Medicare beneficiaries who qualify for some level of medical assistance. Those entitled to full benefits under Medicaid generally have most of their health care expenses, including prescription drugs, paid for by a combination of Medicare and Medicaid. However, Federal law also specifies several groups of dual eligibles who, while not entitled to full Medicaid benefits, are entitled to more limited medical assistance, specifically payment of Medicare Part A or Part B premiums or cost sharing, such as payment of Medicare deductibles and coinsurance. These groups are certain qualified Medicare beneficiaries (QMBs), specified low-income Medicare beneficiaries (SLMBs), qualified disabled and working individuals (QDWIs), and certain qualifying individuals (QIs).

For purposes of the low-income subsidy under Part D, in the proposed rule we proposed to define the term ''full-benefit dual eligible individual'' as an individual who for any month has coverage under a PDP or MA-PD plan and is determined eligible by the State for medical assistance for full benefits under title XIX for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under Section 1115 of the Act. We proposed that comprehensive benefits referred to in this section do not include those benefits received under Pharmacy Plus demonstrations authorized under section 1115 of the Act. For individuals who become medically needy by ''spending down'' excess income; that is, incurring medical expenses which are subtracted from the individual's income, the individual is not eligible as medically needy until he or she satisfies their spenddown obligation. This requirement was reflected in the proposed regulations at § 423.772.

Section 1860D–14(a)(3)(B)(v)(II) of the Act authorizes the Secretary to treat QMBs, SLMBs, and QIs who are not full- benefit dual eligible individuals as full subsidy eligible individuals. This authority does not apply to QDWIs. As proposed at § 423.773(c), the Secretary elects to exercise this authority and treat these QMBs, SLMBs, and QIs as being eligible for the full subsidy.

This decision was based on the fact that nearly all QMBs, SLMBs, and QIs, by definition, would likely meet the requirements to be considered a full subsidy eligible individual. Generally, QMB, SLMB, and QI individuals have income below 135 percent of the FPL applicable to their family size and resources that do not exceed twice the SSI limit. The exception would be in the few States that have more liberalized income and asset rules for these groups under section 1902(r)(2) of the Act. We did not believe that treating these groups as full subsidy eligible individuals will have a large cost impact. Further, we believed that it would ease the administrative burden of having to educate these individuals on the need to apply for the subsidy.

Finally, the statute gives the Secretary the option to permit a State to make subsidy eligibility determinations by using the methodology it uses under section 1905(p) of the Act if the Secretary determines that this would not result in any significant difference in the number of individuals who are made eligible for the subsidy. This would permit a State to use the same resource methodologies that it uses to determine Medicaid eligibility for QMBs, SLMBs, and QIs if the Secretary determines that the use of those methodologies would not result in any significant differences in the number of individuals who are made eligible for a subsidy. This includes the less restrictive methodologies the State uses under section 1902(r)(2) of the Act to determine eligibility for QMBs, SLMBs, and QIs. In the proposed rule, we chose not to exercise this option.

This means that when making eligibility determinations for other low-income subsidy eligibles, all States would use the same resource methodologies across the country. The rationale for not electing this authority was twofold. First, uniformity in the

application process is a desired goal and having alternative resource methodologies that would vary among States would detract from that goal. Second, based on the administrative burden and complexity that would be involved in administering this alternative process, we saw very little benefit in terms of the number of individuals who would be determined subsidy eligible.

Comment: A number of commenters supported our definition of family size. Some of those supporting our definition further urged that the regulations specify that applicants will be able to self-attest as to the number of family members they claim without the need for further documentation.

Response: As explained elsewhere in the preamble in our discussion of the use of a simplified low-income subsidy application, we anticipate that such things as income and resources will be verified to the extent possible using automated data matches. This reduces both the administrative cost of making eligibility determinations, and the burden on applicants to provide documentation as to their income and resources. Similarly, we anticipate that in most cases an applicant's declaration of the size of his or her family will be accepted without the need for further documentation from the applicant.

Comment: While a number of commenters supported our definition of family size, a number of other commenters requested clarification or objected to the definition. All of these commenters argued that our definition did not follow SSI statutory rules, and therefore would make it more difficult and complex to determine eligibility for a low-income subsidy. Many of these commenters argued that since low-income subsidy eligibility was supposed to be based on SSI statutory income and resource rules, the rules under which SSI pays benefits to individuals or couples should also be followed.

Response: We understand the concerns expressed by these commenters. As explained previously, and in the preamble to the proposed regulations, we did consider using the SSI statutory framework of individual or couple. However, as we also explained, we do not believe that the Congress intended the definition of family size to be so restrictive for low-income subsidy eligibility purposes. Moreover, the SSI statute does not include a definition of family size. Therefore, we proposed to define family size to include the applicant, his or her spouse who lives in the same residence, and any individuals related to the applicant who live in the same residence and depend on the applicant or the applicant's spouse for at least one-half of their financial support.

While we recognize that our definition may result in some additional complexity in making eligibility determinations, we believe the definition we have adopted is necessary to take into account the impact that supporting dependent family members may have on the need of an applicant for a low-income subsidy.

Comment: A few commenters suggested that our definition of family size should be revised to automatically include any children under the age of 21 as members of the family, regardless of other considerations such as whether the applicant was providing one-half of the child's support. This commenter also suggested that a pregnant woman should be counted as two family members.

Another commenter stated that the one-half child support test is different than what is used for Medicaid and that there will be additional burden placed on States to do this test.

Response: We do not agree with either of this commenter's suggestions. We included relatives who are dependent on the applicant for one-half of their support in the definition in recognition of the impact supporting such relatives can have on the applicant's financial situation. For this reason, we do not believe it is appropriate to include all children in the applicant's household under age 21 even if they are not dependent on the applicant, or to count a pregnant woman as two family members.

Comment: One commenter said that the definition of family size is vague as to whether relatives of the spouse of an applicant can count toward family size, and suggested that the definition be revised to make that explicit.

Response: We do not believe the definition is as vague as the commenter suggests. Under our proposed definition, family size includes the number of individuals living in the household who are related to the applicant or applicants, and who are dependent on the applicant or the applicant's spouse for at least one-half of their support. The definition places no restrictions on what is meant by ''related'' to the applicant other than that a recognized family relationship exists, and further provides that dependence on the applicant's spouse will allow a person to be counted as a family member. Therefore, we do not believe the definition needs revision as suggested by the commenter.

Comment: We received two comments on our definition of ''full-benefit dual eligible individuals'' in § 423.772. One commenter noted that the proposed regulation defines the term (in part) as someone who has coverage for the month under a prescription drug plan under Part D of title XVIII, or under an MA-PD plan under Part C of title XVIII. The commenter believes this language creates a technical problem with the auto-enrollment provisions set forth in § 423.34(d) of the proposed regulations. That section provides that full-benefit dual eligible individuals who fail to enroll in a PDP or MA-PD during their initial enrollment period will be automatically enrolled into a plan.

The commenter believes these two sections are inherently contradictory because one requires a person to be enrolled in a PDP or MA-PD to be considered a full-benefit dual eligible individual, while the other provides for automatically enrolling someone who is considered to be a full-benefit dual eligible individual in a PDP or MA-PD, even though under the first section the person could not be a full-benefit dual eligible individual because he or she was not already enrolled in a PDP or MA-PD. The commenter suggests revising the language in § 423.772 to define (in part) a full-benefit dual eligible individual as someone who has coverage, or who will have coverage as a result of automatic enrollment for the month under a prescription drug plan.

Response: We understand the commenter's concern. The definition of a full-benefit dual eligible individual in § 423.772 reflects the statutory definition of that term found at section 1935(c)(6) of the Act, which defines a full-benefit dual eligible individual to include individuals who have coverage under a Part D plan. We do not believe we have the authority to change our regulatory definition of ''full-benefit dual eligible individual'' for purposes of this subpart. However, we agree with the commenter that this definition of the term ''full-benefit dual eligible individual'' is problematic for application of the auto-enrollment rules under § 423.34. As discussed more fully in subpart B, section 1860D–1(b)(1)(C) of the Act requires CMS to auto-enroll into PDPs an individual ''who is a full-benefit dual eligible individual'' who ''has failed to enroll in a prescription drug plan or an MA-PD plan.'' Although this statutory provision specifically references the statutory definition of ''full-benefit dual eligible individual'' under section 1935(c)(6) of the Act, if interpreted literally, section 1860D–1(b)(1)(C) of the Act would require CMS to auto-enroll into Part D plans only individuals receiving full-benefits under Medicaid who are already enrolled in

Part D but who have ''failed to enroll in'' a Part D plan, a patently absurd result. We have an obligation to interpret the statute so as to avoid an absurd result and give full effect to the Congress' intended policy. We think it is clear that the Congress required CMS to establish an auto-enrollment process to ensure that individuals who currently receive coverage for Part D drugs under Medicaid continue to receive coverage for such drugs through enrollment in Part D beginning in 2006. Therefore, for purposes of implementing the auto-enrollment process of full-benefit dual eligible individuals, at § 423.34 of subpart B the final rule we define ''full-benefit dual eligible individuals'' as Part D eligible individuals who meet the conditions under section 1935(c)(6)(A)(ii) of the Act but are not enrolled in a Part D plan.

Comment: One commenter expressed concern about what the commenter saw as a possible inequity in the definition of a full-benefit dual eligible individual. Under that definition in our proposed rule, anyone with coverage under a PDP or MA-PD plan who is determined by a State as eligible for full Medicaid benefits under any eligibility group is a full-benefit dual eligible individual. However, the commenter noted that some eligibility groups in some States are not subject to an asset test. The commenter believes this can lead to situations where some persons receiving the full subsidy under Part D would be subject to an asset test but others would not, depending on whether they were in an eligibility group to which an asset test did not apply in a particular State.

Response: While we understand the point the commenter is making, we must note that the definition of a full-benefit dual eligible individual as someone who has been determined eligible for Medicaid under any eligibility group covered under a State's plan is a statutory definition. Accordingly, we have no authority to change that definition in the Part D low-income subsidy regulations.

Comment: One commenter argued that the definition of full-benefit dual eligible individual should be interpreted to include persons participating in that State's optional work incentives buy-in eligibility group, as well as persons eligible because of the State's use of more liberal income disregards under section 1902(r)(2) of the Act. The commenter suggested that if this was not our intention, the regulatory definition should be clarified. Another commenter suggested we clarify the definition to include other protected classes of Medicaid-covered individuals, specifically, individuals covered under Medicaid pursuant to 1915(c) and 1619(b) of the Social Security Act.

Response: As we believe the definition makes clear, a full-benefit dual eligible individual is a person who is eligible for full Medicaid benefits under any group covered under a State's plan. Therefore, we do not believe the definition needs further clarification.

Comment: One commenter noted that full-benefit dual eligible individuals include all persons eligible for full Medicaid benefits under a group covered under a State's plan even if they have income in excess of 135 percent of the Federal poverty line applicable to the individual's family size. The commenter asked if any analysis has been done to determine whether tying eligibility for a low-income subsidy to eligibility for Medicaid will lead to an increased use of qualifying income (also known as Miller) trusts in States where the trusts are recognized under Medicaid.

Response: We are not aware of any analysis that has been done on that subject. Further, even if analysis were to indicate the possibility of increased use of the trusts under these circumstances, the statutory definition of a full-benefit dual eligible individual is clear, and therefore is not subject to change under our regulations to address the possibility.

Comment: We received one comment on the definition of ''full subsidy eligible individuals'' in § 423.772. That section provides that a full subsidy eligible individual is an individual who meets the eligibility requirements under § 423.773(b). The commenter suggested that the latter reference should be changed to § 423.773(b) and (c) to avoid ambiguity.

Response: We do not agree with the commenter's suggestion. Section 423.773(b), as cited in section 423.772, defines a ''full subsidy eligible'' individual, while § 423.773(c), which is the reference the commenter suggests adding, provides that certain individuals must be treated as if they did meet the definition of full subsidy eligible individuals as defined in § 423.773(b). Section 423.773(c) does not change the definition of a full subsidy eligible individual. We believe that adding the reference the commenter suggests would create ambiguity where none exists now.

Comment: One commenter indicated that for any subset of individuals for whom States provide pharmacy-only benefits under a section 1115 demonstration, that subset be excluded from the definition of full-benefit dual eligible, since these programs generally provide the same benefits as offered under Pharmacy Plus Programs.

Response: We agree with this commenter and have further clarified the definition of full-benefit dual eligible individual at § 423.772 to exclude those individuals enrolled in 1115 demonstration programs that provide pharmacy-only benefits to a portion of its demonstration population.

Comment: We received some comments on our proposed definition of income. One comment, which was submitted by several different commenters, was that the definition of income should make it clear that income not legally owned by the applicant, even if his or her name is on the check, should not be counted. Another comment, submitted by two commenters, was that the definition should exclude the same income currently excluded under the Medicaid program when determining Medicaid eligibility for American Indians and Alaska Natives. And finally, one commenter asked if income of another family member from SSI and TANF will be included.

Response: For these comments it is important to note that under the Part D statute, income eligibility for a low-income subsidy is determined using the statutory provisions of the Supplemental Security Income (SSI) program. The statute does not give us the authority to change the way those provisions apply to subsidy eligibility determinations for the low-income subsidy under this subpart. Under the SSI statutory provisions, some income may be counted even if the person does not actually receive it, just as some income a person does receive may not be counted. Similarly, SSI excludes certain types of income received by American Indians and Alaska Natives. The Social Security Administration (SSA), which operates the SSI program, is publishing its own regulations which will explain how the SSI statutory provisions will apply to eligibility determinations for the low-income subsidy. We expect that SSA's regulations will explain in detail how income will be counted when determining eligibility for a low-income subsidy.

Comment: Another commenter noted that under § 423.772, income is defined differently from Medicaid in two ways; the regulatory definition does not include the use of more liberal income methodologies under the authority of section 1902(r)(2) of the Act, and eligibility is based on a family size that can be greater than the one or two that Medicaid normally uses when determining eligibility for the aged and

disabled. The commenter further noted that this means that if States are making eligibility determinations for low-income subsidies, they will have to use different rules than they use under their Medicaid programs.

Response: While the commenter is correct on both points, we note that section 1860D–14 (a)(3)(C) of the Act specifically precludes the use of income disregards authorized under section 1902(r)(2) of the Act in determining low-income subsidy eligibility. With regard to the commenter's point about family size, as we explain elsewhere, we believe the definition of family size we have adopted most closely reflects the intent of the Congress with regard to low-income subsidy eligibility. Therefore, we do not believe we can or should revise the proposed regulations to accommodate the commenter's arguments.

Comment: We received a number of comments about the definition of an institutionalized individual as it applies to cost-sharing subsidies under § 423.782 of the proposed regulation. That section provides that institutionalized individuals have no cost-sharing for covered Part D drugs under their Part D plans. The term ''institutionalized individual'' is defined in § 423.772 of the proposed rule as a full-benefit dual eligible individual who is an inpatient in a medical institution or nursing facility for which payment is made under Medicaid throughout a month, as defined in section 1902(q)(1)(B) of the Act.

Almost all of the commenters urged that persons receiving home and community-based waiver services under the waiver authority under section 1915(c) of the Act be treated as institutionalized individuals for purposes of § 423.782 so that they would not be subject to cost-sharing. Several commenters also suggested that institutions for the mentally retarded (ICFs/MR) be specifically included in the regulations as meeting the definition of a medical institution for purposes of this section. At least one commenter believed that persons in other living arrangements such as assisted living facilities, residential care homes, and boarding homes should be treated as institutionalized individuals under § 423.782. One commenter urged that persons receiving PACE services also be treated as institutionalized individuals for purposes of this Subpart.

The commenters' rationale was that in most of the situations cited in the various comments, the individuals were receiving services in the community as an alternative to institutionalization. Individuals eligible for Medicaid under a waiver under section 1915(c) of the Act are often eligible for waiver services using rules that normally apply in institutions. Therefore, the commenters believe these persons should also be treated as institutionalized individuals for Part D cost-sharing purposes. Some commenters also cited the Olmstead U.S. Supreme Court decision, which requires States to place persons with disability in community rather than institutional settings when possible, as a basis for the commenters' position.

Response: For comments suggesting that ICFs/MR be specifically included in the regulations meeting the definition of a medical institution, we do not believe such inclusion is either necessary or desirable. If we state that ICFs/MR in general meet the definition of a medical institution it could be misleading because one ICF/MR could meet the various certification and service provision requirements set forth in current regulations while others would not. Therefore, we would not want to give the erroneous impression that all ICFs/MR would meet the definition of a medical institution for purposes of the provision under discussion.

For comments urging that persons receiving waiver services, PACE services, or those in various living arrangements such as assisted living facilities and residential care homes be treated as institutionalized individuals for purposes of cost-sharing under § 423.782, we understand why the commenters believe such treatment would be to the advantage of those persons. However, the regulatory provisions under discussion are based on specific statutory language, and we do not believe that language contains the latitude necessary to treat persons in the various situations described by the commenters as institutionalized individuals.

Section 1860D–14(a)(1)(D)(i) of the Act provides that for purposes of cost-sharing, an institutionalized individual is one who meets the definition of that term in section 1902(q)(1)(B) of the Act. That section in turn defines an institutionalized individual as someone who is an inpatient in a medical institution or nursing facility for which payments are made under the Medicaid program throughout a month, and who is determined to be eligible for medical assistance under the State plan. An inpatient is someone who is physically in a medical institution. However, assisted living facilities, boarding homes, residential care homes, etc., do not meet the general definition of medical institutions under the Medicaid or Medicare programs. Individuals receiving services under the waiver authority provided by section 1915(c) of the Act, or under the PACE program, are not inpatients of a medical institution since they are living in the community. When the Congress intends to include such individuals, or give States the option of including such individuals, within the definition of ''institutionalized individuals'', it does so explicitly in the statute. In the absence of such explicit inclusion in the Part D statute, we cannot consider the persons to whom the commenters refer to be institutionalized individuals for Part D cost-sharing purposes. We believe the Congress intended this provision to address the fact that dual-eligible persons residing as inpatients in medical institutions are permitted to retain only a small personal needs allowance, which preclude payment of even nominal copayments. For PACE enrollees, we refer commenters to Subpart T.

Comment: Three commenters objected to the language in the definition of institutionalized individual concerning payment being made under the Medicaid program throughout a month, arguing that an individual could be a full-benefit dual eligible individual recently returned from a hospital stay whose nursing facility stay would be paid for by Medicare Part A for the entire month.

Response: While we understand the commenters' concern, the language in question is a specific statutory requirement under section 1902(q)(1)(B) of the Act. Therefore, we do not believe we can eliminate or even revise that requirement in the regulations. It is worth noting that that if Medicare Part A is paying for the nursing home stay, an individual's drug costs will in all likelihood be covered through Medicare Part A payment, and so the issue of Part D cost-sharing liability does not apply.

Comment: We received several comments on our proposed definition of a personal representative in § 423.772. In the proposed rule we defined a personal representative as someone who is (1) authorized to act on behalf of the applicant; (2) someone acting responsibly on behalf of the applicant if the applicant is incapacitated or incompetent, or (3) an individual of the applicant's choice who is requested by the applicant to act as his or her representative in the application process.

One commenter urged that ''authorized'' to act on behalf of the applicant be defined to mean authorized under State law, and that ''State law'' in turn be defined as including a constitution, statute, regulation, rule,

common law, or other State action having the force and effect of law.

Response: While we understand the commenter's concern, we do not believe that the term ''authorized'' should be restricted in the manner suggested. The intent of this portion of our proposed definition was to enable applicants to designate someone whom they trust to act on their behalf in filing an application for a low-income subsidy. Defining the term ''authorized'' to mean only persons who meet State law-based requirements could effectively restrict an applicant's choice of personal representative to someone with what could amount to a guardianship relationship with the applicant, even if the applicant is not in need of a formal guardian. This could make it very difficult if not impossible for an applicant to even find a qualified personal representative.

Comment: Several commenters suggested that the term ''acting responsibly'' needed further clarification as to who would determine that a personal representative is acting responsibly, and under what circumstances a conflict of interest could be presumed to exist. Two commenters suggested that certain entities for whom the commenters apparently believe a conflict of interest can be presumed to exist, such as insurance agents, Medicare and PDP marketing representatives, and anyone charging a fee for assistance, should be prohibited from acting as a personal representative.

Response: We understand the commenters' concerns about the possibility of personal representatives not acting in the best interests of the applicant. However, we do not believe it is appropriate to establish rules that effectively prohibit entire classes of individuals from acting as personal representatives for applicants based solely on a possibility. If, based on actual program experience, we find that personal representatives are abusing the trust placed in them by applicants and the low-income subsidy program, we will refer for investigation these potential program abuses and publish guidelines to address any specific patterns of abuse that emerge. In the absence of evidence to the contrary, however, we believe that at this time we should assume that personal representatives will for the most part act in the best interests of the applicants who appoint them.

Comment: One commenter expressed concern about a requirement in § 423.904(d)(2)(ii) of the proposed regulations that when taking a low-income subsidy application, States must require a personal representative to certify under penalty of perjury as to the accuracy of the information provided. The commenter believes this requirement will greatly inhibit outreach and enrollment activities by social workers and community service organizations. The commenter believes this requirement would expose any agency, volunteer, SHIP program staff, friend or neighbor to legal liability.

Response: We do not believe this requirement will have the dire consequences the commenter fears. The requirement the commenter cites is a standard part of most if not all applications for Federal benefits, and in all likelihood the majority of State benefits as well. This requirement is intended to deter applicants or their representatives from knowingly falsifying applications for low-income subsidies, and thus only requires the applicants or their representatives to the best of their knowledge. It is not intended to lead to, nor would it be used for the purpose of, prosecuting applicants or representatives for simple errors or inadvertent omissions.

Comment: One commenter indicated that the definition of personal representative should also include an SPAP when the SPAP is functioning as an authorized representative.

Response: Our definition would encompass an SPAP when the SPAP is functioning as an authorized representative. In such a case, the SPAP as an authorized representative, can exercise all the rights of the applicant including completing the low-income subsidy application.

Comment: We received a number of comments on our proposed definition of ''resources'' in § 423.772, and referenced elsewhere in the proposed regulations. In that section we proposed defining the term ''resources'' to mean liquid resources of the individual (and if living in the same household, his or her spouse if the individual is married), such as checking and savings accounts, stocks, bonds, and other resources that can be readily converted to cash within 20 days, that are not excluded from resources in section 1613 of the Act, and real estate that is not the applicant's primary residence or the land on which the residence is located. We included this definition of resources because individuals are subsidy eligible individuals only if they have resources (or assets) below certain limits established under section 1860D–14(a)(3)(D) and (E).

Several commenters urged that the asset test eligibility for the low-income subsidy be eliminated entirely. Eligibility would then be based solely on an applicant's income.

Response: An asset test for low-income subsidy eligibility is specifically required under section 1860D–14(a)(3)(D) and (E). In view of this clear statutory requirement, we have no authority to eliminate the asset test in its regulations.

It should be noted that the Social Security Administration (SSA), which operates the SSI program, is publishing its own regulations which will explain how the SSI statutory provisions, including those pertaining to resources, will apply to low-income subsidy eligibility. We expect that SSA's regulations will explain in detail how resources will be counted when determining eligibility for a low-income subsidy.

Comment: Several commenters suggested that if the asset test could not be eliminated entirely, at least certain specific assets should be excluded from being counted when determining eligibility for a low-income subsidy. Specifically mentioned by commenters were any life insurance, including the cash surrender value of life insurance, burial funds and burial plots, all officially designated retirement funds such as IRAs and 401(k) plans, and vehicles.

Response: We note that of the specific assets mentioned by commenters, burial plots are already excluded from being counted as assets under the SSI program, and vehicles are also excluded from being counted for low-income subsidy purposes because they are not considered liquid assets. For the other assets mentioned, we do not agree that they should be eliminated from the resource test. Section 1860D–14(a)(3)(D) provides that resources will be determined according to section 1613 of the Act, which designates the exclusions from resources for the SSI program. As we explain in the preamble to the proposed rule, we believe that we have some flexibility to narrow our definition of resources to exclude non-liquid resources that would be counted under the SSI program, since the section 1860D–14(a)(3)(E)(ii) of the Act also provides for the development of a simplified application in which applicants attest to their level of resources and submit only minimal documentation. We believe that the implication of this provision is that the Congress envisioned a simple process. Therefore, in order to keep the process simple and minimize administrative cost, we will only consider liquid resources (that is, those that could be converted to cash within twenty days) and real estate that is not an applicant's

primary residence as resources that are available to the applicant to pay for the Part D premiums, deductibles and copayments. While, in the interest of simplicity, we were willing to exclude certain non-liquid resources, we do not believe that the Congress intended to authorize a wholesale departure from SSI resource rules in making subsidy eligibility determinations. Therefore, for purposes of counting liquid resources, we believe it is important to adhere to the resource rules of the SSI program. These include counting items such as the cash surrender value of life insurance and the value of IRAs and 401(k) plans.

Comment: Some commenters suggested that if the assets discussed above could not be excluded entirely from being counted, any disregards applying to them should be substantially increased.

Response: For the reasons explained in the previous discussion, we will not increase disregards for these or any other assets beyond whatever disregards are applicable under the SSI program.

Comment: Many commenters said that the examples of countable resources we included in the proposed definition of resources under § 423.772 was not detailed enough. They urged that the final rule provide a specific list of the resources that would be counted (or, alternatively, that would not be counted) in determining low-income subsidy eligibility. Many commenters also expressed concerns about the provision that resources that can be readily converted to cash within 20 days would be counted. These commenters said the 20-day conversion rule was vague, and needed to be clarified. Another commenter suggested that we exclude resources if liquidating that resource would result in a financial loss or penalty.

Response: For these comments, and as we explain in our discussion of the definition of income elsewhere in this section of the preamble, it is important to note that under sections 1860D–14(a)(3)(D) and (E) of the Act , the resource component of the eligibility determinations for a low-income subsidy is generally determined using the statutory rules of the Supplemental Security Income (SSI) program which govern resource exclusions under that program. As noted earlier, the Social Security Administration (SSA), which operates the SSI program, is publishing its own regulations which will explain how the SSI statutory provisions, including those pertaining to resources, will apply to eligibility determinations for the low-income subsidy. We expect that SSA's regulations will explain in detail how resources will be counted when determining eligibility for a low-income subsidy.

Comment: A few commenters suggested that the rules for counting resources for making eligibility determinations of the low-income subsidy be exactly the same rules as are used by the SSI program when counting resources. These commenters argued that any deviation from the standard SSI rules would make it more difficult for States to determine low-income subsidy eligibility.

Response: As we explained in the preamble to the proposed regulations, the rules for counting resources for low-income subsidy determination purposes are for the most part the same as the standard SSI resource rules. The primary difference is that most non-liquid resources will not be counted when determining eligibility for the low-income subsidy, whereas many such non-liquid resources would be counted under SSI. We believe that rather than making eligibility for a subsidy more difficult to determine, not counting most non-liquid resources will actually make the eligibility determination process easier.

Comment: Several commenters noted that under the Part D statute, the Secretary has the option of allowing States to use the more liberal resource rules that the States may use to determine resource eligibility for QMBs, SLMBs, and QIs when determining low-income subsidy eligibility. These commenters urged that we exercise that option and allow States to use their more liberal resource rules rather than require States to use only the SSI statutory resource provisions, as we have proposed.

Response: As we explained in the preamble to the proposed regulations, a primary goal under the low-income subsidy program is to have nationally uniform standards and rules for determining eligibility for a subsidy. We believe national uniformity is desirable because the low-income subsidy is a national program, and thus to the greatest extent possible should be operated under the same rules regardless of where in the country an applicant lives. Allowing States to use resource rules that would vary from State to State would compromise that uniformity. Also, as we explained in the preamble, we do not believe allowing States to use different resource rules to determine low-income subsidy eligibility would significantly change the number of persons who might be found to be eligible for the low-income subsidy. This is because the option to allow States to use more liberal resource rules could be exercised only in cases where the Secretary found, in a particular State, that use of those rules would not materially increase the number of individuals who would be subsidy-eligible individuals.

Comment: One commenter suggested that in addition to allowing States to use more liberal resource rules, we should require SSA to use a State's more liberal rules as well when making low-income subsidy eligibility determinations.

Response: As explained above, we are not exercising the option to allow States to use more liberal resource rules. However, even if we were to exercise that option, the option applies only to eligibility determinations for the low-income subsidy by a State. The Part D statute contains no authority under which a requirement such as the commenter suggests could be imposed on SSA.

Comment: One commenter suggested that we apply the low-income subsidy resource rules across the board to the Medicare Savings Program groups (that is, the QMBs, SLMBs, and QIs). The commenter believes this would make more people eligible for the Medicare Savings Program because the basic subsidy resource rules count fewer resources than the basic Medicare Savings Program rules.

Response: We would note that to a large degree individual States already have the option to do as the commenter suggests. Under the authority of section 1902(r)(2) of the Act, States can elect to count fewer resources, or disregard greater amounts of resources, for Medicare Savings Program groups than they would otherwise under the basic resource rules. However, while this is an option for States, we do not have the statutory authority to impose the low-income subsidy rules on States' Medicare Savings Programs.

Comment: A few commenters urged that we consider not applying transfers of resources for less than fair market value penalties to low-income subsidy applicants, as we have proposed in our regulations.

Response: For purposes of determining eligibility for the low-income subsidy, we will not be considering the value of assets transferred for less than fair market value. We do not believe that penalties associated with transfers translate into an appropriate method of counting resources for the low-income subsidy.

Comment: We received at least one comment that our definition of resources should exclude the same resources currently excluded under the Medicaid program when determining

Medicaid eligibility for American Indians and Alaska Natives.

Response: As we have explained previously in this section of the preamble, under section 1860D–14(a)(3)(D) and (E) of the Act, resource eligibility for a low-income subsidy is determined using the statutory provisions of section 1613 of the Social Security Act, which governs resource exclusions under the SSI program. Under the SSI program, a number of types and amounts of resources belonging to American Indians and Alaska Natives are already excluded. If they are excluded under SSI statutory provisions, they will also be excluded when determining low-income subsidy eligibility.

Comment: One commenter objected to the provision under which the low-income subsidy resource standards will be increased each year by the percentage increase in the Consumer Price Index, rounded to the nearest multiple of $10. The commenter believes this adds complexity to administering the low-income subsidy program, and suggested that resource standards be consistent across all poverty-level-based Federal programs.

Response: While we understand the commenter's concern, we must note that the process for increasing the resource standards is mandated by section 1860D–14(a)(3)(D) and (E) of the Act. Therefore, we do not have authority to change or eliminate that process under its regulations.

Comment: Several commenters suggested that we clarify the regulations to reflect that an individual can apply and be determined a subsidy eligible individual before enrolling in a Part D plan. Other commenters remarked that the proposed rule implies that an individual must be enrolled in a Part D plan in order to apply for low-income subsidies. They assert that the final regulations should make clear that determinations could be made both before and after enrollment in a Part D plan, and specify the effective date of that coverage. Other commenters suggest that we clarify how information verifying enrollment in a plan is provided to States and how States will be notified if an individual disenrolls from a plan.

Response: Determinations for the low-income subsidy program can be made in advance of a person enrolling in a Part D plan. We believe that fact is clearly articulated in the proposed regulation which requires States to take subsidy applications starting July 1, 2005, well in advance of the open enrollment period for the new Part D benefit, a requirement we retain in the final rule. Therefore, we do not believe we need to make further clarifications in the final rule.

We believe it is important to emphasize here that while determinations may be made in advance of the initial enrollment period beginning on July 1, 2005, a subsidy eligible individual is not entitled to the subsidy until such time as the person's enrollment in a plan is effective. Up until that time, there are no premiums or cost sharing obligations under Part D for which we must subsidize payment under the low-income subsidy. Accordingly, States need only to send us information on whether a person is eligible for the low-income income subsidy. We will provide information on subsidy eligible individuals to Part D plans and will reimburse plans for enrollees who are subsidy eligible individuals as provided under § 423.329(d). We acknowledge that States may require plan enrollment information for purposes of coordination of benefits, but we do not believe that such information is necessary for purposes of determining whether a beneficiary is eligible for the low-income subsidy. Therefore, we will not share enrollment data with the States on a routine basis for the purpose of determining eligibility for the low-income subsidy. In Subpart J, we address the need for this information sharing for coordination of benefit purposes.

Comment: One commenter indicated that the proposed rule disadvantages Social Security Title II beneficiaries who receive Medicare and will receive low-income subsidies. The proposed regulation provides that low-income Medicare beneficiaries will pay little or nothing for prescriptions, while those earning over 150 percent of the Federal poverty line applicable to the individual's family size may have to pay as much as 50 percent of the cost of their prescription for covered Part D drugs, giving them a financial disincentive to return to work if they incur significant prescription expenses. The commenter urges us to consult with SSA about these changes.

Response: The income threshold of 150 percent of the Federal poverty line for low-income subsidy eligibility is established by section 1860D–14(a)3)(E) of the Act, and cannot be changed without a change in the law itself. However, while eligibility for the low-income subsidy is based on income, it is important to be aware that income can be earned income or unearned income. Under the statutory rules of the supplemental Security Income (SSI) program, which are used to determine low-income subsidy eligibility, there are significant disregards for earned income. Under those rules, the first $85 of earned income, plus one-half of any remaining earned income, will not be counted when determining low-income subsidy eligibility. Other earned income disregards may also apply, depending on each applicant's personal situation. Thus, those Social Security Title II beneficiaries who choose to return to work will have the potential for total income that is actually higher than 150 percent of the Federal poverty line as a result of the earned income disregards that will be applied in determining low-income subsidy eligibility.

Comment: Several commenters suggested that our regulations should indicate that the indexing of resources would be rounded up in multiples of $10.

Response: We do not have authority to make this change in the final rule. The reference in sections 1860D–14(a)(3)(D) and (E) of the Act to the ''nearest multiple of $10'' does not provide the discretion to always round up or to always round down. For purposes of indexing, the nearest multiple will be rounded up if it is equal to or greater than $5 and down if it is less than $5.

Comment: Several commenters suggested that we needed to clarify that individuals deemed to be subsidy eligible do not have to take any further action for the low-income subsidy; rather, they only need to enroll in a Part D plan.

Response: We have further clarified in the final rule that individuals deemed subsidy eligible individuals do not need to apply for the low-income subsidy.

Comment: Several commenters expressed support for the proposed deeming of Medicare Savings Program individuals as full subsidy eligible individuals, but expressed concern that SSA will not apply more generous income and asset eligibility rules under Medicaid for individuals potentially eligible for Medicare Savings programs. These commenters indicated that the requirements should be the same for all subsidy-eligible individuals in a State, regardless of where and how they apply.

Response: While States may use more liberalized methodologies under Medicaid for purposes of determining eligibility for Medicare Savings Programs, they may not employ more liberal methodologies under the Medicare Part D low-income subsidy eligibility should an individual apply and request a State eligibility determination. (However, if the State determines the individual is Medicare Savings Program-eligible under its rules

(that is, as a QMB, SLMB, or QI), the individual is deemed eligible for the subsidy) The requirements for counting income and assets are the same under the low-income subsidy program regardless of whether an individual applies at a State office or an SSA field office. These requirements are based on the statutory provisions of the SSI program. For counting income, States and the SSA are specifically precluded from using the more liberalized methodologies permitted under Medicaid under section 1902(r)(2) of the Act. For counting resources, we acknowledge in the proposed rule that we could have permitted States to use the same resources standards that States employ under Medicaid for purposes of determining eligibility for Medicare Savings Programs. However, we elected not to exercise this discretion since this authority does not extend to SSA and we believe national uniformity for purposes of eligibility determinations is a desirable goal.

Comment: Some commenters expressed concern that the proposed rule does not address eligibility issues for Medicaid beneficiaries who become eligible after a spenddown period, either under a medically needy program or in a 209(b) State (that is, a State which does not provide Medicaid automatically to all of its SSI recipients but which uses more restrictive rules than those of the SSI program). They suggested that these beneficiaries should be informed of their eligibility for the low-income subsidy and given an opportunity to apply for the subsidy. When they have met their spenddown, they should be informed of their entitlement to the low-income subsidy as a full-benefit dual eligible individuals.

Response: We agree that the eligibility rules may be confusing for Medicare beneficiaries who become eligible for Medicaid after a spenddown period. In the final rule, we have clarified that individuals treated as full-subsidy eligible individuals will be deemed eligible for a period up to one year. Thus, individuals who have met their spenddown obligation and are eligible for full Medicaid coverage will be notified that they are eligible for a full subsidy under Part D for up to one year without interruption. If the individuals periodically go off Medicaid because they have to meet a new spenddown budget, they will still be ''deemed'' full subsidy eligible individuals for the remaining period of subsidy eligibility. We have specified ''a period up to one year'' to allow us the operational flexibility to deem full subsidy eligible individuals for a period less than 12 months during a calendar year if they are newly identified to us in a month later than January. Thus, an individual may be deemed subsidy eligible for 9 months if they are reported by the State as a full-benefit dual eligible individual in March, for example. If the same person continues to be a full-benefit dual eligible individual in the fall of the same year, he or she will be deemed a full subsidy eligible the next year for the full calendar year.

Comment: We received several comments that proposed § 423.773(c), which requires the State to notify full-benefit dual eligible individuals that they are full subsidy eligible, should conform to proposed § 423.904(c)(3) in subpart S which requires States to notify all individuals deemed full subsidy eligible individuals of their eligibility for the full subsidy. These commenters suggested that the notice be given by July 1, 2005, for those eligible at that time, or at the time they attain eligibility for the Medicaid program that enables them to be treated as full subsidy eligible, if after July 1, 2005. Further, the commenters suggested that the notice should make clear the actions required of individuals treated as full subsidy eligible individuals, should direct individuals to information sources where they may gather additional information, counseling and assistance; and apprise individuals of appeal rights for loss of Medicaid coverage and appeal rights associated with the determination on the level of subsidy. They also suggest that we should develop model notices based on input from beneficiaries and encourage States to include a reminder in their notice letter of the need to recertify their eligibility under the applicable benefits program.

Other commenters suggest that we should modify its final rule to clarify that States will notify full-benefit dual eligible individuals and low-income Medicaid beneficiaries participating in the Medicare Savings Program that they qualify for a full subsidy under the new drug benefit. In addition, we should develop a similar notification with the SSA, or require States to coordinate with SSA, for to SSI recipients in 209(b) States and non–1634 States (that is, a non–209(b) State which requires SSI recipients to file a separate Medicaid application) since there could be SSI recipients in these States who are not receiving Medicaid and who would not appear under the States' eligibility systems.

Response: We have clarified in the final rule that we will send notices of eligibility to all deemed full subsidy eligible individuals. We believe that if we send the notices to all the individuals rather than States, it will ensure more uniformity in the content of and timeliness of the notices. Additionally, our sending the notices to individuals deemed eligible for the full subsidy will ensure we reach people States may not be able to identify, namely Medicare beneficiaries receiving SSI benefits in States where SSI does not automatically entitle a person to Medicaid. Our goal is to begin sending notices to individuals deemed to be subsidy eligible in the Spring of 2005, before the start of taking applications for individuals who are not deemed eligible for the low-income subsidy. We will ensure that the notices clarify that individuals deemed eligible for a full subsidy need not apply to receive the subsidy.

Comment: One commenter suggested that we explain how Part D plans are notified of an enrollees' eligibility for a low-income subsidy.

Response: Once a subsidy individual enrolls in a Part D plan, CMS, through a data match, will inform Part D plans that the individual qualifies for a low-income subsidy.

Comment: One State commenter remarked that the draft regulation does not specify which agency is financially responsible for sending notices to individuals deemed eligible for the full subsidy. The commenter pointed to section 1860D–14(a)(3)(B)(i) of the Act, which references funds to be appropriated to the SSA necessary for the determination of the low-income eligibility determinations. Some commenters asked if the SSA would provide an appropriation to each State to enable States to provide notices to dual eligibles as specified in the proposed rules. The commenters also wondered which entity had responsibility for explaining to full-benefit dual eligible individuals how coverage of Part D drugs in Part D plans work and how such coverage will differ from the coverage they received under the State's Medicaid program.

Response: For reasons discussed above, we have clarified in the final rule that we will send notices of eligibility to all individuals deemed full subsidy eligible individuals. This should relieve States of the financial burden of sending notices to these individuals. We will also educate Medicare beneficiaries, including full-benefit dual eligible individuals, through a variety of methods about prescription drug coverage under the new Part D benefit. (See discussion in Subpart B). However, we expect that States will have an important role in educating Medicare beneficiaries, particularly full-benefit

dual eligible individuals, about the low-income subsidy program and the new Medicare drug benefit. We also note that during Federal Fiscal Years 2005 and 2006, a total of $125 million in grants are made available under 1860D–23(d) of the Act to States with SPAPs to assist in the outreach and education of SPAP enrollees transitioning to Medicare Part D.

Comment: A few commenters suggested that proposed § 423.773(c) should be edited to replace the term ''full-benefit dual eligible'' with ''full subsidy eligible,'' where appropriate. They specifically reference the requirement on States to notify full-benefit dual eligible individuals that they are eligible for full subsidy premiums and deductible, noting that in subpart S a similar requirement is imposed on States to notify full subsidy eligible individuals. The commenters suggest that this inconsistency represents an error in the proposed rule.

Response: We agree that this inconsistency is an error. For reasons previously addressed, we have clarified the final rule to correct this inconsistency and to indicate that we (not States) will send notices to all individuals deemed to be full subsidy eligible individuals.

Comment: Some commenters suggest that SSA should screen applications to identify individuals who appear to have excess assets or income for the subsidy but who may qualify for Medicare Savings Programs in States that use more liberal eligibility rules for such programs. Alternatively, the commenters suggest SSA forward such applications to State offices or use State-specific income and asset rules to determine eligibility.

The commenters noted that by qualifying for Medicare Savings Programs, an individual will automatically be eligible for the low-income subsidy, despite the fact that if the same individual applied, he or she may not have qualified for the subsidy as a result of excess income or resources. The commenters suggest that individuals who qualify should be automatically enrolled by States in Medicare Savings Programs with an opt-out provision. Further, we should make benefit counseling available to these beneficiaries since enrollment in a Medicare Savings Program can affect the amount of assistance a beneficiary may receive through other public assistance programs. Finally, the commenters suggest that individuals who do not enroll in a Medicare Savings Program but who qualify for such a program should still be considered automatically eligible for the subsidy.

Response: We acknowledge that some individuals who apply and qualify for a Medicare Savings Program (as a QMB, SLMB, or QI) with a State's Medicaid office will be considered automatically eligible for the full subsidy, despite the fact that if the same individual applied for a low-income subsidy at the State or SSA, they may not have qualified for the full subsidy as a result of excess income or resources. This scenario is more a function of Medicaid rules permitting States to use more liberalized income and asset methodologies than a lack of uniformity for the rules of the low-income subsidy program. In those States that use more liberalized income and asset methodologies under section 1902(r)(2) of the Act for purposes of determining eligibility for Medicare Savings Programs, individuals may find it more advantageous to apply for Medicare Savings Programs rather than applying for the low-income subsidy directly with States or SSA.

We are working with SSA to design a process that will provide high-level information which does not include income or resource information but will provide the outcome of the subsidy determinations to States for purposes of identifying individuals who apply at SSA and who may also qualify for full Medicaid benefits or Medicare Savings Programs. With this process, we hope to avoid situations in which an individual applies for a low-income subsidy at an SSA office, finds out that he or she has excess income or resources to qualify for the full subsidy or even the subsidy available to other low-income subsidy eligible individuals, and remains unaware that he or she may automatically qualify for a full subsidy if the individual chooses to enroll in a State's Medicare Savings Program (as a QMB, SLMB, or QI).

Comment: We received one comment that SSA needs to use information provided from beneficiaries applying for low-income subsidies to better target the mailings that SSA is required to do under section 1144 of the Act. Commenters note that this provision requires SSA to annually identify beneficiaries potentially eligible for Medicare Savings programs, notify them about the programs, and send copies of the list of individuals identified as potentially eligible for the Medicare Savings Programs to the appropriate State agencies. In addition to using the data on income and assets for the section 1144 of the Act mailings, the commenters suggest that SSA could provide States the income and resource data for determining eligibility for Medicare Savings Program eligibles. Providing this information could reduce the burden on beneficiaries from having to submit this information twice (that is, to SSA for the low-income subsidy and to States for enrollment in Medicare Savings Programs). The commenters suggest that while privacy issues may be of concern, one option to address those concerns would be to allow applicants to consent to sharing information with their State agency to assist the State in determining whether they are eligible for Medicare Savings Programs.

Response: Again, we are working with SSA to design a process to provide subsidy determinations to States for purposes of identifying individuals who apply at SSA and who may also qualify for a Medicare Savings Program in the State. We expect that States will use the determination to contact individuals who may qualify and to assist them in the application process. As the commenter suggests, SSA is unable to provide income and resource information directly to States for privacy reasons. Therefore, the information provided to States will be limited to high-level information on the outcome of the subsidy determination.

Comment: Some State commenters noted that States lack a practical way to determine whether applicants have also applied for the low-income subsidy through SSA. They note that if SSA and States make separate determinations that do not agree some form of reconciliation will be needed. They further note that this need for reconciliation will further complicate processing and add to administrative burden and costs.

Other commenters requested clarification on the data exchange process. The commenters assert that they cannot envision a data exchange process that would be fast enough to prevent an applicant from receiving a denial from SSA and subsequently applying at the State office. They noted that this could result in duplicative work for the State and SSA. The commenters ask that the rule be clarified for this coordination.

Response: We agree that it will be important to design a process in which States can determine if an individual has already filed an application with SSA, and vice versa. We expect to provide further information on this process through operational guidance. We also note that, based on comments, we have clarified in the final rule that multiple applications will not be permitted in cases where an individual has received a positive determination from either SSA or the State. In other words, an individual may not file a second application for the remainder of the eligibility period with the alternate

agency if he or she has received a positive determination from the State or SSA. This requirement is not intended to preclude an individual from reporting subsidy changing events in accordance with the determining agency's rules, but rather to prevent confusion that could arise if a State and SSA process determinations for the same individual.

3. Eligibility Determinations, Redeterminations and Applications (§ 423.774)

In accordance with section 1860D–14(a)(3)(B)(i) of the Act, an application for subsidy assistance may be filed with either a State's Medicaid program office or SSA. Inquiries made by individuals to Part D plans concerning application or eligibility for the low-income subsidy should be referred to State agencies or SSA. Eligibility determinations would then be made by the State for applications filed with the State Medicaid agency or by the Commissioner of Social Security for those filed with SSA.

While our goal is to provide a single application and determination process for the low-income subsidy, we recognize that the statute provides that redeterminations and appeals of eligibility determinations are to be made in the same manner as for medical assistance for those individuals who are determined eligible by the State Medicaid agency. Similarly, the Commissioner will decide how to conduct redeterminations and appeals for those subsidy determinations made by Social Security.

In the proposed rule we noted that eligibility determinations for low-income subsidies would be effective beginning with the first day of the month in which the individual applies for a subsidy, but no earlier than January 1, 2006, provided the applicant meets the requirements for eligibility when he or she applies and has enrolled with a Part D plan . Initial eligibility determinations would remain in effect for a period not to exceed 1 year, beginning no earlier than January 1, 2006.

Because States and Social Security offices will be performing subsidy determinations, States and SSA would need to share data with us. We would then use the data to notify the Part D plan in which the individual is enrolled of the individual's eligibility for the low-income subsidy. We would also use the data to provide information on the individual's income bracket so that Part D plans may identify the cost-sharing amounts and, in the case of other subsidy eligible individuals, the monthly beneficiary premiums that may be charged to a subsidy eligible individual as discussed later in this subpart of the preamble.

Section 1860D–14(a)(3)(E)(ii) of the Act directs the Secretary and the Commissioner of SSA to develop a model simplified application form for the determination and verification of Part D eligible individual's assets or resources. We believe it is important to develop a simplified application for income as well as resources and to develop an application that will address both the full and the other low-income subsidy provisions. Therefore, we have been working with SSA to develop a model application form to be used to determine eligibility for all subsidies. The application will reflect the definitions of income and resources discussed earlier in this subpart.

For the method and degree to which income and resources will be verified, our general policy is to not spend more on verification than the expected return in terms of benefit savings to the Medicare program from such verification. Therefore, as stated in the proprosed rule, we intend to use the most efficient and cost-effective process that will balance the need for program integrity with the goal of reducing the paperwork burden and cost.

We envisioned a process based on an operations research strategy whereby States and SSA would build on existing verification processes used for other programs. We planned on maximizing the use of automated data matches for verification of income and certain liquid resources (which minimize both paperwork burden and cost), and relying on specific targeting or profiling criteria derived from a database that would identify a subset of applications for purposes of in-depth verification. This in-depth verification process would enable SSA and States to focus on elements attested to by the applicant that do not lend themselves to verification by electronic means (that is, countable real estate). By developing a targeted approach, we believed we could strike an appropriate balance between administrative costs and program goals and objectives. We requested comments on this approach.

In developing a simplified application, we also considered a number of other issues in order to streamline the application process. For example, the proposed rule permits a personal representative to assist in the application process. We proposed to define personal representative as an individual who is authorized to act on behalf of the applicant, an individual acting responsibly on behalf of an applicant who is incapacitated or incompetent, or an individual of the applicant's choice who is requested by the applicant to act as his or her representative in the application process.

In addition, we would permit the use of a proxy signature process to allow applications to be taken over the phone or by an Internet process. Under a proxy signature process, an individual attests to the accuracy of the information provided under penalty of perjury prior to submitting the information for processing. Our proposed requirements specify that the individual applying for the low-income subsidy, or a personal representative on his or her behalf complete the application for the low-income subsidy, and certify as to the accuracy of the information provided. Section 1860D–14(a)(3)(E)(iii)(II) of the Act provides that statements from financial institutions shall accompany applications in support of the information provided therein. We believe States and SSA will be able to verify information through data matches with other sources that will substantially eliminate the need for the beneficiaries to bring statements from financial institutions with them when they apply.

As a result, we would reduce an applicant's burden in producing financial statements by not requiring paper copies except when specifically requested. For example, SSA and States may verify some resources for the low-income subsidy through data matches with 1099 files from the IRS, which show the annual amount of interest earned on interest bearing accounts. If the data from the 1099 files indicate the applicant's interest is below a threshold amount relating to the resource limit and the applicant has no countable real estate, the State or SSA could decide that no further information is needed from the applicant relating to certain types of resources. When the threshold is exceeded, additional information may be requested of the individual to support the application. Use of this process would ease the burden on individuals preparing to file an application and will reduce the administrative burden on States and SSA in handling paper verification. Accordingly, § 423.774(d) required the submission of statements from financial institutions only if requested by the State or SSA.

Comment: Some commenters suggested that the regulations should specify that a determination notice be sent to the applicant no later than 30 days after the application is filed. Additionally, they suggested that SSA and States should be required to notify

CMS within 24 hours of an individual being determined eligible for the subsidy. Other commenters questioned whether the State Medicaid agency is required to complete determinations within 45 days as is required for most Medicaid eligibility determinations under § 435.911. These commenters argue that the regulations should specify a time standard that would apply to determinations made by either the State or SSA.

Response: We do not have authority to direct SSA to determine subsidy eligibility within a given time period, and have decided not to impose a specified period on States through regulation. Instead, we will provide operational guidance to States, monitor the time period for determining subsidy eligibility, and take action as appropriate. As general guidance, we expect that States will determine subsidy eligibility within time periods that are at least consistent with the processing of State Medicaid applications.

Comment: Some commenters suggested that in order to avoid delays in beneficiaries being able to use their subsidy benefits while their application is pending, the final rule should offer beneficiaries the option of applying through a presumptive eligibility system. Commenters suggested that the system could be designed in a manner whereby an applicant can complete a form at a provider's office or other location where they declare their family size, income and assets. If the individual's income and resources are below the eligibility levels, they could be found presumptively eligible. The individual could then have the obligation placed on him or her to fill out the complete application within a prescribed period of time. The commenters argue that such a system would encourage beneficiaries to apply since they would see the benefits of the system.

Response: We appreciate that it is important for subsidy determinations to be made as quickly as possible so that individuals will be able to receive extra help with the payment of cost sharing and premiums when enrolled in a Part D plan. We are working with States and SSA on an outreach strategy to try to encourage individuals potentially eligible for the low-income subsidy to apply for the subsidy as early as possible, starting July 1, 2005. Under this outreach strategy, we will encourage individuals to apply and ''pre-qualify'' for the low-income subsidy before enrolling in a Part D plan so that they will know ahead of time whether or not they are eligible for extra assistance with the payment of premiums and cost sharing. However, the subsidy will not be effective until the start of the program when the individual is actually enrolled in a Part D plan.

At this time, we decline to implement a presumptive eligibility process for individuals not deemed to be subsidy eligible individuals. We believe our streamlined process that relies on self-attestation of the information on the application with such verification as SSA or the States determine is appropriate will ensure that individuals quickly receive subsidy determinations from SSA or States, so that they can get the extra help they need. It is worth noting that the simplified application being developed in consultation with SSA will be available on the Internet and will be available to providers if they choose to offer them at their locations. In addition, it is important to note that individuals do not need to apply at State offices or SSA field offices in person. They may apply over the phone via SSA's 1–800 number, they may send applications via the mail or over the internet, and they may have individuals assist them in completing the applications on their behalf.

Comment: Some commenters suggest that we clarify whether individuals who currently receive benefits as a full-benefit dual eligible individual, SSI recipient or under the Medicare Savings Program (as a QMB, SLMB, or QI) are required to undergo a separate and new eligibility determination in order to qualify as a full subsidy eligible individual. The commenters suggested that these individuals should be required to recertify their eligibility under these programs in accordance with existing requirements pertaining to recertification or redetermination.

Response: Individuals who currently receive benefits as a full-benefit dual eligible, SSI recipient or under the Medicare Savings Program are not required to undergo a separate eligibility determination in order to qualify as a full subsidy eligible. They are ''deemed'' or treated as full subsidy eligible individuals without having to complete a separate application. We have clarified this in the final rule at § 423.773(c).

As part of our yearly notice to deemed subsidy eligibiles, we will explain that the loss of Medicaid near the end of the calendar year could impact an individual's status as a full subsidy eligible individual in the next year. Thus if someone loses Medicaid and does not regain eligibility during a year, he or she will retain subsidy eligibility during the remainder of the calendar year, but will no longer be automatically deemed for the full subsidy in the next calendar year.

Comment: Some commenters would like us to better define eligibility determination periods for the low-income subsidy. The commenters suggest that the eligibility determination should be defined as one year. Further, it should not be associated with either a State Medicaid program redetermination or an SSA redetermination.

Another commenter suggested that we should interpret the ''month of application'' for a low-income subsidy individual to mean the first day of the month a Part D plan is notified by us of the individual's eligibility for the low-income subsidy. Alternatively, the commenter suggests that the application processing timeframes be developed and implemented in such a way as to avoid administrative burden and beneficiary confusion. For example, we should specify that the application processing timeframes would start beginning with the month in which the State agency received a ''complete'' application. The commenter asserts that incomplete applications must be rendered ''complete'' or rejected within 30 days. Further, complete applications should be processed no later than 30 days from the date the application was rendered complete, meaning Part D plans should be notified within 30 days of the date the application was rendered complete that an individual is eligible for a low-income subsidy. Once notified, these individuals would be moved into the appropriate internal plan and cost-sharing would be appropriately reflected for that individual sooner rather than later.

Response: We do not have the authority to accept the first commenters' suggestion. Under section 1860D–14(a)(3)(B)(ii) of the Act, the statute, initial determinations for individuals who apply for the subsidy are effective beginning with the month the individual applies, but no earlier than January 1, 2006. These initial determinations shall remain in effect for a period specified by the Secretary, but not to exceed one year, regardless of whether the determination is made by a State or SSA. Redeterminations of eligibility for those applications processed by States are to be made in accordance with the frequency and manner in which the State makes Medicaid redeterminations, which must be conducted at least annually. Redeterminations made by SSA may be of a frequency determined by the Commissioner.

We will address the issue associated with the completeness and timeframe

for processing an application through operational guidance. It is important to note that we do not have authority to direct SSA to determine subsidy eligibility within a given time period, and we have decided not to impose a specified period on States through codification.

Comment: Some commenters question whether retroactive eligibility will be allowed for full-benefit dual eligible individuals. They suggest that the regulations be clarified for that possibility.

Response: Retroactive eligibility for the low-income subsidy is only an issue if a full-benefit dual eligible individual is already enrolled in a Part D plan. For instance, if a person is enrolled in a Part D plan and decides not to apply for the subsidy, he or she may have retroactive subsidy eligibility if the individual later qualifies for Medicaid. By extension of being entitled to full benefits under Medicaid, the individual will automatically be eligible for the low-income subsidy. In this case, subsidy eligibility will extend back to the start date of Medicaid eligibility, which could be up to three months earlier if the individual would have qualified for Medicaid during the three month retroactive period. As such, the individual will be reimbursed by the plan for any extra cost sharing he or she otherwise would not have paid as a full subsidy eligible individual. This would also apply to individuals eligible under a Medicare Savings Program as a SLMB or a QI(but not as QMB, because QMBs cannot receive retroactive benefits under Medicaid statute). For QMBs and other, non-dual eligible individuals who are enrolled in a Part D plan, and later apply and are determined eligible for low income subsidy assistance, their eligibility, consistent with the statute, would be effective on the first day of the month in which they applied for the low income subsidy.

Comment: One commenter indicated that the proposed regulations do not address whether eligibility determinations in one State are transferable to another State. The commenter also noted that there is no discussion of the transfer of information between the State agency and SSA, or the transfer of information between States.

Response: If the eligibility determination for an individual not deemed to be a full subsidy eligible individual was processed by SSA, then SSA ''owns'' the beneficiary for redeterminations and appeals. Since SSA is a national agency applying uniform national standards, redeterminations and appeals will be processed even if a beneficiary moves between States. However, if the beneficiary no longer resides in a State and the State processed the subsidy determination under its own system, the State can no longer reasonably be expected to be held liable for the subsidy redeterminations and appeals, consistent with the manner and frequency a State would redetermine eligibility under Medicaid. The beneficiary in this instance would need to apply in the new State of residence, or could apply with SSA unless otherwise deemed eligible for the full subsidy.

Comment: Several commenters question whether changes in circumstances, such as increases or decreases in income, need to be reported by the beneficiary.

Response: For individuals who apply for the low-income subsidy, changes in financial circumstances that could impact the individual's eligibility for the low-income subsidy should be reported to the agency that processed the subsidy application in accordance with that agency's rules.

SSA will be publishing rules regarding subsidy changing events that could impact low-income subsidy eligibility. For individuals who are deemed eligible for the full subsidy, changes in circumstances that would impact eligibility for Medicaid or SSA should be reported as required under those programs. However, it is important to note that, for administrative ease, we will deem individuals as subsidy eligible for a period not to exceed one year, even if changes in circumstances may cause someone to lose Medicaid or SSI for a period of time. If the person is no longer eligible for Medicaid or SSI after the period of deemed subsidy eligibility, he or she will no longer be automatically eligible for the low-income subsidy and must apply in order to continue receiving the benefit.

Comment: One commenter believes that we should provide prompt identification of an individual's institutional status for the purpose of overriding the cost sharing at the point of sale.

Response: States will be providing information on a full-benefit dual eligible individual's institutional status on a monthly basis to us. We will provide this information to Part D plans. We will address through operational guidance how plans should address situations in which an enrollee's institutional status is different than the information provided to them from us.

Comment: One commenter makes an argument that the statute permits SSA to contract with SPAPs to make determinations of eligibility for financial assistance in accordance with SSA's procedures. In addition, the commenter argues that there is no legal impediment to a State's designation of its SPAP as the State enrollment agency, so long as eligibility determinations and redeterminations are made in the same manner as for Medicaid recipients. The commenters assert there is precedent for this practice. One commenter said that we should ensure that any arrangements with SPAPs to make eligibility determinations are considered for Federal matching funds. Finally, the commenters suggest that SPAPs have direct on-line access to on-line reporting systems to facilitate the SPAP's ability to determine a person's eligibility for the low-income subsidy. They suggest that we clarify in the final regulations and in guidance that State Medicaid programs have the option to permit SPAPS to make initial eligibility determination and redeterminations for subsidies for low-income persons who apply for benefits through an SPAP.

Response: By statute, eligibility for the low-income subsidy program must be determined by the State Medicaid agency or the Social Security Administration. While it cannot be the entity ultimately responsible for determining eligibility, SPAPs can serve as an intake point for low-income subsidy applications. SPAP offices will be able to access the SSA application from the Internet in order to assist individuals in applying for a subsidy. We also note that entities other than SPAPs, including community organizations and other non-Medicaid State offices, can provide assistance to individuals in completing the SSA application.

Comment: Some commenters note that the enrollment process for Part D plans is separate from the application process for the low-income subsidy. They note that there is no mechanism in the proposed rule to permit a beneficiary to apply for the low-income subsidy at the time of enrollment in a Part D plan. They also note that Part D plans are not required to inform beneficiaries that a subsidy may be available to them. They suggest that SPAPs should be allowed to make determinations and redeterminations of subsidy eligibility in order to facilitate applications for SPAP enrollees.

Response: Again, while SPAPs may serve as an intake point for low-income subsidy applications the State Medicaid agency or the Social Security Administration retains ultimately responsible for eligibility determinations. For the comment that

Part D plans are not required to inform beneficiaries that a subsidy may be available, we agree. However, we believe many Part D plans will encourage their enrollees to apply if they indicate they are low-income and need extra assistance with premiums and cost sharing. We also encourage SPAPs to inform their members of the availability of the low-income subsidy to provide extra assistance with premiums and cost sharing under Medicare Part D, and to assist their members in completing the SSA application.

Comment: Many State commenters suggest that States should be allowed to meet their statutory obligation for the low-income subsidy by receiving applications and passing them to SSA for the determination process. They assert that use by States of a streamlined low-income subsidy application process through SSA would reduce the burden on States of doing separate determinations. They also suggest that the process include use of web-based applications accessed with Federally funded computers at Medicaid eligibility sites, paper applications that are batched and sent to SSA by the eligibility sites, and phone applications conducted directly with SSA. Another commenter suggested that States that only collect applications and forward them to SSA should not be responsible for redeterminations and appeals for these applications. This commenter also believes these States should not be responsible for screening applications for Medicare buy-in programs.

A few State commenters also assert that we have made contradictory statements with regard to the role of SSA and States in taking applications for the low-income subsidy. They indicate that we have issued guidance that States could batch up applications and ship them to SSA for processing, and that SSA would make the determinations, send the notifications, and conduct the appeals for the low-income subsidy program. However, the commenters point out that the regulations in § 423.774 and § 423.904(a), and the statute at section 1935 of the Act, direct States to make eligibility determinations and redeterminations for low-income premium and subsidies.

Finally, several State commenters seek clarification on whether States could be required to perform administrative functions such as providing personnel resources for answering questions and assisting applicants, making determinations and redeterminations, making systems changes to record determinations and redeterminations made by the State, printing applications, conducting appeals, sending notices to clients, coordinating with financial institutions for verification and developing and sending reports to us.

Response: The statute clearly sets forth the requirement that eligibility for the low-income subsidy program will be determined by either State Medicaid agencies or by the Social Security Administration. As such, States must have the ability to determine eligibility if someone requests a ''State'' subsidy determination. As part of this obligation, States are required to send notices of subsidy determinations, process redeterminations, and handle appeals.

We encourage States to consider using the SSA application form and process as their default process for processing low-income subsidy applications. Under this process, States would assist individuals who agree to complete an SSA application. Once completed, States would submit the applications to SSA for processing. While States would still have to develop a process to determine eligibility for an individual who specifically requests a ''State'' determination as opposed to an ''SSA'' determination, States could offer the SSA low-income subsidy application process to individuals in order to reduce the administrative burden associated with sending notices, processing appeals and redeterminations, and verifying information reported on subsidy eligibility applications. Again, States should be mindful that the statute does not permit States to refuse to accept and act on subsidy eligibility applications if the applicants insist on having them treated as applications with the State agency.

We will be working with SSA to provide operational guidance to States on how they may utilize the SSA process for those applicants who agree to use the SSA application. The SSA process includes an internet-based application that may also be accessed in paper form. Under this process, individuals need not apply in person with the SSA or States; however, if they do apply in person at a State office, the State would be obligated to assist individuals in completing the application and to screen individuals for Medicare Savings Program eligibility.

Comment: Some State commenters expressed concern that, should the States process determinations, redeterminations, and appeals, as well as SSA, it is not possible to create equal systems for clients, resulting in two competing processes in an already complex system. They note that in some States, beneficiaries have limited access to field offices compared to State offices. They also argue that, even if the State follows the Federal guidelines, it does not seem likely that a beneficiary following the State process will experience the same procedure as a client using the SSA process. The commenters ask for reconsideration of this issue, or alternatively, clarification about how continuity would be assured.

Response: For individuals who apply for the subsidy, one notable area of inconsistency could be the timing and manner of redeterminations of subsidy eligibility. This process, by statute, is dependent on which entity processed the application. If SSA processed the application, SSA will determine the manner and frequency of the redeterminations. If a State processed the application through its own subsidy eligibility determination system, the manner and frequency of the redetermination will be consistent with how the State redetermines eligibility for Medicaid. For individuals deemed eligible for the full subsidy, the redetermination process will be based on the underlying program that automatically qualified the individual for the subsidy, for example, Medicaid or SSI.

Comment: Some State commenters indicated that they did not believe States would be able to achieve the degree of automation at the start of the program as envisioned by CMS in the preamble of the proposed rule for purposes of verifying an applicants' income and resources. They also noted that existing State eligibility systems are not easily modified or adapted without considerable State expense. Finally, a few commenters suggested that the regulation implies that States may be able to access other agencies' databases to verify income and resources. The commenters suggest that such databases be listed or otherwise specified.

Response: We recognize that existing State eligibility systems are not easily modified or adapted without considerable State expense; however, the law is clear that States must be able to determine low-income subsidy eligibility. States therefore need to develop a process to support the determinations when specifically requested of them.

We strongly recommend that States consider using the SSA application as their default application for processing low-income subsidy applications and encourage States to assist applicants in filing their applications with SSA. While States would still have to develop a process to determine eligibility for an

individual who requests a ''State'' determination as opposed to an ''SSA'' determination, States may use the SSA low-income subsidy application and process in order to reduce the administrative burden associated with sending notices, processing appeals and redeterminations, and verifying information reported on subsidy applications. States could focus most of their attention on assisting individual with completing the SSA application, and screening and enrolling individuals in the Medicare Savings Program.

Comment: One commenter asks that we keep the period of comment on the proposed rule open until comments are due on the SSA's regulation.

Response: We cannot keep the comment period open on this proposed rule until the comments are due on the SSA regulation regarding low-income subsidy determinations. We are working closely with SSA during the regulations process to ensure consistent rules regarding low-income subsidy are put in place by both agencies.

Comment: Since generally only 50 percent Federal financial participation (FFP) is provided for the State's role in the administration of the low-income subsidy program, several State commenters asserted that the cost associated with administration of the Medicare program could prohibit the provision of other State services. States noted that they would have to use a significant amount of resources from their general fund and asked us to consider reducing the State's responsibilities due of the lack of funding for the costs associated with implementation of the low-income subsidy program. The State commenters suggest that FFP associated with the State role in this program should be derived from a cost allocation methodology that attributes 100 percent to the Medicare program.

Response: While we sympathize with the commenters' concerns, we do not have the authority to change the Federal financial participation rate available to States. The statute specifies that States are to be reimbursed according to the normal Federal match for administrative costs, which is generally 50 percent.

Comment: A few commenters expressed concern that the eligibility process for the low-income subsidy is different than the process the State uses to determine eligibility for Medicaid. The commenter indicated that by having different methodologies, States will be more error prone in making determinations. The commenters also noted that they would incur programming costs and additional staff training to incorporate this new method, and suggested that Federal financial participation be increased to 100 percent to account for these costs.

Response: The process for determining eligibility for the low-income subsidy is based on statutory provisions that specifically preclude States and SSA from using the more liberalized methodologies permitted under Medicaid for purposes of counting income. For counting resources, we acknowledge in the proposed rule that we could have permitted States to use the same resources standards that States employ under Medicaid for purposes of determining eligibility for Medicare Savings Programs, if such standards would not significantly increase the numbers of individuals who are eligible for the low-income subsidy. However, as we noted in the preamble to the proposed rule, we elected not to exercise this discretion since, as we noted in responses to previous comments, we believe national uniformity for purposes of eligibility determinations is a desirable goal.

For the suggestion that the Federal financial participation rate should be 100 percent, we note that we do not have the authority to change the Federal financial participation rate available to States. The statute specifies that States are to be reimbursed according to the normal Federal match for administrative costs, which is generally 50 percent.

Comment: Some commenters believe that it is unclear whether the Federal government will require subsidy applicants to show proof of Medicare enrollment in order to apply for the subsidy. If not, the commenters expect that States will have coordination problems, as they are reliant on periodic, and not real-time, data matches to assess Medicare enrollment.

Response: We are exploring options for States to verify Medicare eligibility if the applicant cannot provide proof.

Comment: Some commenters suggested that low-income subsidy applicants, no matter where they apply, should have the opportunity to be considered for full Medicaid eligibility. They suggest that the simplified application form should include an option for persons to have their application reviewed for Medicaid eligibility.

Response: The statute specifies that, in addition to determining eligibility for the low-income subsidy, States are directed to screen for eligibility for medical assistance programs for the payment of Medicare cost sharing, and to offer enrollment to eligible individuals for such programs. As a practical matter, we believe States will identify individuals with limited income and resources who may qualify for full Medicaid benefits as part of this process. In addition, it is important to emphasize that we are working with SSA to design a process to provide subsidy eligibility determinations to States for purposes of identifying individuals who apply at SSA and who may also qualify for a Medicare Savings Program in the State. We expect that States will use this information to contact individuals who may qualify for assistance with Medicare cost sharing and to assist them in the application process for the Medicare Savings Programs.

Comment: Some commenters suggest that the verification process for information provided on low-income subsidy applications should not impose an undue burden on applicants. They argue that the need to provide documentation of income and assets is one of the most significant barriers to enrollment in Medicare Savings Programs. They suggest that States should have access to SSA's automated systems to verify financial eligibility information for the low-income subsidy program. Further, States should only be permitted to ask for one bank statement and only in such cases where an applicant refuses to sign an authorization form to permit the eligibility worker to obtain the information directly from the financial institution. Some commenters also suggest that documentation should be produced as a last possible resort.

Response: Individuals will not have to bring volumes of information with them when they apply using the SSA application process. The simplified application developed by SSA, in consultation with CMS, is based on the principle of self-attestation. While some information may be requested from applicants on an exception basis, based on responses to certain questions or based on inconsistencies from electronic data matches, the majority of applicants will not need to provide additional information beyond what is submitted and attested to in the application form.

As we have indicated in other responses, we recommend that States encourage and assist applicants in applying for the low-income subsidy using the SSA application (that is, assist applicants in completing the SSA application and forward it to the SSA to make the determination). In such cases, SSA would verify income and resources for the low-income subsidy utilizing its automated systems. For individuals who prefer a ''State'' rather than ''SSA'' determination, we encourage States to use an application form similar to the

one utilized by SSA and also to find ways to streamline the verification process by utilizing electronic data matches to the greatest degree possible. However, we recognize that States may not be able to achieve the same verification process utilized by SSA. This may encourage some applicants to apply using the SSA process rather than the State process.

Comment: Some commenters encourage CMS and SSA to retain the strategy to devise a uniform application that reflects uniform eligibility requirements. The commenters suggest that the application be designed to serve as the Medicare Savings Program application and full Medicaid application as well. The commenters also suggest that the combined form should reflect our proposed definition of countable assets in § 443.772 and be at least as streamlined as the model Medicare Savings Program application adopted by CMS and States. The commenters assert that the draft SSA application includes questions on life insurance, burial accounts, in-kind support and maintenance, and transfers of assets that do not appear on the model Medicare Savings Program application.

Response: While nothing prevents a State from developing a special addendum to the low-income subsidy application to address questions specific to Medicaid or Medicare Savings Programs eligibility, the application for the low-income subsidy program must reflect the definition of countable income and resources outlined in this final rule. For reasons we have previously explained, the definition of income and resources used for purposes of the low-income subsidy program could vary from the definitions used by State Medicaid programs for purposes of determining eligibility for full Medicaid or for programs that provide assistance with Medicare cost sharing. Some States may use more liberalized methodologies than the basic SSI statutory rules for counting income and resources, on which the low-income subsidy application is based. For these reasons, questions on life insurance, burial accounts, and in-kind support and maintenance need to be clearly articulated in the application in order to determine income and resources for the low-income subsidy. Questions regarding transfers of assets for less than fair market value will not be included on the application as we do not believe that penalties associated with such transfers are appropriate when counting resources for the low-income subsidy.

Comment: A few commenters suggest that § 423.774 be strengthened and revised to ensure that eligible older adults and persons with disabilities remain enrolled in the low-income subsidy from year to year. They suggest that we rewrite the final rule to define the eligibility period as one year, regardless of which entity made the determination. They argue that the statute and Congressional intent support an interpretation giving the Secretary of HHS the authority to determine the term of the eligibility determination period and the Commissioner and the States the authority to determine the manner in which redetermination or appeals are made. They argue that redeterminations in this context are meant to convey reconsiderations, not renewals of eligibility. Commenters further suggest the Secretary use his discretion to establish an annual, passive reenrollment process that would apply regardless of whether the initial determination was made under a State Medicaid plan or by the Commissioner of SSA. They suggest that the process should entail the use of a pre-printed renewal post-card with instructions to return the card only if there are corrections about eligibility status.

Response: We do not agree that we have the discretion outlined by the commenter. Consistent with the statute, the proposed and final regulations state that the initial determination is effective for up to a year. Thereafter, the timing of redeterminations of eligibility depends on which entity processed the application. If SSA processed the application, SSA will determine the manner and frequency of the redetermination. If a State processed the application under its own subsidy eligibility determination system, the manner and frequency of a redetermination will be consistent with how the State redetermines eligibility for Medicaid.

Comment: One commenter questioned whether the proxy signature process discussed in the preamble meant that we are relaxing its requirement for signatures on applications.

Another commenter suggested that the regulation clearly set limits as to how telephonic proxy designations are made and acted upon. Also, proxy certification should only apply to the accuracy of the proxy's transcription, and not to the accuracy of the underlying information.

Response: Under a proxy signature process, an applicant verbally attests under penalty of perjury that the information provided in an application is correct and valid. As specified in the preamble to the proposed rule, we permit the use of proxy signatures for the low-income subsidy application. SSA plans to use a proxy signature for the application it is developing to allow individuals to attest to their income and resources when applying over the telephone and Internet. If States develop their own application, we encourage them to consider a similar signature proxy process. We do not agree that we need to provide further specificity in the regulation on this issue. This process does not alter our position on requirements for signatures in any other contexts.

Comment: Some commenters suggest that the Commissioner of SSA should handle all appeals in order to ensure uniformity in the appeals process. One commenter suggested that requiring the States to handle Medicare appeals would require an investment in additional staff and resources and represent an unfair burden on States because only one-half the costs would be covered by the Federal government. Another commenter recommends that the redetermination and appeals process be consistent among SSA and Medicaid agencies to eliminate confusion among applicants.

A few other commenters request clarification in the final rule as to whether fair hearing rights under State Medicaid programs apply to adverse eligibility or renewal decisions made by the State. Similarly, they request clarification as to whether decisions made by the State or SSA to reduce or terminate a subsidy upon renewal triggers continued coverage at the pre-reduction levels pending the appeal. One commenter argued that this right derives from Supreme Court precedent which established the absolute right to a pre-determination hearing pending the loss of welfare of Medicaid benefits.

Response: Appeals of subsidy eligibility determinations will be handled by the entity that made the underlying decision. If SSA processed the initial application or redetermination, SSA will handle the appeal based on procedures established by the Commissioner. If a State processed the application or redetermination, the appeal will be consistent with the process the State uses for appeals under Medicaid. Consistent with the statute, States will receive normal administrative match for activities associated with appeals of eligibility for the low-income subsidy.

For the question of continued coverage, we agree with the commenter that decisions made by the State or SSA to reduce or terminate a subsidy would trigger a right to continued coverage at the pre-reduction levels pending the appeal. This is based on the fact that the subsidy program, unlike the Medicare

drug benefit itself, is a needs-based program. This is also consistent with how States process appeals under Medicaid.

Comment: Some commenters assert that there should be a provision for prompt reconsideration of a subsidy eligibility determination for beneficiaries who believe that they have been erroneously denied eligibility or approved for the wrong subsidy category.

Other commenters suggest that we need to clarify that all aspects of subsidy determinations, including eligibility, calculation of subsidy or copayment categories, the premium subsidy amount, or the amount of any late enrollment penalty, are subject to appeal.

Response: As indicated earlier, subsidy eligibility determinations or appeals are acted upon by the entity that made the underlying decision. We will be implementing operational guidance regarding when someone does not agree with the premium subsidy amount or late enrollment penalty.

4. Premium Subsidy (§ 423.780) and Cost-Sharing Subsidy (§ 423.782)

In accordance with section 1860D–14 of the Act, the proposed regulations specified the Part D premium subsidy and the Part D cost-sharing subsidy amounts available to subsidy eligible individuals, with the specific subsidy amounts varying depending upon the individual's income and resources/assets level.

a. Full Subsidy Eligible Individuals

In accordance with section 1860D–14(a)(1)(A) of the Act, full subsidy eligible individuals are entitled to a full premium subsidy equal to 100 percent of the ''premium subsidy amount,'' not to exceed the monthly beneficiary premium for a Part D plan (other than an MA-PD plan) offering basic prescription drug coverage, that portion of the monthly beneficiary premium attributable to basic prescription drug coverage for a Part D plan (other than an MA-PD plan) offering enhanced alternative coverage, or the MA monthly prescription drug beneficiary premium (as defined in section 1854(b)(2)(B) of the Act) for a MA-PD plan selected by the beneficiary.

Under section 1860D–14(b)(2) of the Act, the premium subsidy amount for a PDP region is equal to the greater of the low-income benchmark premium or the lowest monthly beneficiary premium for a prescription drug plan that offers basic prescription drug coverage in the region. Further, under section 1860D–14(b)(2) of the Act, the low-income benchmark premium amount for a PDP region equals either the weighted average of the monthly beneficiary premiums for all basic prescription drug plans (if all prescription drug plans in the PDP region are offered by the same PDP sponsor), or if the PDPs in the region are offered by more than one PDP sponsor, the weighted average of (i) the monthly beneficiary premiums for all PDPs in the region (including any fallback plans) consisting of basic prescription drug coverage, (ii) the monthly beneficiary premiums attributable to basic prescription drug coverage for all PDPs in the region offering alternative prescription drug coverage, and (iii) the MA monthly prescription drug beneficiary premium for MA-PD plans. Because section 1860D–14(b)(2)(A)(ii) of the Act references section 1851(a)(2)(a)(i) of the Act, the premiums of cost plans under section 1876 of the Act, PACE plans, and private fee-for-service plans are excluded for purposes of determining the weighted average in the region. This is because section 1851(a)(2)(a)(i) of the Act refers only to MA coordinated care plans.

Table P–I below is an illustration of the premium subsidy determination.

TABLE P–1
DETERMINATION OF THE PREMIUM SUBSIDY AMOUNT

Plan Options in Region		Low-Income Premium Subsidy (Full)		
Plans	Monthly Beneficiary Premium 1	Percentage of Part D enrollees in each plan 2	Premium times Percentage (weighted average)	Maximum Premium Subsidy for Eligible Individual Enrolling in Plan
PDP 1 Offered by Sponsor A	40.00	15%	6.00	36.00
MA-PD Plan 1	38.00	5%	1.90	36.00
PDP 2 Offered by Sponsor B	36.00	40%	14.40	36.00
MA-PD Plan 2	20.00	15%	3.00	20.00
MA-PD Plan 3	0.00	25%	0.00	0.00
Weighted Average Basic Premium in Region =			25.30	

The greater of the Low Income Premium Benchmark Amount (25.30) or the lowest PDP premium in the region (36.00) equals 36.00, so the maximum premium subsidy is the lower of 36.00 or the actual plan premium for basic coverage.

1 Assumes no supplemental premium or late enrollment penalties, and for MA-PD plans, any reduction in premium due to application of a credit against the premium of a rebate under 42 CFR 422.266(b).

2 Assumes enrollment weights from the prior year's reference month (not first year of program)

Table P–1 illustrates the determination of the premium subsidy amount in a hypothetical region in which there are 2 PDPs, each offered by different sponsors, and 3 MA-PD plans. Because there are PDPs offered by more than one sponsor, the maximum premium subsidy amount is the greater of 2 amounts: the low-income premium benchmark amount or the lowest PDP premium in the region. The former is calculated by summing the products of the plan monthly beneficiary premium for basic prescription drug coverage and the plan percentage of Part D enrollment in the region, and equals $25.30. The lowest monthly beneficiary premium for a PDP in the region, however, is $36.00. Therefore, in this exhibit, the full monthly premium subsidy amount for the region is determined to be $36.00. Consequently, a full subsidy eligible individual would have a choice of 3 zero-premium plans in which to enroll

(PDP 2, MA-PD plan 2, and MA-PD plan 3), because the maximum premium subsidy amount equals or exceeds the monthly beneficiary premiums for these plans. However, if a full subsidy eligible individual chose to enroll in PDP 1 or MA-PD plan 1 , he or she would be obligated to pay the difference between the plan premium and the premium subsidy amount ($4 or $2, respectively) each month.

We also stated in the proposed rule that fallback plan premiums would be treated the same as those for risk-bid plans in the calculation of the low-income benchmark premium amount.

In accordance with section 1860D–14(b)(2) of the Act, the low-income benchmark premium amounts are determined without the addition of any amounts attributable to late enrollment penalties.

Individuals eligible for the full premium subsidy who are subject to late enrollment penalties under proposed § 423.46 would also be entitled to an additional subsidy equal to 80 percent of any late enrollment penalty for the first 60 months in which the penalties are imposed, and 100 percent of any penalties in any subsequent month, in accordance with section 1860D–14(a)(1)(A)(ii) of the Act and proposed § 423.780(c).

Section 423.782 of the proposed rule incorporates the provisions of sections 1860D–14(a)(1)(B), 1860D–14(a)(1)(C), 1860D–14(a)(1)(D), and 1860D–14(a)(1)(E) of the Act relating to the elimination of the deductible, continuation of coverage above the initial coverage limit (that is, no coverage gap), and reductions in cost-sharing. Specifically, full subsidy eligible individuals have no deductible. In addition, these individuals have continuation of coverage from the initial coverage limit (under paragraph (3) of section 1860D–2(b) of the Act and § 423.104(d)(5)) through the out-of-pocket threshold (under paragraph (5) of the same section and § 423.104(d)(5)(iii)). In other words, there is no coverage gap, for these individuals and Medicare pays for the full benefit once the catastrophic level is reached. In addition, the cost-sharing subsidies paid by CMS under this subpart will count toward the application of the out-of-pocket threshold.

In accordance with section 1860D–14(a)(1)(D)(i) of the Act, institutionalized full-benefit dual eligible individuals have no cost-sharing below, or above, the out-of-pocket threshold. We proposed to define ''institutionalized individual'' for this subpart as a full-benefit dual eligible individual who is an institutionalized individual as defined in section 1902(q)(1)(B) of the Act.

Under section 1860D–14(a)(1)(D)(ii) of the Act, non-institutional full-benefit dual eligible individuals in 2006 with incomes that do not exceed 100 percent of the Federal poverty line for their family size will pay no more than $1 for generic drugs or preferred drugs that are multiple source drugs (as defined in section 1927(k)(7)(A)(i) of the Act),$3 for any other drug, or, if less, the amount charged to other full subsidy eligible individuals (other than institutionalized full-benefit dual eligible individuals) for costs below the out-of-pocket threshold. These $1 and $3 copayment amounts are increased beginning in 2007 by the percentage increase in the CPI (all items, U.S. city average), rounded to the nearest multiple of 5 cents.

In accordance with section 1860D–14(a)(1)(D)(iii) of the Act, all other full subsidy eligible individuals and full-benefit dual eligible individuals with income above 100 percent of the FPL for their family size in 2006 will pay copayment amounts of $2 for a generic drug or preferred drugs that are multiple source drugs (as defined in section 1927(k)(7)(A)(i) of the Act) and $5 for any other drug, for costs up to the out-of-pocket threshold. In accordance with section 1860D–2(b)(4) and 1860D–2(b)(6) of the Act, these copayments are indexed based on an annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of 5 cents (see § 423.104(e)(5) of this proposed rule).

In the proposed rule we noted that a question had been raised concerning whether an MA-PD plan could choose to reduce or eliminate copayments for full-benefit dual eligible individuals. We stated that specialized MA plans (under section 231 of the MMA, as defined in proposed Title II regulations at § 422.2) offering benefits only to dual eligible individuals could choose to reduce or eliminate copayments for their members as a supplemental benefit. Otherwise, the Part D copayments stipulated by the MMA for low-income individuals cannot be reduced or eliminated. This is because any reduction of the copayments must apply to all plan members under the uniformity of benefits provisions, set forth in § 423.265(c) of the proposed rule. Accordingly, MA-PD plans other than special MA-PD plans for dual eligibles may not offer their members who are dual eligible lower co-payments or co-insurance than those paid by its other plan members.

b. Other Low-Income Subsidy Eligible Individuals

In accordance with section 1860D–14(a)(2)(A) of the Act, for other low-income subsidy eligible individuals who do not qualify for the full subsidy, we proposed and in the final rule set a scale for the premium subsidy in a stepped fashion. The sliding scale premium subsidy will range from 100 percent of the benchmark premium amount for individuals at or below 135 percent of the FPL for their family size, to no subsidy for individuals at 150 percent of the FPL for their family size. In contrast to full subsidy eligible individuals, other low-income subsidy eligible individuals subject to the late enrollment penalties under § 423.46 will be responsible for 100 percent of the penalties. In the proposed rule we invited comments concerning the manner in which the sliding scale premium subsidy would be calculated for individuals with income from 135 percent up to 150 percent of the FPL for their family sizeOther low-income subsidy eligible individuals will have their annual deductible reduced from $250 to $50 in 2006. This $50 is indexed to grow in accordance with section 1860D–2(b)(6) of the Act beginning in 2007 based on the annual percentage increase in average per capita aggregate expenditures for Part D drugs, rounded to the nearest multiple of $1. Other subsidy eligible individuals will have continuation of coverage from the initial coverage limit (under paragraph (3) of section 1860D–2(b) of the Act and 423.104(d)(4) through the out-of-pocket threshold (under paragraph (4) of that section and 423.104(d)(5)), meaning no coverage gap or ''donut hole.'' For coverage through the out-of-pocket threshold, these individuals would pay cost sharing that would not exceed the 15 percent coinsurance, substituting for the higher beneficiary coinsurance described in section 1860D–2(b)(2) of the Act (see § 423.104(d)(2) of this proposed rule). The cost-sharing subsidies will count toward the application of the out-of-pocket threshold. After the out-of-pocket threshold is reached, these individuals' cost-sharing will be limited to the copayment or coinsurance amount specified under section 1860D 2(b)(4)(A)(i)(I) of the Act (see § 423.104(d)(5)), which, in 2006, means co-payment amounts of $2 for a generic drug or preferred multiple source (as defined in section 1927(k)(7)(A)(i) of the Act) and $5 for any other drug. In accordance with sections 1860D–2(b)(4) and 1860D–2(b)(6) of the Act, the $2 and $5 copayments will be indexed based on

an annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of 5 cents.

- Premium Subsidy (§ 423.780)

Comment: Some commenters were interested in what types of data interfaces we envisioned so that States would know coverage details.

Response: We are working through the data system requirements and will address these issues in further operational guidance.

Comment: Several commenters requested clarification on how we plan to arrive at the weighted average required to calculate the premium subsidy amount for a given region. Some were concerned that the term ''weighted average'' is not defined in the context of calculating the low-income premium benchmark.

Response: In response to public comment on this methodology, we are including new language in regulatory text to clarify our policy on how the weighted average will be determined for the low-income benchmark premium. We intend to use the same methodology for determining the weighted average for the low-income premium benchmark as is used in § 423.279(b) for determining the weighted average for the national average monthly bid amount. The low-income benchmark premium amount for a region is a weighted average of the monthly beneficiary premiums for plans, with the weight for each plan equal to a percentage with the numerator equal to the number of Part D eligible individuals enrolled in the plan in the reference month (as defined in § 422.258(c)(1)) and the denominator equal to the total number of Part D eligible individuals enrolled in all Part D plans in a PDP region included in the calculation of the low-income benchmark premium amount in the reference month.

For purposes of calculating the low-income benchmark premium amount for 2006, we assign equal weighting to PDP sponsors (including fallback entities) and assigns MA-PD plans a weight based on prior enrollment. New MA-PD plans are assigned a zero weight. Again, PACE, private fee-for-service plans and 1876 cost plans are not included.

Comment: One commenter recommends that PDP premium amounts be regulated to ensure that subsidy eligible individuals may enroll in any PDP and be assured a fully subsidized premium. Another commenter suggested that full- benefit dual eligible individuals not pay additional amounts over the premium subsidy amount. The commenter argued that if a dual enrolls with a higher premium plan, that is the fault of the enrollment system. Another commenter also suggests that CMS or the Part D plans provide clear notice to consumers about set premium standards, ''benchmark premiums,'' so consumers can evaluate plans with full understanding of their premium options and liability.

Response: We disagree with the first two comments. Subsidy eligible individuals, including full subsidy eligible individuals, may choose to pay a higher premium in order to enroll in the Part D plan of his or her choice, and we do not have the authority under the statute to limit these individuals' choices. The Part D plan with the higher premium may provide a richer benefit package that better meets the individual's prescription needs than other plans. We will ensure that beneficiaries are provided complete information in which to evaluate their options, including understanding premium liability, if any.

Comment: Several commenters requested certain clarifications in the regulations regarding American Indian and Alaska Native (AI/AN) Medicare beneficiaries. The Indian Health Service (IHS), Indian Tribes and Tribal organizations, and urban Indian organizations (collectively, I/T/Us) provide various services and other benefits to AI/ANs, including operating pharmacies and sometimes paying premiums, cost sharing, and similar charges for those AI/ANs who are eligible for various public and private health insurance and health care programs. Commenters requested that the regulations clarify that I/T/U pharmacies may pay Part D premium amounts, either in full for non-subsidy eligibles, or amounts remaining after application of low-income subsidies, for AI/AN Medicare beneficiaries that they also serve.

Response: The clarification requested by the commenters is a matter for the Indian Health Service rather than for CMS and we therefore will not address this issue in this regulation.

Comment: Commenters asked for clarification in the regulations as to how the requirement to apply the ''greater'' premium calculation (for example, premium subsidy amount) options will be applied and enforced.

Response: We are working through the data system and collections requirements and will address these issues in further operational guidance.

Comment: Some commenters requested clarification about the linear sliding scale for the premium subsidy and whether this will be for ranges of percentages of the Federal poverty level or by individual percentages. The commenters prefer the simplest methodology to implement the scale and request guidance from us on how this should be calculated. We received comments suggesting that there should be as few as possible different premiums reductions for low-income beneficiaries between 135 percent and 150 percent of FPL (that is, as few ''steps'' as possible). Commenters said the administrative burden of tracking and implementing a multitude of different premiums for these other low-income beneficiaries would vastly outweigh any perceived equity achieved by setting the premium in many steps carefully calibrated to relate directly to the individual's income level.

Response: We requested comments on this issue and had proposed the breakdown be in 5 percent increments. Given the comments received, we will be implementing the sliding scale premium in four groups as follows: beneficiaries with incomes at 135 percent of the FPL will receive a 100 percent premium subsidy; beneficiaries with income greater than 135 percent but at or below 140 percent of the Federal poverty level will receive a 75 percent premium subsidy; beneficiaries with incomes greater than 140 percent but at or below 145 percent of Federal poverty level will receive a 50 percent premium subsidy; and beneficiaries with incomes greater than 145 percent but below 150 percent of Federal poverty level will receive a 25 percent premium subsidy.

Comment: One commenter indicated that there should be no late penalty, or at most a minimum late penalty, if an SPAP is paying for an individual's premiums for Part D.

Response: We do not have the legal authority to make the changes requested by this commenter. In addition, SPAPs are not obligated to pay a late penalty fee on behalf of the subsidy eligible individual.

Comment: Some commenters requested that the premium subsidy for any late enrollment penalty should be 100 percent for at least the first year in which a beneficiary is enrolled in the Part D program.

Other commenters argued that imposing any late enrollment premium penalties on individuals eligible for the low-income subsidies is overly punitive. They suggested that we delay the late enrollment penalties for those eligible for the low-income subsidies or waive any late enrollment penalties for this population.

Some commenters suggested that we should allow the 100 percent subsidy of

the late enrollment penalty as soon as a beneficiary becomes eligible for the full premium subsidy just as it now proposes to do after month 60.

Comments were also received requesting that the reduced late enrollment penalty under § 423.780(c) apply for beneficiaries for whom SPAPs pay premium costs, including the late enrollment penalties.

Response: We recognize the concern of the commenters for the needs of low-income beneficiaries. However, this change would require a legislative change as § 1860D–14(a)(1)(A) of the Social Security Act requires late enrollment penalties. Section 1860D–13(b) of the Act imposes the same late penalty on all beneficiaries; section 1860D–14(a)(1)(A)(ii) of the Act however, provides that full subsidy eligible individuals will only be responsible for paying 20 percent of any late enrollment penalty imposed for the first 60 months during which these beneficiaries are enrolled in a Part D plan and no late enrollment penalty thereafter. Late enrollment penalties for full subsidy eligible individuals enrolled in SPAPs are subsidized in the same manner as full subsidy eligible individuals who are not enrolled in an SPAP.

Comment: Some commenters asked for operational clarification as to how we will determine that the enrollee is subject to a late enrollment penalty. Clarification was requested as to who will ask for information and documentation; how the information would get to us; and, how the enrollee can question or appeal the imposition of the penalty.

Response: We will issue further operational guidance on these processes.

- Cost-sharing subsidy (§ 423.782)

Comment: Many commenters expressed concern that the cost-sharing requirement would impose a burden on full-benefit dual eligible individuals and were particularly concerned that a beneficiary could be forced to choose between paying for medications and meeting other needs. Under the Medicaid statute, an individual cannot be denied medication for failure to pay a copayment, and commenters urged inclusion of the same standard for full-benefit dual eligible individuals under the Medicare prescription drug program.

Response: Requiring providers to give prescriptions to individuals who cannot meet copayment requirements would necessitate a legislative change because the MMA does not include the same prohibition that is contained in the Medicaid statute. Therefore, we are unable to make this recommended change.

We note that institutionalized full-benefit dual eligible individuals have no cost-sharing responsibilities. For the remaining full-benefit dual eligible individuals with income below 100 percent of the Federal poverty level, the law specifies a ceiling in 2006 of copayments that do not exceed $1 for a generic drug or a preferred drug that is a multiple source drug, and $3 for any other drug. Copayment amounts are increased on an annual basis from these base amounts, as required by § 1860D–14(a)(4)(A) of the Act.

Additionally, under the law, specialized MA plans offering drug benefits to dual eligible individuals and pharmacies may exercise the option of reducing or eliminating copayments for dual eligible beneficiaries. Alternatively, States may elect to pay such copayments on behalf of these individuals.

Specifically, specialized MA plans (as defined in § 1859(b)(6) of the Act) offering benefits only to dual eligible individuals may choose to reduce or eliminate copayments for their members as a supplemental benefit. For all other plans, Part D copayments cannot be reduced or eliminated for dual eligible individuals by a non-specialized MA-PD plan unless reduced or eliminated for all other plan enrollees. However, we note that sections 1894(b)(1)(A)(i) and 1934(b)(1)(A)(i) of the Act preclude beneficiary cost sharing, including copayments, for PACE enrollees. We have included discussion of the conflicting MMA and PACE statutory copayment provisions in subpart T preamble language of this regulation.

Further, pharmacies may also waive or reduce cost-sharing requirements on behalf of a subsidy eligible individual, provided the waiver is not offered as part of any advertisement or solicitation, as specified in section 1128(B)(3) of the Social Security Act, as amended by section 101(e)(2) of the MMA.

Finally, the new Medicare drug benefit will replace significant State spending on dual eligible individuals' drug costs. States, in turn, may choose to use State dollars to pay for cost-sharing and provide supplemental drug coverage, although they will not receive a Federal match under Medicaid if they choose to do so.

Comment: One commenter questioned whether reduction of cost-sharing obligations by specialized MA plans (using premium rebate dollars) violates the uniformity of benefits provision.

Response: The reduction of cost-sharing obligations by specialized MA plans does not constitute a violation of the uniformity of benefits provision in the law, as long as the reduction is applied uniformly to all enrollees in the plan.

Comment: One commenter requested, for full-benefit dual eligible individuals, clearer guidance on ensuring that plans are providing the lesser of a copayment amount of $1 for a generic drug or preferred multiple source drug of $3 for any other drug, or the amount charged to other individuals with income below 135 percent of the FPL and resources not greater than 3 times the amount an individual may have and still be eligible for benefits under the SSI program. Specifically, the commenter requested guidance on dealing with noncompliance by plans and ensuring that non-institutionalized dual eligibles are informed of this provision.

Response: The regulation does clarify the first point raised by the commenter. In addition, we are currently working on an oversight process for noncompliance and will release further operational guidance on this issue.

Comment: One commenter suggested that adjustments made to cost-sharing amounts be rounded down to the nearest multiple of 5 cents or 10 cents (of the percentage increase in CPI), rather than rounded upward. The commenter cites that it is illogical to round upward and charge consumers more than their estimated spending limit.

Response: Rounding downward to the nearest multiple of 5 cents or 10 cents for any adjustment made to cost-sharing amounts would necessitate a legislative change because the methodology for making adjustments is stated in § 1860D–14(a)(4)(A)(ii) of the Social Security Act as ''adjustments in $1 and $3 cost-sharing amounts be rounded to the nearest multiple of 5 cents and 10 cents, respectively.'' Therefore, this change cannot be adopted.

Comment: One commenter sought clarification on the definition of out-of-pocket limits/thresholds, particularly if subsidy eligible are subject to copayments after reaching the out-of-pocket limit.

Response: For 2006, the premium and cost-sharing subsidy amounts for various subsidy eligible groups are as follows (Preamble, subpart P, Table P–2):

For 2006, the premium and cost-sharing subsidy amounts for various subsidy eligible groups are as follows (Table P–2):

FPL & Assets	Percentage of Premium Subsidy Amount (1)	Deductible	Copayment up to out-of-pocket limit	Copayment above out-of-pocket limit
Full-benefit dual eligible—institutionalized individual	100%*	$0	$0	$0
Full-benefit dual eligible– Income at or below 100% FPL (non-institutionalized individual)	100%*	$0	The lesser of: (1) an amount that does not exceed $1- generic/preferred multiple source and $3–other drugs, or (2) the amount charged to other full subsidy eligible individuals who are not full-benefit dual eligible individuals or whose incomes exceed 100% of the FPL	$0
Full-benefit dual eligible– Income above 100% FPL (non-institutionalized individual)	100%*	$0	An amount that does not exceed $2-generic/preferred multiple source and $5–other drugs	$0
Non-full benefit dual eligible beneficiary with income below 135% FPL and with assets that do not exceed $6,000 (individuals) or $9,000 (couples)	100%*	$0	An amount that does not exceed $2–generic/preferred multiple source and $5–other drugs	$0
Non-full benefit dual eligible beneficiary with income below 135% FPL and with assets that exceed $6,000 but do not exceed $10,000 (individuals) or with assets that exceed $9,000 but do not exceed $20,000 (couples)	100%*	$50	15% coinsurance	An amount that does not exceed $2–generic/preferred multiple source drug or $5–other drugs
Non-full benefit dual eligible beneficiary with income at or above 135% FPL but below 150% FPL, and with assets that do not exceed $10,000 (individuals) or $20,000 (couples)	Sliding scale premium subsidy (100%-0%) See attached chart	$50	15% coinsurance	An amount that does not exceed $2–generic/preferred multiple source drug or $5–other drugs

(1) Premium subsidy amount as defined in § 423.780(b)

*The percentage shown in the table is the greater of the low income benchmark premium amount or the lowest PDP premium for basic coverage in the region.

For 2006, the sliding scale premium and cost-sharing subsidy amounts for other subsidy eligible individuals are as follows:

FPL & Assets	Percentage of Premium Subsidy Amount(1)
Income at 135% FPL, and with assets that do not exceed $10,000 (individuals) or $20,000 (couples)	100%
Income above 135% FPL but at or below 140% FPL, and with assets that do not exceed $10,000 (individuals) or $20,000 (couples)	75%
Income above 140% FPL but at or below 145% FPL, and with assets that do not exceed $10,000 (individuals) or $20,000 (couples)	50%

FPL & Assets	Percentage of Premium Subsidy Amount(1)
Income above 145% FPL but below 150% FPL, and with assets that do not exceed $10,000 (individuals) or $20,000 (couples)	25%

(1) Premium subsidy amount as defined in § 423.780(b)

Comment: One commenter requested that MA organizations be allowed to obtain OIG advisory opinions that expressly permit them to reduce or waive premiums and cost-sharing for low-income members enrolled in MA plans.

Response: The law does not permit general/nonspecialized MA organizations to reduce or waive premiums and cost-sharing because these actions will violate bid integrity and uniform premium requirements.

Comment: A few commenters questioned whether a non-specialized MA plan can reduce cost sharing for its enrollees, as long as the reduction applies uniformly to all of its enrollees.

Response: The reduction would be classified as a supplemental benefit and cannot be included in the basic bid. The non-specialized MA plan may buy down the supplemental premium with beneficiary or rebate dollars. Reduction through the use of subsidy dollars is prohibited and inclusion of reduction costs in the basic bid or in allowable costs for purposes of reinsurance or risk sharing is also not permitted.

Comment: One commenter requested specification that plans cannot use an alternative benefit design to charge cost-sharing to low-income beneficiaries that exceeds the amounts set out in the regulation.

Response: Plans may not use alternative benefit designs to charge cost-sharing that exceeds the applicable $1/$3 and $2/$5 amounts set in the law. In the case of the other subsidy eligible individuals, they may not be charged cost sharing that exceeds 15 percent coinsurance for covered part D drugs obtained between the deductible and out-of-pocket threshold. The Part D plans may establish an alternative cost sharing structure with cost-sharing tiers based on an expected coinsurance of 25 percent. If a subsidy eligible individual enrolls in the plan with an alternative cost sharing structure, the beneficiary is responsible for the cost-sharing under the plan for a particular drug up to 15 percent, with our paying the difference if any. For example, if under a plan a covered part D drug has coinsurance of 10 percent, the beneficiary is responsible for the full 10 percent. If under a plan a covered part D drug has coinsurance of 20 percent, the beneficiary is responsible for 15 percent and CMS for 5 percent, provided this design is actuarially equivalent.

5. Administration of Subsidy Program (§ 423.800)

In the proposed rule we discussed establishing a process to notify the Part D sponsor that an individual is both eligible for the subsidy and the amount of the subsidy. Because we had not yet developed such a process, comments were invited concerning notification to the Part D sponsor that an individual is eligible for a subsidy and the amount of the subsidy.

Similarly, we requested comments on the proposed requirement that the Part D sponsor notify us that premiums or cost-sharing have been reduced and the amount of the reduction. We were also considering the process for reimbursing the Part D sponsor for the amount of the premium or cost-sharing reductions. Finally, we requested comments on how to best reimburse subsidy eligible individuals for out-of-pocket costs relating to excess premiums and cost-sharing incurred before the date the individual was notified of his or her subsidy eligibility but after the effective date the individual became a subsidy eligible.

We also requested comments on how to deal with premiums and cost sharing paid by charities or other programs, for example, the Ryan White program or State Pharmacy Assistance Programs, on behalf of an individual during a period when he or she is determined to be subsidy eligible. We specifically requested comments on whether Medicare should treat these programs for purposes of premium or cost sharing reimbursement as we would other employer-sponsored insurance programs in which Medicare is a primary payer for purposes of coordination of benefits. In addition, we requested comments on whether beneficiaries should be responsible for reimbursing any cost sharing or premiums paid on their behalf by another program or charity.

In accordance with section 1860D–14(c)(2) of the Act, reimbursement to Part D plans may be computed on a capitated basis, taking into account the actuarial value of the subsidies and with appropriate adjustments to reflect differences in the risks actually involved. (Refer to Subpart G of this rule for a discussion of interim payments and final reconciliation payments.)

Subsidy amounts under section 1860D–14 of the Act are counted toward the out-of-pocket threshold at section 1860D–2(b)(4)(C)(ii) of the Act. Part D plans will be responsible for tracking the application of the low-income subsidy amounts as described in § 423.100.

Comment: Many commenters expressed concern about the lack of a specified timeframe in which we must notify plans that enrollees are eligible for a subsidy, raising concerns that if there were lengthy periods between enrollment in a Part D plan and notification of subsidy eligibility, low-income beneficiaries would have to pay prohibitive costs and they may not use their Part D benefits. Some commenters suggested that we be required to notify plans within 24 hours after an application for the subsidy is approved. One commenter suggested that we should provide a daily tape match to Part D plans that provides the low-income subsidy enrollee identifier. One commenter expressed concern about retroactive determinations of low-income subsidy eligibility and the burden this could place on a MA organization that would have to refund premium and cost-sharing amounts paid by a member before either the member or the MA organization was informed of the member's low-income subsidy eligibility. The commenter suggested that we limit the period of retroactivity of low-income subsidy eligibility determination to no more than three months. One commenter asked for specific guidance on the data exchange requirements for a Part D plan. One commenter believed that the proposed rule did not adequately explain how Part D plans are to determine which beneficiaries are enrolled in the low-income subsidy. One commenter asked if the notification of the Part D plan would occur after a full-benefit dual eligible individual enrolls in a plan. Finally, one commenter asked if we could also notify SPAPs when notification is sent to Part D plans about low-income subsidy eligibility.

Response: We do not have authority to direct SSA to determine an individual's eligibility for the low-income subsidy within a given time period. In further operational guidance,

we will work with States to ensure timely State determinations of subsidy eligibility. As general guidance, we expect that States will determine subsidy eligibility within time periods that are at least consistent with the processing of State Medicaid applications. Retroactive eligibility is only an issue if an individual is enrolled in a Part D plan, and subsequently applies for and is determined eligible as a full-benefit dual eligible individual. For instance, if an individual is enrolled in a Part D plan and decides not to apply for the low-income subsidy, he or she may have retroactive subsidy eligibility if the individual later qualifies for Medicaid. By virtue of being entitled to full benefits under Medicaid, the individual will automatically be eligible for the low-income subsidy. In this case, subsidy eligibility will extend back to the start date of Medicaid eligibility, which could be three months earlier if the individual would have qualified for Medicaid during the three-month retroactive period. In such cases, the individual will be reimbursed for the extra cost sharing he or she otherwise would not have paid as a full subsidy eligible individual. This would also apply to individuals under a Medicare Savings Program as a SLMB or QI (but not as a QMB, because QMBs cannot receive retroactive benefits under the Medicaid statute). In further operational guidance, we will specify how these reimbursements will be made. For QMBs and other individuals who are enrolled in a Part D plan, and later apply and are determined eligible for low-income subsidy assistance, consistent with the statute, their eligibility would be effective on the first day of the month in which they applied for the low-income subsidy.

We will address the method of notification of Part D plans and will explore issues involving notification to SPAPs in future operational guidance.

Comment: Two commenters suggested the need for additional clarification about the manner in which plans must notify us on the amount of the subsidy reductions received by beneficiaries. One of these two commenters suggested we provide a methodology while the other commenter suggested that Part D sponsors have up to 60 days to inform us that the reduction in premium and cost-sharing has been implemented and that implementation should be effective no later than the first day of the second month following the month in which the low-income determination was sent by us to the Part D sponsor. The commenter further suggested that there should not be any special or separate notice that the Part D sponsor must send to CMS to indicate that the reduction in premium or cost-sharing has been implemented noting that this notification will be part of the monthly membership transaction file that Part D providers send to us.

Response: We will issue further operational guidance on the notification methodology that Part D plans must use. However, we will expedite notification to plans that its enrollee is a subsidy eligible individual. In addition, we similarly expect Part D plans to confirm that the reductions in premiums and cost-sharing have been implemented by plans in a timely fashion.

Comment: One commenter expressed concern that the rule does not explain how reimbursements will be made to Part D plans. Another commenter expressed concern that pharmacies will impose the cost-sharing reduction at the point-of-sale for low-income subsidy individuals. The commenter suggested we develop an explicit regulatory requirement to ensure such reductions occur at the point-of-sale. The commenter suggested we add a pass-through requirement to the final regulation.

Response: This comment is addressed by the regulation at § 423.329(d)(2). The interim payments referenced in section § 423.329(d)(2)(i) are made in anticipation of low income subsidies that will reduce beneficiary cost-sharing at the point of sale. The final payments in § 423.329(d)(2)(ii) will reimburse plans for adjustments made at the point of sale. There is no need for an additional pass-through requirement, since plans will only be reimbursed for subsidies that actually were used to reduce beneficiary cost sharing at the point of sale.

Comment: Commenters expressed concern about the methodology that will be developed to implement reimbursement for cost-sharing on a capitated basis. One commenter asked that Part D plans have the opportunity to work with us as it develops a methodology, while another commenter noted that reimbursement for low-income subsidies on an aggregated capitation basis—rather than on an individual member basis—would make calculation of individual subsidies difficult for purposes of counting them toward TROOP as required by the statute. One commenter recommended that Part D sponsors offering Part D plans that serve a significant number of American Indians/Alaska Natives not have available to them the option of having the cost-sharing subsidies reimbursed to them on a capitated basis.

Response: Subsection (d) of § 423.800 was inadvertently included in the proposed rule and has been removed. This is addressed in § 423.329(d)(2). Plans will be reimbursed for subsidies that actually were incurred to reduce beneficiary cost sharing at the point of sale. Interim estimated payments related to plan assumptions may be included with monthly capitated payments to assist plans with cash flow, and later reconciled to actual incurred costs. Although we initially will pay the low-income subsidy on a claims-paid basis, we reserve the right to pay on a capitated basis as allowed by 1860D–14(c)(2). Further information on payment methodology will be issued in separate guidance.

Comment: Commenters raised concerns about the reimbursement of cost-sharing expenses incurred by subsidy eligible individuals before they have been notified of their eligibility but after the date the subsidy eligibility is effective. Several commenters expressed concern that low-income enrollees cannot afford to pay cost-sharing even with the expectation that these out-of-pocket costs will eventually be reimbursed and recommended, as an alternative, that we adopt a presumptive eligibility system. Alternatively, these commenters suggested that the regulations provide that beneficiaries may present their notice of approval for the subsidy to their pharmacy and that pharmacies would accept this notice as adequate to relieve the beneficiary from making a copayment. One commenter expressed concern that plans would violate the requirement to reimburse these costs unless more stringent compliance requirements are adopted in the regulations, including a requirement that plans have a 10-day period for reimbursement after the date a beneficiary's subsidy is effective. Another commenter suggested strengthening the reimbursement requirement by explicitly stating that Part D plans must make these reimbursements on their own initiative without requiring beneficiaries to affirmatively seek the reimbursement and that these reimbursements must be made 15 days after the eligibility has been received by the plans. One commenter requested that we permit SPAPs, which may pay the cost-sharing for individuals who are subsequently determined to be subsidy eligible, to be reimbursed for their contributions.

Response: Individuals may incur out-of-pocket costs from premiums and cost-sharing before eligibility determinations and notification to plans are made.

The rule requires plans to directly reimburse the beneficiary, according to

the data it has kept on the beneficiary's incurred and paid expenses. We will then reimburse the plan for these expenses. We will have in place a mechanism to pay plans directly for the incurred and paid expenses. We will issue further operational guidance on this issue.

Programs like the Ryan White AIDS Drug Assistance Program or SPAPs may pay the premiums and cost-sharing for beneficiaries until the low-income subsidy eligibility determinations are made. The rule requires plans to reimburse these programs for payments made after the effective date of the eligibility determination. Therefore, we have revised § 423.800, new subsection (d), to reflect this change.

Comment: One commenter recommends that Part D plans be required to reimburse State programs and charitable organizations that pay cost sharing on behalf of the Part D beneficiaries who are later found to be low-income subsidy eligible individuals.

Response: We have clarified in the final rule that plans must reimburse organizations paying cost-sharing on behalf of such individuals, any out-of-pocket costs relating to excess premiums and cost-sharing paid before the date the individual is notified of subsidy eligibility and after the date subsidy eligibility is effective.

Q. Guaranteeing Access to a Choice of Coverage

1. Overview (§ 423.851)

Subpart Q implements the provisions of sections 1860D–3, 1860D–11(g), 1860D–12(b)(2), 1860D–13(c)(3) and 1860D–15(g) of the Act. In this section, we address a beneficiary's right to have access to a choice of at least two Medicare options for prescription drug coverage; the requirements and limitations on fallback plan bidding; review and approval of fallback prescription drug plans; contract requirements specific to fallback plans; and the determination of fallback plan enrollee premiums and CMS payments to those plans.

2. Terminology (§ 423.855)

a. Eligible Fallback Entity

In § 423.855 we state that an eligible fallback entity is defined for a given contract period and is an entity that meets all the requirements to be a PDP sponsor, (except that it does not have to be a risk-bearing entity) and does not submit a risk bid under § 423.265 for any prescription drug plan for any PDP region for the first year of that contract period. We also state that an entity will be treated as submitting a risk bid if that particular legal entity is acting as a subcontractor for an integral part of the drug benefit management activities of a PDP sponsor (or an entity applying to become a non-fallback PDP sponsor) that is submitting a risk bid; however, the same is not true if the entity is a subcontractor to an MA organization offering an MA-PD plan (or a subcontractor to an entity applying to offer an MA-PD plan).

Comment: A commenter asks that we not allow under any circumstances for the pharmacy benefits management (PBM) component of the fallback plan to be the same entity contracted with either as an MA-PD or a risk PDP in the same area. The commenter stated that to do so would reduce competition in the area, which could ultimately reduce beneficiary choice and access to drugs. Another related comment stated that under the current definition and contracting requirements described in the preamble and proposed regulation that it may be possible for two legally independent, but affiliated PDP sponsors to submit bids in the same region and undercut the clear intent of the statute requiring that plans be offered by different organizations in order to meet the access requirements.

Response: Section 1860D–3(a) of the Act requires that each Part D eligible individual have access to a choice of at least two plans in the area in which they reside. Additionally, the statute makes it clear that the beneficiary access requirement is not satisfied for an area if only one entity offers all the qualifying plans in the area. We will be closely monitoring PDP sponsors, MA organizations and their subcontractors to ensure that the same legal entity is not operating both plans in a fallback area. We note that there is no prohibition against a PBM operating as a subcontractor to an MA-PD plan as well as being a sponsor of a fallback PDP. We also note that a PBM can operate as a subcontractor to all kinds of PDPs, including fallback PDPs, and to MA-PDs in any region. There is also no prohibition against an MA organization offering both an MA-PD plan and a fallback plan in the same region.

In the proposed rule we incorrectly stated at 69 FR 46670 that MA organizations offering MA-PD plans could not simultaneously offer fallbacks. We clarify in this final rule our belief that such a reading would not comply with the clear language of sections 1860D–12(b)(2) of the Act which governs contracts with PDP sponsors and not MA organizations offering MA-PDs or with section 1860D–11(g)(2)(B) of the Act which speaks only in terms of prescription drug plans, and not MA-PD plans. We will be diligent in reviewing applications in order to exclude entities that have been set up to serve no other function than to circumvent the statute. An entity will not be considered separate and distinct if it is merely the instrumentality, agency, conduit, or adjunct of the other entity. However, to the extent that other legitimate legal arrangements are negotiated in the marketplace to facilitate the offering of Part D risk plans, we will not preclude such arrangements. We have not made any further changes to the definitions of PDP sponsors or eligible fallback entities to further restrict qualifications in response to these comments.

Comment: Many commenters asked that governmental entities be able to sponsor fallback PDPs in order to provide for a smooth transition of prescription drug coverage from Medicaid or other Federally-matched programs. Some asked that Medicaid agencies be considered as potential fallback plan sponsors. Several commenters asked whether the definition of an eligible fallback entity should be modified so that an SPAP can serve as the fallback plan for SPAP clients in the event that the fallback option must be implemented because not enough PDPs or MA-PD plans express interest in service in a State (all other beneficiaries would enroll with the Part D fallback provider).

Response: We are unable to accept these suggestions because under section 1860D–41(a)(13) of the MMA, governmental entities are not eligible to become PDP sponsors. This is consistent with the MMA transfer of responsibility for providing prescription drug benefits for dual eligibles from State programs to the Medicare program (under § 1935(d)(1) of the Act), and is set up for the most part so as not to supplant other government funding for prescription drug benefits (under section 1860D–24(c)(2) of the Act). As modified in § 423.4 and discussed in subpart A of this preamble, the definition of PDP sponsors includes sponsors of fallback plans.

Comment: One commenter suggested that in order to encourage traditional PBMs to serve as ''risk bearing'' entities, we should only allow pharmacy benefit administrators (PBA) to serve as fallback plans. According to the commenter, these entities serve as traditional administrators of prescription drug programs, rather than the PBM entities that have evolved from the PBA model, and this PBA model for the fallback plans would prevent the conflict of interest that exists today when a PBM

owns and operates its own mail order facility.

Response: Although we appreciate the intent behind this comment to avoid conflicts of interest that could theoretically result in higher costs for the Part D program, we believe that restricting eligible fallback plan entities to only pharmacy benefit administrators would be unnecessarily restrictive and inconsistent with the statutory definition provided in section 1860D–11(g)(2) and described in § 423.855. The statute does not limit the type of entities that can apply to meet the requirements to be either PDPs or MA-PDs, and we do not think there is any benefit to doing so. On the contrary, our goal is to do everything possible to maximize participation in the Part D program by any and all qualified entities in order to maximize beneficiary access to a choice of private plans and competition among these plans. Therefore, we have not modified the definition of eligible fallback entity, other than to clarify that it is a form of PDP plan, and have adopted it as proposed.

In the preamble to the proposed rule we interpreted the bidding restrictions to mean that if an organization wins the fallback bidding, that is, signs a fallback contract, it is effectively barred under § 423.265(a)(2) from bidding as a risk plan in that region for 4 years—for the 3-year contract term, it is barred everywhere, and in the 4th year, it is barred from bidding as a risk plan in that region. As we described in the proposed rule, this is because eligible fallback entities are restricted to only those entities that have not submitted an at-risk bid, or agreed to serve as a subcontractor to an entity that has submitted an at-risk bid to sponsor a PDP. As a result of this restriction in bidding, eligible fallback entities must decide not to submit either a full-risk, or limited-risk bid in any region (either as a primary sponsor or as a subcontractor for a PDP sponsor) in order to be eligible to be a fallback prescription drug plan in any region. If an organization is awarded a fallback contract and ''offers a fallback plan'', it is effectively barred under § 423.265(a)(2) from bidding as a risk plan in that region for 4 years—for the 3-year contract term, it is barred everywhere, and in the 4th year, it is barred from bidding as a risk plan in any region in which it offered a fallback plan. A fallback contractor is arguably offering a fallback plan even if it is only ''on standby'' to do so.

In the proposed rule we also suggested an alternative interpretation of what it means to ''offer a fallback plan'' in a region for purposes of section 1860D–12(b)(2)(C) of the Act, that is, not just signing the contract, but also actually offering prescription drug benefits to enrollees after a fallback service area has been identified. With the second interpretation, if the fallback contract was not activated and no plan was offered during year 3, the entity could be eligible to bid at risk for year 4.

Comment: We received several comments on our interpretation of our authority in this area. One commenter asserted that we do not have the statutory authority to bar a fallback entity from at risk bidding for up to 4 years. Another commenter supported the alternative interpretation of what it means to ''offer a fallback plan'' in a region. This commenter agreed with CMS that the alternative interpretation is ''reasonable and consistent'' with the statutory intent ''to prevent plans from converting their enrollment under a fallback contract to enrollment under an at-risk plan''. They also suggested that if a fallback plan were not activated in year one or year two of the contract cycle, it should be able to submit a risk bid for years two and three, respectively. They encouraged us to adopt this interpretation in the final rule—believing it to be in the best interests of the program in that it will provide for better competition if more entities are encouraged to participate in Part D, whether as potential fallback plans or PDPs.

Response: We appreciate this comment and agree that this interpretation furthers the goal of facilitating competition by allowing former fallback contractors to enter the risk bidding a year sooner (assuming they did not actually provide a fallback plan in year 3 of the contract cycle). We do not agree, however, that a fallback contractor should be released from its three-year contract and, therefore, free to submit a risk bid any earlier than year 4. If we were to permit this, we would be undermining the safety net provided by the three-year contract cycle that exists to ensure timely access to fallback coverage in the event that a sufficient number of risk plans were to withdraw from the market to create a fallback service area during or after years 1 or 2. Moreover, we would also be undermining the attractiveness of risk bidding by eliminating an important disincentive to stay out of the market in year one. Thus, an entity that is awarded a fallback contract—even if it is only on standby—may not submit a risk bid for the 3 years that it maintains its fallback contract. For example, a fallback contractor for the period 2006–2008 may not submit a risk bid for any of those years (even if the fallback contractor is merely on standby for that entire period). In addition, if the sponsor offers a fallback plan in regions 1 and 2 for 2008, then such sponsor is prohibited from risk bidding in such regions for 2009. The sponsor may, however, submit risk bids for regions other than regions 1 and 2 for 2009 (although if it does so, it may not seek a fallback contract for the period 2009–2011). In addition, if the sponsor was on standby for all of 2008, but never actually offered a fallback plan in 2008, the sponsor may submit a risk bid for any region for 2009 (but again, if it does so, it is prohibited from seeking to become a fallback contractor for the period 2009–2011). Therefore, we have adopted the provisions in § 423.855 and § 423.265(a)(2) that provide these limitations as proposed.

Comment: Numerous commenters asserted that the contracting restrictions and other (unspecified) requirements to become an eligible fallback plan are too severe, and that they believe we will not have any organizations stepping forward to become fallback plans.

Response: We agree the requirements for fallback plans are more severe than for full risk plans. We have intentionally made these requirements stricter than for risk-bearing plans because we believe this is an important strategy to maximizing participation in the competitive bidding program and to limit the attractiveness of participating as a fallback PDP for those plans that could participate on an at-risk basis. Our goal is to have either full or limited risk plans provide MA-PD and PDP prescription drug coverage in all regions. To that end, one of our selection criteria will likely be an appraisal of whether the fallback entity's pharmacy benefit management subcontractor is also participating as a subcontractor under risk plan offerings. The implementation of the fallback plan is viewed as a last resort—as its name implies—a plan to ''fall back'' on in the event a choice of two qualifying drug prescription plans is unavailable in a service area or region. We are aiming to design our bidding process so that fallback plans are not required at all, that is, to do everything possible to facilitate full-risk plans and to provide for limited-risk plans in a particular region if full-risk plans are not available. In fact, if any fallback plans are needed, the Congress requires us to submit an annual report with recommendations for further limiting the need for such plans and maximizing future participation by limited risk plans.

b. Fallback Prescription Drug Plan (Fallback Plan)

In the proposed rule under § 423.855 we stated that a fallback prescription drug plan is a PDP offered by an eligible fallback entity that provides only actuarially equivalent standard prescription drug coverage, as well as access to negotiated prices, including discounts from manufacturers, and that meets other requirements as specified by CMS.

Comment: Several commenters stated that we should amend the phrase 'actuarially equivalent standard prescription drug coverage'' with the phrase 'defined standard coverage' to reflect the clear intent of the Congress to limit the benefit offered by a fallback plan. Others urged us to make sure the final regulation is clear about what structures such as premiums or cost sharing can be different and about what protections must be in place to ensure that consumers are clearly informed of the differences and are protected against unfair practices.

Response: We agree that the statute requires fallback plans to offer standard coverage, but we point out that it makes a distinction between two types of coverage that are both considered ''standard''. For purposes of administering the Part D benefit we must maintain the distinction between defined standard coverage and actuarially equivalent standard coverage as described in § 423.100. We continue to think that beneficiaries and taxpayers may be able to get better value from actuarially equivalent packages that employ all of the cost and utilization management tools, particularly co-payment tiering, to drive to the most cost-effective utilization on the part of beneficiaries and the best price concessions from manufacturers, so we certainly will not preclude such offerings. However, we cannot say with impunity that PDPs offering defined standard coverage could not offer equal value through other formulary management tools and competitive negotiations with manufacturers. Consequently, we have modified § 423.855 to reflect that fallback PDPs may offer either defined or actuarially equivalent standard benefits. We do not believe this flexibility in any way impedes PDP plans from offering competitive plans that beneficiaries would prefer. We also note that we will be closely reviewing fallback plan formularies and benefit designs, as well as cost, quality and utilization management programs to ensure that they are reasonable and appropriate for a region in which beneficiaries do not have alternative plans from which to choose.

Comment: Several commenters recommended that we require that all price concessions be passed through to the beneficiary. One commenter also recommended that we not allow any pricing differentials on what is paid to pharmacies for reimbursement of the dispensing fee or ingredient costs. They also believe the fallback plan should be required to adequately reimburse pharmacies with appropriate dispensing fees and an appropriate product cost reimbursement.

Response: We agree with the commenters that fallback plans must pass through all price concessions that are known and available at point-of-sale to the beneficiary and, furthermore, must operate under conditions of complete price transparency in general. All other price concessions obtained (as discussed in detail in subpart G) must be reported to CMS and subtracted from paid claim amounts upon reconciliation. We note that some portion of these latter price concessions are passed through to the beneficiary in the form of lower premiums, but another portion is not and is passed through solely to the Medicare program in the form of lower program expenditures. It would be impractical to require that all price concessions be passed through to the beneficiary at the point of sale because certain price concessions can only be calculated retrospectively.

Nonetheless, we require that fallback plans pass through all price concessions that are known at the time of the sale in the point-of-sale price, because we do not believe that section 1860D–11(g)(5)(A)(i) of the Act allows us to reimburse fallback plans for any amount in excess of actual costs incurred. Therefore, fallback plans may not claim any amount in excess of the discounts and dispensing fees obtained from participating pharmacies as drug claim costs. All returns on investment must be negotiated as part of the management fees and performance measures. We note that this policy differs somewhat from our requirements for risk plans. We believe that risk plans will be motivated to pass through as much discount as practicable at the point-of-sale due to price competition, and we will encourage this through our Price Compare website. Even if they do not, however, they are paid prospectively and are in compliance with § 1860D–2(d)(1)(B) of the Act and § 423.104(g)(1) of this rule, so long as all price concessions are reported and deducted from claims costs in the reinsurance and risk corridor final payment processes. Fallback plans, on the other hand, are paid on the basis of 1860D–11(g)(5)(A)(i) of the Act and § 423.871(e)(1) of this rule, and our payments must be limited to the actual costs of covered Part D drugs provided to the fallback plan enrollees. Since fallback plans will submit their claim costs to us for direct reimbursement, we require that these claims represent actual point-of-sale costs. We have added a definition of actual costs to § 423.855 and modified § 423.871(e)(1) to clarify this interpretation.

As for the recommendation to prohibit pricing differentials among fallback plan contracts with network pharmacies, we do not believe that such a requirement would be consistent with the goal of creating a competitive market for prescription drugs and obtaining the best possible prices for beneficiaries and the Medicare program. We also do not believe that there is any prohibition on fallback plans contracting with subset(s) of preferred pharmacies, just as risk plans may; such subsets of preferred pharmacies may indeed have different pricing arrangements. Although we agree with the commenter that fallback plans should adequately reimburse pharmacies through appropriate dispensing fees and product cost reimbursement, we note that this result must be obtained through competitive price negotiations and that we may not interfere in such negotiations by attempting to define or require ''appropriate'' fees.

Comment: Several commenters asked that certain PDP requirements be extended to fallback plans. For instance, one commenter argued that the same out-of-network requirements applicable to PDPs should apply to fallback plans, and others suggested that they should be required by regulation to coordinate benefits with SPAP's in the same manner as must PDPs, or that they should comply with all the access and quality standards applicable to PDPs and MA-PD plans, including all grievances and appeal procedures.

Response: We agree and wish to clarify that a fallback plan is a special type of PDP and as such must meet all of the requirements established for Part D plans, including prescription drug plans, in these regulations, except as otherwise specified by CMS in this subpart or in separate guidance. In some cases, the statutory provisions applying to fallbacks will be such that to apply the requirements of PDPs to fallbacks would create a conflict in the statute. For example, fallback plans obviously could not be required to submit bids under section 1860D–11(b) of the Act, since fallbacks are paid on a different basis from risk contractors. Similarly, fallback contractors will not be required

to report information necessary for calculating reinsurance, because fallbacks do not receive any reinsurance payments. In these cases, where there is an apparent conflict in the statute, this subpart, or in our guidance, we would not require fallback plans to meet the requirements of PDPs. However, where there is no conflict, we believe that fallback plans should be considered PDPs and have amended the definition of PDP in subpart A to include a fallback plan. Thus, for example, a fallback plan will be required to meet all of the requirements for beneficiary protections under subpart C that apply to other Part D plans. In addition, fallbacks would be subject to most of the provisions in subpart K governing the terms of the contract and procedures for termination. However, a fallback plan would not be subject to the same licensure and solvency requirements that apply to PDP sponsors under subpart I. Fallback plans would be required to have regional networks that meet the access requirements specified in § 423.120, including meeting the Tricare standards for retail pharmacies at the State level, but they would not necessarily have to meet the Tricare standards at the local level of the eventual fallback service area, as this particular area could not have been foreseen. We have amended the definition of fallback plan in § 423.855, and the definitions of PDP and PDP sponsor in § 423.4, accordingly.

c. Qualifying Plan

Under § 423.855, a qualifying plan is defined as either a full-risk or limited risk prescription drug plan (PDP) or an MA-PD plan that provides basic coverage, or an MA-PD plan that provides supplemental coverage for no additional charge to the beneficiary. Specifically, if the MA-PD plan coverage includes supplemental prescription drug coverage, then in order to meet the definition of a ''qualified plan'' the MA-PD must be able to apply a premium rebate under Part C of Medicare as a credit against the supplemental coverage premium, leaving no cost to the beneficiary for the supplemental coverage. MA-PD plans must also be open for enrollment and not operating under a capacity waiver in order to be counted as a qualifying plan in an area. Similarly, we have modified § 423.855 to clarify that a PDP must not be operating under a restricted enrollment waiver, such as those that may be granted to special needs plans or employer group plans, in order to be counted as a qualifying plan in an area. No comments were received on these provisions, and they will be adopted as proposed.

3. Assuring Access to a Choice of Coverage (§ 423.859)

a. Access Standards

In § 423.859(a) we state that we will ensure that each Part D eligible individual has available a choice of enrollment in at least two qualifying plans offered by different entities in the geographic area in which he or she resides. Therefore, beneficiaries in an area must have a choice of two plans that provide basic coverage (or an MA-PD plan that provides supplemental coverage for no additional charge to the beneficiary). However, to meet the access test, different sponsors must offer the two qualifying plans, and at least one of the plans must be a PDP. There were no comments on these statutorily-based requirements and we are adopting § 423.859(a) as proposed.

b. Fallback Service Area

In § 423.859(b) we state that if before the start of a contract year (or at any other time) we determine that Part D eligible individuals in a PDP region do not have available a choice of enrollment in a minimum of two qualified plans as described in § 423.859(a), we will establish a ''fallback service area.'' Thus, a fallback service area is any area within a PDP region in which we have determined that Part D eligible individuals do not have available a choice of enrollment in two qualified plans, at least one of which is a prescription drug plan. Three examples of the application of a fallback service area follow:

- Example 1—We would establish a fallback service area in an area where an MA regional PPO plan is offered but no PDP is offered in the region. Since beneficiaries in the region would only have the choice of a MA-PD and not a stand-alone PDP, we would define the area as a fallback service area.
- Example 2—A fallback service area would also be designated if only one PDP is offered in a region, but in some or all parts of the region neither a regional (PPO) MA-PD plan nor a local MA-PD plan are available to beneficiaries. Since beneficiaries would not have a choice of two qualifying plans, we would define the areas within the region that only have access to the PDP, and not an MA-PD plan, as fallback service areas. As a result, it would be possible for only certain areas (counties) within a region to be designated as fallback service areas.
- Example 3—A fallback service area would also be designated in any area in which only one entity offered all qualifying plans, even if that sponsor offered two PDPs, or one PDP and one MA-PD plan with basic coverage, covering the entire region.

Comment: One commenter stated that a fallback plan should at a minimum be Statewide.

Response: In the MMA the Congress directed CMS to form Medicare Advantage regions of not less than 10 and no more than 50 encompassing the 50 States and the District of Columbia, and to create PDP regions that are consistent with these to the extent practicable. Discussion of the analysis and comments on the PPO and PDP regions has been published separately. However, in the event that we determine that only sections of a region are fallback service areas, we are prohibited by law from allowing the fallback plan to service the entire region, no matter its size. We recognize that this policy may result in fallback service areas that are much smaller than the regions on which the contracts are based. Our compensatory strategy is to encourage national or other large-scale fallback contracts in order to maximize operational efficiencies while operating under this sort of uncertainty.

c. Waivers for Territories

Section § 423.859(c) of this regulation makes Medicare beneficiaries residing in the U.S. territories—which include American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, and the U. S. Virgin Islands—eligible to enroll in Part D. We have the authority to waive any Part D requirements, including the requirement that access to two qualifying plans is available in each service area, as required to ensure access to qualified prescription drug coverage for Part D eligible individuals residing in the U.S. territories. In addition, entities wishing to become prescription drug plans in the territories may request waivers or modifications of Part D requirements that facilitate their operation in those areas.

In the proposed rule we suggested a number of Part D requirements that we were considering waiving and requested comments on these and any other potential waivers that would facilitate the offering of Part D coverage in the territories. The only comments received for the territories concerned the design of the regions, and these have been addressed in separate guidance. As a result, we retained the broad waiver authority in § 423.859(c) without modification, and will continue to conduct research to determine how best to facilitate Part D coverage in the territories. For risk-based applicants, we anticipate we would provide a table identifying requirements for waivers, and applicants would have to provide a

rationale for how a waiver would facilitate risk-based access in the territories. We would review each waiver, and if it is approved, it will apply to all similarly situated risk plans in the territories. Waivers of the bid requirements will not be entertained. Similarly for Fallback applicants, if there is a need for any of these, we would entertain waiver requests. Additionally, we will modify the payment incentive and performance guarantee arrangements as may be necessary to ensure fallback participation in the territories.

4. Submission and Approval of Bids (§ 423.863)

In § 423.863 we establish a separate bidding process for fallback plans distinct from the risk bidding process addressed in § 423.265 of our regulations, and state that the solicitation, timing and format requirements for this process will be provided in separate guidance.

Comment: A commenter asserts that neither the MMA nor the proposed rule address whether a PDP applicant approved by CMS may withdraw its application without any adverse consequences to the PDP applicant if a fallback plan is invoked in the same region. The commenter recommends that this option should be available if a plan does not wish to compete against a fallback plan.

Response: We fundamentally do not think that risk plans need to be concerned about competing against a fallback plan. Risk plans will have the competitive advantages of corporate marketing and brand recognition and the ability to offer more varied benefit designs (including supplemental benefits), as well as being offered to all enrollees in a region—not just to those in fallback service areas. We are also anticipating that efficient risk plans may have the opportunity to earn higher levels of profit. While there is a possibility that a fallback plan could enter a region if there is only one PDP risk plan, our strategic approach to encourage the offering of risk plans should also make them attractive to beneficiaries relative to fallback plans. And while we do not believe we have the authority to prevent a risk bidder from withdrawing its bid prior to entering into a PDP contract, we expect risk-based applicants to participate in the solicitation process in good faith, with the full expectation of participating in the regions for which they apply regardless of the anticipated presence of a fallback in that region. Accordingly, we intend to scrutinize applications and bids.

In § 423.863(b) we state that, except as otherwise noted, the provisions of § 423.272 apply for the negotiation and approval of fallback PDP contracts. We state that if access requirements have not been met after applying § 423.272(c), we will contract for the offering of a fallback PDP in that area, and that all fallback service areas in any PDP region for a contract period must be served by the same fallback plan. Fallback plans must be prepared to provide Part D services at the same time as risk plans, and in the event of mid-year changes, we will approve a fallback PDP for any new fallback service areas in a PDP region in a manner so that the fallback plan is offered within 90 days of notice. Under no circumstances may we contract for only one fallback PDP for all fallback service areas in the 50 States, the District of Columbia, and the territories.

Comment: One commenter pointed out that according to § 423.863(b)(5), in the event of mid-year changes we must approve a fallback prescription drug plan so that the fallback is offered within 90 days of notice. The commenter is concerned that this leaves open the possibility that beneficiaries could be without a PDP for a period of up to 90 days, and urges us to clarify that fallback plans must enter into a mid-year market as soon as practicable.

Response: We share the commenter's concern with ensuring access and continuity of care for beneficiaries in the unlikely event of either a risk plan or fallback prescription drug plan failure. We will make every effort to eliminate this possibility through our selection criteria that will involve scrutiny of financial and business stability, and will favor firms with national capacity. In addition, we will select fallback plans, in part, on their operational capability to be up and running quickly. We believe it would be a very rare occurrence to need a fallback plan in mid-year for a reason that could not be foreseen in time to have an alternate fallback plan in place, and thus we cannot foresee a circumstance in which there would be the possibility of a gap in access to a PDP. (Contract provisions in § 423.509 and § 423.510 require a 90-day notice of intent to terminate a plan. In 423.508, if a contract is terminated by mutual consent, the sponsor and CMS will work out an appropriate time frame to ensure time to secure a fallback plan.) In cases where a new fallback would be invoked mid-year due to plan withdrawal, beneficiaries might face different cost sharing and different formularies, but they would be eligible for an SEP and would be allowed to choose the MA-PD or PDP in the area (if there is one) instead of the new fallback plan. In the unlikely event of this occurrence, our goals will be to explain any differences to affected beneficiaries, and to limit disruption as much as possible.

Comment: One commenter stated that our suggestion in the proposed rule that we expected to award two fallback contracts for the entire country, assuming fallback contracts are needed, is arbitrary and does not serve the best interests of either beneficiaries or CMS.

Response: Because we now believe that two may not be sufficient to competitively provide for fallback coverage should it be necessary, we plan to award as many contracts as needed to provide potential fallback services. However, we still plan to have only a very limited number. We anticipate awarding a sufficient number of fallback contracts to ensure that any designated fallback area(s) are provided for at the start of the program, as well as later in the event of plan closure or failure. However, we do not anticipate awarding so many as to dampen the incentive for potential fallback plans to offer excellent customer service and competitive drug prices. We also plan to pursue every opportunity to ensure the option of at least two risk plans in every area, and do not anticipate the need to activate fallback plans.

In the preamble to the proposed rule we stated that in general we would enter into contracts with fallback plans using Federal acquisition rules on a timetable ensuring that such contracts were in place at the same time as prescription drug plans would otherwise be offered. However, in regulation we more correctly stated that we would use competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 USC 403(5)) to enter into a contract under this paragraph, and that the provisions of section 1874A(d) of the Act with regard to limitation of liability for Medicare contractors for payments on behalf of Medicare would apply. Thus the fallback plans must be competed, and their terms and conditions may be negotiated. Because fallback plans will be subject to competitive procedures, we have clarified subpart N to make clear that those appeals procedures would not apply to fallback plans or fallback entities.

Comment: We received comments asking that an alternative to the ''indefinite delivery'' type contracting be considered, including the use of cost plus fixed fee contracts.

Response: We do not believe the fallback contracts will be Federal Acquisition Regulations (FAR) contracts

per se, even though we plan to use the FAR competitive procedures to enter into fallback contracts. Section 1857(c)(5) of the Act, which is incorporated by section 1860D–12(b)(2)(B) of the Act, authorizes us to exercise the authority granted to the Secretary under Part D of Title XVIII without regard to provisions of law or regulations relating to the making, performance, amendment, or modification of contracts of the United States, as we determine is inconsistent with the furtherance of the purposes of Title XVIII.

Based on this authority, we proposed that for risk contractors, the contracts would not be written or entered into in accordance with the FAR or the Departmental acquisition regulations set forth in title 48 of the CFR. In addition, in the Medicare Advantage context, the MA contracts have not been considered to be FAR contracts and have not contained FAR provisions within them. We believe that it would be in furtherance of the purposes of Title XVIII to maintain consistency among the Medicare Advantage, risk, and fallback contracts to the extent possible. Therefore, as with both the risk and Medicare Advantage contracts, the fallback contracts will not contain many of the FAR or HHS-specific provisions automatically included in many government contracts.

In addition, because the contracts would not be written under the FAR or 48 CFR provisions, we do not believe it is accurate to refer to the standby contracts as indefinite duration, indefinite quantity (IDIQ) contracts—which is a term used under the FAR. Nonetheless, we expect to have umbrella provisions, which provide the necessary flexibility to deploy a fallback plan during a contract year in the event of a risk plan failure. Although the fallback contracts will not be written in accordance with the provisions of the FAR or 48 CFR, and will not look like typical ''FAR contracts,'' as we stated in the proposed rule at 69 Fed. Reg.46734, unlike both risk and MA contracts, we will enter into fallback contracts using the Federal acquisition rules on a timetable to ensure that the contracts are in place on time (that is, at the same time as the risk plans would otherwise be offered).

In anticipation of the approach discussed above, we intend to time the fallback solicitation process so that we can actively encourage participation in risk contracting and minimize the need for fallback plans while ensuring they are available if necessary. To this end, we intend to begin the fallback solicitation process after the risk plan solicitation process. We may also conduct a second risk plan solicitation (for applications) only for areas we determine to be likely fallback areas. Final fallback bids under this process would be due shortly after the risk bids are due with fallback contracts awarded in the fall. Further details on the fallback plan solicitation process will be provided in separate guidance.

In the preamble to the proposed rule we referred to the non-interference provision of the MMA and noted, for our negotiations with potential fallback plan sponsors, that we could not interfere with negotiations between drug manufacturers and pharmacies and PDP sponsors, and could not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs. However, we noted that at the same time the revenue requirements standard in 5 USC 8902(i), discussed in subpart F of the preamble, require us to ascertain that the bid ''reasonably and accurately reflects the revenue requirements for benefits provided under that plan.'' Therefore, we concluded that while we may not set the price of any particular drug, or require an average discount in the aggregate on any group of drugs (such as single-source brand-name drugs, multiple-source brand name drugs, or generic drugs), we will take appropriate steps to evaluate whether the bid is reasonably justified. As specified in 5 USC 8902(i), we have the authority to take steps to ensure that benefits are ''consistent with the group health benefit plans issued to large employers,'' in order to ensure that the bid amounts submitted are comparable to those available on the private market. For example, if the price reference points appear to be particularly high (or low), we may request an explanation of the bidders' pricing structure, and the nature of their arrangements with manufacturers to ensure that there is no conflict of interest leading to higher bids. We also proposed to negotiate price-related performance targets with fallback plans, consistent with current market practices in which commercial plan sponsors negotiate price-related reference points with PBMs. We said we would also consider potential contractors based on their bids for administrative functions like claims processing.

Comment: We received a few comments that did not support our analysis of our negotiating authority. One commenter specifically recommended that we clearly indicate in the final rule that we will not set price benchmarks, create incentive payments, or otherwise interfere with the price structures for Part D drugs, whether provided through fallback plans or not.

Response: As stated in the proposed rule, we believe that section 1860D–11(g)(5)(B)(i) of the Act makes clear that the Congress contemplated taking prices into account in calculating incentive payments for fallback entities. Moreover, even though the performance measures and the potential incentive payments will be defined in advance, the determination of actual incentive payments will be made at the end of the contract period, and thus does not represent interference in the bidding process.

As is the case with risk bids, we continue to believe we have the authority to negotiate for fallback plans in four broad areas: administrative costs, aggregate costs, benefit structure, and plan management. We will evaluate administrative costs for reasonableness in comparison to other bidders. We will examine aggregate costs to determine whether the revenue requirements for the defined standard or actuarially equivalent standard prescription drug coverage as defined in § 423.100 are reasonable and equitable. We will be interested in steps that the plan is taking to control costs, such as through measures to encourage use of generic drugs, therapeutic interchange to preferred brand-name drugs, and formulary compliance. We will be interested in reviewing the formulary to ensure that it is appropriate for a region in which beneficiaries do not have alternative plans from which to choose. We will examine and discuss any proposed benefit structures or changes to benefits in later years, particularly with regard to any potentially discriminatory features. Finally, we will review performance metrics and discuss any identified issues with regard to plan management, such as customer service. No changes will be made to § 423.871 in response to these comments.

Comment: One commenter supported our position that we have the authority to negotiate with plans to ensure a good price for beneficiaries, and if the price reference points appear to be particularly high (or low), to request an explanation of the bidders' pricing structure, and the nature of their arrangements with manufacturers to ensure that there is no conflict of interest leading to higher bids. The commenter urged us to apply these same authorities to plans in non-fallback situations, as well as to fallback plans, and notes these ''pricing dangers'' may also occur in areas where there is no fallback plan, but just one MA-PD and one at-risk PDP.

Response: We appreciate the support of our position and agree that similar, although not identical, controls are required for evaluation of risk plan bidding. Since risk plans are by definition at risk for ineffective cost management, there is less need for us to set targets in order to incentivize reasonable and appropriate cost controls. Please refer to our discussion of risk plan bid negotiation in subpart F, as well as to our guidelines on risk bid submission published separately.

Comment: Numerous commenters wrote in about performance measures for fallback plans. Some expressed their approval of our intent to base incentives on various performance measures. Some commenters suggested specific measures such as: using cost per days supply instead of cost per prescription to ensure an apples-to-apples comparison, and including more specific measures of customer service such as: speed and efficiency in handling enrollee calls, timeliness and accuracy of communication materials to enrollees, comprehensiveness and accuracy of business support to pharmacies, prescribers and CMS, retail pharmacy network access, and mail service pharmacy performance.

However, the majority of commenters had serious doubts about the number, and kinds of performance measures we proposed. Some were worried there were too many proposed performance plan measures, and several believed that we were suggesting that the final rule was going to allow negotiated discounts for prescription drugs to be the sole performance measure for a fallback plan. Other commenters said they believed that fallback plans should not be expected to put their management fees at risk due to factors beyond their control, or for measures that are not mutually agreed upon with CMS, and others said that drug price discounts should not be used as a performance measure at all.

Response: We appreciate the supportive comments, and especially the suggestions for specific performance metrics we could utilize. We also agree that fallback plans should not have their management fees put at risk due to factors beyond their control. We have identified a number of performance measures that are used in the private sector as performance guarantees for which management fees are put at risk and we intend to adopt these practices to ensure best practices in benefit management.

Despite the comments arguing against the use of performance incentives tied to price discounts, we will be placing performance clauses in the contracts with fallback entities that tie performance payments to the fallback plan's ability to secure lower drug prices for beneficiaries and lower costs for Medicare. We note that in the absence of performance guarantees or incentives, fallback plans are no-risk cost-based arrangements that are reimbursed by Medicare for costs (including administrative fees and negotiated profit) incurred. In future guidance we will provide a number of measures that would encourage an efficient entity to bid on a fallback plan contract (because it believes it can meet the performance metrics), and also give a successful bidder an incentive to provide quality services to its beneficiaries at the best possible price (because it would have the opportunity to earn greater profits). We note that this increased profit opportunity is the result of performance incentive payments and not the retention of any spread between negotiated prices with pharmacies and the target pricing proposed in the fallback contract bid.

As stated in § 423.871(d), as part of the payment process for fallback plans authorized by section 1860D–11(g)(5) of the Act, we will assess the performance of plans with regard to specific performance measures and tie this performance to an incentive payment. Incentive payments may be either performance guarantees (with downside risk to management fees) or performance incentives (with upside potential for additional profit). These measures will include, but are not limited to, measures for cost containment, quality programs, customer service, and benefit administration (including claims adjudication). ''Cost containment'' refers to processes in place to ensure that costs to the Medicare Prescription Drug Account and to enrollees are minimized through mechanisms such as generic substitution. The term ''quality programs'' refers to drug utilization review processes in place to avoid occurrences such as adverse drug reactions, drug over utilization and medical errors. The term ''customer service'' refers to processes in place to ensure that the entity provides timely and accurate filling of prescriptions and delivery of pharmacy and beneficiary support services. We will be surveying enrollees of fallback plans to assess customer satisfaction with plan services. The terms ''benefit administration and claims adjudication'' refer to processes in place to ensure that the entity provides efficient and effective benefit administration and claims adjudication, such as accurately programming and updating its benefit administration information systems, and providing timely and accurate claims adjudication.

We believe the suggested performance standards are reasonable and largely consistent with private sector best practices. As the potential performance guarantees and incentives mentioned above illustrate, we will select (and will continue to refine) measures that focus on key indicators of the many aspects of prescription drug benefit management that are important to us and to beneficiaries. These measures will be updated and revised to reflect opportunities to ensure that best practice is reflected in each fallback PDP contract year.

Comment: One commenter indicated support for the concept of paying for performance, but expressed concern that the proposed regulations would subject only fallback plans (and not at-risk PDPs or MA-PDs) to performance standards that would rate these plans on their success at cost containment. The commenter argued that under this approach the fallback plans would have a greater incentive to make formulary choices based on the amount of discount they receive from manufacturers, rather than on the most appropriate and cost-effective clinical treatments. If this were to occur, it could put beneficiaries enrolled in fallback plans—including those who have no other real options—at a significant disadvantage. The commenter recommended that performance standards for all Part D plans need to balance both cost containment and access to clinically appropriate medications.

Response: The MMA was designed in large part to foster a competitive market place by making every effort to encourage at-risk plans to contract with us, thereby creating competition among plans and choice for beneficiaries. We believe that both cost containment and quality performance will be logical outgrowths of plans competing for beneficiaries in the same area. Contract provisions outlined under (subpart K) § 423.505 and performance measures provided under § 423.871(d) are all designed to protect the beneficiary and are a condition of contracting with CMS. Nonetheless, we too believe that fallback PDPs, which are paid costs, may not always have the same incentives as at-risk plans to negotiate aggressive discounts and otherwise minimize net costs, as opposed to net reimbursement. Consequently, the point of the performance guarantees is to bolster the incentives to undertake those activities aggressively. We understand, for instance, that if we were to base performance incentives on rebates

obtained, this would create an incentive to steer patients toward drugs that receive higher rebates from manufacturers, rather than toward drug choices that optimize both therapeutic outcomes and cost effectiveness for the patient and the payer. Consequently, when evaluating costs, we will avoid metrics such as average rebate level or average rebate per script (as we suggested in the proposed rule) in favor of better measures of net cost to the program.

Comment: We received several comments regarding fallback plan quality programs. One suggested we change the language from over- and under-utilization to ''appropriate use''. One commenter wanted us to include a statistically significant sample of MTMP enrollees to identify medication management. Another suggested that in addition to reducing medication errors and avoiding adverse drug events, fallback PDPs should offer quality programs on prescription drug therapy that include adherence and persistency programs.

Response: We appreciate these comments and share the commenters' goals of ensuring comparable and appropriate quality assurance programs in fallback plans. As noted already, fallback plans are subject to all of the requirements for PDPs and other Part D plans (except as otherwise noted in this subpart or in separate guidance) and readers are referred to subpart D for discussion of related comments and responses on quality requirements and initiatives. We have modified § 423.871(d)(1)(ii) to reflect the requirements to monitor for appropriate utilization.

In the preamble to the proposed rule we stated that in contrast to plans that contract on a risk basis, fallback entities will be paid for covered Part D drugs on the basis of cost, and thus these entities will have less of an incentive to negotiate low drug prices. Consequently, because the statute directs us to pay management fees that are tied to performance measures, and directs that there must be a measure for costs, we said we were considering tying the performance payments of fallback entities to the average discounts they are able to negotiate, including discounts from manufacturers. We noted that this type of incentive contracting is found in the commercial pharmacy benefit management market today. We requested comments on alternative reference points or alternative methodologies that could promote competitive pricing.

Comment: We received a number of comments around using AWP as the price reference point for negotiated prices. Numerous commenters supported our use of a price benchmark and believe it represents due diligence on the part of the agency to ensure that beneficiaries and the Medicare program are not penalized with high prices in areas in which there are no choices among plans. Some recommended that we use AWP as a reference point to measure the cost containment by fallback plans. Others agreed with our expressed concern that the use of a fluctuating benchmark like AWP was in some ways problematic.

Response: Despite its frequent fluctuations and inherent vulnerability to manipulation, the AWP remains the primary measuring stick for drug costs. We will therefore be incorporating it into our performance targets, but we will also be looking at other indicators or proxies for financial performance, such as rates of generic substitution, that will provide other perspectives on cost management.

Comment: One commenter recommended that we clarify that ''actual costs'' incurred to provide the drug benefit include administrative costs, and not simply actual drug costs.

Response: We appreciate the recommendation to clarify these terms in regulation. The actual costs referenced in § 423.871(e)(1) refer to the actual costs incurred by the fallback plan for the acquisition of drugs, and are net of administrative expenses. Administrative costs, including return on investment, should be included in the computation and negotiation of management fees. We have added the definition of actual costs to § 423.855 and modified § 423.871(e)(1) to clarify these terms.

Comment: Several commenters urged us to eliminate the requirement that fallback entities apply direct or indirect remuneration as an ''offset'' to actual costs incurred by the fallback entity.

Response: We do not believe that we have the authority to reimburse fallback contractors for costs at a rate above their actual acquisition costs. In § 423.308 we state that ''*Actually paid* means that the costs must be actually incurred by the sponsor and must be net of any direct or indirect remuneration (including discounts, chargebacks or average percentage rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred by the sponsor for the drug.'' In the proposed rule we also explained (for allowable costs for risk plans) that we understand that today a significant volume of price concessions are not applied in the context of point of sale claims data, but rather in periodic accounting adjustments, and that they are frequently reported along with administrative fees paid by the manufacturer. We are aware and concerned that, in some cases, plan sponsors may accept lower administrative costs or receive services at less than market value in lieu of some or all of the price concessions. We are concerned that this practice may result in improper shifting of costs in order to inappropriately maximize cost reimbursements. We intend to monitor these arrangements closely to ensure that actual costs are not improperly inflated. We are also concerned that these accounting and business practices would be incompatible with the requirement to disclose all price concessions for purposes of determining actual costs and we, therefore, are proposing to require that the true cost of all price concessions be segregated from administrative fees in all records. We require that all price concessions passed through to the plan sponsor or beneficiary in any form be subtracted when calculating actual costs. Again, we have added the definition of actual costs to § 423.855 and modified § 423.871(e)(1) to clarify this policy.

Comment: One commenter requested that we extend the confidentiality protections of the Medicaid rebate statute to all negotiated pricing information submitted to, or reviewed by, CMS under Part D, including information obtained under subparts F, G, K, Q, and R of the proposed rule.

Response: We received several comments regarding extending the confidentiality provisions of the Medicaid rebate statute to Part D. As discussed in subpart F of this preamble, Part D bid information that determines payment is protected under section 1860D–15, since the bid information is used to actually pay the sponsors (if, for example, it is an estimate of reinsurance, or it supports the actuarial value of the bid). We believe this same protection applies to the information submitted in response to a fallback plan solicitation or as part of the cost reconciliation process. We also do not believe we have the authority to extend the confidentiality provisions of the Medicaid rebate statute where the Congress has not authorized us to do so. The Congress has been quite clear when it wishes the Medicaid rebate statute to apply. For example, in section 1860D–

2(d)(2) of the Act, the Congress specifically stated that certain aggregate negotiated price concessions described in that provision would be protected under section 1927(b)(3)(D)—the Medicaid rebate confidentiality provisions to which the commenter refers. Similarly, section 1860D–4(c)(2)(E) of the Act applies the Medicaid rebate confidentiality provisions to disclosures made under that provision. Finally, section 101(e)(4) of the MMA amended section 1927(b)(3)(D) to specifically add to that section the information disclosed under sections 1860D–2(d)(2) or 1860D–4(c)(2)(E). Therefore, we do not believe the Medicaid rebate confidentiality provisions would apply, except where the Congress specifically indicated they should. For further information regarding the Disclosure of Information provision, please refer to subpart G, § 423.322. Please refer to subparts F and G for discussion of comments and responses related to confidentiality of pricing information submitted with the bid and upon reconciliation.

Section 423.871(f) of the regulation implements section 1860D–15(d) and (f) of the Act. Under these provisions the Secretary is authorized to collect any information necessary to carry out section 1860D–15 of the Act, but information ''disclosed or obtained pursuant to the provisions of [section 1860D–15] may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out [section 1860D–15 of the Act].'' We have clarified that information disclosed to determine Medicare payment or reimbursement to the fallback entity may be used by the officers, employees and contractors of HHS (including OIG) only for the purposes of, and to the extent necessary in, determining payment or reimbursement, and we have modified § 423.871(f) accordingly. We also note, however, that this restriction does not limit CMS or OIG authority to conduct audits and evaluations necessary to ensure accurate and correct payment and to otherwise oversee Medicare reimbursement to fallback entities, or to conduct other statutorily-authorized quality, research, and oversight functions. Nor does this restriction necessarily limit the ability of others with independent authority to collect data using their own authority. As we did in subpart D of this preamble, we interpret sections 1860D–15(d) and (f) of the Act as limiting the use of information collected under the authority of that section. If information is collected under some other authority, however, we do not believe that section 1860D–15 of the Act would limit its use—because the information would not be collected ''pursuant to the provisions'' of section 1860D–15 of the Act. QIOs have independent authority to collect data, and to fulfill their responsibilities. To the extent QIOs need access to data from the transactions between pharmacies and Part D sponsors, these data could be extracted from the claims data submitted to us. We refer readers to subpart D for a more extensive discussion of this issue.

5. Rules Regarding Premiums (§ 423.867)

In § 423.867 we proposed that the monthly beneficiary premium charged under a fallback prescription drug plan offered in all fallback service areas in a PDP region must be uniform (except as provided with regard to any enrollment penalty, low-income assistance, or employer group waivers under § 423.458(c). It must equal 25.5 percent of an amount equal to our estimate of the average monthly per capita actuarial cost, including administrative expenses as calculated by the Chief Actuary, under the fallback prescription drug plan of providing coverage in the region. In calculating administrative expenses, we said we would use a factor based on similar expenses of prescription drug plans that are not fallback prescription drug plans. No comments were received on these statutorily determined provisions and they will be adopted as proposed.

In § 423.867(b) we proposed that fallback plans would not receive any applicable late enrollment penalties since they do not bear risk for increased expenses attributable to individuals to whom the penalty applies. We required that monthly beneficiary premiums for enrollees in fallback prescription drug plans be deducted from Social Security benefits (as provided in § 422.262(f)(1)) or in any other manner provided under section 1840 of the Act. Both § 422.262(f)(1) (as provided under sections 1854(d)(2)(A) and 1840 of the Act provide for the collection of monthly premium through the withholding of benefit payments. For those beneficiaries for whom Federally based monies are not available, section 1840(e) allows for premiums to be ''paid to the Secretary at such times, and in such manner, as the Secretary shall by regulations prescribe''.

In the proposed rule we interpreted the reference to section 1840(e) as requiring direct payment to us when Federal benefit withholds were not available. We stated: ''Premiums from beneficiaries enrolled in fallback plans would not be collected by the plan. Instead, these premiums would be withheld from social security checks (or from other benefits as permitted under section 1840 of the Act). Beneficiaries who do not receive social security checks or otherwise have premiums deducted from other benefits or annuities would pay us directly.'' We have clarified that we have the authority to require that premiums be collected by fallback plans, and to deduct such amounts from payments due to fallback plans in the case of any individual who does not receive such benefits or annuities, or who receives insufficient benefits or annuities to cover the monthly premium. We believe this procedure is more familiar to beneficiaries and to plans, and allows the plan to be in closer touch with the beneficiary's enrollment status. Therefore, we have modified § 423.867(b) to reflect this clarification.

6. Contract Terms and Conditions (§ 423.871)

In § 423.871 we state that the terms and conditions of contracts with eligible fallback entities offering fallback prescription drug plans will be the same as the terms and conditions of contracts for other Part D plan sponsors, with the following exceptions:

- The contract term for a fallback prescription drug plan will be for a period of 3 years (except as may be renewed after a subsequent bidding process). However, a fallback prescription drug plan may be offered for any year within the contract period only if that area is a fallback service area for that year.
- An eligible fallback entity with a contract under this part may not engage in any marketing or branding of a fallback prescription drug plan. This refers to marketing activities promoting the plan and its sponsor to Part D eligible beneficiaries as addressed in § 423.50 of this rule. Section 423.50 includes in the definition of marketing materials: membership communication materials, such as membership rules, subscriber agreements, handbooks and wallet card instructions, letters about contractual changes, changes in premiums, benefits, plan procedures, and membership or claims processing activities. It also refers to required dissemination of information on approved plan characteristics to enrollees as required in § 423.128 of our proposed rule. The prohibition on marketing and branding means that in none of these required activities or materials may the fallback plan sponsor

use its corporate identity to brand the fallback plan; only references to the approved name of the fallback plan or Medicare may be used. Beneficiary education and outreach to employers potentially interested in providing supplemental coverage will remain solely our responsibility.

- Payment will be based on reimbursement for actual costs (taking into account price concessions) of covered Part D drugs provided to Part D eligible individuals enrolled in the plan, and management fees tied to the performance measures that we establish including but not limited to those for cost containment, quality programs, customer service, and benefit administration (including claims adjudication).
- Each contract for a fallback prescription drug plan must require an eligible fallback entity offering a fallback prescription drug plan to provide us with the information that we determine is necessary to carry out the fallback plan payment provisions, and calculate accurate payments, including, but not limited to, all documentation relating to including 100 percent of drug claims, costs, rebates and discounts, and disclosure of all direct and indirect remuneration as offsets to the claim costs.
- We can amend the contract at any time, as needed, to reflect the exact regions or counties to be included in the fallback service area(s).
- Competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5)) will be used in fallback plan contracting.
- Other contract terms will be specified during the bid solicitation process.

We note that like all Part D plans, fallback prescription drug plans must abide by all Federal and State laws regarding confidentiality and disclosure of beneficiary health information, including the obligation of fallback prescription drug plans as HIPAA covered entities to comply with the HIPAA Privacy Rule.

Comment: One commenter asked us to clarify that the service area of a fallback plan will not be changed except by mutual agreement of the parties.

Response: Under umbrella contracts, service area applies to two different aspects of the contract: one is where the fallback plan is actually operating a plan in any given year, and the other is the service area to which the umbrella provisions pertain, meaning the total potential service area. A fallback plan would be required to provide service as determined necessary by CMS in any additional area covered under the umbrella terms but not beyond that service area.

Comment: One commenter recommended that we publish in advance of bidding any proposed performance standards that we intend to use under the proposed fallback contract. The commenter also recommended that provisions be included in § 423.871 to ensure that any performance standards, as well as the requirements and process to establish that the standards have been met, cannot change during the term of a contract.

Response: In accordance with § 423.871, we may specify other contract terms during the bid solicitation process. The performance standards we intend to use under contracts will be provided in the fallback solicitation documentation prior to bidding. [Competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5)] will be used in fallback plan contracting and potential fallback plan sponsors will need to compete on these performance measures. Under Part D plan contract terms and conditions, as described in § 423.516, we agree not to implement any significant regulatory requirements for a Part D plan other than at the beginning of the year.

7. Payment to Fallback Plans (§ 423.875)

As provided in § 423.875, the amount payable under approved fallback prescription drug contracts would be the amount determined under the specific contract negotiated for each such plan under § 423.871(e). In the proposed rule we proposed some alternative payment mechanisms, including draw down accounts and prospective payments, as well prospective or retrospective rebate allocation methodologies.

Comment: One commenter recommended that we use a prospective payment approach, and asked for more detail on how that system would work.

Response: We published separately the proposed guidelines on payment methodologies to Part D plans. Further guidance will be included in the fallback plan solicitation documentation. Our goals are to avoid any undue burden to fallback plans and at the same time develop a method of payment that requires a limited amount of adjustment.

R. Payments to Sponsors of Retiree Prescription Drug Plans

1. Introduction

Subpart R implements section 1860D–22 of the Act, which provides for subsidy payments to sponsors of qualified retiree prescription drug plans. Sponsors of qualified plans can receive an annual subsidy equal to 28 percent of specified retiree drug costs.

We received 87 comments on subpart R in response to the August 2004 proposed rule. Below we summarize the major proposed provisions in the subpart and respond to public comments. (For a detailed discussion of our proposals, please refer to the proposed rule (69 FR 46736).)

2. Options for Sponsors of Retiree Prescription Drug Programs

The enactment of Title I of the MMA has provided sponsors of retiree prescription drug plans with multiple options for providing drug coverage to their retirees. In the preamble of the proposed rule, we reviewed the various options available to sponsors. We believe the availability of these various options will encourage sponsors to continue to assist their retirees in having access to prescription drug coverage. For the benefit of the sponsors, we again summarize the options below.

Generally, employers and unions who offer drug benefits to their retirees (and their dependents) who are eligible for Medicare Part D can choose to:

(1) Continue to provide prescription drug coverage through employment-based retiree health coverage. If such coverage is at least actuarially equivalent to the standard prescription drug coverage under Part D (as defined in § 423.104 of the final rule), the sponsor is eligible for a special Federal subsidy for each individual enrolled in the sponsor's plan who is eligible for Part D but elects not to enroll in Part D;

(2) Contract with a prescription drug plan (PDP) or Medicare Advantage-prescription drug (MA-PD) plan to offer prescription drug benefits to retirees who are eligible for Medicare. Alternatively, the retiree plan sponsor itself could apply to be a Part D plan for its retirees. Such plan may consist of ''enhanced alternative coverage'' (as defined under § 423.104(f) of the final rule), offering drug coverage that is more generous than the standard prescription drug coverage under Part D (as defined under § 423.104 of the final rule); or

(3) Provide separate prescription drug coverage that supplements, or ''wraps around,'' the coverage offered under Part D plans in which the retirees (and their Medicare eligible dependents) enroll.

The first option is the subject of this subpart R. The latter two options, which involve the employer or union's retirees (and their dependents) enrolling in Part

D, were discussed in the preamble of the proposed rule for subpart J, § 423.454(b)

We note that if employers or unions elect to sponsor enhanced alternative coverage under Part D or provide separate supplemental coverage that wraps around Part D, this will affect the point at which their retirees (and their dependents) are eligible for catastrophic drug coverage, which will have consequences for the participants, the sponsors, the plans, and the Medicare program. As specified in subpart C of the final rule, individuals enrolled in a Part D plan are eligible for catastrophic drug coverage after they incur out-of-pocket drug costs in the amount specified under § 423.104(d)(5)(iii) of the final rule. Under the reinsurance provisions at § 423.329(c), Medicare will reimburse Part D sponsors 80 percent of their gross costs for providing catastrophic coverage (excluding administrative costs and reduced by any discounts, rebates, and similar price concessions). Only drug costs paid by a Part D enrollee, or on behalf of a Part D enrollee by another individual, a charitable organization or a qualified State Pharmacy Assistance Program but excluding insurers, government-funded health care programs, group health plans, and similar third party arrangements, would count toward the annual out-of-pocket threshold. We refer to those drug expenditures that count toward the out-of-pocket threshold as ''true out-of-pocket (TrOOP) expenditures.''

Under these rules, sponsors who provide retirees (and their dependents) enhanced alternative coverage in effect delay the point at which an individual's total drug spending will trigger catastrophic coverage, since participants in the plan will have lower cost-sharing, and thus have lower out-of-pocket costs. Similarly, when employers or unions sponsor supplemental coverage that wraps around Part D coverage, there will be an increase in drug expense that must be incurred before catastrophic coverage is triggered, since drug costs paid for by such plans do not count toward the out-of-pocket annual limit. By delaying the provision of catastrophic coverage, these plans lower the cost of Part D to the Federal government by lowering our reinsurance payments.

As discussed above, under MMA, sponsors of retiree prescription drug plans can provide coverage that supplements or ''wraps around'' the Part D standard benefit in two ways. First, plan sponsors can purchase integrated supplemental coverage directly from a specific Medicare prescription drug plan (PDP) or Medicare Advantage plan that includes prescription drugs (MA-PD). Second, plan sponsors can maintain a free-standing plan which is not tied to a specific PDP or MA-PD and is meant to supplement any of the Part D plans that Medicare-eligible retiree plan participants enroll in.

We also note that the choice between integrated and separate supplemental coverage has operational implications for plan sponsors. If the sponsor purchases integrated coverage through a PDP or MA-PD, the enrollment of retirees in Medicare Part D will be handled by the PDP or MA-PD. Under this approach, the dispensing pharmacy will only need to undertake one transaction to the PDP or MA-PD; there would not be separate standard Part D and supplemental coverage transactions. In contrast, when sponsors provide coverage through a separate plan, they (or their plan administrator) will only handle enrollment for their free-standing coverage; retirees will be responsible for enrolling in Part D coverage of their choice. We are sensitive to the concerns of plan sponsors regarding the operational challenges of coordinating separate plans with Part D plans. Therefore, we are exploring approaches that stakeholders may be able to use to coordinate benefits at point-of-sale among these plans through the use of a single point of contact for coordination of benefits and facilitation of TrOOP calculation at the Part D plan..

CMS has a program that can assist plan sponsors and administrators with identifying Medicare eligible individuals covered under their plans. This is a process called the Voluntary Data Sharing Agreement (VDSA) process. Plan sponsors that enter into VDSAs will be better prepared for enrolling their retirees into either integrated supplemental coverage through a Part D plan, establishing a separate plan to supplement or ''wrap around'' Part D coverage, or applying for the retiree drug subsidy. There is no requirement that any employer enter into a VDSA; it is strictly a voluntary process. (For more information on VDSAs, go to the website at *http://www.cms.hhs.gov/medicare/cob/employers/emp_vdsa.asp*). Other existing CMS programs permit group health plans and other secondary payers to sign agreements to receive Medicare paid claims data for the purpose of calculating their secondary payment liability.

When an employer or union elects to sponsor retiree coverage through a Part D plan, the employer, union or entity seeking to offer or administer such coverage may submit written requests to us for permission to waive requirements under Part D that hinder the design of, offering of, or enrollment in an employer-sponsored group prescription drug plan (as defined under § 423.454) or a MA-PD plan offered exclusively to the sponsor's retirees and their spouses and dependents. We believe these waivers will facilitate efficient administration and integration of sponsor-provided enhanced alternative coverage with other retiree health benefits offered by the sponsor. For example, the PDP or MA organization could request permission to restrict enrollment in its Part D plan to the retiree plan sponsor's retirees (and their dependents). Similarly, should the plan sponsor wish to enroll its retirees (and their dependents) in its own plan, with enrollment limited to such individuals, the sponsor could apply to be a Part D plan sponsor organization offering a PDP or MA-PD plan, and request such waivers as necessary. Further guidance on waivers will be provided to assist sponsors in evaluating this option.

We encourage plan sponsors to carefully review each option and determine which one is most beneficial to the sponsor and its retirees. We believe that the variety of options will encourage sponsors to retain drug coverage for their retirees.

3. Definitions (§ 423.882)

The final subpart R rules provide definitions that are critical to understanding how the retiree drug subsidy functions. We received comments regarding only a few of the proposed definitions under subpart R: group Health Plan, qualifying covered retiree, allowable retiree costs, and sponsor. We also amended the definition of gross covered retiree plan-related prescription drug costs based upon comments received in response to the definition of a covered Part D drug in § 423.100 in subpart C, and added a definition of sponsor agreement in response to comments received on the proposed rule.

A. *Group Health Plan*: In general, the subsidy is paid for allowable retiree costs in a sponsor's group health plan. The statute and the proposed regulations incorporated the definition of Group Health Plan that appears in section 607(1) of the Employee Retirement Income Security Act (ERISA), 29 U.S.C. 1167(1). (This is also the definition used in the health care continuation of coverage provisions of ERISA, as added by the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA).) The statutory definition, incorporated in the proposed regulations, also specifically includes

plans maintained for their employees by the Federal Government, plans maintained by State or local governments, and church plans exempt from Federal taxes, even if they are not subject to ERISA or COBRA requirements.

In the preamble to the proposed rule we said we intended to model our rules on the COBRA regulations (26 CFR § 54.4980B–2, Q.6) that apply for determining the number of group health plans sponsored by an employer or a union, which is important for purposes of applying the actuarial equivalence test. Under the COBRA rules, all health benefits provided by a single employer constitute one group health plan, unless it is clear from the instruments governing an arrangement or arrangements that health care benefits are being provided under separate plans, and the arrangement or arrangements are operated pursuant to such instruments as separate plans. The COBRA rules also provide that if a principal purpose of establishing separate plans is to evade any requirement of law, then the separate plans will be considered a single plan to the extent necessary to prevent the evasion. To the extent that the COBRA rules require that an arrangement be considered a single group health plan, the sponsor must follow special rules for determining actuarial equivalence described in section 4(b)(3) of this subpart of the preamble below.

Comments: Several plan sponsors, health plans, and employer advocacy groups suggested that we adopt the rules in the COBRA regulations for determining the number of plans sponsored by an employer or union, but remove the requirement that the arrangements be operated as separate plans. Some plan sponsors wanted the flexibility to differentiate between various groups of retirees within a single plan without compromising their plan's eligibility status. (For example, some sponsors separate their retirees according to years of service, family status, location, retirement date, coverage level, contribution structure, etc.) An actuarial association agreed that we should give employers and unions the flexibility to define plans and move away from a single plan definition to allow multiple benefit options to be included within a plan.

An employer advocacy group discouraged us from requiring a separate filing, other than the attestation of actuarial equivalence, to satisfy any documentation requirement for plan definition purposes. A beneficiary advocacy group approved the use of the COBRA rules for determining the number of plans, but suggested limits on how actuarial valuation rules should be applied if there are multiple drug benefit options.

Response: For the purposes of subpart R, the term group health plan will mean plans that meet the definition of group health plan in ERISA section 607(1), 29 U.S.C. 1167(1), including plans established or maintained for its employees by the Government of the United States, by the government of any State or political subdivision, or by an agency or instrumentality of the foregoing; plans established or maintained under or pursuant to one or more collective bargaining agreements; and plans established or maintained for its employees (or their beneficiaries) by a church or by a convention of churches which is exempt from tax under section 501 of the Internal Revenue Code. Provided they meet the definition of group health plan in ERISA section 607(1), those arrangements are treated as group health plans even if the plans are not subject to ERISA or COBRA. Sponsors should use the rules in the COBRA regulations and other guidance issued by the Treasury Department and Internal Revenue Service for determining the number of group health plans offered by a plan sponsor. However, as discussed in § 423.884, the final rule generally gives a sponsor with different benefit options (including different cost-sharing arrangements) within a single group health plan a significant degree of flexibility to choose whether to measure actuarial equivalence and receive subsidy payments for aggregated benefit options or to apply the rules separately for each benefit option.

Comments: A business advocacy group recommended that defined contribution accounts such as Health Reimbursement Accounts (HRAs), Health Savings Accounts (HSAs), Archer Medical Savings Accounts (MSAs) and Flexible Spending Arrangements (FSAs) be considered group health plans for purposes of qualifying for the retiree subsidy. In addition, they recommended that sponsors establishing account-style plans that credit amounts during an individual's active service toward retiree benefits have the discretion to allocate payments between medical and drug costs for purposes of the actuarial equivalence test.

Response: The final rule clarifies that Health Reimbursement Arrangements (HRAs) (as defined in Internal Revenue Service Notice 2002–45, 2002–28 I.R.B. 93, and Internal Revenue Ruling 2002–41, 2002–28 I.R.B. 75) and health Flexible Spending Arrangements (FSAs) (as defined in Internal Revenue Code (IRC) section 106(c)(2)) are treated as group health plans given the nature of these arrangements, including that they generally are treated as health plans by employers and unions subject to ERISA. The term group health plan generally will not include health savings accounts (HSAs) (as defined in IRC section 223) or Archer MSAs (as defined in IRC section 220), unless these accounts are treated as part of a group health plan under ERISA rules. While HSAs and Archer MSAs may not be group health plans, any high deductible plans that sponsors provide in connection with HSAs and Archer MSAs are group health plans.

However, regardless of whether an account-type arrangement is a group health plan, the nature of such a plan raises certain challenging questions for purposes of the retiree drug subsidy program. For example, how should the value of the prescription drug coverage available through an account be determined if the account can be used to pay for prescription drug coverage and other benefits? Will beneficiaries be able to adequately compare that arrangement to benefits available through Part D, particularly if the account stands alone and is not offered in conjunction with other types of coverage (such as high-deductible plans)? How can it be determined whether these arrangements are creditable coverage for purposes of implementing the late enrollment penalty in § 423.46?

We intend to offer further guidance on these issues and on what types of account-based arrangements can be considered for the subsidy.

Drug costs paid or reimbursed from funds in an HRA, which is generally funded solely by the employer, do not count as an incurred drug cost for purposes of the True Out-of-Pocket (TrOOP) rules, while drug costs paid or reimbursed from funds in other types of accounts, which can be funded by the employee, do count towards TrOOP. (See subparts C and J of this preamble (Coordination of Benefits), for a more detailed explanation of the rules for calculating TrOOP expenditures.)

B. *Qualifying Covered Retiree*: The statute defines qualifying covered retirees as Part D eligible individuals, who are not enrolled in a Part D plan but who are covered under a qualified retiree prescription drug plan. The statute indicates that qualifying covered retirees include Part D eligible individuals who are spouses and dependents of covered retirees. The proposed rule used the statutory definition without further clarification.

Comments: An association of actuaries requested that the final regulations clarify whether a qualifying covered retiree, under the retiree drug subsidy calculations, includes an employee who is receiving coverage following a disability and who is also entitled to Medicare Parts A or B on account of that disability (and therefore eligible for Part D). One employer advocacy group suggested that disabled Medicare-eligible individuals under age 65 be considered retirees for subsidy purposes, and that employers might drop coverage entirely if we decide not to allow it.

An employer advocacy group encouraged us to deem persons with End Stage Renal Disease (ESRD) as qualified retirees for purposes of the subsidy, because these individuals might receive lower drug coverage without such designation.

A government association sought clarification on the status of domestic partners who are Part D eligible individuals and their eligibility as qualifying covered retirees' dependents, for purposes of calculating the retiree drug subsidy.

Response: For the purposes of subpart R, the term qualifying covered retiree means a Part D eligible individual who is: (1) a participant or the spouse or dependent of a participant; (2) covered under employment-based retiree health coverage that qualifies as a qualified retiree prescription drug plan; and (3) not enrolled in a Part D plan. In general, sponsors will have flexibility to determine whether an individual is a retiree, and to determine who are dependents of retirees based on the coverage rules under the plan. However, a participant is presumed to not be a retiree if the person is receiving health coverage based on current employment status as determined under the Medicare Secondary Payer (MSP) rule (§ 411.104 of this chapter) (regardless of whether such rules apply to the sponsor). We believe this approach gives reasonable flexibility to sponsors in terms of defining who is a retiree or dependent for purposes of the subsidy provisions. Under this definition, for example, sponsors generally can treat a person who is entitled to Medicare based on disability as a retiree for these purposes; sponsors can treat as a dependent any person to whom the sponsor is providing coverage in connection with a qualified covered retiree even if the person is not the retiree's dependent for Federal or State tax purposes; and they can treat as retirees self-employed persons and other individuals who previously provided services to the sponsor of the group health plan on a contractual, rather than employment, basis.

End Stage Renal Disease (ESRD) beneficiaries who are not active workers meet the definition of a qualifying covered retiree if they do not enroll in Part D. Accordingly, sponsors can count for purposes of the retiree drug subsidy the allowable retiree costs of ESRD beneficiaries, including those costs incurred in the first 30 months of eligibility when the sponsor's plan is primary to Medicare.

Comments: Comments from employers, employer advocates and government entities informed us that the retiree drug subsidy program not only affects retirees of the sponsors, but also the possible dependents of non-Medicare eligible workers or retirees who will be eligible for Medicare and therefore covered by the reporting requirements.

Response: In response to the comments regarding non-Medicare eligible, active employees who have dependents who are Medicare Part D eligible individuals, the sponsor would not be eligible to claim the subsidy for the dependents because the covered worker is not in a retiree status. For covered retirees who are not themselves Part D eligible individuals, but who have dependents who are Part D eligible individuals, the sponsor would be able to claim the dependents' eligible prescription drug expenses under the subsidy.

C. *Gross covered retiree plan-related prescription drug costs*: The proposed rules defined this term as ''non-administrative costs incurred under the plan for *covered Part D drugs* during the year ... including costs directly related to the dispensing of *covered Part D drug*''. Section 423.100 of the final rule now makes a distinction between a ''covered Part D drug'' and a ''Part D drug.'' A ''Part D drug'' is a drug that may be covered under Part D pursuant to section 1860D–2(e) of the Act and a ''covered Part D drug'' is a Part D drug that is in a Part D plan formulary. For purposes of calculating the appropriate drug costs for the retiree drug subsidy, sponsors of retiree prescription drug plans may count costs incurred for any drug that can be covered under Part D. Accordingly, we have changed the definition of gross covered retiree plan-related prescription drug costs to mean non-administrative costs incurred under the plan for *Part D* drugs during the year ... including costs directly related to the dispensing of Part D drugs.

D. *Allowable Retiree Costs*: The proposed rule defined Allowable Retiree Costs as gross covered retiree plan-related prescription drug costs between the cost threshold and cost limit that are actually paid by either the qualified retiree prescription drug plan or the qualifying covered retiree (or on the retiree's behalf), net of any manufacturer or pharmacy discounts, chargebacks, rebates, and similar price concessions.

Comments: Several beneficiary advocacy groups wanted us to adopt a definition of allowable retiree costs that included only the employer's financial contribution to retiree drug coverage, not any of the payments made by the retiree. They believe that including contributions from the retiree could result in ''improper cost shifting.''

Response: There is no statutory authority to exclude retirees' payments in the definition of allowable retiree costs. The statute specifies that retiree drug subsidy payments are made for gross covered prescription drug costs paid by or on behalf of a qualified covered retiree. Thus, as long as coverage meets the actuarial equivalence standard, costs paid by the retiree will be included along with sponsor payments under the plan in determining retiree drug subsidy payment amounts.

Comment: An association of actuaries found it difficult to understand what we are is defining as gross costs to be used in determining allowable retiree costs, but this might be due to a simple terminology difference, so they suggest we provide examples to clarify what costs should be used.

Response: The statute indicates that gross covered retiree plan-related prescription drug costs are costs incurred under the plan, not including administrative costs but including the costs directly related to the dispensing of Part D drugs. The final rule retains the basic statutory definition. We may (if needed) issue further guidance to clarify what costs constitute gross covered retiree plan-related prescription drug costs.

Comment: A government entity found the term price concessions problematic because, as used in its contract with a pharmacy benefit manager (PBM), that term refers to confidential and proprietary information. Also, rebates are included in the pricing quoted to the PBM, and are not an identifiable line item that can be easily subtracted to determine allowable retiree costs.

Employer groups requested that we distinguish what will be included in the definition of price concessions for the purpose of calculating allowable retiree costs.

Specifically, the groups provided a number of comments on why price concessions relating to performance guarantees and point-of-sale discounts

should not be included in allowable retiree costs.

They claim that including such price concessions when calculating allowable retiree costs would require a large, nearly impossible administrative burden. Performance guarantees or incentives, as well as point of sale discounts, lower the price of the prescription drug in a manner that would make it burdensome for the sponsor to determine the gross allowable costs. Thus, the employer groups argue that, in the instance where performance guarantees and point-of-sale discounts occur, reporting the actual cost to the sponsor as the gross cost should be sufficient.

Response: The statutory provisions of the MMA specify that allowable retiree costs may include only costs actually paid by the sponsor or by or on behalf of a qualifying covered retiree, and that rebates, chargebacks and average percentage rebates must be subtracted from those costs. To comply with the statute, the final regulation retains the requirement that these and similar price concessions be taken into account in determining allowable retiree costs.

We anticipate providing any additional clarification that is required for price concessions in further guidance. However, pending such guidance, performance guarantees that are not predicated on actual drug costs incurred, but rather on matters such as customer service performance standards or identification card delivery, are likely not the types of price concessions that need to be taken into account in determining allowable retiree costs. Moreover, to the extent point-of-sale discounts and other price concessions are passed through to the beneficiary and plan at the point-of-sale for a given drug expense, the allowable retiree costs and gross covered retiree plan-related prescription drug costs for the expense would be equal, and the point-of-sale discounts and other price concessions would not have to be further subtracted from these costs when a sponsor calculates allowable retiree costs as defined in § 423.882.

Comments: For sponsors with fully insured plans, a health industry association and insurers ask that we provide sponsors with the flexibility to have the retiree drug subsidy calculated based on the sponsor's premiums, using reasonable actuarial methods to determine what portion of the premium is allocated to gross covered prescription drug costs of qualifying covered retirees within the cost threshold and cost limits. Commenters support that position by arguing that employers and unions purchasing insurance do not pay actual incurred drug costs; they pay a premium based on expected costs, which may be pooled with a broader group of employers and unions. In a given year, an employer's or union's retirees may incur drug costs that are more than or less than the premium paid. They expressed concern that if drug costs actually paid by the insurer rather than premiums paid by the employer or union were the measure for subsidy payments, for any given retiree the employer or union would be getting a subsidy payment that is likely higher or lower than the allowable cost actually incurred by the employer or union (via the premium) for that retiree.

As noted, the commenters propose using reasonable actuarial methods to determine a percentage of the premium that approximates what was paid for Part D-eligible retirees within the cost thresholds and cost limits. They also request being allowed to perform these calculations on an aggregate basis for all employers and unions with a specific retiree drug plan, since the experience for the employers and unions is pooled when determining premiums.

Another fully insured plan sponsor recommended that if the plan sponsor contracts with an at-risk health plan, the retiree drug subsidy should be a flat payment based upon the amount paid instead of adjusted for actual experience and requested clarification as to how we anticipate the subsidy to be integrated with fully insured plans.

Response: The statute specifically requires that a subsidy payment be based on allowable retiree costs attributable to gross covered retiree plan-related prescription drug costs, which are actual prescription drug costs incurred under the plan (not including administrative costs but including costs directly related to the dispensing of Part D drugs) for a qualifying covered retiree. In general, we believe the statute envisions that the incurred costs are costs actually paid by the insurer for each qualifying covered retiree. However, we also recognize the concerns that were raised in the comments. Therefore, in lieu of submission of the cost data under § 423.888(b)(2), the sponsor and insurer may choose instead to have data submitted in the following manner. If an sponsor chooses monthly, quarterly or interim annual payments as described in § 423.888(b)(5), the interim subsidy payments made during the year can be based on a determination by the insurer using reasonable actuarial principles that allocates a portion of the premium costs charged to the sponsor (excluding administrative costs, risk charges, etc., but including premium costs that the sponsor requires the retiree to pay) to the gross covered prescription drug costs incurred for a sponsor's qualifying covered retirees between the cost threshold and the cost limit. If the insurer determines premiums based on the pooling of a sponsor's experience in a given policy, the insurer will be permitted to make such determination based on the aggregate experience incurred under the policy for the sponsor's qualifying covered retirees. However, a revised cost determination must be submitted to us (within the same time frame that year-end data is required under § 423.888(b)(4)) that reflects the actual allowable retiree costs attributable to gross retiree plan-related prescription drug costs within the cost limit and cost threshold that were incurred under the plan for each of the sponsor's qualifying covered retirees. Thus, we must receive data described in § 423.888 that indicates the extent to which actual gross costs and allowable costs for a sponsor's qualifying covered retirees were more or less than the sponsor's previously-allocated premium costs. We will accept data submitted directly by the insurer. Upon receiving this data, we will adjust the payments made for the plan year in question in a manner to be specified by us.

Comment: Several plan sponsors wanted clarification that subsidy payments go to the plan sponsor, not the insurer.

Response: The statutory language is clear that the retiree drug subsidy is paid to the plan sponsor.

Comment: Commenters suggested that we provide guidance on whether the prices negotiated with sponsors of qualified retiree prescription drug plans are exempt from the Medicaid best price calculation.

Response: In section 1927(c)(1)(C) of the Act, best price is defined as the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, non-profit entity, or governmental entity within the United States. Among the exemptions listed in the statute are any prices charged which are negotiated by a qualified retiree prescription drug plan as defined in section 1860D–22(a)(2) of the Act. Therefore, prices negotiated between a qualified retiree prescription drug plan sponsor and a manufacturer will not go into the Medicaid best price calculation.

E. Sponsor:

The proposed regulations state that sponsor means plan sponsor as defined in ERISA (29 U.S.C. 1002(16)(B)), which is an employer in the case of an

employee benefit plan established or maintained by a single employer or an employee organization (for example, trade union) in the case of a plan established or maintained by an employee organization. In the case of a plan established or maintained by two or more employers or jointly by one or more employers and one or more employee organizations, ERISA defines the sponsor as the association, committee, joint board of trustees or other similar group of representatives of the parties who establish or maintain the plan. The MMA modifies the definition when the plan is maintained jointly by one employer and one employee organization; if the employer is the primary financing source, sponsor means only the employer.

Comments: A governmental organization indicated that plans such as its own are exempt from ERISA and therefore may not fall within the strict definition of an ERISA plan. This plan believes that Congressional intent was to include plans like it, and requests that we include a provision to allow governmental plans offering a qualified retiree prescription drug plan to receive the retiree drug subsidy.

A State government entity expressed concern over the definition of sponsor and whether or not it would be included under the Part D final regulations even though it is not covered under ERISA. A national association of public employee retirement systems indicated its preference that the final regulations not contain a definition of plan sponsor, or if they must, that the definition of plan sponsor defer to applicable State and local laws and regulations. The association suggested this because they think that imposing a definition in the final regulations could have unintended impact on State and local laws.

Response: As noted above, the definition of a group health plan includes plans sponsored by Federal and State government plans and their political subdivisions, agencies and instrumentalities. Thus, we agree that under the MMA, States and other governmental organizations can potentially qualify as sponsors. We believe the definitions for sponsor and for group health plan as stated in the proposed rule clearly indicated this. We believe a more specific definition of a sponsor in the final rule that takes into account the various types of sponsor arrangements that may exist would be problematic. We will consider issuing additional guidance to sponsors based on their particular facts and circumstances.

F. Benefit option:

In response to comments we received on applying the actuarial equivalence test to individual plans (summarized in the discussion of actuarial equivalence in section 4(b)(3) of the preamble, below), we have added in the final rule a definition of benefit option, which we define as a particular benefit design, category of benefits, or cost-sharing arrangement offered within a group health plan.

4. Requirements for qualified retiree prescription drug plans (§ 423.884)

(a) Overview

(1) General Requirements

In the proposed rule, we outlined the general requirements for applying for the retiree drug subsidy, including the submission of an attestation of actuarial equivalence and the disclosure notices to beneficiaries. We requested comments on the most effective methods of conducting outreach as well as prospective venues for conducting the outreach.

Comments: Several commenters emphasized that it was critical that we provide guidance on the retiree drug subsidy process as soon as possible in light of the fact that enrollment is to begin in 2005. Several comments requested that we publish the final rule by December 31, 2004 and issue guidance before that date.

Response: We respect the prospective sponsors' need to have guidance on the retiree drug subsidy as soon as possible due to the complexity and timing of the process. In addition to promulgating this final rule and issuing other guidance as quickly as possible, we will continue to conduct outreach to various groups to educate the stakeholders on the requirements for applying for the retiree drug subsidy.

(2) Privacy and Confidentiality

The HIPAA Privacy Rule at 45 CFR part 160 and subparts A and E of part 164 (''Privacy Rule'') applies to ''covered entities,'' which include group health plans and health insurance issuers, as defined in 45 CFR 160.103. Third party administrators would be business associates, as defined in 45 CFR 160.103, of group health plans. Sponsors would not become covered entities by sponsoring a plan. Sponsors typically do not perform administrative activities for their group health plans and therefore do not have access to the claims information or similar protected health information (PHI) we require in this regulation to support the retiree drug subsidy payment. Much of the data that we would need to support the retiree drug subsidy payments, as outlined above, would be PHI held by group health plans, health insurance issuers, or third party administrators on behalf of group health plans.

As indicated in the proposed rule, we believe that we have the authority to mandate the disclosure of the PHI in accordance with our oversight authority under section 1860D–22(a)(2)(B) of the MMA, and covered entities on behalf of individuals eligible for benefits under Part A or Part B can comply with the mandate (without first obtaining specific authorization from individuals) pursuant to ''the required by law'' provisions of the Privacy Rule (45 CFR 164.512(a)). We have added a paragraph, § 423.884(b) to clarify that a disclosure to us by a group health plan or health insurance issuer is required by law when necessary for the sponsor to comply with this subpart.

As noted above, typically group health plans and issuers or third party administrators acting on behalf of group health plans, have PHI that CMS requires for the submission of cost and claims data for payment of the retiree drug subsidy pursuant to § 423.888(b)(2) and other sections. In these situations, it may be unlawful, under the Privacy Rule, for PHI to be shared with the sponsors. Therefore, for purposes of this subpart, the sponsor must have a written agreement with the group health plan or health insurance issuer, as applicable, regarding disclosure of records, and the plan or issuer must disclose to us, on the sponsor's behalf, the information necessary for the sponsor to comply with this subpart. Sponsors of self-funded plans with access to such data will be able to either provide this data to us themselves or have a group health plan or insurer provide the data to us on their behalf. We asked for comments on the impact this transfer of data will have on the plan sponsors, group health plans, issuers and third party administrators.

Comments: An business consulting firm indicated that employers do not collect Medicare information on their retirees because of HIPAA privacy concerns and that requiring employers to store this data will add a great deal of administrative complexity and cost. A pharmaceutical company recommended that we require that only total aggregate cost data (not broken out by individual retirees) be submitted to us for payment purposes in order to protect patient privacy. An employer advocacy group agreed that we have the authority to mandate disclosure of PHI for retiree drug subsidy purposes and requested that we clarify that individual authorization not be required for such disclosure. A human resource

management association also agreed that we have the authority to mandate disclosure of PHI and requested that we clarify that the disclosures will not violate State privacy statutes.

Response: As noted above, employers will not be required to collect or maintain Medicare data on their retirees for purposes of collecting the retiree drug subsidy. They can direct their group health plans or health insurance issuers, as well as third party administrators (or other business associates), to submit the required protected data to us on their behalf. We agree that individual authorization will not be required for the disclosure of the data to us since the disclosure is required by this regulation for purposes of payment of the retiree drug subsidy.

The HIPAA Privacy Rule preempts a contrary provision of State law except in specific circumstances, such as if the State law is more stringent-that is, more protective of privacy-than the Privacy Rule. (See 45 CFR Part 160, subpart B). Therefore a sponsor, or an issuer, plan or third party administrator on behalf of a sponsor, may need to comply with State privacy laws as well as the HIPAA Privacy Rule in disclosing information to us.

Comments: Several pharmaceutical companies requested that we extend the confidentiality protections under the Medicaid rebate law to data submitted to us under § 423.888.

Response: We agree that the rebate information being disclosed to us is confidential. We believe that protections provided under other sections of the regulation will ensure this. We anticipate issuing further guidance regarding this issue.

(b) Actuarial Attestation

In order to be eligible for a subsidy, the coverage of a sponsor's qualified retiree prescription drug plan must be at least actuarially equivalent to the standard Part D coverage. The sponsor will have to annually submit to us an attestation that its coverage meets this requirement. We discuss below the methodology and the standards for the sponsor submission of the actuarial attestation.

1. Timing, Who Can Submit, and Public Access to Data

(a) We proposed to require that the attestation be submitted to us before September 30, 2005 for the calendar year 2006 and at least 90 days before the beginning of the calendar year (or plan year, depending on whether the final rule used a plan year approach) for subsequent years. We also proposed to require that an attestation be submitted to us at least 90 days prior to the effective date of any material change to the drug coverage of the plan that impacts the actuarial value of the coverage.

Comments: Among the comments that we received, a business consultant requested that we shorten the time period for submission of the actuarial attestation to 30 days prior to the start of the year because most employers and unions do not know their final plan design 90 days in advance. An actuarial consultant, on the other hand, indicated that the 90 day timeframe was reasonable and sufficient to accomplish the objectives of the MMA. We received comments from several employer groups recommending that we not require subsequent annual attestations from sponsors that had not implemented any changes in their retiree drug coverage since the previous submission of the attestation for the plan.

Response: In the final rule, we require that the attestation be submitted 90 days before the start of the plan year and by September 30, 2005 for plan years ending in 2006 (see our discussion of plan year vs. calendar year under § 423.888), unless an extension request has been filed by the date under rules specified by the Secretary. We also require the filing of attestations 90 days prior to the effective date of any material change. We believe this process provides us sufficient time to review the attestation and to notify the sponsor of any problems (for example, attestation not signed by a qualified actuary), yet is flexible enough to permit extensions in necessary cases.

The final rule retains the requirement that sponsors submit a new actuarial attestation on an annual basis, even if a sponsor has not implemented any changes to its retiree coverage since the previous submission of the attestation for the plan. The thresholds for Part D coverage will change each year and this may impact whether the sponsor's plan is actuarially equivalent.

Comment: A beneficiary advocacy group indicated that a requirement of 90 day advance notice to beneficiaries of any change that will render coverage no longer actuarially equivalent is an important protection.

Response: To be consistent with the policy on creditable coverage and reflect statutory requirements, the final rule requires that sponsors provide notice to beneficiaries prior to any change that will render coverage no longer creditable. See the discussion in subpart B of the preamble for further guidance on creditable coverage notice requirements. Advance notice regarding changes in actuarial equivalence is not required by the MMA, and we decline to impose that requirement in the final rule. See also our response to the following comment.

Comment: Several union and beneficiary advocacy groups recommended that we provide public access to the assumptions and methods used by sponsors for their attestations of actuarial equivalence. A union suggested that we develop a form, similar to the Department of Labor's 5500 form (used for ERISA disclosures), for sponsors to file with their attestations, which would then be accessible for public inspection. The unions and beneficiary advocates indicated that public access to this data would increase public confidence in the retiree drug subsidy program and would permit the retirees to monitor the sponsors' filings for accuracy. Business advocacy groups indicated that the Congress neither required employers or unions to disclose their actuarial equivalency calculations to anyone but us for audit purposes, nor gave individuals the right to challenge an employer's or union's actuarial equivalency determination. An actuarial consultant recommended that the attestation of actuarial equivalence and the application for the subsidy should be submitted and therefore disclosed to CMS only. The consultant indicated that the data submission and the application may have proprietary information embedded in it, as well as beneficiary data subject to privacy concerns.

Response: While we understand the rationale for requiring public disclosure of certain attestation data, we have concerns that requiring public disclosure of the assumptions and methods used for the actuarial attestation could inhibit the desire of sponsors and their service providers to file for the subsidy and to maintain their retiree drug benefits, for example, for fear of disclosure of proprietary data. We want to further study this issue to determine if there is a level of public disclosure of attestation data that will enhance beneficiary confidence in the retiree drug subsidy program but will not deter sponsors from filing for the subsidy and maintaining their retiree coverage.

(b) In the proposed rule, we require that the attestation be certified by the attesting actuary. We also required that the attesting actuary be a member of the American Academy of Actuaries.

Comments: We received several comments from small employers stating that we should accept attestations of actuaries with the insurance carriers or with third party administrators who can attest on behalf of the sponsor that the sponsor's retiree drug coverage is

actuarially equivalent to Part D. It was indicated that small employers may not have the resources to hire an actuary for the attestation.

Response: We agree that sponsors can submit attestations of actuaries employed by insurance carriers, pharmacy benefit managers or the third party administrators of their retiree drug plans. The attestation will be submitted in a form or forms approved by us in additional guidance. We expect to require the attestation to solely address the sponsor's plan and meet all requirements for the attestation.

Comment: One health care industry organization requested that due to the cost of an annual attestation, small employers should be allowed to submit an application, their eligibility list and plan benefit descriptions, provide us with two years of experience or premium data, and have our actuaries perform the attestation on behalf of their plan.

Response: The statute states that, as a condition of receiving the retiree drug subsidy, the sponsor must provide the attestation to us. As indicated above, a sponsor can have an outside actuary do the attestation and the attestation may be submitted directly by such outside actuary or by the plan sponsor to us pursuant to the procedures outlined in this final rule.

2. Establishing Actuarial Equivalency

In the proposed rule, we outlined three options for the actuarial equivalence standard. The first option was a single prong gross value test in which the plan design of the sponsor's retiree drug plan will be compared with the plan design of standard prescription drug coverage under Part D without taking into account the financing of the coverage. This test would generally require that the expected amount of paid claims (or plan payout) under the retiree prescription drug coverage be at least equal to the expected amount of paid claims under the standard Medicare Part D benefit. The second option involved using the ''gross value'' test as in option one but restricting the subsidy payment to no more than what the sponsor contributed towards the cost of the retiree drug coverage. The third option was a two-prong test in which the first prong is the gross value test as in option one, and the second prong is a net value test which takes into account the sponsor's contribution toward the financing of the retiree prescription drug coverage.

The proposed rule also discusses several variants for determining the value of the second prong of option three, the net value test. The lowest variant proposed is the average per capita amount that Medicare will expect to pay for the retiree drug subsidy. A second variant was the after-tax value of the retiree drug subsidy, since the subsidy is not subject to Federal income tax. The highest variant stated in the proposed rule would compare the gross value of the plan design reduced to account for the level of benefits financed by the beneficiary (that is, by subtracting out the retiree premiums) to the expected value of paid claims under standard prescription drug coverage under Part D minus the retiree's expected monthly beneficiary premium for the coverage. As we indicated in the preamble to the proposed rule, adopting a higher variant for the net value could arguably provide greater protection for beneficiaries against cost-shifting but also make it more difficult for sponsors to qualify for the subsidy. Conversely, adopting a lower variant would allow more sponsors to qualify for the subsidy but may discourage some employers and unions from increasing their contributions to reach the higher threshold level.

Comments: We received numerous comments on this standard. The vast majority of the comments, including those from both the business groups and beneficiary advocacy groups, supported the two-prong test (option three) as best serving our stated goals of maximizing the number of retirees that retain their employer and union retiree drug coverage and not creating windfalls to the sponsors. Several comments supported the single prong gross value test (option one) because they felt there was no legislative authority to require any other test. The comments were varied regarding the value of the second prong of option three, the net value test. The beneficiary advocacy and union groups generally supported the highest variant stated in the proposed rule, asserting that lower values would allow sponsors to shift additional costs to retirees while still qualifying for subsidy payments. They believe a higher variant would give sponsors a disincentive for such cost-shifting. Employer and business groups supported the lowest variant, the expected per capita value of the retiree drug subsidy. They expressed concern that higher thresholds would make fewer employers and unions eligible for the subsidy, and thus conflict with the critical goal of giving as many employers and unions as possible an incentive to retain their retiree coverage.

Several employer groups proposed an additional variant for the net value test. The subsidy provides an incentive to sponsors to continue providing retiree drug coverage rather than reduce coverage and provide benefits that supplement those provided under standard prescription drug coverage under Part D. Therefore, in determining whether the drug coverage provided under a sponsor's group health plan is of sufficient value to qualify for the subsidy, the employer groups argued that the sponsor's coverage should be compared to the value of the standard prescription drug coverage that a retiree would receive if the retiree had both the Part D coverage and the sponsor's supplemental coverage. This approach will have the effect of delaying the point at which the individual can qualify for catastrophic coverage under Part D, which is only available when an individual's true out-of-pocket (TrOOP) expenses exceed a specified threshold. Because beneficiary out-of-pocket drug costs reimbursed through group health plans are excluded from TrOOP, the existence of employer or union coverage that reimburses retirees for some of their out-of-pocket drug costs would mean it would take longer for the beneficiary to qualify for catastrophic coverage under his or her Part D plan, and the value of the Part D coverage to the retiree therefore would be less.

These same groups also proposed that we allow sponsors to use the expected per capita value of the retiree drug subsidy as a proxy for this test since, by their calculation, both tests result in approximately the same value for Part D.

Response: While the single prong gross value test will maximize the number of beneficiaries retaining their employer and union-based drug coverage, it will be the most likely of all the options to create windfalls to the sponsors. The second option raised in the proposed rule using the gross value test as in option one but restricting the subsidy payment to no more than what the sponsor paid into the retiree drug coverage has the advantages of eliminating windfalls and being simple to describe and operationalize. However, we had questions about the adequacy of the legal basis underpinning that policy, and we did not receive any comments that would help alleviate those legal questions.

Accordingly, we agree with the majority of the comments that the two-prong test (option three) accomplishes our goals of maximizing the number of beneficiaries retaining employer and union-based retiree drug coverage while not creating windfalls to sponsors. Thus, our final regulations state that in order to qualify for the retiree drug subsidy, a sponsor's plan must meet the gross value test (which is equivalent to

the test used in determining whether coverage is creditable prescription drug coverage under § 423.56), and an additional test that takes into account retiree premium payments.

Balancing the various policy goals and statutory restrictions in determining the appropriate way of valuing standard prescription drug coverage (to which sponsors should be comparing their coverage under the net value test) is a difficult challenge. The more stringent we set the standard, the fewer the number of sponsors that will qualify for the subsidy, which will likely have an adverse impact on the future availability of retiree drug coverage. However, a higher value is less likely to create windfalls to sponsors. In addition, as noted above, we believe the applicable statutory provisions under section 1860D–22(a)(2)(A) of the Act impose some constraints on the methods that can be used in determining actuarial values for this purpose.

We believe the most appropriate way of balancing these competing issues is to establish in the final rule that employment-based retiree drug coverage satisfies the actuarial equivalence standard if its actuarial value (as determined after reducing the gross value of the benefit by expected retiree premiums) is at least equal to the net value of defined standard prescription drug coverage under Part D (as determined after reducing the gross value of the benefit by the expected monthly beneficiary premiums), with the net value of the defined standard prescription drug coverage reflecting the impact of employer or union-sponsored prescription drug coverage that would supplement the beneficiary's defined standard prescription drug coverage. As explained previously, the existence of coverage supplemental to the standard prescription drug coverage would postpone the point at which the retiree would receive catastrophic coverage under defined standard prescription drug coverage (as defined under § 423.100). This would have the effect of decreasing the expected amount of paid claims under the defined standard prescription drug coverage, and thus would decrease the actuarial value of the coverage.

We agree with commenters that it is reasonable to take this approach given that many employers and unions will be deciding between continuing to provide retiree drug coverage as a primary payer for retirees (and accept a subsidy), and coordinating their retiree drug coverage with Part D (with the sponsor becoming a secondary payer for Part D drugs). Sponsors are likely to consider the impact of their supplemental coverage on the value of the Part D benefit for their retirees (for example, reducing the value of the reinsurance subsidy for catastrophic coverage) in their calculations. We believe that using this approach will help maximize the number of Medicare beneficiaries that retain their employment-based retiree coverage.

Because § 423.100 defines the term ''standard prescription drug coverage'' under Part D to mean either defined standard prescription drug coverage or actuarially equivalent standard coverage, we clarify that sponsors must use defined standard coverage (and not actuarially equivalent standard coverage) as the fixed point of comparison for applying the actuarial equivalence standard.

We disagree with commenters who suggested that we lack the legal authority to adopt a two-prong net actuarial equivalence. We believe our two-prong net actuarial equivalence best reflects Congressional intent. Under section 1860D–22(a)(2)(A) of the Act, the sponsor of employment-based retiree health coverage is entitled to the retiree subsidy only if the sponsor provides us with an attestation that the ''actuarial value of the prescription drug coverage under the [sponsor's] plan ... is at least equal to the actuarial value of standard prescription drug coverage.'' As discussed above, were we to interpret this statutory provision as only allowing an actuarial equivalence standard that compares the gross value of the prescription drug benefits provided under the sponsor's plan to the gross value of the benefits provided under standard prescription drug coverage, sponsors who contribute little or nothing toward the cost of their retirees' prescription drug coverage would receive a windfall. We do not believe the Congress intended to provide subsidies to sponsors when the sponsor's retirees pay all or most of the plan premium for prescription drug coverage. The conference report to the MMA explains that the purpose of the retiree subsidy is to help employers retain and enhance their prescription drug coverage so that the current erosion in coverage would plateau or even improve. (See H.R. Conf. Rep. No. 108–391, at 484 (2003)). This erosion in employer-sponsored prescription drug coverage reflects the rising financial burden for sponsors who finance, in substantial part or in whole, the cost of such coverage. (See ''Current Trends and Future Outlook for Retiree Health Benefits: Findings from the Kaiser/Hewitt 2004 Survey on Retiree Health Benefits'') As suggested in the Conference report, providing a subsidy to these sponsors would lower their financial cost of providing retiree prescription drug coverage, thereby decreasing the likelihood a sponsor will terminate such coverage. However, providing a subsidy to sponsors that bear little or none of the cost of providing retiree prescription drug coverage but instead shift the cost of such coverage to retirees would do little to reverse this trend. We believe we have an obligation to interpret the statute in a manner that would avoid the absurd result of providing a windfall to sponsors that bear little or none of the cost of their retiree prescription drug coverage, thereby giving effect to the Congress' likely intent.

We also believe our interpretation reflects a permissible reading of the statute. We believe the statute affords us significant discretion in adopting a methodology to determine actuarial equivalence under Part D, including for purposes of the retiree subsidy. First, we interpret section 1860D–11 of the Act as allowing us to establish more than one process for assessing the actuarial value of prescription drug coverage. Section 1860D–11(c)(1) of the Act states that the Secretary ''shall establish processes and methods for determining the actuarial valuation of prescription drug coverage, including—(A) an actuarial valuation of standard prescription drug coverage under section 1860D–2(b).'' We believe the use of the plural terms ''processes'' and ''methods'' authorizes us to adopt a methodology for determining actuarial equivalence for purposes of the retiree subsidy that differs from the methodologies used to determine actuarial equivalence under other sections of this Part, such as the determination of whether alternative coverage is creditable prescription drug coverage under § 423.56 of the final rule.

Second, we believe our interpretation of the actuarial equivalence requirement under section 1860D–22(a)(2)(A) of the Act to take into account the sponsor's financial contribution finds support under section 1860D–2(c)(1) of the Act. Section 1860D–2(c)(1) of the Act establishes a multi-step test for comparing the actuarial value of alternative prescription drug coverage to standard prescription drug coverage. In the first step under section 1860D–2(c)(1)(A) of the Act, the Secretary looks only at plan design and ensures that the actuarial value of the total coverage provided under the alternative prescription drug coverage is at least equal to the actuarial value of standard prescription drug coverage.'' In the second step under section 1860D–2(c)(1)(B) of the Act, however,

government financing is taken into account. Section 1860D–2(c)(1)(B) of the Act provides that the ''unsubsidized value of the [alternative] coverage must be at least equal to the ''unsubsidized value of standard prescription drug coverage.'' The unsubsidized value is determined by subtracting the government reinsurance and direct subsidies provided under section 1860D–15 of the Act from the total value of the alternative prescription drug coverage. While this is the inverse of how sponsors will determine the actuarial value of prescription drug coverage provided under their plans and standard prescription drug coverage for purposes of this subpart, it does demonstrate that the Congress believed that a determination of the actuarial value of prescription drug coverage could take into account the financing of the coverage.

We also note that there is precedent for us taking into account financing in determining the value of coverage. For example, in accordance with section 1854(e) of the Act, currently premiums are included in the comparison of beneficiary liability for cost sharing under a MA plan to the cost-sharing required under original fee-for-service Medicare, although we note that premiums will not be included in this comparison beginning in 2006.

Comment: We received several comments from employer groups and actuarial consultants requesting that we not issue a fixed numerical value for the net value test and allow sponsors to calculate a value based upon their own claims experience. Some commenters had requested advance indication of safe harbors relating to minimum benefit designs that would meet the requirements for actuarial equivalence to ease the uncertainty associated with the various filing processes and increase the likelihood of filing success.

Response: We agree with commenters requesting that we not issue a fixed numerical value for the net value test and instead will require sponsors to calculate the value of the prescription drug coverage provided under the sponsor's plan and defined standard prescription drug coverage under Part D based upon their own claims experience for plan participants or their spouses or dependents who are Part D eligible individuals. Section 1860D–22(a)(2) of the Act requires sponsors to provide an attestation of actuarial equivalence ''with respect to a Part D eligible individual who is a participant or beneficiary under'' the sponsor's plan. We believe requiring sponsors to base their actuarial valuation on these individuals' claims experience best reflects the true value of the prescription drug coverage under the plan, as compared to the defined standard prescription drug benefit, for those individuals. However, we recognize that not all sponsors will have sufficient claims data to support a reasonable calculation of the actuarial value of prescription drug coverage under the sponsor's plan and defined standard prescription drug data based on actual claims data. We will allow these sponsors to utilize alternative normative databases in accordance with CMS guidance.

We will issue further guidelines on the appropriate methodology for the actuarial equivalence test in line with the standard outlined above. The guidelines will include simplified actuarial methods that could be used to qualify for the retiree drug subsidy. We believe these simplified methods will be particularly useful for sponsors that may have difficulty measuring the impact of their benefit design on the value of defined standard prescription drug coverage because the design differs significantly from the defined standard prescription drug coverage.

For example, we anticipate that if there is an out-of-pocket maximum in the sponsor's plan (that is less than the out-of-pocket threshold under § 423.104(d)(5)), sponsors will be able to disregard the value of Part D catastrophic coverage that would be provided if participants enroll in defined standard prescription drug coverage under Part D. We also anticipate developing and publishing simplified actuarial methods for comparing a sponsor's plan with the defined standard prescription drug benefit that includes the actuarial impact of any supplemental employer or union coverage.

Comment: We received one comment from an association of church plans stating that we should allow sponsors to use the single prong gross value test to determine whether their coverage is actuarially equivalent to Part D if the sponsors will certify that the retiree drug subsidy payment will go into a trust for the benefit of the beneficiaries in the plan.

Response: If we allowed certain sponsors to use the single prong gross value test for the actuarial equivalence standard in applying for the retiree drug subsidy, there would be no guarantees of prohibiting windfalls to those sponsors. Accordingly, the two prong standard, as defined in the final rule, shall apply to all sponsors who apply for the retiree drug subsidy.

3. Applying the Actuarial Equivalence Test to Plans with Multiple Benefit Designs and Cost Sharing

As noted above, the proposed rule proposed to use the COBRA regulations as a model for determining how many group health plans a sponsor provides and which benefit options are included within a single health plan. Under those rules, all benefit options offered by a sponsor would be treated as a single group health plan unless through its documents and operations, the sponsor treats them as separate plans. Under the proposed rule, sponsors would then be required to determine actuarial equivalence for each plan as a whole. That is, a plan would be actuarially equivalent if, on average, the actuarial value of retiree drug coverage under the sponsor's employment-based retiree health plan were at least equal to the actuarial value of defined standard prescription drug coverage under the actuarial standards described above.

Comments: While several employer groups agreed with our use of the COBRA definition of a plan as a model for determining what benefit options are included within an employer's group health plan, they indicated that sponsors need additional flexibility to distinguish among retirees with different arrangements within a single plan for the purpose of determining actuarial equivalency. They felt that sponsors should be given the discretion to aggregate all retirees in a single plan as a whole or to apply the test to each individual benefit option within a plan. An association of actuaries commented that, if we give employers and unions the flexibility to define plans, then employers and unions will presumably do so in a way that will maximize their subsidy payment. However, a beneficiary advocacy group questioned whether, if an aggregate average is allowed across multiple options for purposes of the test, payment could be made on the basis of incurred costs in a drug option that does not meet the actuarial equivalence standard on its own. The same group suggested using the enrollment numbers to determine a weighted average across multiple options in order to protect retiree's interest.

Response: We believe section 1860D–22(a)(2)(A) of the Act is subject to two reasonable interpretations: under the first interpretation the actuarial equivalence standard would be applied to the group health plan as a whole, and under the second interpretation the actuarial equivalence standard would be applied for each benefit option (including separate cost-sharing

arrangement) within a single group health plan. At this point in time, we elect not to choose between these two reasonable interpretations of the statute. The final rule provides sponsors with flexibility by allowing them to choose whether to apply the net prong of the actuarial equivalence test for each benefit option, or to apply the net prong of the actuarial equivalence test on an aggregated basis for all benefit options within a group health plan that satisfy the gross test and creditable coverage standard of § 423.56. This flexibility will accommodate sponsors that have a wide variety of benefit options for their retirees. However, each benefit option in the sponsor's plan must independently satisfy the gross prong of the actuarial equivalence test. The gross test is equivalent to the actuarial equivalent standard applied for purposes of determining whether a group health plan is creditable prescription drug coverage. As explained in subpart B, the actuarial equivalence standard for creditable prescription drug coverage is separately applied to each benefit option in the sponsor's group health plan. We do not believe it would be appropriate to provide sponsors a subsidy under this subpart for qualifying covered retirees enrolled in a benefit option that is not creditable prescription drug coverage. Therefore, the final rule provides that sponsors must apply the gross prong of the actuarial equivalence standard to each benefit option for which the employer seeks to receive a retiree drug subsidy.

4. Applying the net test to plans with integrated drug and non-drug premiums.

Comments: One commenter noted that it was unlikely that retiree health plans would include a separate identifiable premium for drug benefits and that an estimate of the portion of the total premium relating to the drug benefits would have to be made prior to doing a net value calculation on actuarial equivalency. An employer consultant firm commented that employers and unions should have wide latitude to restructure, redesign, or otherwise limit or improve benefits and the employer's or union's contribution thereto. A human resource management association requested that the final rule clarify that employers and unions may determine how such amounts are to be allocated based on sound actuarial principles.

Response: We agree that sponsors (both those with insured benefits and those with self-funded benefits) generally should have flexibility to design premium structures that are most appropriate for their employees and retirees. We also recognize that many employers and unions offer medical and drug benefits as an integrated package providing support to the beneficiaries and supplementing their current Medicare Parts A and B coverage, and in addition have included the drug benefit since Medicare has not previously provided coverage for outpatient prescription drugs. Accordingly, in many respects for those employers and unions that decide to take the retiree drug subsidy, this subsidy will help maintain retiree health coverage, including both medical and drug benefits.

The final rule provides maximum flexibility to sponsors in allocating the premium between the medical and drug benefits for the purpose of determining the actuarial equivalence of the drug benefit. By doing so, we are not allowing for a windfall subsidy payment to the sponsors since, in order to meet the net test for actuarial equivalence test and qualify for the retiree drug subsidy, the sponsors will have to make a substantial financial contribution towards the retiree health coverage.

(c) Sponsor Application for Subsidy Payment and Required Information

In the proposed rule, we proposed to require that a plan sponsor who wishes to be paid the retiree drug subsidy must annually submit to us a subsidy application, actuarial attestation, and a list of qualified covered retirees, no later than 90 days prior to the beginning of the plan year. For a subsidy to be paid for 2006, we proposed that the application be submitted no later than September 30, 2005. Plans that begin coverage in the middle of a year would have to submit the application 90 days prior to the date the coverage begins. Sponsors that establish new plans after September 30, 2005 would have to submit the application no later than 150 days prior to the start of the new plan.

Comments: Plan sponsors, actuarial consultants, business consultants and health care industry advocates indicated that there was a need for an extension beyond the September 30, 2005 due date for the submission of the retiree drug subsidy application, attestation and the list of qualifying covered retirees. Many felt that while they could provide the application prior to September 30, 2005, they might not be able to provide an attestation as they might not have made the final plan design determination and have the final list of qualified beneficiaries until 30 days prior to the start of the plan year. Another comment from an employer advocacy association recommended that we shorten the advance submission of an attestation for new plans from 150 days prior to the effective date of coverage to 90 days prior to the effective date.

Response: We reviewed public comments on the effect that the application data requirements and the impact that the timeframe of the application deadlines will have on plan sponsors. In order for plan sponsors to receive a subsidy payment for January 2006, the final rule generally retains the requirement that all plan sponsors (regardless of their plan year) apply for the subsidy payment no later than September 30, 2005. We believe this is necessary to reduce confusion and uncertainty for retirees and for employers and unions that may be claiming a subsidy for a retiree enrolling in Part D coverage when the initial enrollment period for the new program opens in November 2005. However, to accommodate sponsors that are unable to obtain all necessary data in time, we will allow sponsors to obtain an extension under procedures and conditions we establish. In general, the procedures will include a requirement that sponsors file the extension request prior to September 30, 2005, and have the extension application include the names of retirees for whom the sponsor believes it may be claiming subsidy payments in 2006. For future years we will require that plan sponsors apply for the subsidy no later than 90 days prior to the start of their plan year, unless an extension has been filed with us and granted by us under procedures we establish. For sponsors that institute retiree prescription drug coverage after September 30, 2005, we will require that these sponsors submit an application, attestation, and all of the necessary data as outlined in § 423.884(c)(2) at least 90 days prior to the start of the new plan for the first plan year. (We agree that the advance attestation submission for new plans need not be 150 days.)

We feel that we need this 90 day period to review the retiree drug subsidy application and contact the sponsor if any further information is needed. However, we will accept updates to the application up to the beginning of the plan year. As provided for in § 423.884(c)(6) and discussed subsequently, additional periodic updates relating to eligibility data are also required during the year.

We also intend to build in safeguards in the Part D application process for beneficiaries to decrease the instances in which a sponsor attempts to claim a subsidy payment for an individual who (unknown to the sponsor) has enrolled in a Part D plan. We would expect such safeguards to include a process that could enable retiree plans to obtain

relevant information before the individual's Part D enrollment takes effect. For further discussion on enrollment protections, see § 423.36 of the subpart B preamble.

Comments: Plan sponsors, health plan advocates, carriers, insurers and administrators raised numerous other issues regarding the retiree drug subsidy application. They asked for clarification on who is responsible for signing the subsidy application. Plan sponsors and an employer advocacy association requested confirmation that the plan sponsor may act with the assurance that the plan is qualified for the subsidy upon submission of its signed completed application and a signed attestation to us so that they may communicate plan information to its retirees and their dependents sooner. A taxpayer advocacy association felt that we need to enhance the certification requirements of § 423.884 and § 423.888 to reflect what is required in § 423.505(l). That provision requires certification by the CEO, CFO or an individual delegated the authority to sign on behalf of one of these officers, or who reports directly to the officer of the accuracy, completeness and truthfulness of all the information related to the enrollment data, claims data and payments.

Response: The final rule requires that the application be signed by the sponsor or by an authorized representative of the sponsor. A sponsor or its authorized representative must certify that the information on the application is true and accurate to the best of its knowledge and belief. The final rule does not specifically require that certifications for subsidy payments meet the same standards as § 423.505(l). However, we will be providing further guidance on the terms and conditions of the application.

Comment: The proposed rule indicated that the application would require the sponsor to comply with a number of specific requirements (including the terms and conditions for receiving retiree drug subsidy payments) and that the application would constitute an agreement between the sponsor and CMS (the sponsor agreement). Several employer advocacy groups requested clarification regarding whether, upon submission of a signed application, the sponsor may act with the assurance that the sponsor is qualified for the retiree drug subsidy.

Response: Although we intend to streamline the application process as much as possible, the mere submission of a subsidy application does not qualify an entity to receive subsidy payments. The sponsor cannot assume it is eligible for a subsidy payment until we (or our subsidy contractor) review the sponsor's application and provide written notification regarding the sponsor's eligibility to receive a subsidy payment. (We have clarified this in the regulation text by adding a definition of ''sponsor agreement'' at § 423.882.)

Comments: We were asked to clarify the application process for those sponsors with multiple tax identification numbers.

Response: For a sponsor that includes separate entities with multiple tax identification numbers, the final regulation allows them to determine the appropriate tax identification number and other appropriate information (such as contact data) to include as outlined in the data requirements for that application.

Comments: Several plan sponsors, business consultants, insurers/carriers and health care industry advocates indicated that they do not collect the health insurance claim (HIC) or Social Security numbers of their retirees and their dependents, which we proposed to require as part of the application process in the proposed rule, due to privacy issues and historical business practices. They said this requirement could create an administrative burden for them. They also raised concerns about the ability to identify qualifying covered retirees, given uncertainty about whether some people (particularly dependents) are entitled to Medicare Part A or B and not enrolled in Part D.

Response: We believe that it is necessary to require the data as outlined in the proposed rule to establish the sponsor's eligibility for the retiree drug subsidy and to verify the qualified retirees and their dependents (as defined in § 423.882) that are enrolled in the sponsor's plan. Further, based on discussions with stakeholders, we believe sponsors and their vendors should be able to track the data elements that we require in this section. However, we understand that some sponsors may not collect the HIC numbers of their Medicare retirees; thus the final rule requires that either the HIC number or the social security number of qualifying covered retirees be provided. We strongly urge, however, that sponsors provide both the HIC and social security numbers of their qualifying covered retirees if they collect both in order to reduce the potential for error and to increase the confidence range of the submitted data.

We recognize that determining whether a person (particularly a dependent) is eligible for Part D may pose some difficulty for certain sponsors. However, sponsors are able to enroll in voluntary data sharing agreements (VDSAs) with us that would allow sponsors to submit a list of retirees and covered dependents prior to submitting an application for the retiree drug subsidy and have us determine which retirees and dependents are qualified covered retirees. More information about the CMS Employer Voluntary Data Sharing initiative can be found at *http://www.cms.hhs.gov/medicare/cob/employers/emp__vdsa.asp*. We may also explore other approaches that could be used to provide necessary information to sponsors.

Comments: A health care industry association and outside vendors who provide eligibility and claims data to plan sponsors and who will be submitting data to us for enrollment and payment under the subsidy stated their concerns about the False Claims Act. They requested that we clarify their potential liability and possible relief from liability for data submitted that was provided by them.

Response: The False Claims Act provides a remedy for false claims submitted to the Federal government if a person or entity ''knowingly'' submits a false claim, or knowingly causes another to submit a false claim. Section 901 of the MMA expressly states that nothing in the title dealing with Medicare contractor reform shall be construed to compromise or affect existing legal remedies for addressing fraud or abuse, and we believe it is clear that the law is intended to apply for the retiree drug subsidy program. However, innocent mistakes and errors do not result in liability under the Act. Rather, the False Claims Act imposes liability on a person or entity which acts with actual knowledge of the false claim; acts in deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information (31 U.S.C. § 3729(b)(1–3)). Thus, the False Claims Act's liability provisions were not intended to apply to a merely inadvertent reporting error or an innocent mistake by a sponsor. We note that parties have a continuing obligation to disclose to the government any new information indicating the falsity of the original statement.

A sponsor, or its authorized representative requesting the subsidy on behalf of the sponsor, must certify that the information on the application is true and accurate to the best of its knowledge and belief. Thus, as noted above, innocent mistakes in the application, as opposed to intentional misstatements or statements made with deliberate ignorance of or reckless

disregard for the truth, will not result in False Claims Act liability, unless the sponsor (or its authorized representative) subsequently fails to inform the government of information indicating the falsity of the original statements.

Comments: Plan sponsors, business consultants, insurers/carriers and plan administrators asked us to clarify the frequency and manner in which updates will be required. They recommended that they provide periodic enrollment updates to us as they identify qualified retirees and their dependents that become eligible for Medicare. Additionally, comments suggested allowing sponsors to file updated information during the year following the September 30 deadline, and to allow sponsors to submit new census data only if there are no material changes to the plan.

Response: The final rule requires periodic updates of beneficiary data as outlined in § 423.884(c)(6) to keep our database accurate and reduce the possibility of overpayments or underpayments.

To reduce the lag time between the occurrence of a change in the enrollment and the adjustment of the subsidy payment, and to minimize situations in which a sponsor is attempting to claim a subsidy payment for someone who has enrolled in Part D, the final rule requires a monthly update by all sponsors of the enrollment data, regardless of the subsidy payment frequency (unless we specify a different frequency in other guidance). Such data shall be provided in a manner we specify.

In general, sponsors will be expected to provide to us on a periodic basis the changes, additions and deletions to their enrollment data. To ensure development of a procedure that is most administratively feasible for sponsors and CMS, we will consider the possibility of permitting the submission of entire enrollment files. We anticipate issuing further guidance on the frequency and the manner of the enrollment updates.

Table R–1, containing the key dates involved in the sponsor retiree drug subsidy application process is included at the end of this section.

TABLE R–1
KEY DATES

Publication of Final Rule	January 2005
Application for Retiree Drug Subsidy Due Date for All Sponsors seeking the Retiree Drug Subsidy for plan years which end in 2006, regardless of whether they operate on a calendar year	No later than September 30, 2005, unless an extension request is filed with CMS prior to the due date
Attestation of Actuarial Equivalence Due Date for all Sponsors seeking the Retiree Drug Subsidy for plan years which end in 2006	No later than September 30, 2005, unless an extension request is filed with CMS prior to the due date and granted by CMS
Retiree drug subsidy Program Begins	January 1, 2006
For plans operating on a non-calendar year basis—Application for Retiree Drug Subsidy Due Date for Sponsors seeking the Retiree Drug Subsidy for all subsequent years	90 days prior to beginning of each plan year (that is, for plan years which begin in 2006 and end in 2007 and for each plan year thereafter), unless an extension request is filed with CMS and granted by CMS.
For plans operating on a calendar year basis—Application for Retiree Drug Subsidy and Attestation of Actuarial Value Due Date for Sponsors seeking the subsidy for all subsequent years	September 30, 2006 (for 2007) and each September 30 thereafter for subsequent years, unless an extension request is filed with CMS and granted by CMS
Application for Sponsors that institute coverage after September 30, 2005	90 days prior to the start of the new plan
Notice to CMS of mid-year plan changes that materially affect actuarial valuation	90 days prior to the plan change
Notice to enrollees of plan changes that result in the plan no longer providing creditable coverage	Prior to the plan change.

(d) Surety bond

We sought comment on whether to require a surety bond type of instrument or preferred creditor status as part of the enrollment process in order to address situations related to businesses that may terminate or experience bankruptcy prior to completion of a final reconciliation.

Comments: CMS received comments from private and governmental plan sponsors that this will be an unnecessary cost and burden to them and especially problematic for governmental entities.

Response: After review of the comments we have determined that since all subsidy payments will be made by us after submission of cost data, the degree of risk to us in connection with the year-end reconciliation process is not significant enough to justify requiring a surety bond type of instrument or preferred creditor status certification, particularly given that many plan sponsors and administrators are subject to other laws and contractual obligations that should provide protections.

(e) Creditable Coverage and Notification

Section 1860D–22(a)(2)(C) of the Act specifies that in order for a sponsor's plan to meet the definition of a qualified retiree prescription drug plan, the sponsor must provide for disclosure of whether coverage is creditable prescription drug coverage in accordance with the proposed requirements set forth under proposed § 423.56 of the final rule. This includes, for example, providing advance notice to beneficiaries in the plan of any material change that causes their coverage to no longer be creditable prescription drug coverage. The rules for providing notices of whether coverage is creditable prescription drug coverage are described in subpart B, including the rules for coverage sponsored by an employer or union not claiming the subsidy.

5. Retiree drug subsidy amounts (§ 423.886)

As outlined in the final regulations, § 423.886 governs the subsidy amount a sponsor of a qualified retiree prescription drug plan receives for each qualifying covered retiree that is enrolled with the sponsor in a given year. The sponsor is eligible to receive a retiree drug subsidy payment for each qualifying covered retiree equal to 28 percent of the allowable retiree costs that are attributable to the gross costs that exceed the cost threshold and do not exceed the cost limit. Section 1202 of the MMA amends the Internal Revenue Code of 1986 to provide that these subsidy payments will be exempt from Federal tax. Further guidance on the Federal tax treatment of the subsidy will be under the auspices of the U.S. Department of the Treasury.

Debts owed to us that are generated by an overpayment of the subsidy to a sponsor, including collection of interest, administrative costs, and late payment penalties will be governed by regulations at 45 CFR Part 30, subpart B.

Comments: Many tax-exempt plan sponsors including governmental plans commented that the tax-exempt nature of the subsidy payments means that taxable plan sponsors can receive a subsidy that is approximately 35 percent higher in value than what the tax-exempt sponsors can receive. They requested that we address this disparity in the final rule for Part D to make sure all plan sponsors are treated equally. An employer advocacy group also asked for clarification on how the subsidy should be calculated for allowable costs that are attributable to gross retiree costs that exceed the cost threshold and do not exceed the cost limit.

Response: The statute does not allow us to provide additional retiree drug subsidy payments based on tax-exempt status. As for the calculation of subsidy payments, the final rule clarifies that the statute requires the subsidy payment to be calculated by first determining gross retiree costs between the cost threshold and cost limit, and then determining allowable retiree costs attributable to such gross retiree costs. As noted elsewhere, allowable retiree costs are based on gross retiree costs actually paid under the plan (or by or on behalf of the retiree), with rebates and other price concessions subtracted from these gross retiree costs.

Comments: Employers and beneficiary advocacy groups also commented on additional provisions regarding the plan sponsor's use of the subsidy once received. Beneficiary advocacy groups suggested that since employers and unions are allowed to shift costs of retiree plans to retirees by way of premium contributions and cost-sharing, beneficiaries should be entitled to a fair portion of the subsidy amount received by the plan sponsor. Employer groups and business consultants commented that once an employer or other plan sponsor qualifies for the retiree drug subsidy, we have no authority to regulate that employer's or union's or plan sponsor's utilization of the subsidy.

Response: The statute does not impose restrictions on how the sponsors use the subsidy. However, beneficiaries may have rights provided under other laws or by contract.

6. Payment Methods, Including Provision of Necessary Information (§ 423.888)

a. *Plan Year Versus Part D Coverage (Calendar) Year*

Under section 1860D–22(a)(3)(B) of the Act, the cost threshold and cost limits that determine the amount of the subsidy are calculated for ''plan years that end in'' 2006 and subsequent calendar years. However, section 1860D–22(a)(3)(A) of the Act refers to the subsidy amount for a qualifying covered retiree for a ''coverage year,'' that is defined as calendar year. Thus, we believe that, in the context of section 1860D–22 of the Act, we have the interpretive authority to require that the subsidy determinations be made either on a calendar year or plan year basis. In the proposed rule, we proposed to have the rules apply on a calendar year basis because Medicare already operates on a calendar year basis.

Comments: In considering whether sponsors will use plan year or calendar year in calculating the retiree drug subsidy amount, comments varied among private health care companies and health care industry associations. One such entity commented in favor of utilizing a calendar year schedule for simplicity. Others prefer having the flexibility to choose between a calendar year and a plan year that a sponsor may currently be operating in. Employer advocacy associations and actuarial consulting groups suggested giving sponsors flexibility, especially if it means allowing sponsors to choose between plan year and calendar year. A government entity commented in favor of plan year, and discussed utilizing a pro-rata method for determining the subsidy amount for the initial year of a plan using a non-calendar year.

Response: In determining whether sponsors will be required to use plan year or calendar year, we took into consideration the large number of comments in favor of flexibility. We also recognized the costs that plan administrators and sponsors might face if they maintain records for plan purposes based on a period that differs from the calendar year, but are forced to establish a different system that maintains records on a calendar year basis solely for purposes or the retiree drug subsidy program. Finally, we considered costs associated with administering the program by CMS or a subsidy contractor. In response to these considerations, the final rule uses the plan year approach. Thus, if a plan's records are maintained on a calendar year basis, it enables sponsors to calculate retiree drug subsidy payments on that calendar year basis. If a plan's records are maintained based on a year that differs from the calendar year, sponsors can determine those calculations on the non-calendar year basis.

Sponsors of non-calendar plans will use the cost threshold and cost limit for the calendar year in which the plan year ends for purposes of determining subsidy payments. Thus, for example, a sponsor claiming subsidy payments for the plan year running from July 1, 2007 through June 30, 2008 would use the cost thresholds and cost limit amounts published for 2008 in determining subsidy payments. If the sponsor requests payments on a monthly or quarterly basis, adjustments and reconciliations for prior payments will have to be made once the cost threshold and cost limitation for the relevant year have been published.

Subsidy payments are determined based on the plan year that ends in a given calendar year, using the same rule in determining whether a sponsor's plan is actuarially equivalent to Part D raises a challenge. It might require that the sponsor submit an actuarial attestation for a given plan year before the deductible, initial coverage limit, and other elements of the defined standard prescription drug coverage have been determined for the corresponding calendar year. To address that concern, the final rule allow sponsors to use the actuarial value of the standard prescription drug coverage under Part D for the calendar year in which the sponsor's plan year begins, provided the attestation is submitted to us no later than 60 days after the publication of the coverage limits for defined standard prescription drug coverage for the upcoming calendar year. If the attestation is submitted beyond 60 days after the publication of the coverage limits for defined standard prescription drug coverage for the upcoming year,

then the new coverage limits should be used for the attestation.

Note that our decision to allow sponsors to use non-calendar year plans as the basis for the retiree drug subsidy payment should not have an impact on, or impede, the timing of the beneficiaries' right to drop their employer or union coverage in favor of Part D if they choose. For example, beneficiaries should have the option to coordinate obtaining Part D coverage during open enrollment periods and dropping their retiree coverage in a way that avoids late enrollment penalties. Beneficiaries may also have special enrollment periods relating to the loss of creditable retiree coverage. (See § 423.56.)

The use of a plan year approach also requires a transition rule for plan years that begin in 2005 and end in calendar year 2006. The proposed rule outlined three transition options. The first is to start counting gross prescription drug costs for prescriptions filled after January 1, 2006, and pay the subsidy only for claims incurred in 2006. The second option is to determine the subsidy amount based on claims incurred for the entire plan year but prorate subsidy payments to reflect the number of months of the plan year that fall in 2006. The third option is to determine subsidy amounts monthly for the entire plan year and then pay the full subsidy payments, but only for claims that are incurred in 2006.

Comments: Business advocacy groups recommended that the final rules allow employer and union flexibility to select among the three proposed transitions alternatives in determining the subsidy payment for 2006, based on their administrative capabilities and other considerations.

Response: For administrative simplicity, and given the nature of this rule, we believe it is reasonable to specify the particular transition option to be used. Option 1 would require that sponsors meet the cost threshold twice in 2006, a strict test that we believe is not absolutely required under the statute. In comparing transition options 2 and 3, we have concluded that option 3 provides the most equitable result that is consistent with the statute. Under Option 3, sponsors determine claims incurred in all the months of the plan year, including those that fall in 2005, for calculation of the cost threshold for a plan year that ends in 2006. However, subsidy payments are based solely on claims incurred on or after January 1, 2006.

b. Payment Methodology and Frequency

Section 1860D–22(a)(5) of the Act specifies that payments to plan sponsors are to be made in a manner similar to the payment rules in section 1860D–15(d) of the Act, which applies to payments made to PDP sponsors and MA organizations under Part D. We proposed a preferred approach to calculating and paying the subsidy. For each month starting with January 2006, the plan sponsor would certify by the 15th of the following month the total amount by which actual retiree-beneficiary gross drug spending exceeded the cost threshold yet remained below the cost limit. Medicare would pay 28 percent of the certified amount to the sponsor by the 30th of that month. Not later than 45 days after the end of the plan year, the plan sponsor would submit a final reconciliation (except for outstanding rebates) to us for payment by or, if applicable, to us. In the month in which they are received (or recognized), the appropriate share of any discounts, rebates, chargebacks, or other price concessions, along with any adjustments to the actual expenditures for prior months, are reflected. Any amounts owed the government would offset the subsidy payment for that month, and to the extent that the amount owed to the government would exceed any applicable monthly payment, the plan sponsor would pay this amount to us.

We proposed three possible alternatives to this option. The first alternative was for us to make a single payment after the close of the year. Sponsors would submit their cost data, including rebate data, by the start of the fourth month after the close of the plan year. A second alternative would be to make interim payments throughout the year based on the sponsor's estimate of claims, rebates and discounts (determined based on historical data), with a settlement after the end of the plan or calendar year. We would pay less than 100 percent of the subsidy payments that would be calculated from these estimates, given the uncertainties associated with these estimates. The third alternative would be to make lagged payments based on actual claims experience on a periodic basis throughout the year, with the subsidy payments being reduced by a specified percentage to reflect the sponsor's estimate of discounts, chargebacks and rebates. After the year ends there would be a settlement limited to reconciling estimated versus actual discounts, chargebacks and rebates. We also sought comment on the use of bi-annual, quarterly or monthly payment periods under these approaches.

Comments: Generally, comments supported a method that allows flexibility to select the methodology and timing of retiree drug subsidy payments and rebates each year. A number of commenters, including employer consultants and government employers encouraged a monthly payment system. Entities that supported alternative option 1 said that it would protect patient privacy, proprietary information between plans and manufacturers would be kept from potential exposure, and both administrative costs and data collection burdens would be reduced.

One State commenter supported alternative option 2, stating this method takes into account programs that are fully insured and use a Health Maintenance Organization (HMO) that does not segregate actual cost data by plan and is community rated. Additionally, advocates claim that option 2 would be more reasonable for small business because of the lighter administrative burden. Comments critical of the preferred option stated that the 15 day turnaround time for submitting monthly payment requests and the 45-day deadline for year-end reconciliation seemed rather tight, even for employers and unions who have PBMs with excellent administrative abilities.

A business consultant also commented that only the third alternative proposal actually accounts for drug costs of the group health plan on an accrual basis. The other methods appear to follow the cash flow of the plan but fail to recognize accrual accounting required for the plans. They felt that we neglected to consider more user-friendly methods that are proposed for other cost based entities, for example, fallback plans, which we proposed to pay through a debit account system. They felt that the second approach is acceptable because it sets prospective payments and provides for reconciliation, even though it arbitrarily pays less than what the parties agree upon as the prospective rebate.

Another employer advocacy association urged us to develop a point of sale subsidy payment system, and in the interim, provide the sponsors the flexibility to choose the payment methodology that is best for them.

Response: Unless and until such time technology, resources and other considerations would enable us to develop a point-of-sale payment system for the retiree drug subsidy program, the final regulation will provide other methods and frequency options to address the multiple requests for payment flexibility.

A sponsor may annually elect during the application process whether to receive payments monthly, quarterly, or

annually; that sponsor may change its election during the application process of a subsequent year. A sponsor choosing an annual payment method could avoid the need for interim data submissions, estimates and reconciliations, (discussed in more detail below), and may limit the administrative costs because data submissions are less frequent. However, sponsors that do not want to make multiple data submissions but also do not want to wait for subsidy payments until all rebate and other data is received will be able to make an interim annual payment request, with only one additional (final) reconciliation required at year-end.

Sponsors who choose the periodic method of payment must submit periodic requests for payment to us on the same schedule as the payments are to be received, at a time and in a manner specified by us. Final detailed cost data must be submitted no later than 15 months following the end of the plan year. We will make payments to the sponsor at a time and in a manner to be specified by us in future guidance.

In the final rule, we reserved the right to restrict the payment options available to sponsors in 2006 in case of any unforeseen operational impediments.

Comments: Actuarial consultants suggested that we develop approximate methods of determining individual drug spending, because of the difficulty of determining the actual costs and assigning a rebate to a specific person. An employer advocacy group suggested allowing employers and unions to choose their own methodology for reflecting rebates, in order to accommodate their own administrative capabilities and restrictions. A health care industry consultant indicated that group health plans would need to separate rebates by their applicability (individual retirees or entire group). An employer was concerned because they have a fully insured plan which factors rebates into the premium; they suggested that we accept the insurance carrier's attestation that the claims used in the subsidy calculation are net of rebates and other discounts, rather than require them to provide information the sponsor does not have. Another employer encouraged us to allow sponsors and PBMs to freely contract regarding rebate terms, and not require them to file PBM agreements of documentation of those negotiations.

A health care industry consultant recommended that we allow multiple methods for allocating rebates because a single method would unduly constrain health plans in future negotiations with manufacturers for price concessions. An employer suggested the most appropriate way to recognize rebates is to determine the average amount per rebatable prescription and apply it to the actual retiree drug utilization of the plan sponsor. Actuarial consultants and a health care industry association agreed with the suggestion to estimate rebates on a periodic basis to be included in subsidy payments, and then reconcile both rebates and subsidies at the end of the year. One industry association suggested an ongoing accounting of rebates to eliminate the need for reconciliation at the end of the year. They also asserted that the proposed 4 month period after the end of the year was not enough time to count the rebates.

An employer advocacy association proposed a two-phase settlement process for rebates, which would include a preliminary estimate at the end of the year and a final adjustment up to twelve months later; the association states that such a system would provide maximum flexibility and minimum administrative burden on the sponsor.

Response: If the sponsor chooses the monthly, quarterly or an interim annual method of payment, then in addition to the data requirements described below, the plan sponsor must provide an estimate of rebates (based on historical data) upon submission of data for payment. We believe the sponsor's submission of estimated rebates limits the amount of reconciliation at year end; is consistent with data capabilities of the sponsors; limits the extent to which we would be making overpayments during the year; and allows for monthly and quarterly subsidy payments in order to enhance cash flow of sponsors.

Sponsors choosing the monthly, quarterly or an interim annual method of payment will be required to provide an annual reconciliation to us that includes cost data segregated per qualifying covered retiree and actual rebates, discounts, or other price concessions received for the costs, unless we provide for different data requirements in future guidance. If rebates and other price concessions for a plan are not specifically allocated by a manufacturer to the drug spending of a particular qualifying covered retiree, a sponsor (or its designee) will be permitted to assign the price concessions to qualifying covered retirees using reasonable actuarial principles or other methods we may specify.

The reconciliation must take place within 15 months following the end of the plan year. If gross covered retiree plan-related prescription drug costs in a given plan year are reduced at the point-of-sale to reflect rebates, discounts or other price concessions and no additional price concessions for the costs are received for the year, then allowable retiree costs will equal such gross costs for the year. However, any rebates that are received retrospectively would have to be subtracted when a sponsor calculates retiree costs. As a result of the reconciliation, sponsors will, as applicable, repay any subsidy overpayments or be paid any subsidy underpayments in a manner to be specified by us.

If a sponsor chooses the annual payment method, the sponsor will be required to submit cost data per individual retiree, including rebate adjustment within 15 months following the end of the plan year. However, as noted in § 423.884 (c)(6), a sponsor who chooses the annual payment option must still provide updates of enrollment information to us on a monthly basis.

c. Data Collection

The plan sponsor will be required to submit cost data for each qualifying covered retiree. Regardless of what payment methodology is ultimately chosen for the retiree drug subsidy, we would need certain data from the sponsors in order to accurately calculate the amount of the subsidy to which the sponsor is entitled.

In the proposed rule, we requested comments on the level of detail of the cost data that would be submitted to us in order to receive the retiree drug subsidy payment. Option 1 would require that the sponsor submit the aggregate total of all allowable drug costs of all of the qualifying covered retirees in the plan for the time period in question. This aggregate cost would not be broken down to each qualifying covered retiree. Option 2 would require the sponsor to submit the aggregate allowable costs for each qualifying covered retiree for the time period in question. Option 3 would be to combine various elements of the first two options. The sponsor would be required to submit information with the specificity outlined in the second option for each of the first two years of the subsidy's availability. In the third and fourth years, the sponsor would submit its cost data in accordance with the first option. Option 4 would have been for the sponsor to submit the actual claims data for each qualifying covered retiree, though the proposed rule specifically rejected that option given privacy concerns.

Comments: Comments from employers, the healthcare industry, employer advocates and government entities request that we make data

collection and reporting requirements reasonable for plan sponsors. Commenters also stated that we must account for the fact that employers and unions do not customarily record some of the data requested, and third party administrators, insurers, PBMs and like entities also do not maintain all of the data elements required under the proposed rule. Further, comments suggested that we concentrate on attaining aggregate claims data.

Response: We agree that the requirements for submission of cost data should be reasonable and the least burdensome possible. At the same time, we have an obligation to create rules aimed at providing only the subsidy payments authorized by statute. As noted above, in balancing these objectives, the final rule provides that unless we imposes other data requirements in future guidance, when a sponsor chooses either the monthly, quarterly, or interim annual payment option, it must submit to us, at a time and in a manner specified by us, the aggregate gross covered retiree plan-related prescription drug cost data (as defined in § 423.882), as outlined in option 1, along with an estimate of the extent to which its expected aggregate allowable retiree costs will differ from the aggregate gross cost data (based upon expected rebates and other price concessions) for interim payments. However, the aggregate data must be reconciled within 15 months after the end of the plan year, and the sponsor would have to resubmit the total gross cost data segregated by individual retiree and actual rebate/discount/other price concession data and repay any subsidy overpayments (or be paid subsidy underpayments). (Specific detail about each claim would not be required.) Likewise, all sponsors who choose the annual payment option would have to submit the total gross cost data segregated by individual retiree and actual rebate/discount/other price concession data within 15 months after the end of the plan year for payment. We believe that these requirements are reasonable and least burdensome for the sponsors, yet provide the additional information needed by us in assessing the accuracy of payments. As outlined in our earlier discussion on allowable retiree costs, in section 3(C) of this subpart of the preamble, we will provide flexibility to sponsors of insured plans in the submission of interim cost data.

d. Record Retention for Audits

In the proposed rule, we stated that a plan sponsor will be required to maintain and provide access to sufficient records for our audits or audits of the Office of Inspector General (OIG) to ensure the accuracy of the attestation regarding actuarial value and the accuracy of subsidy payments made under this subpart. All records must be maintained for at least 6 years after the end of the plan year in which the costs were incurred.

Comments: Employers, employer advocacy associations and an employer business consultant commented that the data retention period should match the IRS/SSA/CMS data match program period of 3 years to ease the administrative burden on employers, unions, carriers and plan administrators. Employers indicated that if they switched carriers or administrators, it would be difficult to force them to retain records for at least 6 years. A taxpayer advocacy association recommended a 10-year time period, coinciding with the statute of limitations in False Claims Act cases. A governmental employer wanted us to mandate that carriers retain and provide the necessary data to the sponsor for the required period of time. In discussions with sponsors and employer advocacy groups, they indicated that they are required to retain 6 years of certain types of data for the Department of Labor (DOL) audits under ERISA.

Response: The final rule retains the 6-year record retention rule. We believe that 6 years is a reasonable because it is consistent with the period for retaining certain ERISA records and certain information related to the Health Insurance Portability and Accountability Act (HIPAA) administrative simplification rules. However, consistent with the commenters' concern that records would not be retained long enough, we are modifying the regulation text to specify that a sponsor (or its designee) must retain records longer than 6 years if they know that the records are the subject of an ongoing investigation, litigation, or negotiation regarding criminal or civil liability. In such cases, the obligation to retain records need not arise solely through a formal communication from CMS or OIG.

6. Appeals (§ 423.890)

Although the statute does not contain provisions for administrative appeals of the retiree drug subsidy amount, we believe that it is prudent policy to allow an opportunity for review of certain agency decisions issued in relation to this subpart. Examples of these decisions are as follows—

- A retiree prescription drug plan is determined not to be actuarially equivalent.
- An enrollee in a retiree prescription drug plan is determined not to be a qualifying covered retiree.
- A determination of the subsidy amount to be paid to a Sponsor.

Comments: Beneficiaries, beneficiary advocacy organizations and labor organizations requested that they have the opportunity for review and appeal of the retiree drug subsidy application and the payment determination so that they could assist us in verifying that the benefits provided and the payments made under the retiree drug subsidy program were proper and fiscally responsible. Plan sponsors, business advocates and health care industry vendors felt that only they should be allowed appeal rights because the application to receive retiree drug subsidy payments, the actuarial attestation and payment under the retiree drug subsidy program would not affect the benefits provided to beneficiaries under the plan. Plan sponsors and business advocates indicated that third parties, including beneficiaries, should not have standing to appeal our decisions. One employer advocacy association requested that we consider an appeals process that provides plan sponsors an opportunity to develop a detailed record concerning disputes for which they request reconsideration. The employer association also requested that if we determine that no such opportunity needs to be provided, require that its factual determinations relating to such disputes be decided on a de novo basis upon judicial review. They also requested that if an employer or union seeks to reopen a determination on its own, such a right should be unfettered as long as it is made within one year of final determination.

Response: We do not believe that the MMA gives participants or other third parties standing to appeal to us regarding retiree drug subsidy payment determinations. The MMA provides that the subsidy is to be paid to the sponsors if the sponsors meet certain conditions imposed on them. We recognize that participants and beneficiaries in a sponsor's plan have an interest in knowing whether their retiree drug coverage qualifies for the subsidy, and that we have audit responsibilities to ensure the accuracy of payments. But given the absence of any administrative appeals provisions in the statute and our need to also consider the potential burdens that could be posed on retiree health plan sponsors, we do not believe it would be prudent policy to provide administrative appeal rights to individual participants or third parties.

We believe that the appeals process that is outlined in the preamble to the proposed rule provides sufficient due process to protect the interests of the sponsors. To require that a detailed record be developed on appeal or to require de novo judicial review of the administrator's decision would create administrative costs for the retiree drug subsidy program and would be burdensome for us. As we indicated in the preamble of the proposed rule, there is no constitutional property right to the retiree drug subsidy. Because the subsidy payment is not an entitlement, there is no need to provide for an extensive appellate process that includes judicial review.

We also have not accepted one commenter's request that an employer receive an unfettered right to reopen a determination as long as it is made within a year of the final determination. As we stated in the proposed rule, at 69 FR 46750, the Supreme Court has ruled on reopening in the context of cost reports. In that case, the Court stated that the ''right ... to seek reopening exists only by grace of the Secretary,'' *Your Home Visiting Nurse Services, Inc.* v. *Shalala* 525 U.S. 449, 454 (1999), and that a reopening by the Secretary is not a ''clear nondiscretionary duty.'' Id. at 456–7. For these reasons we have decided to retain the rule that while a reopening may be requested by a sponsor, there is no right to reopening under the regulations. We have also amended the regulations to reflect the policy announced in the preamble of the proposed rule that a decision not to reopen is not subject to further review.

7. Change of Ownership (§ 423.892)

Sponsors who apply for a retiree drug subsidy payment would be required to comply with change of ownership requirements.

Comments: We received no public comments in this area that disputed the proposed provisions of change in ownership.

Response: In § 423.892, we would carry over the three situations that constitute change of ownership (CHOW) in § 423.551 of the final rule.

8. Construction (§ 423.894)

Sections 423.894(a) through § 423.894(d) are based on section 1860D–22(a)(6) of the Act, which outlines the employer and union options for providing retiree drug coverage and coordinating with Medicare under the MMA.

Comments: Beneficiary advocacy organizations were concerned that employers and unions will drop employer and union-based coverage if beneficiaries enroll in Part D coverage. Plan sponsors want clarification that if they file for the subsidy, they can tell beneficiaries not to enroll in Part D coverage.

Response: The final rule adopts the provisions as outlined in the proposed rule. Plan sponsors are not permitted to tell qualified retirees and their eligible dependents that they cannot enroll in Part D coverage. The MMA mandates that beneficiaries must be allowed to freely choose whether or not to enroll in Part D.

However, plan sponsors claiming the retiree drug subsidy must offer a prescription drug program that is actuarially equivalent to or better than defined standard prescription drug coverage. If a sponsor elects to apply for the retiree drug subsidy, it is also able to design its eligibility rules under its employer or union-based plan so that qualifying covered retirees and their dependents lose eligibility in the sponsor's plan if they enroll in a Part D plan. The sponsor shall give advance notice of this type of material change to plan participants as required by other notification regulations that govern their plan (that is, ERISA, State or local law).

S. Special Rules for States-Eligibility Determinations for Low-Income Subsidies, and General Payment Provisions

1. Eligibility Determinations (§ 423.904)

The MMA added a new section 1935 to the Act, ''Special Provisions Relating to Medicare Prescription Drug Benefit,'' which specifies the requirements for States regarding low income subsidies under the new part D benefit. In accordance with the statute, our proposed regulations at § 423.904(a) and (b) required States to make initial eligibility determinations for premium and cost sharing subsidies based on applications filed with the States, to conduct periodic redeterminations consistent with the manner and frequency that redeterminations are conducted under Medicaid, and to notify us of eligibility determinations and redeterminations once they are made.

As proposed in § 423.904(c), States would be directed to identify individuals who apply for the low-income subsidy who may also be eligible for programs under Medicaid that provide assistance with Medicare cost sharing and to offer enrollment in these programs. This requirement is consistent with existing obligations imposed on States when they make eligibility determinations for Medicaid. In § 423.904(d), we proposed requiring States to begin accepting application forms for the low-income subsidy no later than July 1, 2005. In § 423.904(d), we also proposed requiring States to make available application forms, provide information on the nature of and requirements for the subsidy program, and provide assistance in completing subsidy applications.

We also proposed requiring that States ensure that applicants or personal representatives attest to the accuracy of the information provided. In verifying application information, we specified that States may require the submission of statements from financial institutions and may require that information on the application be subject to verification in a manner the State determines to be most cost-effective and efficient.

In addition, § 423.904(d) directed States to provide us with necessary information to carry out implementation of the Part D program. This includes information such as income levels for other low-income subsidy eligible individuals under § 423.773 needed to permit Part D plans to determine the amount of sliding scale premium subsidy that a person will receive under § 423.780(b).

We developed uniform criteria for determining resources, income, and family size under the subsidy, which were reflected in the proposed definitions at § 423.772, and the proposed eligibility requirements at § 423.773.

We also stated that we were considering a number of options to ease the burden on States and to ensure, to the degree permissible under the MMA, a consistent eligibility determination process. We invited comments from States on this issue.

Comment: Several commenters suggested that § 423.904(a) be cross-referred to the entire subpart P rules.

Response: We agree with the commenters and have done so in this final rule.

Comment: Many commenters expressed concern that both SSA and States would be making subsidy eligibility determinations and stressed the need for coordinated policies and processes so that identical treatment is ensured, no matter where the applicant goes to apply for the subsidy. It was further suggested that CMS allow States to choose whether to make the subsidy eligibility determinations themselves or forward applications to SSA.

Response: As stated in our response to comments on § 423.774, the statute sets forth the requirement that eligibility for the low-income subsidy program will be determined by either the State Medicaid agencies or by SSA. Therefore, States

must have the ability to determine eligibility if someone requests a ''State'' subsidy determination.

While this obligation is imposed on States, States may encourage applicants to use the SSA low-income subsidy application process in order to reduce the administrative burden associated with sending notices and processing appeals and redeterminations. In other words, States may provide applicants with the SSA application which they will forward to SSA or provide access to a terminal for accessing the SSA application on line and SSA will perform the eligibility-processing role for these applications. However, as we noted in responses to comments in subpart P, States must have the ability to determine eligibility if someone requests a ''State'' subsidy determination. As part of this obligation, if the applicant files a ''State'' application, States are required to send notices of subsidy determinations, process redeterminations, and handle appeals. We are working on a process whereby States and SSA will be able to access timely information on the status of a beneficiary's application filed at either SSA or State offices. We expect to provide further information on this process through operational guidance. We also note that we have clarified the final rule in subpart P, based on similar comments made in subpart P in response to the proposed rule. Section 423.774 now requires that multiple applications not be permitted in cases where an individual has received a positive determination from either SSA or the State. In other words, an individual may not file a second application for the remainder of the eligibility period with the alternate agency if he or she has received a positive determination from the State or SSA. As stated in the response to comments in subpart P, this requirement is not intended to preclude an individual from reporting subsidy changing events in accordance with the determining agency's rules, but rather to prevent confusion that could arise if a State and SSA process duplicate determinations for the individual.

Comment: Some commenters stated that we should impose a time limit on how long States have to notify CMS of eligibility or redetermined eligibility determinations. Several commenters suggested we require States to notify CMS within 24 hours of making such determinations.

Response: We have decided not to impose a specified period on States to notify CMS of eligibility or redetermined eligibility determinations through regulation. Instead we intend to provide operational guidance to States, monitor the time period for determining subsidy eligibility, and take action as appropriate. In general, we expect that States will determine subsidy eligibility within time periods that are at least consistent with the processing of State Medicaid applications.

Comment: One commenter was concerned that States did not have the opportunity to comment on the model application.

Response: SSA published notice of the model application in the **Federal Register** on November 17, 2004 for public comment.

Comment: One commenter states that both SSA and the States should be required to use the same application for the low-income subsidy. Another commenter asked what form of application a State would be required to accept.

Response: We cannot mandate use of the same application form by States and SSA. Where a State finds that it can use the SSA application for the State's low-income subsidy eligibility determination process, we would encourage it to do so. However, as States might need to implement different verification strategies when they actually make the low-income subsidy determinations, they may have to design application forms specific to their determination process. States have expertise in the area of administering means-tested programs and will be developing their application forms based on that expertise. In addition, we will be working with States and SSA to assist States as they design and develop the optimum eligibility process for making low-income subsidy determinations.

Comment: One commenter was concerned about CMS' requirement for States to begin taking low-income subsidy applications by July 1, 2005 due to State concerns about staffing needs and necessary support systems.

Response: We continue to believe that allowing individuals to apply by July 1, 2005, will allow a more seamless transition of prescription drug coverage for individuals eligible for the low-income subsidy. If an individual needs to consider coverage of specific drugs by a particular Part D plan in making an enrollment decision, the greater time in advance of the new plan's coverage effective date allows individuals, doctors and other payers to assure a smooth transition of drug coverage.

In addition, we have clarified in this final rule that CMS will send notices of eligibility to all deemed subsidy eligible individuals. This should relieve States of the financial burden of sending notices to deemed subsidy eligible individuals. We will also educate Medicare beneficiaries, including dual eligibles, through a variety of methods about prescription drug coverage under the new Part D benefit.

Comment: One commenter also asked about the timeframe in which the State is to make the low-income subsidy eligibility determination. This same commenter also asked about the timeframe required for applications taken as early as July 1, 2005, in which eligibility determinations made after July 1st and prior to November 15, 2005, may need to be redone if there is a change in the applicant's circumstances.

Response: We expect that States will determine subsidy eligibility within time periods that are at least consistent with the processing of State Medicaid applications. Initial determinations of subsidy eligibility shall remain in effect for a period of up to a year and can be effective no earlier than January 1, 2006. As discussed in the response to comments in subpart P, changes in financial circumstances that could impact subsidy eligibility should be reported to the agency that processed the subsidy application, according to that agency's rules.

Comment: One commenter requested more detail on the process CMS will use to collect data from State Medicaid agencies.

Response: We will provide the data collection process to State agencies through operational guidance.

Comment: One commenter indicated its desire to avoid the need for beneficiaries receiving assistance from a SPAP to submit the same information on two different application forms: the SPAP eligibility application and the low-income subsidy application. The commenter would prefer to use only the low-income subsidy application for both the subsidy and SPAP eligibility.

Response: SPAPs will be free to use the application designed for the low-income subsidy, or a variation on the application, to determine SPAP eligibility.

Comment: A number of commenters suggested that States should not be permitted to impose additional documentation requirements on beneficiaries over and above what SSA requires, and asked that the language in § 423.904(d)(3) be revised to indicate that statements from financial institutions would be required ''only if the applicant or personal representative is unwilling to authorize the agency to contact the financial institution directly to obtain necessary information.''

Response: The simplified application developed by SSA, in consultation with CMS, is based on the principle of self-attestation. While we expect some information may be requested from applicants on an exception basis, based on responses to certain questions or based on inconsistencies from electronic data matches, we believe the majority of applicants who use the SSA form will not need to provide additional information beyond what is submitted and attested to in the application form.

We acknowledge that States may employ different verification strategies than SSA, if States actually determine the eligibility for the low-income subsidy. SSA has access to a variety of data sources to enable it to verify within acceptable tolerances the majority of income and resource information using electronic data matches. Again, we encourage States to utilize the SSA application process to the greatest extent possible. However, we cannot limit States' authority to require statements from financial institutions by providing that they may do so only if the applicant or personal representative is unwilling to provide authorization to contact the institution. States have the expertise necessary to determine what the best process is for obtaining necessary information.

Comment: A number of commenters suggest that individuals who apply at SSA offices for the low-income subsidy be screened and enrolled in Medicare Savings Programs. They argue that the obligation to screen and enroll should not be imposed solely on States. They also suggest that joint applications be developed for both programs to avoid requesting duplicate information and to streamline verification of income and assets for eligibility purposes.

Response: We received similar comments in reference to § 423.773 and § 423.774. As we indicate in the responses to those comments, we are working with SSA to design a process to provide subsidy eligibility determination to States for purposes of identifying individuals who apply at SSA and who may also qualify for Medicare Savings Programs under the State's Medicaid program. With this process, we hope to avoid situations in which an individual applies for a low-income subsidy at an SSA office, finds out that he or she has excess income or resources to qualify, and remains unaware that he or she may automatically qualify for a subsidy if the individual chooses to enroll in a State's Medicare Savings Program.

In addition, we also noted in response to other comments in § 423.773 and § 423.774 that the application for the low-income subsidy program must reflect the definition of income and resources outlined in this final rule. However, section 1935 (a)(3) of the Act obligates States to make a determination of a subsidy applicant's eligibility for Medicare Savings Programs and to offer them enrollment. States may develop a special addendum to the low-income subsidy application to address questions specific to Medicaid or Medicare Savings Programs eligibility in order to streamline the application process for these programs.

Comment: One commenter suggested that income and resources will not be verified as rigidly for the subsidy programs as for Medicare Savings Programs. The commenter indicated that the subsidy could be approved and the State could later, due to verification requirements for QMB, SLMB, or QIs, find that the subsidy was approved in error. The commenter suggests that there are no provisions for resolving this occurrence and argue for one standard to be used nationwide.

Response: Medicare Savings Programs represent a Medicaid benefit designed to offer low-income Medicare beneficiaries assistance with Medicare premiums and in some cases cost sharing. The low-income subsidy program is a Medicare benefit under part D. While eligibility for the two benefits may be based on similar methodologies for counting income and resources, they are not identical. Moreover, eligibility for the subsidy can be determined by SSA or States. While uniformity may be a desirable goal, verification methods may differ between the two programs. Verification for the low-income subsidy, for example, is based on the principal of self-attestation. Automation will be utilized by SSA, and we hope by States, to the greatest degree possible, with additional information requested on an exception basis.

Comment: Some commenters suggest the proposed regulations regarding State obligations to screen and offer enrollment in Medicare Savings Programs is inadequate. The commenters suggest that CMS specify what ''offer enrollment'' means. They argue that it should not be interpreted to imply that someone who presents himself at a State office to apply for the subsidy is informed that he can return at a later time to apply for a Medicare Savings Program.

A few commenters assert that the applicant must be offered the opportunity to enroll in a Medicare Savings Program during the same visit or contacted via phone or mail without having to provide further documentation or compelling the completion of additional forms. The commenters also suggest that it would be confusing if individuals first receive notices that they are ineligible for the subsidy and later receive notices from the State that they are eligible for a Medicare Savings Program. Again, commenters suggest that CMS align the income and resource rules for both programs under a single application.

Finally, a few commenters also suggest that CMS automatically enroll individuals in Medicare Savings Programs, with an opt-out provision.

Response: Section 1935(a)(3) of the Act specifically requires States to screen individuals applying for the low-income subsidy for eligibility for Medicaid Savings Programs and to ''offer enrollment'' to such individuals under the State plan. Under this provision, we expect that States will perform an initial assessment of whether an individual is likely to qualify for the State's Medicare Savings Programs, either based on the individual's application for the low-income subsidy taken at the State office or based on subsidy eligibility information provided to the State by SSA. The State should encourage the individual to complete the application and assist the individual in doing so. Given the fact that States administer the Medicaid program, and the fact that enrollment in Medicare Savings Programs could trigger estate recovery implications, we are not considering the commenters' suggestions for CMS to automatically enroll individuals in Medicare Savings Programs with an opt-out provision.

Comment: Some commenters suggested that in order to align the enrollment requirements between Medicare Savings Programs and the low-income subsidy, States should not be permitted to pursue estate recoveries against Medicare Savings Program beneficiaries.

Response: We do not have authority under the MMA to implement the commenters' recommendation to prevent States from pursuing estate recoveries against Medicare Savings Program beneficiaries.

Comment: Several commenters suggested that the low-income subsidy application process represents an opportunity to connect Medicare beneficiaries to food stamps and other programs that might provide assistance to them. The commenters suggest that CMS set up an eligibility process in the final regulation that allows low-income Medicare beneficiaries to be enrolled as seamlessly as possible in food stamps, as well as other State administered benefits for which they may qualify. The commenters also remarked that setting

up such a system would likely entail that CMS work collaboratively with SSA, USDA, and State agencies. A few commenters detail specific opportunities such as providing information about food stamps and other major benefit programs in any outreach materials that CMS, SSA and State Medicaid programs distribute; designing procedures that allow applicant information to be shared between SSA, State agencies, and CMS; collaborating with other Federal agencies, primarily USDA and SSA, on ways to enroll eligible applicants in all benefit programs; developing coordinated redetermination processes that are simple as possible for Medicare beneficiaries; and reimbursing SSA for the food stamps program's share of any costs associated with efforts to inform Social Security recipients of the availability of food stamps and other programs.

A few other commenters suggested that CMS ensure that applicants be given the choice of opting out of the other programs, noting that the complex income calculations under the different programs such as food stamps or Section 8 Housing could endanger an individual's ability to enroll in other assistance programs.

Response: We agree that the application process for the low-income subsidy represents an opportunity to improve coordination and awareness of other programs designed to assist low-income individuals. As part of outreach efforts for the low-income subsidy, we will consider encouraging awareness of other programs. However, we do not have the authority to align the eligibility systems of other programs in order to design a single application process for benefits beyond the low-income subsidy under Medicare Part D.

If SSA is the agency that determines subsidy eligibility, SSA's response may include a paragraph regarding the individual's potential eligibility for other programs like food stamps, SSI, and Medicaid, based upon the information SSA received when determining the low-income subsidy.

Comment: One commenter recommended CMS conduct a dynamic enrollment campaign targeted toward beneficiaries who have been determined eligible for subsidies during the pre-qualification process. CMS should also develop a one-step application/enrollment process that requires all prescription drug plans to include information about the availability of subsidies in their marketing materials and requires plans to include specific eligibility questions on enrollment forms.

Response: We will be working on a detailed education and outreach strategy over the next few months. We note, as explained in detail in subpart B, that while we encourage individuals to choose a plan that best meets their needs, full- benefit dual eligible individuals who apply and are found eligible for the low-income subsidy will be enrolled automatically in Part D plans if they fail to choose one. We will also facilitate enrollment in Part D plans of other subsidy-eligible individuals.

Comment: A few commenters asked whether a person screened and found eligible is required to enroll in a Medicare Savings Program as a QMB, SLMB, or QIl. Additionally, the commenter asked whether such enrollment is a condition of eligibility for the low-income subsidy program.

Response: Enrollment for those who qualify for a Medicare Savings Program is optional. The State cannot condition eligibility for the Part D low-income subsidy on the individual applying for the Medicare Savings Program.

2. General Payment Provisions (§ 423.906)

Section 1935(d) of the Act contains provisions on Medicaid coordination with Medicare prescription drug benefits. Specifically, in the case of a person who is eligible for Part D and also eligible for full Medicaid benefits, Federal Financial Participation (FFP) in State Medicaid expenditures is not available for Medicaid covered drugs that could be covered under Part D or for cost sharing related to such drugs. As a result, no Federal payment should be made under Medicaid for covered Part D prescription drugs for full-benefit dual eligible individuals.

We proposed in § 423.906(a) that States could receive the regular Federal match for administrative costs in determining subsidy eligibility. We also proposed, at § 423.906(c), that States may elect to provide coverage for outpatient drugs, other than Part D covered drugs, in the same manner as provided for full-benefit dual eligible individuals or through arrangements with the PDP sponsor or MA-PD.

Comment: One commenter asked that Medicaid coverage not expire for full-benefit dual eligible individuals until they voluntarily enroll in a Part D plan or until CMS or the State has automatically enrolled them in a plan. By changing the date on which Medicaid coverage ends, SPAPs would not be obligated to provide drug coverage during such a period without coverage.

Response: In accordance with section 1935(d) of the Act, in the case of a person who is eligible for Part D and also eligible for full Medicaid benefits, FFP is not available for Medicaid covered drugs that could be covered under Part D or for cost sharing related to such drugs. In these cases Medicare is the primary payer. We do not have the authority to delay the end date of Medicaid prescription drug coverage for such individuals. However, we will deem full-benefit dual eligible individuals as eligible for Part D low-income subsidies, and assign these individuals to a PDP, with the option to disenroll, so that there will be no breaks in coverage between Medicaid and the implementation of Medicare Part D in January 2006 for this population.

Comment: One commenter asked for clarification that FFP would also be available to State Medicaid programs to conduct the periodic eligibility redeterminations. The commenter also asked if work done by States and SPAPs to enroll beneficiaries in the Part D program would be claimable as Federal reimbursable services at the administrative FFP rate under Medicaid program costs just as low-income subsidy eligibility determinations costs are claimed. Finally, the commenter asked about claiming FFP for all administrative expenses associated with State Medicaid agencies or SPAPs administering a ''wrap around'' benefit.

Response: FFP is available to States at the normal Federal match rate to conduct redeterminations. However, because neither States nor SPAPs enroll beneficiaries in Part D plans no FFP is available in that regard. In addition, the statute does not allow for reimbursement for administering a State benefit that supplements, or ''wraps around'' Part D.

Comment: One commenter asked if a State could pay for and receive FFP for non-covered Part D drugs when a Part D plan's enhanced alternative coverage includes supplemental benefits such as coverage of non-covered Part D drugs. In such a case, the commenter asked whether the State Medicaid program wrap around coverage for dual eligible beneficiaries in such plans could continue and whether the State could receive FFP for these non-covered Part D drugs.

Response: In the scenario described, the plan's supplemental coverage of non-covered Part D drugs does not preclude Medicaid from wrapping around these non-covered drugs and receiving FFP for such coverage. However, to the extent that the Part D plan provides coverage for the non-covered Part D drugs, Medicaid could only wrap-around (pay for amounts not covered by the plan for those non-

covered drugs) the plan's coverage. FFP would not be available for amounts which the plan covers as supplemental coverage.

Comment: One commenter strongly recommends that CMS provide States with a template to take into account changes to the State plan that will result from implementation of Part D.

Response: We do not plan to create a template to take into account changes to the Medicaid program because of the implementation of Part D. However, States should be aware that any changes it makes to Medicaid payment, eligibility, or coverage because of the impact of the new benefit must be reflected in the State's plan. A State that does not amend its Medicaid State plan to reflect changes to its Medicaid program risks losing FFP.

3. Treatment of Territories (§ 423.907)

Low-income Part D eligible individuals residing in the territories are not eligible for premium and cost-sharing subsidies. However, in accordance with section 1935(e) of the Act, territories may submit a plan to the Secretary under which medical assistance is to be provided to low-income individuals for covered Part D drugs. Territories with approved plans will receive increased grants under section 1935 (e)(3) of the Act. Proposed § 423.907 contained the provisions explaining the territories' submittal of plans and the grant funding.

Comment: One commenter expressed concern that low-income Medicare beneficiaries in Puerto Rico will have no incentive (due to the rich prescription drug benefit through the Health Reform program), and no means, to enroll in a PDP because the low-income subsidy program is not available to the territories.

Response: While residents of the territories are not eligible for the low-income subsidy, the MMA provides that the territories receive an increase in the grants paid under section 1108 of the Act if the territory has a plan approved by the Secretary for providing medical assistance for Part D drugs. The territories may choose to use these funds to pay Part D premiums and cost sharing for low-income residents. The territories may also design their programs to wrap around the Part D benefit, thus providing an incentive for Medicare beneficiaries to enroll in the Part D program

Comment: One commenter asked that CMS not require the same financial and statistical reporting for the funds provided to the territories added to the grant under section 1108 of the Act so as not to make the grant administratively burdensome.

Response: Reporting requirements are administrative in nature and are not addressed in this regulation. We will work with the territories to design reports that provide CMS with sufficient information to establish accountability without creating overly burdensome reports.

Comment: One commenter believed that a multi-state PDP region including Puerto Rico will compromise the viability of the Medicare Part D program in that territory because of differences in language, culture, income, and cost structure between Puerto Rico and States.

Response: We appreciate the commenter's concerns. The actual designation of the regions has been announced by CMS and is listed on our website.

4. State Contribution to Drug Benefit Costs Assumed by Medicare (§ 423.908 through § 423.910)

Medicare will subsidize prescription drug costs for full benefit dual eligible individuals. However, in accordance with section 1935(c) of the Act, States and the District of Columbia will be responsible for making monthly payments to the Federal government beginning in January 2006 to defray a portion of the Medicare drug expenditures for these individuals. The percentage of State contributions to Medicare Part D funding is reduced over a ten-year period.

The statute directs, and we specified, in § 423.910(b)(2) that State payments will be made in a manner similar to the mechanism through which States pay Medicare Part B premiums on behalf of low-income individuals who are eligible for both Medicare and Medicaid, except that those payments will be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

As we proposed in § 423.908 through § 423.910 to calculate the monthly State contributions we would first calculate an amount we refer to as the projected monthly per capita drug payment. This amount is based in part on a State's Medicaid per capita expenditures for covered Part D drugs for Medicare beneficiaries eligible for full benefits under Medicaid for 2003, which is equal to the weighted average of gross per capita Medicaid expenditures for prescription drugs for 2003 for Medicaid recipients not receiving drugs through a managed care plan and the estimated actuarial value of prescription drugs benefits provided under a comprehensive Medicaid managed care plan for these individuals in 2003. The weighted average would be based on the proportion of individuals who, in 2003, did and did not receive medical assistance for covered outpatient drugs through a comprehensive Medicaid managed care plan.

The gross per capita Medicaid expenditures for prescription drugs for 2003 is equal to the average (mean) per person expenditures (including dispensing fees) for a State during 2003 for covered Part D drugs provided to Medicare beneficiaries receiving full benefits under Medicaid who are not receiving medical assistance for drugs through a comprehensive Medicaid managed care plan, based on data from the Medicaid Statistical Information System (MSIS) and other available data, as adjusted by an adjustment factor.

We would apply an adjustment factor to the gross per capita Medicaid expenditures for prescription drugs. The adjustment factor for a State would have to equal the ratio of the aggregate payments to the State in 2003 under rebate agreements under section 1927 of the Act to a State's 2003 gross expenditures for covered Part D drugs not received through a Medicaid managed care plan, based on data contained in the CMS–64 Medicaid expenditure report. We proposed to define 2003 as CY 2003 (January 1, 2003 through December 31, 2003). The gross per capita Medicaid expenditures for prescription drugs for 2003 will be reduced by this adjustment factor ratio.

The projected monthly per capita drug payment will be equal to 1/12 of the product of the State's Medicaid per capita expenditures for covered Part D drugs for Medicare beneficiaries eligible for full benefits under Medicaid for 2003 and a proportion equal to 100 percent minus the Federal medical assistance percentage (as defined in section 1905(b) of the Act) applicable to the State for the year for the month at issue. This amount will be increased by the growth factor for each year beginning in 2004 through the year for the month at issue. The growth factor for years 2004, 2005, and 2006 will be the average percent change from the previous year of the per capita amount of prescription drug expenditures (determined using the most recent National Health Expenditure (NHE) projections). The growth factor for 2007 and succeeding years will equal the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals for the 12-month period ending in July of the previous year as described in 423.104(d)(5)(iv). We will provide

further detail regarding the sources of data to be used and how the annual percentage increase will be determined via operational guidance to States.

The monthly State contributions for each year, beginning in January of 2006, will be the product of the projected monthly per capita drug payment, the total number of full-benefit dual eligible individuals for the State in the applicable month, and the applicable ten year phased-down factor for the year (see Table S–1). As illustrated in Table S–1, State contributions will decline each year until 2015, at which time the applicable 10 year phased-down factor for each year will be fixed at 75 percent.

As specified in proposed § 423.910(b)(3), failure on the part of a State to pay these State contribution amounts would result in interest accruing on those payments at the rate provided under section 1903(d)(5) of the Act, in accordance with section 1935(c)(1)(C) of the Act. In addition, as required by the statute, we would immediately offset unpaid amounts and accrued interest against Federal Medicaid matching payments due to the State under section 1903(a) of the Act. As specified in § 423.910(e), we would perform periodic data matches to identify full-benefit dual eligibles for purposes of computing State contributions. As we specified in § 423.910(d), States would be required to provide data on full- benefit dual eligible enrollees in order to conduct the data match required under section 1935(c)(1)(D) of the Act.

States will make contributions only on behalf of Medicare beneficiaries who would otherwise be eligible for outpatient prescription drug benefits under Medicaid. States will not make contributions on behalf of individuals such as those QMBs who are not otherwise eligible for Medicaid, SLMBs, and QIs for whom the State will pay only Part B premiums or Medicare cost sharing on their behalf.

In order to give meaning to the term full-benefit dual eligible individual for purposes of the baseline calculation, we needed to define it in a manner that would permit the baseline calculation to operate. Therefore, we proposed that Medicaid eligible individuals who receive comprehensive benefits including drug coverage under Medicaid and are also covered under Medicare Part A or Part B are to be full-benefit dual eligible individuals for purposes of calculating the baseline. The proposed definition of full-benefit dual eligible individuals excluded Medicare beneficiaries who receive Medicaid drug coverage under a section 1115 Pharmacy Plus demonstration.

As we specified in § 423.910(g), to assist States in their budget planning, we must notify States by October 15 each year of the projected monthly per capita drug payment calculation for the next calendar year.

The ten-year phased-down State contribution (PDSC) factors are identified below in Table S–1.

TABLE S–1

ANNUAL PHASED—DOWN PERCENTAGES OF STATE CONTRIBUTIONS TO MEDICARE PART D DRUG BENEFIT COSTS

Year	State Percentage
2006	90
2007	88 1/3
2008	86 2/3
2009	85
2010	83 1/3
2011	81 2/3
2012	80
2013	78 1/3
2014	76 2/3
2015 and thereafter	75

Comment: A few commenters expressed concern that the 2003 baseline per full-benefit dual eligible drug cost would fail to reflect cost containment measures by States. The commenters believed that the legislative reference to the use of ''other available data'' provides for a more expansive view of adjustments. Proposed changes included allowing States to submit documentation of the effects of cost containment measures to periodically re-base the cost, and the use of 2004 as a base year.

Response: The legislation specifies that we inflate the 2003 base year full-benefit dual eligible per capita drug costs for use in 2006 using the NHE projections for the years involved. This inflation factor should take into account changes in the rate of growth of per capita drug costs. Any effort to measure the differential effect of State cost containment against the specified inflation factor could be imprecise and would introduce new reporting requirements. We do not support the use of optional ad hoc State-reported data, which will be inconsistently defined, and would be applied unevenly to States. The use of a later base year, such as 2004, is precluded by the legislative language.

Comment: One commenter recommends that the regulations allow State-specific methods for the estimated actuarial value of capitated prescription drug benefits, allowing States to use their data for the dual eligible population.

Response: Since we believe the data available on managed care drug costs will vary by State, the final rule provides for use of a range of sources of managed care drug cost data.

Comment: One State commenter believes it may pay a disproportionate share in its phase-down contribution for less comprehensive coverage for its full-benefit dual eligible individuals.

Response: We believe that the Medicare drug benefit will pay, on average, more than 96 percent of full-benefit dual eligible individuals' drug costs. Additionally, about 1.5 million of these full-benefit dual eligible individuals are institutionalized, meaning they will not pay any premiums, deductibles or co-payments. While the nominal cost sharing of the Medicare prescription program is slightly higher than the cost-sharing under Medicaid, Medicare provides catastrophic drug coverage, offering additional protection to this vulnerable population. We further believe that Medicare Part D is likely to result in more stable and consistent prescription drug coverage for low-income Medicare beneficiaries since Medicaid is not a secure source of drug coverage, as eligibility is subject to meeting certain income and resource requirements. As a result of these requirements, Medicaid may only provide intermittent drug coverage to the full-benefit dual eligible individual.

Comment: One State commenter asked how member months are being counted, how people in MA plans will be counted for the phased-down payment, and whether individuals from their family planning waiver are included.

Response: For the phase-down baseline, we expect to count every MSIS reported enrollment for each month for individuals who are coded as full-benefit dual eligible individuals. MA plans have no effect on the baseline calculations, although we will distinguish between Medicaid individuals in comprehensive plans and those not in comprehensive plans. This distinction is necessary to establish the weighting between the fee-for-service and capitated populations in the baseline calculations. The only full-benefit dual eligible enrolled individuals who are excluded are those in Pharmacy Plus demonstrations and drug-only 1115 demonstrations. Those

in family planning demonstrations would not be excluded if they received benefits beyond drug coverage.

Comment: One commenter requested clarification on the process to inflate the baseline per-capita drug cost after 2006. The legislation specifies the use of the actual Part D costs for the 12 months prior to July of each year. For 2007 there will not be a 12-month history from 2006 available.

Response: We will provide further detail regarding the sources of data to be used and how the annual percentage increase will be determined via operational guidance to States.

Comment: A few commenters expressed concern about the use of the NHE factor to inflate the baseline to 2003, and suggested that we use either State-specific numbers, or the total public sector number.

Another commenter asked clarification as to which specific NHE projection will be used for the phase-down calculation.

Response: The legislation is clear in directing the use of the NHE estimate for the whole country as the basis for this inflation factor. That source provides very limited options for use. We believe the overall per capita drug cost numbers are the most consistent with the intent of the law. The specific NHE projection factor to be used will be discussed in operational guidance.

Comment: One commenter expressed concern that the 2003 base year data may not be representative of drug utilization experience. The commenter proposes using pooled data from 2001, 2002, and 2003 to obtain a utilization estimate. The commenter also expressed concern over the use of quarterly MSIS dual eligibility codes to establish monthly spending and enrollment base numbers.

Response: We believe that this proposal would introduce significant additional problems associated with the trending forward of that significantly older base data. This proposal also conflicts with the legislative language, which clearly specifies the use of the calendar year 2003 data. We will address the use of quarterly dual eligibility indicators in MSIS by applying an algorithm that incorporates both prior and current quarter values.

Comment: A few commenters proposed that States be allowed to submit drug rebate dollar amounts that reflect only the full-benefit dual eligible population. They propose that these numbers be used instead of the aggregate rebate and drug payment amounts reported on the CMS–64 report.

Response: While this proposal would allow the rebate adjustment to correspond more closely to the population affected by the PDSC, this is inconsistent with the legislative language, and would require that we impose new and complex reporting requirements on the States. We do not support the use of optional ad hoc State-reported data, which will be inconsistently defined, and would be applied unevenly to States.

Comment: A few commenters proposed that we allow States to submit, at their option, rebate collections after 2003 for rebate amounts identified in 2003. These additional rebate amounts would be used to reduce the base year drug costs in the baseline calculations.

Response: This comment presumes that the legislation intended that we use base year data for rebates on an incurred, rather than paid, basis. This is inconsistent with the definition of the CMS–64 referenced by the legislative language. Simply adding incremental collections of 2003 incurred rebates would inappropriately inflate the rebate totals, since the law does not provide for removal of 2003 rebate collections incurred in 2002. There is no standardized reported data that would allow creation of an incurred rebate amount, and no indication in the legislation that this was intended. We believe use of optional State-reported post–2003 rebate collections would introduce inconsistent treatment of States.

Comment: One commenter recommended that States that provide pharmacy-only benefits under an 1115 demonstration to a subset of its population be excluded from the definition of full- benefit dual eligible individual, since these programs generally provide the same benefits as offered by Pharmacy Plus Programs.

Response: We agree with this commenter and have clarified the definition of full-benefit dual eligible individual at § 423.902 to specifically exclude those individuals enrolled in 1115 demonstration programs that provide pharmacy-only benefits to a portion of its demonstration population.

Comment: One State commenter did not object to including its Medicare beneficiaries who are enrolled in its pharmacy assistance 1115 program in the baseline expenditures, but believes it is inappropriate to count them as part of the future Medicaid enrolled population that is multiplied by the trended per person cost as part of the formula.

Response: As indicated above, we will not be including these populations in the baseline expenditures. In order to remain consistent with the definition of the baseline and monthly billing counts, we would also exclude this population from the future Medicaid enrolled population.

Comment: One State commenter recommends CMS use the First Data Bank generic sequence number in lieu of the NDC when determining the excluded list of drugs used in establishing the State's phase-down contribution.

Response: We are using the NDC because it is the only available identifier on the MSIS drug claim record.

Comment: One commenter proposed that we allow States to submit auditable reports of reductions in base year drug payments due to judicial settlements with drug manufacturers and other accounting adjustments to base year cost.

Response: This comment presumes that the legislation intended that we use base year data on an incurred, rather than paid, basis. This is inconsistent with the definition of the MSIS and CMS–64 data sources referenced by the legislative language. Simply adding incremental collections of 2003 settlements would improperly reduce the total payments, since it does not provide for removal of 2003 settlements incurred during 2002. There is no standardized reported data that would allow creation of an incurred settlement amount, and no indication in the legislation that this was intended. The legislation directs that we derive the base year costs from the reported MSIS drug claims data, and there is no viable way to associate these settlement amounts with those individual drug claims; nor can these settlements be accurately associated with the target population on an aggregate basis. We believe use of optional State-reported post–2003 settlements would introduce inconsistent treatment of States.

Comment: One commenter proposed that full-benefit dual eligible individuals be enrolled in plans providing a formulary comparable to the existing Medicaid coverage, and several commenters proposed that that the PDSC payment exclude any payments for drugs outside the Part D formulary.

Response: There is no provision in the legislative language to ensure equivalency of drug formularies under Medicaid dual eligible and Part D coverage. The PDSC payments are based on actual Medicaid program payment levels, and are not linked to the Part D formularies.

Comment: One commenter proposed that 100 percent State funded drug benefits for drugs not in the Part D

formulary be excluded from the PDSC payment.

Response: The baseline is specified to be the actual Medicaid drug payment experience for each State based on MSIS data which does not include State-only programs. The legislation does not provide for adjustments based on subsequent State choices to offer drug coverage that wraps around the Part D coverage. There is no provision for Medicaid or other State programs to receive Federal matching or an exclusion from PDSC payment for drugs provided beyond those excluded drugs. The PDSC payments are based on the savings from historic State utilization levels, and do not guarantee equivalence in coverage formularies.

Comment: One commenter expressed concern about drugs to be excluded from the baseline.

Response: We have developed a list of drug codes for drugs to be excluded from the baseline based on the Part D exclusions in the legislation.

Comment: A few commenters asked that we clarify the start date and ongoing due dates for the PDSC payments.

Response: The final regulatory language includes this information. The ongoing due dates will parallel those for the Medicare Part B premium buy-in process.

Comment: One commenter requested that we move the due date for State notification of baseline amounts from October 15 to August 15 prior to the payment year. This would allow States more budgetary lead time.

Response: The legislation requires that the first year's baseline data be provided to States no later than October 15, 2005 for the 2006 payment year. In order to help support State budgeting needs, it is our intent to provide this information to States as soon as it can be developed. However, the timing to produce preliminary numbers will be contingent on timely State reporting of needed MSIS data.

In regard to years subsequent to 2006, the only changes to the base number will be the inflation factor and the Federal matching rate. States should be able to develop reasonably accurate estimates for later years based on the prior year's base.

Comment: One commenter expressed concern that if we require State payment by check or electronic funds transfer, payment could conflict with State-legislated caps. The commenter proposed that we allow a range of payment options comparable to the Medicare buy-in process.

Response: It is our intent, as evidenced by our clarification of the final regulatory language, to mirror the payment process for the buy-in process set forth in a **Federal Register** notice published on September 30, 1985 at FR 39784. This process includes funds transfers, with a provision that any late payments will be offset against the Medicaid grant with appropriate interest accrual. In this case, the Medicaid offset would be transferred to the Medicare Prescription Drug Account to complete the transaction. Since failure to pay is covered in this notice, we have removed text at § 423.910(b)(3) that was included in the proposed rule.

Comment: A few commenters requested that we include a process for State appeal of the PDSC payment amount.

Response: The legislation does not contain a specific provision for an appeal process. However, it requires CMS to disallow from the Federal financial participation in the State's Medicaid expenditures any amounts which the State should have paid under section 1935 of the act. Because this is a disallowance of Medicaid funds, any State disagreements with the phased-down billing would have to be handled through the existing disallowance process under § 430.42.

Comment: A few commenters expressed concerns about the need for more specific instructions for reporting monthly enrollment to CMS, and proposed the use of the MSIS.

Response: The final regulation includes more specific information on this reporting process. CMS has evaluated this option and has determined that the change of MSIS from quarterly to monthly reporting would represent an undue hardship to States. The enrollment reporting file would also require the addition of fields to address other program needs, such as subsidy determinations.

Comment: One commenter requested more detail on the process to be used to establish the actuarial value of the capitated prescription drug benefits for full-benefit dual eligible individuals in comprehensive managed care plans.

Response: We have provided clarification in the final regulation at § 423.902, based on feedback obtained from State workgroups addressing this issue.

T. Part D Provisions Affecting Physician Self-Referral, Cost-Based HMO, PACE, and Medigap Requirements

In the August 2004 proposed rule, subpart T discussed several other regulatory areas affected by the provisions implementing the Medicare prescription drug benefit. This section discussed the revised requirements for physician self-referral prohibition, cost-based HMOs, PACE organizations, and Medigap policies.

1. Definition of Outpatient Prescription Drugs for Purposes of Physician Self-Referral Prohibition (§ 411.351)

Section 1877 of the Act, also known as the physician self-referral law, prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which the physician (or an immediate family member of the physician) has a financial relationship (ownership, investment, or compensation), unless an exception applies. Section 1877 of the Act also prohibits the DHS entity from submitting claims to Medicare for DHS furnished as a result of a prohibited referral.

Outpatient prescription drugs are a DHS under section 1877 of the Act. As a result of the Medicare prescription drug benefit provisions, we proposed to amend the physician self-referral definition of ''outpatient prescription drugs'' at § 411.351 to include the additional outpatient drugs covered under the new Part D benefit. In other words, under the proposed definition, physician referrals for outpatient prescription drugs covered under Part D would be subject to the physician self-referral prohibition. We have finalized this proposal without substantive change because we believe that referrals for Part D drugs are subject to the same risk of over-utilization and anti-competitive behavior as referrals for Part B drugs when a financial relationship exists between the referring physician and the entity furnishing the drugs.

Comment: We received a number of comments, which supported our proposal. Some of the commenters cited analyses, which supported our proposed action.

Response: We appreciate the support given to our proposal. We believe that applying the physician self-referral provision to referrals for either Part B or Part D drugs will reduce the potential for over-utilization and other program abuse.

2. Cost-Based HMOs and CMPs Offering Part D Coverage (§ 417.440 and § 417.534)

Section 1860D–21(e) of the Act provides that Part D rules will generally apply to reasonable cost reimbursement HMOs and CMPs (Competitive Medical Plans) that contract under section 1876 of the Act and that offer qualified prescription drug coverage to Part D eligible individuals in the same manner as such rules apply to the offering of

qualified prescription drug coverage under MA-PD local plans. As a result, we proposed revising § 417.440(b) of this chapter to specify that a cost-based HMO or CMP may offer qualified prescription drug coverage. We also proposed adding new § 417.534(b)(4), specifying that to the extent that a cost HMO or CMP chooses to participate in the Part D program by offering qualified prescription drug coverage to its members, any costs associated with the offering of Part D benefits may not be claimed on its Medicare cost report. After reviewing comments and responding (below), we are adopting the proposed policy as final.

In the proposed rule, we incorrectly stated at 69 FR 46753 that cost-based HMOs and CMPs would offer qualified prescription drug coverage to Part D eligible enrollees under § 417.440(b)(1)(iii) as a basic benefit. We clarify in this final rule our belief that such a reading would not comply with the clear language of section 1876(c)(2)(A)(ii)(I) of the Act which provides that cost-based HMOs and CMPs may only offer non-Part A/B Medicare benefits as optional supplemental benefits. In this final rule, we therefore amend § 417.440(b)(2) to make the requirement clear that cost-based HMOs and CMPs may offer qualified prescription drug coverage to Part D eligible enrollees only as an optional supplemental benefit.

Section 1860D–21(e)(2) of the Act stipulates that section 1876 reasonable cost contractors offering qualified prescription drug coverage may only offer such coverage to individuals enrolled in its reasonable cost contract, or individuals who receive services covered under Medicare Parts A and B through its reasonable cost contract. After reviewing comments and responding (below), we are adopting the proposed policy as final. However, it is important to note that the HMO or CMP offering the cost plan is free to also apply to be a PDP sponsor and may, if approved, then offer a separate Part D plan to Part D eligible individuals enrolled in original Medicare who are not enrollees of its cost plan.

Section 1860D–21(e)(3) of the Act provides that the Part D bids of section 1876 reasonable cost contracts will not be included in the computation of the national average monthly bid amount and the low-income benchmark premium amount. We discuss the national average monthly bid amount in the subpart F preamble and the low-income benchmark premium amount in the subpart P preamble.

We proposed that the waiver authority provided in section 1860D–21(c) of the Act would be available to section 1876 reasonable cost HMOs and CMPs in the same manner as it is available to MA-PD local plans, namely that we will waive any requirement otherwise applicable under this part for section 1876 reasonable cost HMOs and CMPs to the extent such requirement conflicts with or is duplicative of a requirement under part 417, or such waiver is necessary to promote coordination of the Part D benefits with the benefits offered under part 417. We discuss section 1860D–21(c) of the Act and this waiver authority in subpart J of the preamble. We invited comment on whether there are any Part D requirements otherwise applicable to the offering of qualified prescription drug coverage under MA-PD local plans that would be uniquely problematic to implement for section 1876 reasonable cost HMOs and CMPs. After reviewing and responding to comments (below), we have not identified any additional Part D requirements that will be uniquely problematic for section 1876 reasonable cost HMOs and CMPs to implement. Nevertheless, in § 423.458(d) of the final rule, we provide for a process that will allow for waiver of Part D provisions for cost HMOs and CMPs that offer qualified prescription drug coverage under Part D to the extent that the provision duplicates, or is in conflict with provisions otherwise applicable to the section 1876 cost HMO/CMP under section 1876 of the Act, or when a waiver is necessary to promote coordination of the Part D benefits with the benefits offered under part 417.

Comment: Some commenters suggested that we make clear that once a cost plan offers Part D that it becomes an MA-PD plan and that some (or all) Part C provisions then supersede or replace section 1876 (and part 417 of title 42 CFR) provisions as controlling on such a cost plan. For instance, some commenters suggested that the State preemption authority in section 1856(b)(3) of the Act related to MA plans, and incorporated by reference in section 1860D–12(g) of the Act, should be interpreted to apply to the entire benefit package that a cost HMO/CMP offers and not just the prescription drug coverage portion of the package.

Response: We do not agree. We interpret section 1860D–21(e)(1) of the Act as providing that only those provisions of Part D and related provisions of Part C pertaining to the offering of qualified prescription drug coverage by a MA-PD local plan would apply to the offering of such coverage by a cost HMO or CMP. Consequently, the provisions of Parts C and D, including the preemption provisions under sections 1860D–12(g) and 1856(b)(3) of the Act, would not apply to benefits offered under a reasonable cost contract other than any qualified prescription drug coverage. In other words, the section 1876 cost-based HMO/CMP does not gain preemption protection related to the ''entire benefit package'' it offers. Accordingly, the preemption authority at section 1860D–12(g) of the Act does not, in and of itself, ''immunize'' the cost HMO/CMP from State laws with respect to the benefits the cost HMO/CMP offers under the authority in section 1876 of the Act.

Comment: One commenter said that section 1860D–21(e) of the Act says that a cost HMO/CMP that offers qualified prescription drug coverage to its members is deemed to be an MA-PD local plan. This commenter suggested that CMS should allow a cost plan that elects to offer qualified prescription drug coverage to its Part D eligible cost enrollees to apply related Part C provisions to those members.

Response: We do not necessarily agree. Section 1860D–21(e) of the Act extends to cost plans provisions of Part C applicable to MA-PD local plans to the extent they relate to the offering of qualified prescription drug coverage. Section 1860D–21(e) of the Act, however, does not deem a reasonable cost contract offering qualified prescription drug coverage a MA-PD local plan for all purposes. Consequently, those provisions applicable to MA-PD local plans that are unrelated to the offering of qualified prescription drug coverage would not apply to reasonable cost contracts. In other words, it is only in this limited way that a cost plan offering qualified Part D coverage is deemed to be an MA-PD.

Comment: One commenter suggested modifying § 417.436 to provide that that the requirement at § 417.436(a)(5) that a cost HMO or CMP disclose to its enrollees that they may receive services through any Medicare provider or supplier has no effect with respect to the offering of qualified prescription drug coverage under the reasonable cost contract.

Response: We believe that § 423.458 is clear in providing that rules related to Part D coverage, whether offered by a PDP or an MA-PD, are provided in the part 423 regulations. Therefore, it is not necessary to specifically say in the part 417 regulations that a specific part 423 regulation applies. Section 423.128(b) describes the specific information that PDPs and MA-PDs must disclose related to their Part D benefit offerings, which includes ''a disclosure of out-of-network

coverage consistent with § 423.124(a)''—see § 423.128(b)(6).

Comment: One commenter asked that we clarify that a legal entity that operates a Medicare cost plan may operate as a PDP sponsor as long as it meets all the relevant licensure and other requirements.

Response: We concur and have clarified this point in our preamble discussion in this subpart.

Comment: One commenter asked us to clarify that the definition of service area for cost HMOs/CMPs is found at § 417.1, while the definition for MA plans is found at § 422.2. The commenter asked us to clarify that the reference to service areas for MA-PD plans in § 423.120(a) had no applicability to cost plans.

Response: We agree with the commenter that the reference to service area of an MA-PD plan in § 423.120(a) does not apply to cost HMOs/CMPs that offer Part D coverage. The effect of section 1860D–21(e)(2) of the Act is not to ''deem'' that a cost plan offering qualified Part D coverage actually becomes an MA-PD local plan. Rather, it is that the rule applicable to the *provision of Part D coverage* by the cost plan to enrollees of the cost plan is similar to the *provision of Part D coverage* by MA-PD local plans. As we provide in subpart J of this rule at § 423.458(d), we will waive provisions in § 423.120(a) to the extent they duplicate or conflict with section 1876 provisions applicable to cost plans under section 1876 of the Act or part 417 of title 42 CFR, or to the extent waiver is necessary to improve coordination of Part D benefits offered under the plan with the other benefits offered by the cost plan. Although we do not specifically mention such a waiver at § 423.120(a) for a cost HMO/CMP offering qualified prescription drug coverage, such a waiver is available, to the extent it would meet the conditions for waiver in § 423.458(d).

Comment: One commenter asked if the disclosure requirements in § 423.128, to the extent they were more stringent than the disclosure requirements under section 1876 of the Act and § 417.436 of the title 42 CFR, would only apply to the Part D portion of a cost plan's benefit offerings.

Response: To the extent that a ''coordination'' waiver has not been granted under § 423.458(d), the disclosure requirements in § 423.128 would apply to the Part D portion of a cost plan's benefit offering.

Comment: One commenter suggested that section 1860D–21(e) of the Act provides to us clear authority to allow us to apply ''deeming'' authority in § 423.165 to cost HMOs/CMPs offering qualified Part D coverage to cost enrollees, which allows us to deem an entity as meeting certain requirements under this part if the entity is fully accredited (and periodically reaccredited) by a private national accreditation organization approved by us.

Response: We agree that section 1860D–21(e) of the Act extends the deeming authority under § 423.165 to section 1876 cost HMOs/CMPs, provided the provisions of § 423.165 are not otherwise waived under § 423.458(d) with respect to section 1876 cost HMOs/CMPs.

Comment: One commenter asked us to clarify that the waiver authority in § 423.458(c), which permits us to waive or modify any requirement under this part that hinders the design of, the offering of, or the enrollment in an employer- or labor-sponsored group prescription drug plan, would also apply to section 1876 cost HMOs/CMPs.

Response: We responded to a similar comment in the subpart J preamble. In short, we do not interpret the statute as permitting us to apply our waiver authority related to employer- or labor-sponsored group coverage as extending to the Medicare Part A and B benefits offered by a Medicare cost plan.

Comment: A few commenters asked if section 1876 cost plans that did not offer qualified prescription drug coverage would be permitted to offer non-qualified prescription drug coverage. One commenter also asked if such coverage would be creditable coverage under Part D fearing that such cost members would be penalized for electing Part D late.

Response: Section 1876 reasonable cost plans that do not offer their members qualified prescription drug coverage may offer non-qualified prescription drug coverage to their members, but only as an optional supplemental benefit and in accordance with § 417.440(b)(2). Such coverage will be considered creditable prescription drug coverage only if it meets the standards set forth in § 423.56(a) of the final rule.

Comment: One commenter asked if we would permit cost plans to waive Part A/B and to apply this waiver to the Part D premium that would otherwise be imposed on cost plan members.

Response: Such a waiver will not be permitted. A cost plan must claim its reasonable costs for services provided under the plan that are covered under Parts A and B in accordance with the applicable requirements of part 417 of this chapter. If the cost plan elects to provide its enrollees qualified prescription drug coverage under Part D, payment for such benefits will be governed by the payment rules under this part. In other words, the financing of services provided under the cost plan that are covered under Parts A and B is separate from the financing of any qualified prescription drug coverage provided under the plan. Please see § 417.534(c) where we clearly state that ''no costs related to the offering or provision of Part D benefits will be reimbursed under this Part [417].'' To the extent that we permitted waiver of A/B to apply to reduction in Part D premiums, dollars applicable to part 417 would flow to Part D, and therefore such a proposal cannot be allowed. If a cost plan wants to reduce cost-sharing values for A/B services as currently permitted, it may continue to do so. However, the revenue thus forgone related to benefits offered under part 417 cannot be passed over to reduce premiums required under part 423.

Comment: One commenter asked if the waiver of State premium taxes and the preemption authority granted under section 1860D–12(g) of the Act to PDP sponsors and prescription drug plans would also apply to cost plans offering qualified Part D. The commenter suggested that such a waiver and such authority should also be extended to the cost plan's A/B benefit offerings under part 417.

Response: We have previously provided guidance to cost plans related to State premium taxes. As we have previously indicated, we do not believe that States can impose a premium tax on the reasonable costs that we reimburse cost plans for covered Medicare Part A and B services. Such payments by us do not technically represent a premium so much as they represent reimbursement, under the Medicare program, for benefits to which Medicare enrollees are entitled. On the other hand, we have also said that premiums changed to cost plan members for the actuarial value of fee-for-service deductibles and coinsurance are properly construed as premiums and would be correctly subject to State taxes. On the other hand, for premiums related to the Part D offering of a cost plan, there is specific preemption and waiver of State taxes. See the subpart J preamble for an additional discussion on this issue.

3. PACE Organizations Offering Part D Coverage

a. Overview

Section 1860D–21(f)(1) of the Act provides that a PACE program may elect to provide qualified prescription drug

coverage to its enrollees who are Part D eligible individuals.

Currently, sections 1894 and 1934 of the Act require PACE organizations to provide enrollees with all medically necessary services including prescription drugs, without any limitation or condition as to amount, duration, or scope and without application of deductibles, co-payments, coinsurance, or other cost sharing that would otherwise apply under Medicare or Medicaid. Up until January 1, 2006, payment for drugs covered under Medicare Parts A and B is included in the monthly Medicare capitation rate paid to PACE organizations for Medicare beneficiaries, while payment for outpatient prescription drugs is included as either a portion of the monthly Medicaid capitation rate paid to PACE organizations for Medicaid recipients, or as a portion of the amount equal to the Medicaid premium paid by non-Medicaid recipients.

The MMA alters the payment structure for Part D drugs for PACE organizations by shifting the payer source for PACE enrollees who are full-benefit dual eligible individuals (as defined under section 1935(c)(6) of the Act) from Medicaid to Medicare, and in part from the beneficiary to Medicare in the case of non-full-benefit dual eligible individuals who elect to enroll in Part D.

Consequently, in order for PACE organizations to continue to meet the statutory requirement to provide prescription drug coverage to their enrollees, and to ensure that they receive adequate payment for the provision of Part D drugs, from January 1, 2006 forward, we explained in the proposed rule that PACE organizations would need to offer qualified prescription drug coverage to their enrollees who are Part D eligible individuals. We also indicated that prescription drug coverage for PACE enrollees who are ineligible for Part D (Medicaid-only enrollees) would continue to be funded by the State in which each PACE organization is located through its monthly capitation payment to the PACE organization.

Section 1860D–21(f)(1) of the Act provides that in the case of a PACE program that elects to provide qualified prescription drug coverage to its enrollees who are Part D eligible individuals, the requirements under this Part apply to the provision of the coverage in a manner that is similar to the manner in which the requirements apply to the provision of such coverage under MA-PD local plans. Furthermore, the PACE organization may be deemed to be MA-PD local plan.

We believe that the Congress did not intend to alter the way in which PACE services, including outpatient prescription drugs, are currently being provided to enrollees. Therefore, we proposed that PACE organizations not be deemed to be MA-PD local plans. Rather, we proposed that PACE organizations would be treated in a manner that is similar to an MA-PD local plan for purposes of payment under Part D for qualified prescription drug coverage provided under their PACE plans. We stated that we believed this approach was consistent with section 1894(d)(1) of the Act, which provides that payments will be made to PACE organizations in the same manner and from the same sources as payments are made to a MA organization.

PACE organizations have a longstanding history of providing prescription drug coverage under the authority of sections 1894 and 1934 of the Act and 42 CFR part 460. Therefore, many of the new Part D requirements are duplicative of, conflict with, or do not promote coordination with, the PACE benefit. For these reasons, many of the Part D requirements will be waived for PACE organizations. A background of the PACE model is provided below, followed by a discussion of Part D administrative and payment related requirements as they relate to PACE organizations.

b. *Background*

Sections 4801 through 4803 of the Balanced Budget Act of 1997 (Pub. L. 105–33) established PACE as a Medicare benefit category and a State plan option under Medicaid. PACE organizations provide services to frail, elderly individuals as an alternative to nursing home placement. The PACE benefit currently includes all Medicare benefits under Parts A and B, all services covered under the Medicaid State plan, and any other service(s) deemed necessary by the PACE interdisciplinary team.

The PACE benefit also currently includes all outpatient prescription drugs, as well as over-the-counter medications that are indicated by the participant's care plan. Thus, all PACE organizations currently provide at least the equivalent of qualified prescription drug coverage as described under subpart C.

PACE organizations are risk-bearing entities that receive a capitated monthly rate from Medicare for Medicare-covered services and from Medicaid for Medicaid-covered services. As required by sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act, the PACE organization pools payments received from all sources in order to provide all services needed by its enrollees, including services covered by neither Medicare nor Medicaid. Currently, most PACE enrollees are dually eligible for Medicare and Medicaid; however, participants may be eligible for Medicare only or Medicaid only. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act require the PACE organization to provide all covered services to enrollees regardless of the source of payment. Sections 1894(b)(1)(A)(i) and 1934(b)(1)(A)(i) further clarify that PACE programs cannot charge deductibles, co-payments, coinsurance, or other cost-sharing responsibilities to PACE participants. Consequently, a PACE organization may not charge its participants any cost sharing.

The PACE Medicare and Medicaid regulations are located in 42 CFR part 460. As directed by sections 1894 and 1934 of the Act, these regulatory requirements are a blend of MA and Medicaid managed care requirements, as well as requirements from the PACE Protocol that was created by On Lok, Inc. under a demonstration waiver program with the Secretary. Thus, although certain PACE requirements are the same or similar to MA and Medicaid managed care requirements, many are unique to PACE.

We received 11 formal letters of comment from industry representatives, PACE organizations, States, and contractors. Most commenters identified multiple concerns, regarding the Part D administrative and payment related provisions in relation to PACE. Many commenters also expressed support for the waivers we proposed, as well as recommended that we waive additional Part D rules because they conflict with, duplicate, or do not promote coordination with, the PACE statute and regulations. We thank the commenters who submitted comments on waiver issues, and we have summarized all of the comments below. However, as explained below, we have chosen to finalize only our proposed waiver of section 423.265(b), which would have required PACE organizations planning to offer Part D prescription drug plans to submit bids and supplemental information no later than the first Monday in June of each year. We will issue further guidance that will list additional Part D provisions that we will waive for PACE organizations. In issuing such guidance, we will take into consideration all of the comments we received regarding waivers.

c. Application of Payment Related Part D Requirements to PACE Organizations

In using the term, payment related requirements, we are referring to

subparts F, G, and P of this regulation concerning submission of bids and monthly beneficiary premiums, plan approval, payments to PACE organizations for qualified prescription drug coverage, and premium and cost-sharing subsidies for low-income individuals.

In accordance with subpart F, we proposed that each organization would submit a Part D bid that would reflect its average monthly revenue requirements to provide qualified prescription drug coverage, including enhanced alternative prescription drug coverage, for a Part D eligible individual with a national average risk profile. This bidding process would have occurred in a similar manner as for traditional Part D plans. In accordance with § 423.265(c)(3) of this regulation, Part D bids were to be prepared according to CMS guidelines on actuarial valuation and actuarially certified.

We also proposed that plans would use qualified actuaries to prepare their bids in accordance with these principles. However, we were concerned that requiring small PACE organizations to independently contract with actuaries would be costly and burdensome. In order to minimize their cost, we suggested that PACE organizations collectively contract with an actuary to develop the methodology for establishing a bid, but stated that each bid would need to be actuarially certified.

Finally, we indicated that since PACE organizations are required to enroll Medicare-only individuals who meet PACE eligibility requirements, all PACE organization bids would be required to include the portion of the bid attributable to the cost of providing the enhanced alternative prescription drug coverage.

In the proposed rule, we proposed policies addressing each of the three primary categories of PACE enrollees: individuals enrolled in Medicaid, but not Medicare (Medicaid-only); individuals enrolled in Medicare and Medicaid (Dual eligible individuals); and individuals enrolled in Medicare, but not Medicaid (Medicare-only).

First, we indicated that prescription drug coverage for Medicaid-only enrollees would continue to be funded by Medicaid through a portion of the monthly capitation rate paid to the PACE organization because these enrollees are ineligible to receive Part D prescription drug coverage.

For dual eligible and Medicare-only PACE enrollees, we proposed that PACE organizations would offer enhanced alternative prescription drug packages with no enrollee cost sharing.

For both dual eligible individuals and Medicare-only enrollees, we proposed that we would pay PACE organizations the direct subsidy, calculated under § 423.329(a)(1). In addition, the PACE organization would receive low-income premium and subsidy payments or partial subsidy payments for those enrollees who qualify for the low-income subsidy. We noted that dual eligible beneficiaries would be deemed eligible for the full low-income subsidy under § 423.773(c), which included a premium subsidy not to exceed the basic premium for coverage under the Part D plan selected by the beneficiary, but no more than the greater of the low-income benchmark premium amount or the lowest beneficiary premium amount for a PDP offering basic prescription drug coverage in the PDP region where the beneficiary resides. To the extent a discrepancy occurred between the low-income premium amount and PDP or MA-PD plan's bid, § 423.286(d)(1) of the proposed rule required beneficiaries to pay this amount as a premium which would have been established by the PDP or MA-PD plan during the bidding process. The PACE regulations, however, conflict with this Part D provision since they preclude a PACE organization from charging premiums to dual-eligibles.

In addition, Medicare-only enrollees would have been required to account for the additional cost of providing a prescription drug package to enrollees without the application of cost sharing. This amount would have represented the ''enhanced'' portion of the Part D premium. Because PACE organizations are not precluded from charging premiums to Medicare-only enrollees, it would have been permissible for them to pass on the responsibility for any payment discrepancy and enhanced alternative coverage to their Medicare-only enrollees in order to comply with Part D requirements. The premium amounts actually paid by enrollees would have varied depending on whether the enrollee was eligible for both Medicare and Medicaid or only eligible for Medicare and according to whether the enrollee qualified for the low-income premium subsidy.

We were concerned about the impact on low-income dual eligible and Medicare-only PACE enrollees and requested public comment on other approaches to handling this premium differential.

We also indicated in the proposed rule that reinsurance and risk corridor costs as defined in § 423.308 would be applicable to PACE organizations and that PACE organizations would be required to track allowable costs for all Part D eligible PACE enrollees pertaining to reinsurance payments and under § 423.336(c) pertaining to risk corridor amounts. Specifically, low-income subsidy amounts received by the PACE organizations would count towards the annual out-of-pocket threshold applicable to reinsurance.

Comment: We received many bidding related comments. Some commenters requested that PACE organizations not be required to bid, others requested that PACE organizations be permitted to delay their bid submission until after the average benchmark premium and low income subsidy amounts are set, and others requested that we grant a waiver of the bidding requirements under subpart F of the proposed rule on behalf of PACE organizations. Commenters viewed the bidding process as administratively burdensome and costly to small scale PACE organizations that are currently able to effectively provide prescription drug coverage to enrollees under the authority of the PACE statutes and regulations.

Commenters did not view the bidding approach outlined in the proposed rule to be consistent with the unique attributes of PACE, including existing PACE statutory and regulatory guidance for the provision of prescription drugs which precludes cost sharing and small PACE organization enrollment as compared with traditional Part D plans.

Some commenters proposed a transition period during which PACE organizations would base their Part D bid on the amounts currently paid to them by Medicaid for drug coverage. These commenters recommend that we utilize the same data gathered under section 1935(c) of the Act as a basis for paying PACE organizations for the prescription drug costs of dually eligible individuals enrolled in PACE. Each State currently providing PACE as an option under its State plan would be required to reduce its capitation payment for dual eligible PACE enrollees by the amount of Medicaid expenditures for Part D covered drugs beginning January 2006. The difference between the old and new State payment amounts would be the basis for the PACE organizations' bids. Specifically, in States with more than one PACE organization, the bids of all PACE organizations located in the same State would be equal.

These commenters indicate that this proposed bidding approach would not only be consistent with the current cost of providing prescription drug coverage to the PACE population, but it would be less administratively burdensome to small organizations. In addition, a transition approach would also allow

us, States, and the industry additional time to evaluate the impact of Part D on PACE and develop a payment approach consistent with the PACE model. The commenters proposed that the transition period continue until an evaluation of the impact of the Part D program on PACE could be completed or appropriate legislative or regulatory changes could be made to reconcile the conflicting provisions of the PACE and Part D requirements.

Response: Because the MMA shifts responsibility for prescription drugs from Medicaid to Medicare for the full-benefit dual eligible beneficiaries, it will no longer be possible for PACE organizations to receive prescription drug payment on behalf of these beneficiaries from Medicaid. In addition, section 1860D–21(f) of the Act indicates that to the extent a PACE program elects to provide qualified prescription drug coverage to Part D eligible individuals, Part D requirements apply to the provisions of such coverage in a manner that is similar to that of MA-PD local plans. As stated previously, PACE organizations will be treated in a manner that is similar to that of MA-PD local plans, including the bidding provisions of subpart F. We do not view the proposed transition period as ''similar to'' the requirements under which MA-PD plans will operate. In addition, section 1860D–21(f)(3) of the Act implies that PACE organizations will submit bids by indicating that PACE organizations bids will not be included in national average benchmark amounts. We do not have the statutory authority to waive the Part D bidding requirement. Thus, PACE organizations will be required to submit bids in accordance with subpart F.

Comment: Many commenters expressed concern that requiring PACE plans to bid, and basing premium and subsidies on MA-PD bids rather than PACE bids will create an unlevel playing field for PACE.

Commenters were concerned that the small size of PACE organizations will hinder their ability to achieve volume related price breaks from drug manufacturers that may be available to the larger Part D plans. Thus, PACE organization Part D bids will be higher than those of traditional Part D plans. Because PACE organizations primarily serve dual eligible individuals with the exception of a few low-income Medicare-only enrollees, subsidy payments that accurately capture the cost of providing prescription drugs will be critical to the continued financial stability of PACE organizations. This importance is magnified by existing PACE statutory and regulatory provisions that preclude PACE organizations from imposing enrollee cost sharing upon any enrollee and from imposing premiums upon any Medicaid eligible enrollee. Thus, commenters believed that it was essential that the low-income premium and subsidy payments paid by us to PACE organizations on behalf of low-income enrollees be comparable to the cost of providing the benefit.

Response: We agree that PACE organizations differ from traditional Part D plans in terms of the number of enrollees. Thus, we do not view PACE organizations as closely comparable to traditional Part D plans for purposes of competition.

We believe that the small size of PACE organizations will hinder their ability to achieve volume related price breaks from drug manufacturers that may be available to the larger Part D plans. Thus, PACE organizations' Part D bids will be higher than those of traditional Part D plans. The MMA addresses this key difference, specifically as it relates to payment in section 1860D–21(f)(3) of the Act by indicating that the bids of PACE organizations are not to be included in determining the standardized bid amount. Ironically, however, bids included in the computation of the standardized bid amount are directly related to subsidy payments made to all plans, including PACE organizations. Because PACE organizations primarily serve dual eligible individuals, with the exception of a few low-income Medicare-only enrollees, subsidy payments that accurately capture the cost of providing prescription drugs will be critical to the continued financial stability of PACE organizations. This importance is magnified by existing PACE statutory and regulatory provisions that preclude PACE organizations from imposing enrollee cost sharing upon any enrollee and PACE regulatory provisions that preclude PACE organizations from imposing premiums upon any Medicaid eligible enrollee. Thus, it is essential that the direct subsidy, as well as the low-income premium and subsidy payments paid by us to PACE organizations on behalf of low-income, enrollees be comparable to the cost of providing the benefit.

The MMA did not amend sections 1894 and 1934 of the Act and it is clear that Part D applies to PACE. We have determined that the conflicting PACE and Part D requirements related to beneficiary cost sharing and the PACE preclusion of charging any Medicaid eligible enrollee a premium would result in a significant Part D payment discrepancy to PACE organizations absent our intervention. As a result, we are considering the application of section 1894(d)(2) of the Act and § 460.180(b)(5) of the PACE regulation authority which authorize the Secretary to adjust payment to PACE organizations based on ''other factors'' as appropriate. These adjustments will take into account the PACE preclusion of and the preclusion of charging any Medicaid eligible enrollee a premium. Additional CMS guidelines will be issued to PACE organizations following publication of this rule. These guidelines will outline the PACE/Part D payment methodology, including an appropriate payment adjustment applicable to PACE organizations. We believe that this guidance will minimize disruption to PACE organizations and their enrollees.

Comment: We received public comment in support of our proposed waiver on behalf of PACE organizations of the bid submission deadline of no later than the first Monday in June for each Part D plan intending to offer a Part D prescription drug plan in the subsequent calendar year under § 423.265(b).

Response: As indicated in the proposed rule, a new PACE organization may take from 2.5 to 3 years to develop the capacity to offer PACE services, including capital expenditures associated with construction or renovating space for a PACE Center. In addition, as required by sections 1894 and 1934 of the Act, many activities associated with PACE involve the States. For example, PACE applications are submitted to the State for review prior to our review and the PACE program agreement is a 3–party contract; CMS, the State in which the potential PACE program is located, and the PACE organization. Although we originally proposed that the bid submission deadline be broadly waived for all PACE organizations, we would like to clarify that we expect PACE organizations that are operational prior to the first Monday in June of each year to meet the bid submission deadline. However to the extent they are unable, we will waive the bid submission deadline for those organizations since PACE bids are not included in the computation of any average benchmark amount or low-income benchmark premium amount. In addition, we do not believe that it would be appropriate for a potential PACE organization that contracts with us after the June deadline to be unable to receive payment under Part D until the following year's June deadline is met and the bid has been approved. Therefore, the requirement of

§ 423.265(b) of this regulation will also be waived on behalf of potential PACE organizations which are not operational by the first Monday in June in order to promote coordination of benefits between Part D and PACE. As a result, new PACE organizations will be permitted to submit their Part D bids beyond the June deadline.

Further discussion of Part D waivers on behalf of PACE organizations is included below.

d. Application of Administrative Related Part D Requirements to PACE Organizations

In using the term, administrative related requirements, we are referring to requirements that pertain to subparts A, B, C, D, I, J, K, L, M, N, and O, of this regulation concerning general Part D provisions, eligibility and enrollment, benefits and beneficiary protections, cost control and quality improvement, compliance with State law and preemption by Federal law, coordination under Part D with other prescription drug coverage, application of procedures and contracts, the effect of a change of ownership or the leasing of facilities, grievances and appeals, coverage determinations, Medicare contract determinations, and sanctions.

In the proposed rule we identified several administrative related Part D provisions that we intended to waive on behalf of PACE organizations.

(1) Sections 423.48 and 423.128 of the proposed rule specified requirements for providing information about Part D and for the dissemination of plan information. These sections also indicated that plans would be required to provide information to CMS regarding benefits, formularies, premiums, , and enrollee satisfaction. This information would be published in Medicare's comparative plan brochures and provide key information for beneficiaries to use in making informed decisions about Part D prescription drug coverage. We indicated that the differences between MA-PD plans/PDPs and PACE would complicate comparison and confuse beneficiaries. In addition to specific eligibility requirements for enrollment in PACE, PACE organizations exist only in those States that elect to include PACE in their Medicaid State plan. We indicated that including PACE information in the comparative brochure would be misleading. As a result, we proposed that the requirements for providing information about Part D and for the dissemination of plan information be waived on behalf of PACE organizations in order to promote the coordination of benefits between Part D and PACE.

(2) Section 423.104(g) of the proposed rule would require MA-PD plans and PDPs to provide enrollees with access to negotiated drug prices. Since PACE enrollees receive the vast majority of their prescription drugs directly from the PACE organization with no applied, the negotiated price requirement is already accounted for under part 460. Therefore, we proposed a waiver of § 423.104(g) in order to promote better coordination of benefits between Part D and PACE.

(3) Section 423.120(a)(1) of the proposed rule would require that a plan's contracted pharmacy network be located within specified distances from enrollees. Because PACE enrollees receive their prescription drugs directly from their PACE organization as opposed to through a pharmacy, the distance between the enrollee and a network pharmacy is irrelevant. We believe that requiring a PACE organization to set up a pharmacy network would be burdensome, costly, and unnecessary and diverts funds from patient care. Thus, we proposed to waive this requirement in order to promote better coordination of benefits between PACE and Part D.

(4) Section 423.120(c) of the proposed rule would require plans to employ the use of a card or other type of standardized technology to assist enrollees in accessing negotiated prices for Part D drugs. Since PACE participants do not routinely acquire their prescription drugs directly from pharmacies, requiring PACE organizations to develop standardized technology would be burdensome, costly, and unnecessary and diverts funds away from patient care. Therefore, we proposed to waive proposed § 423.120(c) under the authority of section 1860D–21(c)(2) of the Act for PACE organizations to promote better coordination of benefits between Part D and PACE.

(5) Section 423.124 of the proposed rule specified access requirements for drugs obtained through out-of-network pharmacies. These provisions would ensure that enrollees residing in long term care facilities have access to drugs in an out-of-network long term care pharmacy and AI/AN enrollees have access to an out-of-network I/T/U pharmacy. Enrollees who obtain their Part D covered drugs from these out-of-network pharmacies would be financially responsible for deductibles or applicable under network pharmacies.

Under the current PACE regulations in § 460.90(a) and § 460.100, PACE organizations are responsible for all prescription drugs, including those provided to any participants residing in long term care facilities, AI/AN participants, and those associated with an emergency health event or an approved urgent care need. As noted previously, PACE participants are not responsible for deductibles, co-payments, coinsurance, or other associated with prescription drugs. In the PACE program, when participants are out of the service area and need prescription drugs, the PACE organization would arrange payment in full with the pharmacy.

As noted previously, PACE organizations are required to provide all PACE enrollees with prescription drug coverage. Therefore, we view the out of network pharmacy requirements as duplicative of PACE regulations. Thus, we proposed to waive § 423.124 of the proposed rule for the reasons noted above.

(6) Section 423.104(g)(2) of the proposed rule specifies that a plan may not offer enhanced alternative prescription drug coverage unless it also offers basic prescription drug coverage. In this instance, PACE organizations vary from MA-PD plans in that their enrollees are exempt from . It would be impractical to offer basic prescription drug coverage to PACE enrollees because stand-alone basic prescription drug coverage assumes beneficiary. Thus, we proposed to waive § 423.104(g)(2) of the proposed rule to promote coordination of benefits between Part D and PACE.

(7) Public disclosure requirements in proposed § 423.132 provide that a PDP or MA-PD plan must ensure that its pharmacies inform enrollees of any differential between the negotiated price for a covered Part D drug and the lowest priced generic equivalent. This requirement is inconsistent with the PACE model. PACE participants or their caregivers work with the PACE interdisciplinary team in making care planning decisions and have input into all aspects of their care, including prescription drug use. For this reason, we proposed a waiver of the public disclosure requirement in proposed § 423.132 under the authority of section 1860D–21(c)(2) of the Act for PACE organizations in order to promote better coordination of benefits between Part D and PACE.

(8) Requirements associated with privacy, confidentiality, and accuracy of enrollees' records under Part D are included in § 423.136 of the proposed rule. We view these requirements as duplicative of § 460.200(e) of the PACE regulation. We believe that the PACE regulations are providing the same protections as would be provided under

proposed § 423.136. For the reasons noted above, we proposed to waive § 423.136. We note that we also believe the requirements of § 423.136 are duplicative of § 460.210 of the PACE regulation.

(9) The medication therapy management program requirements in proposed § 423.150 would require MA-PDs and PDPs to employ pharmacists to counsel beneficiaries who have chronic conditions and use multiple drugs to ensure they are taking safe combinations of prescription drugs and using the drugs properly. PACE enrollees typically suffer from multiple health conditions that necessitate close monitoring by their interdisciplinary team. Currently, PACE organizations have pharmacists on staff or under contract, working with PACE primary care physicians as they develop the participants' care plans and monitor their drug regimens. In addition, the PACE interdisciplinary team, through its daily interactions with PACE participants and their caregivers, provides counseling to ensure that medication regimens are followed. We believe that the existing PACE regulations satisfy or exceed the medication therapy management program requirements in proposed § 423.150. For the reasons noted above, we proposed to waive § 423.150 for PACE organizations in order to promote the coordination of benefits between Part D and PACE.

(10) Proposed § 423.401 specifies licensing requirements for PDPs. A PDP must be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan. A similar requirement exists for MA-PDs. Organizations that are not licensed under State law would obtain certification from the State that the organization meets financial solvency and other standards required by the State for it to operate.

We view these requirements as duplicative of PACE requirements. First, sections 1894(e)(2)(iv) and 1943(e)(2)(iv) of the Act require PACE organizations to meet applicable State and local laws and requirements. In addition, sections 1894(f)(2)(B)(v) and 1934(f)(2)(B)(v) of the Act require PACE organizations to be at full financial risk. Therefore, we believe PACE organizations are meeting the intent of these MA requirements. For the reasons noted above, we proposed to waive § 423.401 for PACE because we believe this section is duplicative of PACE requirements.

(11) Subpart M proposed process requirements for grievances, coverage determinations, reconsiderations, and appeals under Part D. We believe the PACE grievance and appeals processes under § 460.120 and § 460.122 meet the intent of the MMA since they would accommodate complaints regarding prescription drug coverage. Therefore, we proposed to waive § 423.560 through § 423.638 for PACE organizations because we believe they are duplicative of PACE requirements.

(12) Subpart K includes requirements governing the application process, contracts with PDP sponsors, and reporting requirements. Sections 1894 and 1934 of the Act, as well as PACE regulations in subparts B and C specify application and contract (called a program agreement in accordance with sections 1894 and 1934 of the Act) requirements for PACE that duplicate requirements in subpart K. For this reason, we proposed to waive the sections in subpart K that address the application process and contract requirements.

We concluded by requesting comment on these proposed waivers including any additional waivers that may be needed to integrate the Medicare prescription drug benefit and the PACE benefit.

Commenters expressed support for all the administrative related waivers on behalf of PACE organizations that were identified in the proposed rule, requested clarification as to the breadth of specific waivers, and identified additional waivers that would be necessary to minimize disruptions to the PACE program in implementing Part D.

We proposed in § 423.458(d) of the proposed rule to codify section 1860D–21(c)(2) of the Act (as extended to PACE organizations under section 1860D–21(f)(1) of the Act), which establishes authority for us to waive Part D provisions for PACE organizations that: (1) duplicate PACE requirements; (2) conflict with PACE provisions; or, (3) as may be necessary to improve the coordination of benefits provided under Part D and the PACE program. Thus, we begin with a discussion of the administrative related Part D requirements.

Comment: One commenter requested confirmation as to whether PACE organizations will be required to provide Part D coverage to its enrollees who are Part D eligible individuals because section 1860D–21(f)(1) of the Act indicates that PACE organizations have a degree of discretion in whether or not to provide Part D coverage. Another commenter stated that to require a PACE eligible individual to obtain prescription drug coverage from a plan other than PACE (a PDP for example) would fragment care coordination associated with PACE.

Response: Section 1860D–21(f)(1) of the Act provides that PACE programs may elect to provide qualified prescription drug coverage to Part D eligible individuals enrolled in the program. However, section 1935(c)(6) of the Act prohibits Medicaid from paying for Part D drugs provided to full-benefit dual eligible individuals and requires that these drugs be paid for under Medicare Part D. Due to this statutorily mandated shift in payer from Medicaid to Medicare for full-benefit dual eligible individuals, we believe that PACE organizations will elect to provide Part D coverage to full-benefit Part D eligible individuals in order to receive adequate payment for providing Part D drugs.

In addition, section 1894(a)(1)(B)(i) of the Act requires that PACE enrollees receive Medicare benefits solely through the PACE program, and, therefore, prohibits them from simultaneously enrolling in both a PACE program and a separate Part D plan. As discussed elsewhere in this preamble under subpart B, Part D eligible individuals who enroll in a PACE plan offering qualified prescription drug coverage under Part D will be deemed to have elected to receive their Part D benefits through such PACE plan, and will be ineligible to enroll in another Part D plan, including a PDP. In addition, § 423.32(f) specifies that enrollees of PACE organizations offering qualified prescription drug coverage shall remain enrolled in that plan as of January 1, 2006 and receive benefits offered by that plan until one of the conditions of § 423.32(e) is met.

Effective January 1, 2006, States will continue to include the cost of prescription drugs in their monthly capitation payments to PACE organizations on behalf of those individuals ineligible for Part D coverage (Medicaid-only enrollees).

Comment: We received a comment indicating that there are cost benefits of the PACE model as an alternative to nursing home care. The commenter indicated that implementation of Part D should not place excessive burdens on PACE organizations and recommended that we develop a workgroup with the National PACE Association (NPA) and States in order to work through the administrative related issues with implementing Part D into PACE so as to minimize the administrative burden on PACE organizations.

Response: We appreciate the potential burden associated with implementing the Part D benefit into the existing PACE model. As a result, we proposed to

utilize waiver authority under § 423.458(d) of this rule: (1) in instances where Part D requirements are duplicative of PACE requirements; (2) in instances where Part D requirements conflict with PACE requirements; or, (3) in order to promote coordination between Part D and PACE. Under this authority, we are waiving section 423.265(b), which would have required PACE organizations planning to offer a Part D prescription drug plan to submit bids and supplemental information no later than the first Monday in June of each year. We will also use this authority to issue further guidance regarding additional Part D provisions that will be waived for PACE organizations. We believe that these waivers will minimize the administrative burden on PACE organizations that elect to provide Part D coverage.

Comment: We received many comments supporting our proposal to identify Part D provisions that we will waive on behalf of PACE organizations without requiring individual waiver applications. One commenter also requested that we outline a waiver application process that could be followed by organizations to the extent additional waivers are identified after publication of this final rule. As waivers are granted through this process, the commenter requested that we apply the waivers to other similarly situated organizations offering or seeking to offer qualified prescription drug coverage as a PACE organization that otherwise meets conditions of the waiver.

Other commenters requested that PACE waivers apply to other similar health plans such as social HMOs, Massachusetts Senior Care Options programs, or other plans that also serve significant numbers of full-benefit dual-eligible individuals.

Response: We believe that the application of § 423.458(d) waivers will minimize disruption of the positive aspects of the structure of PACE. However, to the extent a PACE organization identifies a specific need for additional Part D waivers, the organization may request such waivers from us under the authority of § 423.458(d) of this regulation. We will determine on a case-by-case basis whether to grant the waiver. If we grant it, the waiver will apply to all similarly situated PACE organizations, but will not apply to non-PACE organizations.

The waiver submission and review process for PACE organizations will be issued as additional CMS guidance. We will issue additional guidance to these programs following publication of this rule.

The following list summarizes comments we received on waiver issues. As stated previously, the only waiver we are finalizing at this time is a waiver of the June bid submission deadline in section 423.265(b). We will take into consideration comments regarding other waivers and issue further guidance on the Part D provisions that will be waived for PACE organizations.

(1) Several commenters indicated that due to the differences between traditional Part D plans and PACE, inclusion of PACE in a comparison brochure would confuse beneficiaries. These commenters supported our proposal to waive § 423.48 and § 423.128 concerning plan information. However, one commenter expressed concern that those eligible for special programs such as PACE, should be informed of all choices available under Part D. This information should include differences between obtaining services from a traditional Part D plan or PACE. The commenter believed that beneficiaries should also be informed of what would occur if they disenrolled from PACE to obtain benefits from a PDP. This commenter would like to work with us in developing appropriate materials and distribution mechanisms.

(2) One commenter asked for clarification that PACE organizations will not be required to share in the cost of enrollment related costs under § 423.6, reasoning that PACE organizations are neither subject to MA requirements related to dissemination of annual enrollment information, nor do PACE organizations contribute towards their costs.

(3) Commenters indicated that to the extent requirements under § 423.44 are duplicative of requirements under § 460.164 through § 460.172 of the PACE regulation or impede coordination of PACE and Part D benefits, these requirements should be waived, allowing for continued coordination of the prescription drug benefit with all other benefits provided by PACE organizations. One commenter recommended that existing requirements governing disenrollment from PACE organizations should apply in lieu of § 423.44.

(4) We received a comment in support of our proposed waiver of § 423.104(g)(2) of the proposed rule (now identified as § 423.104(f)(2) in the final rule) that indicates that a plan may not offer enhanced coverage for purposes of reducing co-payments and deductibles unless it also offers a plan with basic coverage. The commenter agreed with our rationale indicating that it would be impractical for a PACE organization to offer basic prescription drug coverage to PACE enrollees because stand-alone basic prescription drug coverage assumes beneficiary which is a PACE statutory preclusion.

(5) Commenters supported our proposal to waive the negotiated price requirements of § 423.104(h) of the proposed rule (now identified as § 423.104(g) in this final rule). One commenter pointed out that we had incorrectly referred to this section as § 423.104(g) on page 46756 of the proposed rule.

(6) Commenters concurred with our proposal to waive the pharmacy access requirements under § 423.120(a)(1). In addition, a commenter recommended a waiver of § 423.120(a)(4) of the proposed rule (now identified as § 423.120(a)(8) in the final rule) related to pharmacy network contracting. PACE organizations generally have close working relationships with a very limited number of pharmacies that can respond to the specialized requirements of PACE enrollees, for example, 24/7 access and specialized dispensing requirements. Requiring PACE organizations to contract with any willing pharmacy provider is not consistent with the PACE model and could compromise the PACE organizations' ability to negotiate favorable contract terms based on volume with one or two suppliers.

(7) One commenter indicated that PACE organizations typically provide an open formulary to the primary care physicians that allow immediate access to a wide variety of covered Part D prescription drugs in many different dosages and delivery forms. These open formularies do not restrict access or result in co-payment amounts charged to enrollees. Thus, the commenter does not believe the formularies used by PACE organizations should be subject to the requirements of § 423.120(b). This commenter also asked for clarification as to whether ''preferred drug lists'' utilized by PACE organizations would be subject to the requirements of § 423.120(b). These lists provide prescribing physicians with current data on the relative costs of various medications, such as name brand vs. generic alternatives. Physicians are not restricted from prescribing alternatives that do not appear on the preferred drug list, and the list does not result in co-payment amounts charged to enrollees. The commenter recommended that these preferred drug lists not be subject to the requirements of § 423.120(b).

(8) Several commenters concurred with our proposal to waive the standardized technology requirements of § 423.120(c). One commenter suggested that such technology be

limited to one card in order to avoid data sharing and coordination requirements.

(9) Several commenters concurred with our proposal to waive the out-of-network pharmacy requirements of § 423.124.

(10) Several commenters concurred with our proposal to waive the disclosure of price differences between the Part D drug and generic equivalent requirement of § 423.132.

(11) Several commenters concurred with our proposal to waive the privacy, confidentiality, and accuracy of records requirements of § 423.136.

(12) One commenter requested clarification regarding our proposal to waive the MTMP requirements of § 423.150 and whether we had intended to list the additional provisions of this section including cost and utilization management programs, quality assurance programs, programs to control fraud, abuse, and waste, CMS consumer satisfaction surveys, an electronic prescription program, and accreditation. The commenter believes that the existing PACE requirements satisfy or exceed each of these requirements.

(13) We received a comment requesting that consumer satisfaction surveys administered to PACE enrollees under § 423.156 take into account the differences between PACE enrollees and traditional Part D plan enrollees.

(14) We received a comment requesting that quality improvement organization activities performed under § 423.162 take into account the differences between PACE enrollees and traditional Part D plan enrollees.

(15) We received public comments concurring with our proposal to waive the licensure requirements of § 423.401 to reflect that PACE organizations' fiscal soundness is governed by requirements under sections 1894(e)(2)(iv) and 1934(e)(2)(iv) of the Act and § 460.80 of the PACE regulation.

(16) We received public comments of concurrence of our proposal to waive the application requirements of subpart K of this rule, agreeing that these requirements are addressed under subparts B and C of § 460. This commenter also requested that we utilize information already available in PACE organizations provider applications and program agreements to the greatest extent possible.

(17) One commenter requested clarification as to whether the requirements of the following sections would be waived on behalf of PACE organizations; § 423.502, § 423.503, § 423.504, § 423.505, § 423.506, § 423.507, § 423.508, § 423.509, § 423.510, and § 423.514. The commenter indicated that these requirements duplicate current PACE requirements.

(18) Commenters also indicated that the requirements of subpart K would be burdensome for plans, providers, and pharmacies in terms of tracking coverage issues. Adherence to these requirements would result in significant new expenditures for plans, advocates, clinics, pharmacies, long term care providers, and other providers in terms of care coordination and advocacy for beneficiaries to access the correct coverage. It will also be necessary to coordinate with other Part D plans concerning low-income enrollees at risk for institutionalization. The commenter suggests that we hire an outside facilitation contractor to review and match data with mechanisms similar to sharing of information on crossover claims. Yet, the commenter has concerns about the ability of States, plans, providers, and others to gear up quickly to handle the tracking and interface that working with these contractors would require.

(19) In addition, one commenter indicated that the minimum enrollment requirements of § 423.512 of the proposed rule should be waived on behalf of PACE organizations as such requirements do not currently apply to PACE organizations.

(20) Several commenters concurred with our proposal to waive the determinations and appeals processes of subpart M on behalf of PACE organizations. Commenters agreed that these requirements are being met by PACE organizations under § 460.120 and § 460.122 of the PACE regulation.

The MMA did not amend sections 1894 and 1934 of the Act and it is clear that Part D applies to PACE. As a result, we have determined that in order to merge the PACE and the Part D statutory requirements, waivers we identified in the proposed rule, as well as waivers beyond those identified in the proposed rule and via public comments will be necessary. Therefore, we are considering the application of § 423.458(d) waiver authority for all administrative related Part D requirements that duplicate or conflict with PACE requirements or do not promote coordination between Part D and PACE. Additional CMS guidelines will be issued to PACE organizations following publication of this rule to include the waiver submission process and a comprehensive listing of all Part D waivers applicable to PACE organizations. We believe that this guidance will minimize disruption to PACE organizations and their enrollees.

In accordance with § 423.458(d) of this regulation, PACE organizations will also be permitted to submit Part D waiver requests beyond those identified in CMS guidelines on an individualized basis.

We received several comments regarding the application of subpart S, which pertains to State eligibility determinations for subsidies and general payment provisions.

Comment: One commenter recommended that we develop a workgroup with the NPA and States to further discuss impacts related to the phased-down State contribution and PACE capitation rates. The phased-down State contribution is a percentage based on drug costs in the year 2003. Subpart T of the proposed rule indicates that States must continue to include drug costs in the Medicaid monthly capitation payment to PACE organizations on behalf of Medicaid-only PACE enrollees. Thus, 2 commenters believe that States will be required to develop two different PACE capitation rates; one for dual eligible beneficiaries and one for Medicaid only enrollees. Given the small percentage of Medicaid only PACE enrollees, the complexities in developing a separate Medicaid-only PACE capitation rate may be administratively cumbersome.

Response: The MMA shifts payment responsibility for prescription drugs from Medicaid to Medicare for full-benefit dual eligible beneficiaries. As a result, States will need to take into account the Part D premium payments when calculating the PACE capitation rate for full-benefit dual eligibles. The MMA does not change the prescription drug payment scheme for Medicaid-only eligible beneficiaries. Thus, we agree with the commenter that the States will need to establish separate capitation rates for Medicaid eligible PACE enrollees, including one for dual-eligible beneficiaries for whom the PACE organization elects to provide Part D coverage, and one for non-dual eligible (Medicaid-only) beneficiaries. In the case of full-benefit dual eligible PACE enrollees for whom the PACE organization elects to provide Part D coverage, the State in which the PACE organization is located will pay a phased-down contribution to Medicare that defrays a portion of the drug expenditures for these individuals assumed by Medicare Part D. State Medicaid agencies will be required to participate in this phased-down State contribution scheme under § 423.910 of this regulation. This amount will capture the full extent of a State Medicaid agency's responsibility for Part D prescription drug expenditures

on behalf of full benefit dual-eligible beneficiaries for whom the PACE organization elects to provide Part D coverage. In the case of Medicaid eligible PACE enrollees whose drug costs continue to be funded by Medicaid, States will continue to include a prescription drug cost amount in their monthly capitation payment to PACE organizations.

4. Medicare Supplemental Policies

a. Overview and Background

In the proposed rule, we included two provisions related to Medicare supplemental (Medigap) policies. As required under section 1882(v) of the Act, as added by section 104 of MMA, we set forth standards for the written disclosure notice that Medigap issuers must provide to their policyholders who have drug coverage. In addition, in order to reflect the addition of the Medicare drug benefit by MMA, we proposed to revise the definition of a Medigap policy.

• Medicare Supplemental Policies

A Medigap policy is a health insurance policy sold by private insurance companies to fill the ''gaps'' in original Medicare plan coverage. A Medigap policy typically provides coverage for some or all of the deductible and coinsurance amounts applicable to Medicare covered services and sometimes covers items and services that are not covered by Medicare. Under section 1882 of the Act, Medigap policies generally may not be sold unless they conform to one of the 10 standardized benefit packages that have been defined, and designated as plans A through J, by the NAIC. Three States (Massachusetts, Minnesota, and Wisconsin) are permitted by the statute to have different standardized Medigap plans and are sometimes referred to in this context as the waiver States.

Three of the 10 standardized Medigap plans (Plans H, I, and J) contain coverage for outpatient prescription drugs. In addition, there are Medigap policies issued before the standardization requirements went into effect (''prestandardized'' Medigap plans) that cover drugs, as well as Medigap policies in the waiver States, some of which have varying levels of coverage for outpatient prescription drugs.

• Legislative Authority and Background

In connection with the addition of a prescription drug benefit to Medicare, the MMA also prescribes changes to the law applicable to Medigap policies. Among other requirements, section 1882(v) of the Act, as added by section 104 of the MMA, requires Medigap issuers to provide a written disclosure notice to individuals who currently have a policy with prescription drug coverage. (Section 1882(v)(6)(A) of the Act specifies that this is to be called a ''Medigap Rx policy.'') The MMA also requires that the Secretary establish standards for this disclosure notice in consultation with the NAIC.

The purpose of this disclosure notice is to inform an individual who has a Medigap Rx policy about his or her Medigap choices once the new Medicare Prescription Drug Benefit Program goes into effect on January 1, 2006. Specifically, effective on that date, section 1882(v) of the Act will prohibit the sale of new Medigap Rx policies, and require the elimination of drug coverage from Medigap Rx policies held by beneficiaries who enroll under Part D. The statute permits the renewal of Medigap Rx policies if the policy was purchased prior to January 1, 2006, and the individual does not enroll in Part D.

In addition, beneficiaries who do not enroll in Part D during the Initial Enrollment Period, and choose to enroll later, will be charged higher Part D premiums unless they can establish that they had creditable prescription drug coverage prior to enrolling in Part D. Under section 1860D–13(b)(4)(F) of the Act, and § 423.56(a) of this rule, Medigap policies meet the definition of creditable prescription drug coverage if they also meet actuarial equivalence requirements.

Issuers of Medigap insurance policies are required to provide disclosure notices to policyholders with Medigap Rx policies that inform them of their options under the new legislation, as well as informing them whether or not their policies constitute ''creditable prescription drug coverage.'' As explained in the preamble to subpart B of this rule, to be considered creditable prescription drug coverage, the coverage must be determined (in a manner specified by the Secretary) to provide prescription drug coverage the actuarial value of which (as defined by the Secretary) equals or exceeds the actuarial value of defined standard prescription drug coverage under Medicare Part D. Subparts B and F of this rule provide additional detail on creditable coverage and actuarial equivalence.

b. Definition of Medicare Supplemental Policy

Because of the importance of these disclosure notices to beneficiaries, we believe it is necessary to clarify what comes within the scope of a Medigap Rx policy. We proposed to revise and clarify the definition of a Medicare supplement (Medigap) policy currently codified at § 403.205, to reflect the addition of the Medicare drug benefit by MMA.

We proposed to revise the definition of a Medigap policy, effective January 1, 2006, to include any insurance policies or riders that contain a prescription drug benefit, and that are primarily designed for, or are primarily marketed and sold to Medicare beneficiaries. We also proposed to clarify that any rider attached to a Medigap policy is an integral part of the policy. All the requirements that apply to the base policy, such as guaranteed renewability or disclosure requirements, would apply to the rider. Thus, for instance, if an issuer offers an optional prescription drug rider that can be added to any other policies, addition of the rider to a Medigap policy would make the entire policy a Medigap prescription drug policy (Medigap Rx policy) subject to the disclosure requirements for these policies in section 1882(v) of the Act.

Moreover, we proposed that any stand-alone drug policies that were not previously considered to meet the definition of a Medigap policy will meet that definition as of January 1, 2006 when the prescription drug benefit takes effect, if the policy is primarily designed for or primarily marketed and sold to Medicare beneficiaries. New sales of these policies would be prohibited after December 31, 2005.

c. Standards for the disclosure notice that Medicare Supplemental (Medigap) issuers are required to provide to individuals who currently hold policies with drug coverage

• General

We believe that the statute is quite clear about the choices that need to be made by beneficiaries who hold Medigap Rx policies. Therefore, we proposed to establish standards for the disclosure notice in the form of a required notice that sets forth those choices.

• Timing and Content of the Disclosure Notice

The statute requires Medigap issuers to send a written disclosure notice to each individual who is a policyholder or certificate holder of a Medigap Rx policy at the most recent available address of that individual. The issuers must send the disclosure notice during the 60-day period immediately proceeding the initial Medicare Part D enrollment period. The initial enrollment period (IEP) for Medicare Part D runs from November 15, 2005 through May 15, 2006. Accordingly, Medigap issuers must send the written disclosure notice between September 16, 2005 and November 15, 2005.

The written disclosure notice must inform the individual of his or her Medigap options if the individual does or does not enroll in Medicare Part D. These include the following:

- If the individual does enroll in Part D, he or she can keep the Medigap policy but the drug coverage must be eliminated.
- If the individual enrolls in a Medicare Part D PDP during the IEP, the individual also has the right to buy another Medigap plan from the same issuer that does not include drug coverage. The individual has a guaranteed right to buy Plan A, B, C, or F (including the high deductible Plan F) or one of the new Medigap benefit packages mandated by section 104(b) of the MMA (which have been designated Plans K and L), if these plans are offered by the issuer and available to new enrollees. The issuer may also offer other Medigap plans on a guaranteed issue basis.
- If the individual does not enroll in Part D, he or she has the option of keeping the Medigap policy with drug coverage.
- If the individual does not enroll in Part D during the IEP, the individual may continue enrollment in his or her current Medigap plan without change, but the individual will lose the right to buy another Medigap plan on a guaranteed issue basis. In addition, if the current Medigap plan does not provide creditable prescription drug coverage, there are limitations on the periods in a year in which the individual may enroll in Medicare Part D and any such enrollment may be subject to a late enrollment penalty (increased premium) if the current Medigap plan does not provide creditable prescription drug coverage.

We also proposed to require that the disclosure notice contain information on the potential impact of an individual's election on his or her Medigap premiums.

It is important to note that the disclosure requirement in section 104 of the MMA that applies to Medigap issuers is separate from the disclosure requirement contained in section 101 of the MMA (section 1860D–13 of the Act). The disclosure requirement in section 104 of the MMA applies exclusively to issuers of Medigap policies and contains very specific statutory criteria for the disclosure notice. The disclosure requirement in section 101 of the MMA applies to various forms of prescription drug coverage, including Medigap.

As discussed in subpart B of this preamble, section 101 of the MMA requires that these entities, including Medigap issuers, disclose to the Secretary, as well as to the Part D eligible individuals, whether the coverage they provide currently meets the actuarial equivalence requirement for creditable coverage. The entities must also notify the individuals if the coverage changes so that it no longer meets the actuarial equivalence requirement. Section 101 of the MMA directs the Secretary to establish procedures for the documentation of creditable prescription drug coverage by these entities.

- Medigap Policies as Creditable Coverage

Medigap issuers will be responsible for determining whether the drug coverage under their policies is creditable drug coverage in accordance with subpart B of this final rule. We cannot offer guidance for the likelihood that any particular pre-standardized policy, or policy in a waiver State, will meet this test. However, for standardized plans, the CMS actuaries determined that drug coverage in standardized Medigap Plans H and I cannot meet this standard. Since actuarial equivalence can be demonstrated using a group's experience, it is possible to have a specific group for which the drug coverage in standardized Medigap Plan J would be creditable prescription drug coverage. However, based on the distributions of drug utilization that the actuaries have seen so far, they believe that drug coverage in standardized Medigap Plan J will be unlikely to meet the definition of creditable prescription drug coverage based on this rule.

- Required Disclosure Notice

Section 1882(v) of the Act requires us to establish standards for the disclosure notice that issuers must provide to policyholders of Medigap Rx policies. In the proposed rule, we proposed a model disclosure notice with basic language that would be required to be included in all disclosure notices sent by Medigap issuers for policies that do not provide creditable coverage. We respond below to comments we received on the proposed model disclosure notice. However, because we have determined that the format and content of the notice could be improved based on information gathered through consumer testing, we now plan to publish the final model disclosure notice separately from this final regulation. We also plan to publish a model disclosure notice for policies that do provide creditable coverage.

Comment: We received numerous comments related to our proposed clarifications to the definition of a Medigap policy. Many commenters believe the proposed clarifications are too far-reaching and that all limited health benefit plans would be considered Medigap policies under the proposed clarifications to the definition. Many of these commenters added that they do not believe that we have the authority to make the proposed modifications to the definition of a Medigap policy.

One commenter supports our clarification that a rider to a Medigap policy becomes an integral part of the policy. The commenter stated that it is black-letter insurance law that a rider attached to an insurance policy becomes a part of the policy.

Response: We believe that the addition of the Part D drug benefit to Medicare makes it essential to clarify the definition of a Medigap policy. There has been some confusion about whether a rider attached to a Medigap policy is considered to be part of the policy, and therefore subject to Medigap requirements such as guaranteed renewability.

Similarly, there was ambiguity in the past about whether a policy that covered only prescription drugs, either as a separate, ''stand-alone'' policy or as a rider to another policy, met the definition of a Medicare supplement policy. The ambiguity was created by the fact that there was no Medicare drug benefit to supplement, and it has been resolved with the enactment of the Medicare drug benefit. With respect to both of these situations, we believe that it is extremely important to make clear which Medicare beneficiaries are entitled to receive a notice about their rights under the MMA.

First, it is necessary to clarify that a rider to a Medigap policy is not a separate insurance product, but rather is incorporated into, and becomes an integral part of, the policy. In order to carry out the intent of the MMA provisions, we believe that Medigap policies with drug riders must be treated the same as Medigap plans H, I, and J; prestandardized Medigap Rx plans; and Medigap plans with drug coverage in the waiver States. Accordingly, if a beneficiary has an outpatient prescription drug rider attached to his or her Medigap policy, that beneficiary should receive the disclosure notice that MMA requires Medigap issuers to send to their policyholders who have Medigap drug coverage. In addition, because new sales of Medigap policies with drug coverage are prohibited after December 31, 2005, the drug coverage offered through a rider to a Medigap policy should be eliminated from the policy (that is, the drug rider should be cancelled) as of the date of the

individual's enrollment in Medicare Part D.

We also believe it is necessary to clarify that stand-alone, limited benefit drug policies will be considered Medigap policies once the Part D drug benefit is implemented, but only if the coverage provided by the policy is primarily designed to supplement Medicare, or if the policy is primarily marketed and sold to, Medicare beneficiaries. Because these limited benefit drug polices will not be considered Medigap policies until the Part D prescription drug benefit is implemented on January 1, 2006, these plans are not subject to the requirement in section 104 of MMA that Medigap issuers send a disclosure notice to policyholders with drug coverage before that date. However, we encourage issuers of these policies to send the notice voluntarily, during the 60-day period immediately preceding the initial Part D enrollment that begins in November 2005.

We reject the argument that we lack the statutory authority to revise the regulation's definition of a Medigap policy. We are simply clarifying the scope of the definition. The statutory definition of a Medicare supplemental policy, set out in section 1882(g)(1) the Act states, in part, that a Medicare Supplemental policy ''provides reimbursement for expenses incurred for services and items for which payment may be made [by Medicare] but which are not reimbursable by reason of the applicability of deductibles, coinsurance amounts, or other limitations imposed pursuant to [title XVIII].'' Section 1882(g)(1) of the Act specifically excludes a MA plan, or any policy or plan sponsored by an employer or labor organization, from the definition. However, the language quoted above could be read to include *any* other policy that is not specifically excluded, if the policy pays anything toward the cost of an item or service that is generally covered under Medicare, but is not specifically reimbursable because of the application of deductibles, coinsurance, or other limitations. As of January 1, 2006, prescription drugs will be covered by Medicare, and we are simply clarifying that stand-alone policies will meet the definition.

As noted above, some commenters claim that the proposed clarifications are so far-reaching that all limited benefit plans will be considered Medigap policies. However, the definition also states that a Medicare Supplemental policy is a health insurance policy or other health benefit plan ''offered by a private entity to individuals who are entitled to have payment made under [title XVIII].'' The definition currently in the regulations essentially interprets this language to mean that a Medicare supplement policy is a policy that is offered to Medicare beneficiaries because they are Medicare beneficiaries. In other words, it does not encompass policies that are offered to a broader population, and happen to be purchased by a Medicare beneficiary.

Accordingly, since 1982, the regulatory language at § 403.205(a)(2) has specified that a Medigap policy means a policy or plan that is primarily designed, or is advertised, marketed, or otherwise purported to provide payment for expenses incurred for services and items that are not reimbursed under Medicare because of deductibles, coinsurance or other limitations under Medicare. Any policy that is not primarily designed to supplement Medicare reimbursements and that is not offered and sold primarily to Medicare beneficiaries would not be considered a Medigap policy. Therefore, we disagree that the proposed clarification of the definition in the regulation could be interpreted to apply to any limited benefit policy purchased by a Medicare eligible individual, regardless of how it is marketed and designed.

Many commenters believed that the language in proposed § 403.205(c) could be interpreted to mean that any individual or group health insurance policy or rider could be considered a Medigap policy. We have changed the regulatory language at § 403.205(c) to clarify that the individual or group health insurance policy or rider is a Medigap policy if the policy otherwise meets the definition in § 403.205.

Comment: One commenter asked that we clarify that the antiduplication disclosure statements applicable to limited benefit plans that are appended to the NAIC Model Regulation for Medicare supplemental insurance do not apply to stand-alone limited health benefit plans that are considered Medigap policies.

Response: The antiduplication statements that the commenter refers to do not apply to Medigap policies. We believe it is necessary to clarify that if a limited health benefit plan is considered a Medigap policy because of the way it is designed, marketed and sold, the sale of such a plan would be prohibited because it does not meet the requirements for standardization of Medigap policies.

Comment: We received numerous comments related to the proposed model disclosure notice that was published as part of the preamble to the Title I regulation. Commenters expressed concern about the model disclosure notice containing statements about the value of the Part D drug benefit being greater than the value of outpatient prescription drug coverage under a Medigap policy. Many commenters believe that the concept of ''value'' is subjective and goes beyond the concept of actuarial equivalence. Commenters stated that beneficiaries might consider their Medigap drug coverage to be of greater overall value than the Part D benefit for a number of reasons, including the fact that the Medigap drug coverage is guaranteed renewable and does not use drug formularies.

Commenters also stated that the proposed disclosure notice was too long and complicated and contained unnecessary information related to Part D benefit options. Commenters expressed concern about having any statements in the disclosure notice that may be viewed as requiring Medigap issuers to promote or advocate the competing alternative coverage under the Part D benefit. These commenters believe that information about the new Medicare drug benefit will be readily available from a variety of other sources and that including such information in the disclosure notice is confusing and is not required by MMA. They believe that statements about the value of Part D benefits and information concerning Part D enrollment are irrelevant for purposes of this disclosure notice.

Many commenters believe that we should adopt NAIC's version of the model disclosure notice as the disclosure notice that Medigap Rx issuers must send to policyholders. The NAIC version of the model disclosure notice was developed by a work group comprised of State insurance regulators, consumer representatives and Medigap issuers.

Response: We disagree that information concerning Part D enrollment options is irrelevant for purposes of this disclosure notice. The statute requires that the disclosure notice provide information to Medigap Rx policyholders explaining options in the event the individual does or does not enroll in Part D during the IEP. Therefore, we believe it is important to have some discussion about the Part D enrollment process in order to provide meaningful context for the Medigap options. For individuals who do not enroll in Part D during the IEP the statute requires the disclosure notice to explain, among other things, that the individual will be subject to a late enrollment penalty if his or her current

coverage does not provide creditable drug coverage and he or she later chooses to enroll in Part D. The test for creditable coverage is based on whether the economic value of the coverage is actuarially equivalent to the value of Part D coverage. Therefore, we believe it is appropriate to address how the actuarial value of Part D compares to the individual's current Medigap drug coverage.

As noted previously, we will publish the final standards for the disclosure notices separately from this final rule. We will give due consideration to the comments we received on the model disclosure notice set forth in the proposed rule. In addition, we have conducted a series of interviews with beneficiaries about the format and content of the model disclosure notice. Once we have completed our evaluation, the results of this consumer testing will also inform any changes we may make to the disclosure notice. We appreciate the efforts of the NAIC in developing a model disclosure notice and we intend to have further consultations with the NAIC.

Comment: Commenters expressed concern that the period for transition to Part D was too short and requested that we consider options to provide beneficiaries with additional time to adjust to the new changes. One commenter suggested that the Secretary use the ''exceptional circumstances'' authority to establish a special Part D enrollment period lasting at least through 2007 for beneficiaries who have Medigap drug coverage, thereby allowing for a longer period of transition to Part D. The commenter stated that Medicare beneficiaries may be reluctant to give up their Medigap drug coverage for a benefit that is new and untested and that an SEP would permit a longer period to enroll in Part D without a premium penalty. In the alternative, the commenter suggested that Medigap Plan J be deemed actuarially equivalent to Part D so that beneficiaries with Plan J who have the most drug coverage could enroll in Part D without penalty after the initial enrollment period.

Another commenter expressed concern about the possibility of a beneficiary being initially notified of creditable coverage when the coverage is no longer creditable or never was creditable. The commenter suggested that, in these cases, an SEP into Part D be established, along with a guaranteed issue right to a Medigap policy without drug coverage.

Response: The statute establishes the IEP for Part D as November 15, 2005 through May 15, 2006. Beneficiaries with Medigap drug coverage who enroll in Part D during the IEP have a guaranteed issue right to buy a Medigap policy without drug coverage. We are sympathetic to the complexity of the choices that beneficiaries must make during this time period, but we believe there is a strong public policy value in creating an incentive for immediate, widespread enrollment in this new, heavily subsidized benefit in order to ensure the affordability of the Part D benefit and the stability of the associated premium. It is our goal to provide beneficiaries with information that will help them make informed decisions about their health care options.

Since the statute clearly defines the IEP and provides a Medigap guaranteed issue right for beneficiaries who have Medigap drug coverage and who enroll in Part D during the IEP, we do not believe that it is an appropriate use of the Secretary's authority to create a blanket SEP for exceptional circumstances for these beneficiaries. We believe that the Secretary's authority to establish SEPs for exceptional circumstances should be reserved for situations that are not specifically contemplated in the statute and that this authority should be exercised on a case-by-case basis depending on the circumstances of a particular situation.

Even in a case where we would create an SEP for exceptional circumstances, there is no corresponding statutory authority to create a Medigap guaranteed issue right. The classes of beneficiaries who have Medigap guaranteed issue rights are clearly set out in section 1882(s)(3)(B) and section 1882(v)(3)(B) of the Act. We do not have statutory authority to establish additional classes of beneficiaries who would be entitled to buy a Medigap policy on a guarantee issue basis.

We do not believe that the statute permits us to deem all Medigap Plan J coverage as creditable coverage. Whether or not Plan J drug coverage will be considered creditable coverage must be based on whether the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage as demonstrated through the use of generally accepted actuarial principles and in accordance with the requirements of § 423.265(c)(3). Moreover, as noted above, it is unlikely that Plan J policies could meet this standard. Finally, for the concern about the possibility of a beneficiary being initially notified of creditable coverage when the coverage is no longer creditable or never was creditable, the regulations at § 423.38(c) permit the establishment of an SEP for Part D in cases where an individual was never informed that the coverage that he or she had was not creditable, or if current coverage is reduced so that it is no longer creditable coverage. If an individual establishes to CMS that he or she was not adequately informed that his or her prescription drug coverage was not creditable, the individual may apply to CMS to have such coverage treated as creditable coverage for purposes of applying the late enrollment penalty provisions at § 423.46.

Comment: One commenter urged us to establish Medigap guaranteed issue rights for individuals who lose partial benefits under a retiree plan and for individuals who lose Medicaid eligibility.

Response: The classes of beneficiaries who have Medigap guaranteed issue rights are clearly set out in section 1882(s)(3)(B) and section 1882(v)(3)(B) of the Act. We do not have statutory authority to establish additional classes of beneficiaries who would be entitled to buy a Medigap policy on a guaranteed issue basis. In limited cases, we have the authority under section 1851(e)(4)(D) of the Act to establish SEPs for MA enrollees that may trigger Medigap guaranteed issue rights for MA enrollees. This authority applies if we determine that there are exceptional circumstances that warrant an SEP, but it does not permit us to establish new classes of beneficiaries who would have Medigap guaranteed issue rights.

Comment: Comments were received suggesting that if a Medigap issuer becomes a Part D sponsor that the sponsor be allowed to limit enrollment in the Part D coverage to its Medigap policyholders.

Response: While the statute prohibits a Medigap issuer from providing drug coverage that supplements the Part D benefit, a Medigap issuer can choose to become a PDP or an MA-PD if the issuer wishes to offer the Part D benefit. However, a PDP sponsor or MA-PD plan must offer prescription drug coverage to all Part D eligible beneficiaries residing in the plan's service area, unless a specific statutory waiver authority applies. Examples include capacity or special needs waivers under Part C of Medicare, or an employer waiver under section 1860D–22(b) of the Act.

Comment: Comments were received requesting regulatory guidance on the MMA provision that provides for the application of the antiduplication penalties set out in section 1882(d)(3)(A)(ii) of the Act in cases where a Medigap policy with drug coverage is renewed for a Part D enrollee. The commenters expressed concern that a Medigap issuer may be

subject to penalties whether or not the issuer knows about the individual's decision to enroll in Medicare Part D. The commenter's request that the antiduplication provisions be enforced consistently using a standard whereby only ''knowing'' violations would be subject to penalty.

Response: Section 1882(v)(4)(A) of the Act, added by section 104 of the MMA, states that the penalties described in section 1882(d)(3)(A)(ii) of the Act shall apply for a violation of the prohibition on the sale, issuance, and renewal of a Medigap policy that provides drug coverage in the case of an individual who is enrolled in Medicare Part D. We are not incorporating the guidance suggested by the commenter into these regulations because these provisions are under the jurisdiction of the OIG of HHS. We recommend that Medigap issuers take reasonable steps to determine the policyholder's Part D status at the time the Medigap policy with drug coverage is due for renewal.

Comment: One commenter questioned whether HMO Medicare supplemental plans offered to its members are considered to be Medigap plans and, if so, whether these plans would be prohibited from offering prescription drug benefits to retirees.

Response: Medicare managed care plans that offer supplemental benefits are not Medicare supplemental (Medigap) policies. The statutory definition of Medicare supplemental (Medigap) policies contained in section 1882(g)(1) of the Act specifically excludes MA plans. While Medigap plans are prohibited from supplementing Part D drug coverage, MA plans will be permitted to offer coverage that supplements Part D drug coverage.

Comment: One commenter suggested that a process be defined for validating and approving a Medigap issuer's assessment whether the drug coverage under its policies is creditable in accordance with the final rule implementing the Part D drug benefit. This commenter also suggested that the determination of creditable coverage should consider the possibility that changes in Part D over time could cause a plan to become creditable coverage over time. The commenter recommends that proper advance notice of Part D changes be scheduled to allow time for creditable coverage determinations, disclosure to beneficiaries and decision-making time for beneficiaries. The commenter also suggested that aggregation of data (combining all ages, gender, locations, formularies) for a particular benefit design be allowed as reasonable in determining creditable coverage.

Response: The issues raised by the commenter are applicable to all forms of creditable coverage and are addressed at § 423.56.

III. Provisions of the Final Rule

For the convenience of the reader, in this section, we briefly summarize major provisions of the proposed rule on which we requested public comments, and our final decisions. It is important to note that this section is not intended as a comprehensive list of all changes to the final rule. For a detailed discussion of a specific issue, see the relevant portion of the preamble to this final rule.

Auto-enrollment

We requested comments on:

- Responsibility for auto-enrollment: Should CMS or the State perform the auto-enrollment function (or a contracted entity or entities on their behalf)?
- Timing of auto-enrollment.
- Auto-enrollment of MA-onlys: How to provide Part D to those full-benefit dual eligible individuals who are in an MA-only plan and who have failed to enroll in a PDP or MA-PD plan?
- How to provide Part D to a full-benefit dual eligible individual enrolled in an MA-only plan when the premium for the MA-PD plan(s) offered by the same MA organization exceeds the low-income premium subsidy amount?

Final Decision: Our response seeks to balance the twin goals of ensuring prescription drug coverage and respecting beneficiary choice. We will:

- Stipulate that CMS-not the States-will perform auto-enrollment;
- Perform the auto-enrollment in the fall of 2005 as soon as eligible Part D plans are known, and auto-enrollment will be effective January 1, 2006. After 2006, full-benefit dual eligible individuals will be auto-enrolled into plans as soon as their Medicare Part D eligibility is determined;
- Auto-enroll on a random basis among available PDPs with monthly beneficiary premiums at or below the low-income subsidy amount;
- Reserve the ability to conduct re-auto-enrollment if we find such action necessary to ensure adequate coverage for this population;
- Facilitate full-benefit dual eligible individuals who are MA enrollees into the MA-PD with the lowest Part D premium offered by their MA organization, and who are cost plan enrollees into their cost plans Part D benefit (if any) with the lowest Part D premium, even if the premium is not covered by the low-income premium subsidy amount.
- May facilitate enrollment for all others deemed or determined eligible for the low-income subsidy, that is, Qualified Medicare Beneficiaries (QMBs), Specified Low-Income Medicare Beneficiaries (SLMBs), Qualifying Individuals (QI–1s), and others who qualify for low income subsidies.

Optional Involuntary Disenrollment for Disruptive Behavior

We solicited comments on the applicability of MA rules to PDPs for involuntary disenrollment for disruptive behavior.

Final Decision: We developed policy to permit PDP sponsors to disenroll individuals for disruptive behavior consistent with statutory intent, while creating the necessary due process safeguards for individuals who are subject to our disenrollment rules and may, as a result, lose Part D coverage. In the final rule, we—

- Removed the expedited process;
- Required PDP sponsors to provide a reasonable accommodation as determined by CMS and in exceptional circumstances we deem necessary; and
- Reserved the right to deny a request from a fallback prescription drug plan to disenroll an individual for disruptive behavior.

Enrollment and Disenrollment Processes

We envisioned a paper enrollment form process and requested comments on other possible enrollment mechanisms that address data security and integrity, privacy and confidentiality, authentication, and other pertinent issues. We also asked if we should require PDPs to disenroll individuals if they no longer reside in the service area.

Final Decision: We will maintain the flexibility to allow PDPs to develop alternative mechanisms other than paper enrollment forms. We will look to our recent experience with the drug card for other mechanisms we may consider, such as enrollment over the telephone and through the Internet. We will require plans to disenroll individuals upon receipt of notification that they have moved outside of the plan service area.

Release of Beneficiary Information for Marketing

Should we provide individual beneficiary information to Part D sponsors for marketing purposes because Part D is an entirely new, voluntary benefit that would not otherwise be available to beneficiaries absent positive enrollment?

Final Decision: We will consider provision of such information pending

further research of the needs and capabilities of both organizations and CMS. If/when we do provide such information to PDPs and MA organizations, we will work with industry and advocates to develop appropriate guidance.

Creditable Coverage

We asked for comment on the format, placement, and timing of creditable coverage notices. We also asked whether there are more forms of coverage that we should consider creditable coverage?

Final Decision: We support linking the notice of creditable status to other required documents that sponsors must provided to plan participants as an acceptable vehicle provided it is conspicuous and includes standard information elements. We have revised § 423.56(c) and (d) to allow notices of creditable and non-creditable status to be provided in the same manner other required documents.

To ensure beneficiaries are making informed choices, we require that notice must be provided to all Part D eligible individuals prior to the commencement of the Annual Coordinated Election Period (AEP), which begins on November 15, 2005, and also prior to the AEP each year. We also believe there are three other key times when notice must be provided—(1) prior to the commencement of the individual's initial enrollment period for Medicare Part D; (2) prior to the effective date of enrollment in such coverage or any change in creditable status of that coverage; and (3) upon request by the beneficiary. We revised § 423.56(f) to require that notice be provided, at minimum, at these 4 times.

We revised § 423.56(b) to include section 1876 cost plans and coverage offered by State high risk pools as well as a provision permitting us to recognize other types of coverage as potentially creditable in guidance following publication of the final rule.

Marketing Multiple Products

Since companies frequently offer additional products that could provide additional tools to help beneficiaries manage expenses and financial security, we asked for comments on allowing such products to be provided in conjunction with PDP services and the appropriate limitations on such activities.

Final Decision: We will allow only additional health-related products to be marketed to Medicare beneficiaries in compliance with HIPAA. Additional non-health related marketing of products would need written authorization by the beneficiary.

Incurred Costs (TrOOP)

We asked a number of questions on how to treat certain costs for purposed of TrOOP accounting: How should we define group health plan (GHP), insurance or otherwise, and other third party arrangements for purposes of TrOOP? How should we treat HSAs (FSA, HRA, MSA) under TrOOP: Can we treat HSAs, FSAs, and MSAs as beneficiary money, and HRAs, as GHP? Should the price differential between the cost of an extended supply of a drug purchased at a retail pharmacy versus a mail-order pharmacy be counted as an incurred cost against the annual out-of-pocket threshold? What is the status of financial assistance and free goods and services from pharmaceutical manufacturers under the anti-kickback provisions? (Sections 1128A(a)(5), 1128A(i)(6) of the Act).

Final Decision: We included definitions in § 423.100 that are consistent with our goals of defining ''payments made by a beneficiary or another person on their behalf'' as broadly as possible, while maintaining the integrity of the exclusions of ''group health plan, insurance or otherwise, and other third party arrangements'' intended in the statute. These include:

- treating HSAs, FSAs, and MSAs as beneficiary money, but HRAs as a Group Health Plan for purposes of TrOOP accounting.
- allowing beneficiary payment differentials to count toward TrOOP in cases in which a beneficiary accesses a covered Part D drug consistent with the out-of-network policy in § 423.124(a) of this final rule, and when a beneficiary purchases an extended supply of covered Part D drugs at a retail rather than a mail-order pharmacy.
- allowing appropriate waivers or reductions of Part D cost-sharing by pharmacies to count toward TrOOP.
- allowing financial assistance from pharmaceutical manufacturers to count toward TrOOP.

Dispensing Fee

We invited comments on three definitions of ''dispensing fees''.

Final Decision: We will include only those activities related to the transfer of possession of the covered Part D drug from the pharmacy to the beneficiary, including charges associated with mixing drugs, delivery, and overhead (Option 1).

Covered Part Drug Definition

Part B/D Issues: We solicited comments concerning any drugs that may require specific guidance with regard to their coverage under Part D, and any gaps that may exist in the combined ''Part D & B'' coverage package.

Final Decision: We identify issues and discuss coverage of the following with respect to the definition of Part D drug:

- Vaccines.
- Compounded Drugs.
- Parenteral Nutrition.
- Insulin Supplies.
- Exclusion of A/B Drugs if individual could have enrolled in A or B.
- Tying Arrangements.

Long Term Care Facility Pharmacies

We requested comments regarding our definition of the term long-term care facility in § 422.100. We also solicited comments regarding how we should guarantee ''convenient access'' to the pharmacy benefit for Part D enrollees who reside in LTC facilities? We welcomed comments regarding how to balance convenient access to long-term care pharmacies with appropriate payment to long-term care pharmacies under the provisions of the MMA.

Final Decision: We have expanded the definition of the term ''long-term care facility'' in § 423.100 of our final rule to encompass not only skilled nursing facilities, as defined in section 1819(a) of the Act, but also any medical institution or nursing facility for which payment is made for institutionalized individuals under Medicaid, as defined in section 1902(q)(1)(B) of the Act.

In addition, we are adopting an approach requiring Part D plans to demonstrate ''convenient access'' to network long-term care pharmacies that will inject competition into the long-term care pharmacy market, but also allow the option of maintaining the relationships and levels of service that long-term care facilities now enjoy vis-à-vis their contracted long-term care pharmacies. We will require plans to demonstrate (in their applications) ''convenient in-network access'' to long-term care pharmacies and use of specialized any-willing-pharmacy (AWP) contracts for long-term care pharmacies to inject competition into the long-term care pharmacy market.

Network Access Standards—Home Infusion

In the proposed rule preamble, we stated that we were considering using the authority in section 1860D–4(b)(1)(C) of the Act (which establishes requirements regarding convenient access to network pharmacies) to require that plans contract with a sufficient number of home infusion pharmacies in their service areas to provide reasonable access for Part D enrollees, as stand-alone drug plans may not have an incentive to include home infusion pharmacies in their networks. We solicited comments on whether we should use the authority in section

1860D–4(b)(1)(C) of the Act to require that both MA-PD plans and PDPs contract with a sufficient number of home infusion pharmacies in their service area to provide reasonable access for Part D enrollees? How could such a requirement be structured?

Final Decision: We will require plans to provide adequate access to home infusion pharmacies but do not specify requirements in the final rule. Plans will be required to tell us how they will provide such access in their service area.

Network Access Standards—Tricare Standards (Retail)

We proposed to apply these access standards such that a PDP or regional MA-PD plan would have to meet or exceed the access standards across each region in which it operates, and a local MA-PD plan would have to meet or exceed the access in its local service area.

Final Decision: We will require plans to meet the TRICARE access standards at the State level.

Network Access Standards—Non-Retail

We requested comments on whether we should allow plans to count certain non-retail pharmacies, such as I/T/U pharmacies, toward the pharmacy access standards in some (or all) cases. We also solicited comments on permissible ways to ensure Part D enrollees' access to FQHC and rural pharmacies.

Final Decision: We will allow plans to count I/T/U pharmacies and other rural institutional pharmacies (for example, FQHCs, RHCs) toward the pharmacy access requirements in all cases, provided such pharmacies are under contract with the plan and do not substitute for available retail access in their network.

Network Access—I/T/U Pharmacies

We asked: How will I/T/U pharmacies and IHS beneficiaries achieve maximum participation in Part D benefits? What are the advantages and disadvantages for AI/AN enrollees who are eligible to enroll in Part D?

Final Decision: We will require Part D plan sponsors to include I/T/U pharmacies in their networks to the extent that those pharmacies are present in their service areas. We will require that plans offer any willing pharmacy (AWP) contracts to I/T/U pharmacies that include an addendum addressing certain minimum terms and conditions specified by us in separate guidance. We will require Part D plans to demonstrate that they have contracts with a sufficient number of I/T/U pharmacies to ensure ''convenient access'' to prescription drugs for AI/AN enrollees within the service area.

Any Willing Pharmacy

We asked: Should we require that PDP sponsors and MA organizations offering an MA-PD plan make available to all pharmacies a standard contract for participation in their plans' networks? Should ''any willing pharmacy'' provisions apply to non-retail—in particular mail order—pharmacies, as well as to retail?

Final Decision: We will require plans to offer standard terms and conditions to all pharmacies for purposes of ensuring that any pharmacy, and any type of pharmacy, willing to accept the standard contact terms and conditions can join the pharmacy network.

Out-of-Network (OON) Access

We requested comments on how emergency access standards should work. In the proposed rule, we required plans to ensure that their enrollees have adequate access to drugs dispensed at OON pharmacies when they cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy. We requested comments on our proposed out-of-network access requirements.

In the preamble to our proposed regulations, we specified that the case of a Part D enrollee who is residing in a long-term care facility whose long-term care pharmacy does not contract with that enrollee's MA-PD plan or prescription drug plan is one in which we would expect plans to provide out-of-network access to drugs as provided under § 423.124 of our regulations.

Final Decision: We adopt the out-of-network access policy set forth in the proposed rule and clarify that § 423.124(c) of our final rules requires plans to establish reasonable rules to ensure that enrollees use out-of-network pharmacies in an appropriate manner. Plans must ensure adequate access to out-of-network pharmacies on a non-routine basis when enrollees cannot reasonably access network pharmacies.

We have defined the beneficiary cost sharing in relation to the total cost of the drug to the plan and the beneficiary. Therefore, in cases where the total payment is not limited by the plan allowable due to out-of-network status, the cost sharing should be defined as the total paid by the beneficiary, or in the case of a low-income individual, as the total cost sharing paid by both the beneficiary and CMS. However, we changed our proposed policy of allowing out-of-network access for long-term care pharmacies and now require Part D plans to provide network access.

Formularies

We requested comments on many aspects of formulary management, such as:

- Does requiring a formulary to be ''developed and reviewed'' by a P&T committee mean that a P&T committee's decisions regarding the plan's formulary must be binding on the plan?
- Should we strengthen the statutory requirement in section 1860D–4(b)(3)(A)(ii) of the Act by requiring that more than just one pharmacist and one physician on the P&T committee be independent and free of conflict?
- Should we require the direct involvement of a Pharmacy and Therapeutics Committee with cost containment measures, as well as with other areas of quality assurance and medication therapy management?
- What standards and criteria could we use to determine that a PDP sponsor or MA organization's formulary that is not based on the model classification system does not in fact discriminate against certain classes of Part D eligible beneficiaries?
- How can we balance plans' flexibility to maximize covered Part D drug discounts and lower enrollee premiums with the needs of certain special populations of Part D enrollees?
- What should be the minimum timeframes for periodic evaluation and analysis of protocols and procedures related to a plan's formulary by PDP plans and MA-PD plans (for example, quarterly, annually)?

Final Decision: We made changes to the regulatory formulary requirements to balance: (1) building specific requirements into regulatory language to ensure plans offer adequate coverage of the types of drugs most commonly needed by Part D enrollees; with (2) maintaining flexibility to fine-tune formulary review requirements via separate guidance consistent with our final formulary review standards and processes developed based on public comment. The regulatory text revisions:

- Clarify that P&T committee members must be independent and free of conflict with respect not just to plans, but also pharmaceutical manufacturers.
- Specify a role for P&T committees in the approval of policies that guide medical exceptions and other utilization management processes, as well as treatment protocols and procedures related to a plan's formulary.
- Require the provision of adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines—above and beyond the 2–drugs-per-category-and-class requirement.
- Provide us with the flexibility to specify additional requirements regarding plans' P&T committees and formularies via separate guidance.

• Specify that we will review plan formularies consistent with the non-discrimination provisions at § 423.272(b)(2). We intend to conduct a comprehensive review of the plan design consistent with explicit formulary review standards and criteria-driven processes.

Quality Standards

We asked: Are there industry standards for cost effective drug utilization management, and should we adopt any of these standards for PDPs and MA-PD plans? Among the issues we raised in the preamble is whether or not we should use the OBRA '90 Medicaid standards for these programs. OBRA '90 requires pharmacy programs to use proDUR and retroDUR and to offer counseling services.

Final Decision: We require plans to demonstrate that their network providers are required to comply with pharmacy practice standards established by the States, to establish concurrent and retrospective DUR policies and systems, and to establish internal medication error identification and reduction systems.

Medication Therapy Management Programs(MTMP)

We sought comments on what requirements or guidelines for MTMPs should be formulated in our regulations.

Final Decision: We received a significant volume of comments on MTMP. Almost all the comments agreed that MTMP can make a significant difference in improving therapeutic outcomes. Despite some best practice examples, however, no widely accepted MTMP standards of practice were identified. We will not specify further service and service level requirements at this time. We also will not specify multiple chronic diseases and multiple drug requirements.

Anti-Fraud Programs

We stated that we would be interested in comments on possible requirements in the area of fraud, waste and abuse over and above the incentives operating in at-risk plans.

Final Decision: In an effort to consolidate requirements on plans we moved the fraud and abuse provision to subpart K at § 423.504(b)(4)(vi)(H) as a component of a Part D sponsor's overall compliance plan. Plans will be required to add a program to combat fraud, waste and abuse in their prescription drug benefits to their compliance plans. In addition, we eliminated the mandatory self-reporting requirements that were proposed, but we expect all Part D sponsors to comply with the requirement for a comprehensive fraud and abuse plan.

E-Prescribing

We solicited comments on many aspects of developing and implementing e-prescribing standards.

Final Decision: While we included a fairly lengthy discussion of e-prescribing in the August 2004 proposed rule, we intend to issue a separate proposed rule devoted to the standards that will be used for e-prescribing and have reserved § 423.159(a) and § 423.159(b) of this final rule for such e-prescribing standards. Therefore, most of the proposals we made with respect to such standards are not being addressed in this final rule. One standard we are finalizing is the requirement that Part D plans support e-prescribing. We received no comments on this proposal and are adopting it at § 423.159(c).

Evaluating Bids

We asked for comments on whether we should we adopt the standards used by OPM in 48 CFR Chapter 16.

Final Decision: We have adopted most of the proposed rule provisions in the area of bid review, negotiation and approval, with the following clarifications: We-

• Clarify that the OPM-like authority (section 1860D–11(d)(2)(B) of the Act) is in addition to our general authority to negotiate (section 1860D–11(d)(2)(A) of the Act).

• Clarify that we will not be proposing additional regulations based on 48 CFR Chapter 16.

• Clarify that we intend to examine profit using this authority.

• Clarify that we do not intend to require detailed information on acquisition costs from each and every plan. We would request additional information only when necessary.

• Reiterate our interpretation that the bid review authority does not violate the non-interference directive.

Calculations

We solicited comment on the appropriateness of all of our proposed calculations.

Final Decision: We will adopt all of the proposed calculations with the exception of our interpretation of the ''negative premium.'' We will allow for a ''negative premium'' for plans with bids below the benchmark by an amount in excess of the base beneficiary premium.

Data Submission

We asked: What should be the content, format and frequency of data submissions?

Final Decision: Because of the complexity of the MMA payment provisions, collecting 100 percent events data is necessary. While the volume is large, the minimal number of data elements we expect to collect (<25) and the simplicity of our own data processing system should minimize the burden of this approach. Our goal will be to collect the minimum amount of data we need to perform our payment functions.

Payment Adjustments

We solicited comment on many operational aspects of payment of reinsurance and low-income subsidies, as well as for risk corridors and reconciliations.

Final Decision: Reinsurance will be paid on a monthly basis during the year based on estimated reinsurance costs; however, we may move to payment on an as-incurred basis in later years. Low income cost-sharing subsidies will be made on an interim basis. Final reconciliation on reinsurance and low income subsidies will occur after the close of the year.

We solicited comments on the nature of waivers that might be required for MA plans and employer-sponsored plans, among others.

Final Decision: Information on specific waivers we will or will not grant is not addressed in this regulation, but will be described in separate guidance.

Coordination with Other Plans

We requested comment on what basis Part D COB user fees should be imposed on Part D plans.

Final Decision: We intend to issue requirements for coordination with other prescription drug coverage by Part D plans as soon as possible in advance of the statutory deadline of July 1, 2005.

Part B/D Coordination of Benefits

We asked: Should Part D cover Part B drugs denied under Part B because the pharmacy does not have a Medicare supplier number? Are there any other circumstances under which a Part B drug denied coverage under Part B should be covered under Part D? Are automatic claims cross-over procedures feasible between Part B and Part D payers?

Final Decision: Based on the comments received regarding the various B/D coordination issues we described, we do not believe commenters identified any circumstances under which a drug denied coverage under Part B should automatically be covered under Part D, and we will not provide for automatic cross-over procedures.

Tracking TrOOP

We requested comment on the following issues:

Should CMS or the Part D plans be responsible for determining whether claims costs have been reimbursed by alternative coverage?

What are the operational capabilities of plans to manage COB at the point of sale, particularly with respect to alternative wrap around coverage?

Should reporting of third-party claims costs be mandatory or voluntary?

Should we require beneficiaries to give consent for release of data held by third parties as part of their enrollment application?

Are there any temporary or phased-in approaches to tracking TrOOP that may be necessary or advisable given the short timeframe between the final rule and program implementation?

How can Part D plans receive information from beneficiaries or others regarding payment made by entities that do not participate in a centralized coordination of benefits system?

Final Decision: In the proposed rule, we considered two options for operationalizing the data exchange related to the Part D coordination of benefits system and TROOP accounting:

- *Option 1*: The Part D plan s and MA-PD plans will be solely responsible for tracking TrOOP costs.
- *Option 2*: We will procure a TrOOP facilitation contractor to establish a single point of contact between payers, primary or secondary.

While this is not a regulatory issue, we will work toward some variation on Option 2, since we believe this is the most efficient and effective way to implement the TrOOP. Further information will be issued with our requirements for coordination with other plans by Part D plans as soon as possible in advance of the statutory deadline of July 1, 2005.

Appeals

We solicited comments on coverage determinations and notices and exceptions procedures.

We proposed a limited number of elements that must be included in a sponsor's formulary exceptions criteria. We also considered including a number of other exceptions criteria and adding criteria for the review process that is used to evaluate formularies and tier structures. We asked for comment on whether we should specify the decision criteria for beneficiary appeals, or whether Part D plans should be held accountable to follow their own decision criteria.

Final Decision: Consistent with the August 2004 proposed rule, we specify that a coverage determination is made by the Part D plan, not at the pharmacy, and we address notice and timing issues. We have shortened the coverage determination timeframes for making expedited and standard coverage determinations, redeterminations and reconsiderations. We limit tiering exceptions to obtaining a non-preferred drug at the price of a preferred drug, and specify that tiering exceptions need not be granted in cases where a Part D sponsor has a formulary tier in which it places very high cost and unique items, such as genomic and biotech products. We require that plans grant exceptions to tiering when the physician certifies that the preferred drug would not be as effective as the non-preferred on-formulary drug or would have an adverse effect on the individual and the plan agrees with such certification. Similarly, for off-formulary exceptions, if the physician certifies that the on-formulary drug would not be as effective as the prescribed drug or would have adverse effects and the plan agrees with such certification, a formulary exception must be granted. Grievance procedures also are revised to accordance with changes to the Medicare Advantage final rule.

Employer Sponsored Prescription Drug Programs and Appeals

We solicited comments on whether, and to what extent, the application of parallel procedures between employer sponsored prescription drug plans governed by ERISA and plans offered under part 423 of our proposed regulations might be a problem for plans, employers, or eligible individuals. We also solicited suggestions for addressing problems, if any, that result from the application of parallel procedures.

Final Decision: We have added § 423.562(d), which is intended to give ERISA plans the option, according to regulations of the Secretary of Labor, of electing the Part D process rather than the procedures under 29 CFR 2560.503–1 for claims involving supplemental benefits provided by contract with a Part D plan. The provision in § 423.562(d) would not take effect in the absence of regulations by the Secretary of Labor.

Low-Income Subsidy Determinations and Notification

We invited general comments on how we could ensure consistent eligibility determination, redetermination and appeal processes for low-income subsidies. We requested comments on how we should calculate the sliding scale premium subsidy for individuals with income from 135 percent up to 150 percent of the FPL. We offered an example to set a scale in a stepped fashion, for example, a set decrease in the subsidy amount for every 5 percent increase in income level.

Final Decision: We require that the Part D plan be responsible for direct reimbursement to beneficiaries for out-of-pocket costs incurred after the effective date of subsidy eligibility. We also require the Part D plan to have processes for reimbursing a charity or program for any premium and cost sharing amounts paid on behalf of an individual subsequent to the effective date of the subsidy. We adopted the proposed sliding scale premium methodology in this rule.

Fallback Plan Requirements

We invited comment on whether we should define ''offering a fallback plan'' as agreeing to potentially offer a plan in a region, or as actually providing a fallback plan in fallback service areas. We also solicited comment on whether we should use the Indefinite Delivery type of contract.

Final Decision: We adopted the interpretation that offering a fallback plan means actually providing a fallback plan in fallback service areas. We have also determined that fallback contracts will not be written under the FAR or 48 CFR provisions; therefore, it is no longer accurate to refer to the standby contracts as indefinite duration, indefinite quantity (IDIQ) contracts—which is a term used under the FAR.

Fallback Payment

We requested comment on fallback payment methodologies, particularly in regard to prospective or retrospective rebate allocation. We also requested comments on alternative reference points to the Average Wholesale Price (AWP) or alternative methodologies that could promote competitive pricing.

Final Decision: Information on the fallback payment process is not addressed in this final regulation, but will be described in separate guidance. The AWP remains the primary measuring stick for drug costs. We will therefore be incorporating it into our performance targets. However, we will be looking at other indicators or proxies for financial performance, such as rates of generic substitution, that will provide other perspectives on cost management.

Access Standards in the Territories

We asked whether the waivers proposed for the territories were appropriate, and were any others warranted to ensure access to individuals residing in the territories?

Final Decision: The only comments received with respect to the territories concerned the design of the regions, and these have been addressed in separate guidance. As a result, we have retained the broad waiver authority in § 423.859(c), and will continue to conduct research to determine how best to facilitate Part D coverage in the territories. Specific waivers will be addressed in separate guidance.

Subsidy Process

We solicited comments on many aspects of the proposed retiree drug subsidy process.

Final Decision: After reviewing the comments, we made many policy decisions in the final rule, including:

• Announcing that we would allow retiree drug plans the flexibility to receive subsidy payments on a monthly, quarterly or annual basis at their discretion;

• Providing insured plan sponsors the flexibility to use premiums as the cost basis for interim subsidy payments;

• Clarifying what information must be submitted with enrollment data;

• Providing sponsors the flexibility to use either the calendar year or their plan year (if different from the calendar year) for calculating the subsidy and for determining actuarial equivalence; and

• Allowing sponsors broad discretion in determining who meets the definition of a qualifying covered retiree for purposes of the subsidy.

Further details on the implementation of the subsidy program will be provided in separate guidance.

Actuarial Equivalence for Subsidy

We asked for comments on the likely responses of plan sponsors to the different approaches we proposed. In addition, we solicited comments not only on the desirability of the different options, but also on the legal bases for possible options.

Final Decision: The final regulation includes a two-part test for plan sponsors to determine whether ''actuarial equivalence,'' has been met.

Change in Definition of Outpatient Prescription Drugs

We solicited comments on the new definition for purposes of the physician self-referral prohibition.

Final Decision: We finalized this proposal without substantive change.

Waivers Needed for Cost Plans or CMPs

We invited comment on whether there are any Part D requirements otherwise applicable to MA-PD plans that would be uniquely problematic to implement for section 1876 reasonable cost HMOs and CMPs.

Final Decision: We have clarified that Part D will be offered somewhat differently by cost plans:

(1) Cost plans that choose to offer qualified Part D coverage under § 417.440(b)(2) may do so only by offering qualified Part D coverage as an optional supplemental benefit.

(2) Cost plans that offer qualified Part D coverage must offer basic prescription drug coverage. A cost plan that offers basic prescription drug coverage may offer additional qualified Part D coverage choices.

(3) A cost plan that does not offer qualified Part D coverage under § 417.440(b)(1)(iii) may offer non-qualified drug coverage that is not reimbursed under this part or title.

Creditable Coverage Notice for Medigap Policies

The proposed rule set forth a draft disclosure notice for Medigap issuers to use for policies that do not have creditable coverage. We solicited comments on how the draft disclosure notice could be adapted for the types of Medigap policies that do provide creditable coverage.

Final Decision: We have determined that the format and content of the notice could be improved based on information gathered through consumer testing, so we now plan to publish the final model disclosure notice separately from this final regulation. We also plan to publish a model disclosure notice for policies that do provide creditable coverage.

PACE Waivers

We invited comments on the MMA requirements we proposed to be waived for PACE organizations and asked for comment on additional waivers that may be needed to integrate the Medicare prescription drug benefit and the PACE benefit.

Final Decision: We have finalized our proposed waiver of section 423.265(b) and will allow PACE plans to submit Part D bids after the first Monday in June each year. However, we clarified that we expect PACE plans that are operational as of the first Monday in June each year to meet the bid submission deadline. Information on additional waivers will not be addressed in this regulation, but will be described in separate guidance.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether OMB should approve an information collection, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

• The need for the information collection and its usefulness in carrying out the proper functions of our agency.

• The accuracy of our estimate of the information collection burden.

• The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Below is a summary of the information collection requirements in this regulation.

Subpart A—General Provisions

Subpart A does not contain any requirements subject to the PRA.

Subpart B—Eligibility and Enrollment.

• § 423.32 Enrollment process.

(a) A Part D eligible who wishes to enroll in a Part D may enroll during the enrollment periods specified in § 423.38, by filing the appropriate enrollment form with the Part D plan or through other mechanisms CMS determines are appropriate.

The burden associated with this requirement is the time and effort necessary for an individual to submit the required enrollment application to a Part D plan sponsor. We estimate that it will take 30 minutes to complete and submit the required application to the Part D plan. During the first Part D initial enrollment period, it is estimated that 24 million individuals will complete and submit these applications. This estimate is based on preliminary estimates of the number of individuals who will enroll in Part D plans in 2006. In 2007, and beyond, the number of enrollments will be substantially less, since an individual will generally be limited to changing Part D plans during the annual coordinated election period. Therefore, it is estimated 6 million individuals may change their Part D plans annually and that 2 million new beneficiaries will be making first time enrollments into Part D plans.

(b) *Enrollment form or CMS-approved mechanism*. The enrollment must be completed by the individual and include an acknowledgement by the beneficiary for disclosure and exchange of necessary information between the U.S. Department of Health and Human Services (or its designees) and the Part D plan sponsor. Persons who assist beneficiaries in completing the enrollment, including authorized representatives, must indicate they have provided assistance and their relationship to the beneficiary.

The burden associated with this requirement is reflected above under section 423.32(a).

A Part D plan sponsor may require Part D eligible individuals enrolling or enrolled in its Part D plan to provide information regarding reimbursement for Part D costs through other insurance, group health plan or other third-party payment arrangement, in a form and manner approved by CMS.

The burden associated with the requirement for individuals to provide information regarding reimbursement

for Part D costs through other insurance, group health plan or other third-party payment arrangement enrolled or enrolling in a Part D plan is total annual burden of 43,333 hours. We estimate that 2.6 million beneficiaries will need 1 minute to disclose reimbursement for Part D costs to the appropriate entity on an annual basis, for a total annual burden of 43,333 hours.

(d) *Notice requirement*. The Part D plan sponsor must provide the individual with prompt notice of acceptance or denial of the individual's enrollment request, in a format and manner specified by CMS.

The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor to disclose to an individual notice of acceptance or denial of the individual's enrollment request. We estimate that during the first Part D initial enrollment period a total of 24 million notices will be disclosed, affecting approximately 64 Part D plans (based upon an estimate of 2 Part D plans per 34 regions). Given that each Part D plan will be creating disclosure notices for mass mailings, we are proposing the following burden estimates. We estimate that it will take each Part D plan approximately 8 hours to produce each notice—either an acceptance or a denial notice must be provided. We further estimate that on average, it will take each Part D plan sponsor 1 minute to assemble and disseminate each notice. We further estimate that on average, it will take each sponsor 5,860 hours to disclose 375,000 notices during this first year. In 2007, and beyond, we estimate that 93,750 notices will be disclosed annually at 1,465 hours per sponsor. This assumption is based on the premise that once the notices have been standardized, a Part D plan sponsor will mass-produce and mail the required notices.

• § 423.36 Disenrollment process.

(b) The Part D plan sponsor must submit a disenrollment notice to CMS within timeframes CMS specifies; provide the enrollee with a notice of disenrollment as CMS determines and approves; and file and retain disenrollment requests for the period specified in CMS instructions.

The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor to disclose to an individual notice of disenrollment. We estimate that on an annual basis it will require a total of 576,100 notices, affecting each Part D plan sponsors to some degree, as described below. Given that each Part D plan sponsor will be creating disclosure notices for mass mailings, we are proposing the following burden estimates. We estimate that it will take each Part D plan sponsor approximately 8 hours to produce the standardized notice. We further estimate that on average, it will take each Part D plan 1 minute to disclose each notice.

• § 423.38 Enrollment periods.

(c) Under the special enrollment period provisions, an individual is eligible to enroll in a Part D plan or disenroll from a Part D plan and enroll in another Part D plan, if the individual demonstrates to CMS, in accordance with guidelines CMS issues, that the Part D plan sponsor offering the Part D plan substantially violated a material provision of its contract under this part that meets the requirements set forth in this section. The burden associated with this requirement is the time and effort necessary for an individual to submit the required materials to CMS demonstrating that a Part D plan substantially violated a material provision of its contract. Based on our experience with the current Medicare Advantage program, we would expect that few, if any, individuals will avail themselves of this option. Generally, in those instances where CMS has found that an M+C organization has substantially violated a material provision of its contract, CMS has taken the necessary action on behalf of these individuals. Thus, we do not estimate any burden on individuals under this provision.

• § 423.44 Involuntary disenrollment by the Part D plan.

(c) If the disenrollment is for any of the reasons specified in paragraphs (b)(1), and (b)(2) of this section (that is, other than death Part D eligibility), the Part D plan sponsor must give the individual timely notice of the disenrollment with an explanation of why the Part D plan is planning to disenroll the individual. Notices for reasons specified in paragraphs (b)(1) through (b)(2) of this section must be provided to the individual before submission of the disenrollment notice to CMS; and include an explanation of the individual's right to a hearing under the Part D plan's grievance procedures.

(d) A Part D plan sponsor may disenroll an individual from the Part D plan for failure to pay any monthly premium if the Part D plan sponsor can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount.

The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor to submit the required materials to CMS demonstrating that the Part D plan sponsor made reasonable efforts to collect the unpaid premium amount and the time and effort necessary for a Part D plan sponsor to disclose to an individual the notice of disenrollment. We estimate that it will take a Part D plan 5 minutes to submit the required transaction to CMS for each occurrence and that each of the Part D plan sponsors will be required to submit the necessary documentation to CMS 960 times on an annual basis. We estimate that on an annual basis 96,000 individuals will be disenrolled for failure to pay premiums, and it will take each Part D plan 1 minute to disclose each notice and that each Part D plan will be required to disclose 960 notices on an annual basis for a annual burden of 16 hours.

A Part D plan may disenroll an individual whose behavior is disruptive, only after it meets the requirements described in this section and after CMS has reviewed and approved the request.

To disenroll an individual from its Part D plan, based on an individual's behavior, the Part D plan sponsor must document the enrollee's behavior, its own efforts to resolve any problems and any extenuating circumstances. The Part D plan must submit this information and any documentation received by the beneficiary to CMS. The Part D plan sponsor may request from CMS the ability to decline future enrollment by the individual.

The burden associated with this requirement is the time and effort necessary for a Part D plan to document and retain the documentation that meets the requirements set forth in this section. We estimate that it will take a Part D plan 3 hours to capture and retain the required documentation for each occurrence and that each Part D plan will have 1 occurrence on an annual basis.

In addition, the Part D plan must inform the individual of the right to use the Part D plan 's grievance procedures.

The burden associated with this requirement is captured under section § 423.128.

When a Part D plan contract terminates as stipulated under 423.507 and 423.510 the Part D plan sponsor must send a notice to the enrollee before the effective date of the plan termination or area reduction. The notice must give provide an effective date of the plan termination and a description of alternatives for obtaining benefits under Part D.

The burden associated with these requirements is discussed below under sections 423.507 and 423.510.

• § 423.48 Information about Part D.

Each Part D plan and MA-PD plan must provide, on an annual basis, and

in a format and using standard terminology that CMS may specify in guidance, the information necessary to enable CMS to provide to current and potential Part D eligible individuals the information they need to make informed decisions among the available choices for Part D coverage.

The burden associated with this requirement is the time and effort necessary for a Part D plan to submit the required materials to CMS. We estimate that on an annual basis it will take 68 Part D plan sponsors 2 hours to submit the required documentation to CMS.

• § 423.50 Approval of marketing materials and enrollment forms.

(a) At least 45 days (or 10 days if using marketing materials that use, without modification, proposed model language as specified by CMS) before the date of distribution, the Part D plan sponsor must submit the its marketing materials and forms to CMS for review.

The burden associated with this requirement is the time and effort necessary for a Part D plan to submit the required materials to CMS. We estimate that on an annual basis it will take 68 Part D plan sponsors 2 hours to submit the required documentation to CMS.

• § 423.56 Procedures to determine and document creditable status of prescription drug coverage.

(c) Each entity that offers prescription drug coverage under any of the types described in § 423.56(b) must disclose, to all Part D eligible individuals whether such coverage meets the actuarial requirements specified in guidelines provided by CMS. These notices must be provided to Part D eligible individuals, at minimum, at the following times: (1) prior to an individual's initial enrollment period for Part D, as described under § 423.38(a); (2) prior to the effective date of enrollment in the coverage, and upon any change in creditable status; (3) prior to the commencement of the Annual Coordinated Election Period (ACEP) that begins on November 15 of each year, as defined in 423.38(b); or (4) upon request by the individual. In an effort to reduce the burden associated with providing these notices, we have revised our final regulations to allow most entities (with the exception of Medigap insurers) to provide notices of creditable and non-creditable status with other information materials that these entities distribute to beneficiaries (rather than separately) and, as discussed in the preamble, we anticipate providing model language for both types of notices.

The burden associated with this requirement is the time and effort necessary for each of these entities to disclose to an individual notice of coverage. We estimate that it will require slightly over 400,000 entities to provide notices in existing plan materials (including 400,000 employer and union-sponsored group health plans with Medicare-eligible workers, and fewer than 50 other entities including State Pharmaceutical Assistance Programs, a handful of State Pharmacy Plus programs), and over 100 Medigap insurers to provide 1,900,000 separate initial notices in 2005. In addition to these initial notices, we estimate that in each subsequent year these same entities will be required to distribute notices in plan materials (including initial notices to new beneficiaries, annual notices prior to the ACEP, and notices of changes in creditable coverage status), as well as 447,789 additional separate notices to individuals upon request. [Note: A discussion of the costs and burden associated with the disclosure notices for public and private employers and unions sponsoring retiree coverage can be found in the impact analysis section on administrative costs associated with disclosure notice requirements and the PRA section on requirements for qualified retiree prescription drug plans, respectively.]

Given that each entity (with the exception of Medigap insurers) will be creating most of these disclosure notices for inclusion in existing plan materials, we make the following burden estimates. For initial notices of creditable coverage, subsequent notices prior to the commencement of the ACEP, and notices of changes in creditable coverage, we estimate that it will take each entity approximately 8 hours to produce the standardized notice. We further estimate that on average, it will take each entity (with the exception of Medigap insurers) a negligible amount of time to disclose each notice, since they will be incorporating notices into existing plan materials that are provided to beneficiaries (which are already being disseminated to their participants). In the case of Medigap insurers, we estimate that they will spend 1 hour per 60 notices for mass-mailing separate notices to beneficiaries. We further estimate that each entity will spend approximately 5 minutes per notice for providing separate additional copies of the notices to individual beneficiaries upon request. It is estimated that the burden per entity will be as follows:

• On average, the 4 State Pharmacy Plus programs will provide initial notices in existing beneficiary plan materials in 2005 for an annual burden of 8 hours (these notices are required even though, as discussed elsewhere in this preamble, these States may decide to lower their costs while maintaining equivalent benefits by replacing or reforming these programs).

• On average each of the 400,000 group health plans will provide initial notices in existing beneficiary plan materials in 2005 for an annual burden of 2 hours. Additionally, in subsequent years, on average, we estimate that these 400,000 group health plans will provide 100,000 additional separate notices to individuals upon request for an annual burden of 1.25 minutes. We also estimate that in subsequent years, on average, 4,000 of these group health plans will experience changes in creditable coverage status and provide notice of their new creditable coverage status in their plan materials, for an annual burden of 2 hours. We estimate that the annual burden associated with providing notices prior to the ACEP in subsequent years will be negligible, since they will be able to include these notices in their existing plan materials with minimal modifications.

• On average each of the 20 State Pharmaceutical Assistance Programs will provide initial notices in existing beneficiary plan materials in 2005 for an annual burden of 8 hours per State. We estimate that the annual burden associated with providing notices prior to the ACEP in subsequent years will be negligible, since they will be able to include these notices in their existing plan materials with minimal modifications.

• On average each of an estimated 120 Medigap issuers will provide 15,833 separate initial notices in 2005 for an annual burden of 264 hours. Additionally, in subsequent years, on average, we estimate that these 120 Medigap issuers will provide 40 additional separate notices to individuals upon request for an annual burden of 3.3 hours. We estimate that the annual burden associated with providing notices prior to the ACEP in subsequent years will be negligible, since the regulatory impact analysis assumes that the vast majority of beneficiaries with Medigap drug coverage will enroll in Part D.

(e) Each entity must disclose their creditable coverage status to CMS in a form and manner described by CMS. Each entity must disclose their initial creditable coverage status to CMS in 2005, as well as any subsequent change in creditable coverage status.

The burden associated with this requirement is the time and effort necessary for each entity to submit the required creditable coverage status materials to CMS. We estimate that it

will take each entity 1 hour to submit the required documentation to CMS.

Subpart C—Benefits and Beneficiary Protections.

• § 423.104 Requirements related to qualified prescription drug coverage.

(g) A Part D plan sponsor is required to disclose to CMS data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers, as well as data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers that are passed through to beneficiaries, via pharmacies and other dispensers, in the form of lower subsidies paid by CMS on behalf of low-income individuals or the form of lower monthly beneficiary premiums or lower covered Part D drug prices at the point of sale.

The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor to disclose to CMS the aggregate negotiated price data on concessions. We estimate that on an annual basis it will take 100 Part D plan sponsors and 350 MA organizations 10 hours to submit the required documentation to CMS for total annual burden of 4,500 hours.

• § 423.120 Access to covered Part D drugs.

(b) A Part D plan sponsor's formulary must be reviewed by a pharmacy and therapeutic committee that must maintain written documentation of its decisions regarding formulary development and revision.

The burden associated with this requirement is the time and effort necessary for a Part D sponsor's pharmacy and therapeutic committee to document and retain the documentation that meets the requirements set forth in this section.

We estimate that it will take 100 Part D plan sponsors and 350 MA organizations 1 hour each to capture and retain the required documentation on an annual basis for total annual burden of 450 hours.

Prior to removing a covered Part D drug from its plan's formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug, a Part D plan sponsor must provide at least 60 days notice to CMS, State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage (as described in § 423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists.

The burden associated with this requirement is the time and effort necessary for a Part D sponsor to provide notice of at least 60 days to CMS, State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage, authorized prescribers, network pharmacies, and pharmacists of the removal of a covered Part D drug from its formulary.

Given that each entity will be creating disclosure notices for mass mailings, we are proposing the following burden estimates. We estimate that on an annual basis it will take each entity approximately 1 hour to produce the standardized notice. We further estimate that on average, it will take 100 Part D plan sponsors and 350 MA organizations 40 hours to disclose the required notice for a total annual burden of 18,450 hours.

(c) A Part D sponsor must issue and reissue, as necessary, a card or other type of technology to its enrollees to use to access negotiated prices for covered Part D drugs.

The burden associated with this requirement is the time and effort necessary for an entity to provide each enrollee a card. The burden associated with this requirement is reflected in section 423.128.

• § 423.128 Dissemination of Part D plan information.

(a) A part D sponsor must disclose information about its Part D plan(s) as required by this section to each enrollee of a Part D plan offered by the Part D sponsor under this part and to Part D eligible individuals.

The burden associated with this requirement is the time and effort necessary for a Part D sponsor to disclose information and materials about its Part D plan(s). We estimate that it will require 100 Part D plan sponsors and 350 MA organizations 80 hours on an annual basis to prepare the plan materials. We further estimate that on an annual basis, on average, it will require each entity 120 hours on an annual basis to disclose the required materials to enrollees and eligible individuals for a total annual burden of 90,000 hours.

(e) A Part D sponsor must furnish directly to enrollees an explanation of benefits when prescription drug benefits are provided under qualified prescription drug coverage that meets the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for 100 Part D plan sponsors and 350 MA organizations to provide an explanation of benefits when prescription drug benefits are provided to enrollees. We estimate that it will require each entity 160 hours on an annual basis disseminate the required materials for total annual burden of 56,000 hours.

• § 423.132 Public disclosure of pharmaceutical prices for equivalent drugs.

(a) Except as provided under paragraph (c) of this section, a Part D sponsor must require a pharmacy that dispenses a covered Part D drug to inform an enrollee of any differential between the price of that drug and the price of the lowest priced generic version of that covered Part D drug that is therapeutically equivalent and bioequivalent and available at that pharmacy, unless the particular covered Part D drug being purchased is the lowest-priced therapeutically equivalent and bioequivalent version of that drug available at that pharmacy.

Subject to paragraph (d) of this section, the information under paragraph (a) of this section must be provided after the drug is dispensed at the point of sale or, in the case of dispensing by mail order, at the time of delivery of the drug.

The burden associated with this requirement is the time and effort necessary for the Part D sponsor to notify the pharmacy of the disclosure requirement referenced in this section and the burden on a pharmacy to provide the necessary disclosure to the enrollee. While these requirements are subject to the PRA, the burden associated with the requirements is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2) and (b)(3). These paragraphs of the PRA regulation state that a usual and customary business activity incurred by persons in the normal course of business, or a requirement sponsored by the Federal government that is also sponsored by a unit of a State or local government does not impose additional burden.

• § 423.136 Privacy, confidentiality, and accuracy of enrollee records

(c) and (d) For any medical records or other health and enrollment information it maintains with respect to enrollees, a Part D plan sponsor must maintain the records and information in an accurate and timely manner and provide timely access by enrollees to the records and information that pertain to them.

While these requirements properly maintain and disclose enrollee records are subject to the PRA, the burden associated with the requirements is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2) and (b)(3).

These paragraphs of the PRA regulation state that a usual and customary business activity incurred by persons in the normal course of business, or a requirement sponsored by the Federal government that is also sponsored by a unit of a State or local

government does not impose additional burden.

Subpart D—Cost Control and Quality Improvement Requirements for Part D Plans

• § 423.153 Drug utilization management, quality assurance, and medication therapy management prgrams (MTMPs).

(b) A Part D sponsor must provide CMS with information concerning the procedures and performance of its drug utilization management program, according to guidelines specified by CMS.

The burden associated with this requirement is the time and effort necessary for the Part D sponsor to provide CMS with information concerning its drug utilization management program, according to guidelines specified by CMS.

We estimate that is will require 100 Part D sponsors, 30 minutes each to provide the required material to CMS for consideration for a total annual burden of 50 hours.

(c) A Part D sponsor must provide CMS with information concerning its quality assurance measures and systems, according to guidelines specified by CMS.

The burden associated with this requirement is the time and effort necessary for the Part D plan sponsor to provide CMS with information concerning its quality assurance measures and systems, according to guidelines specified by CMS.

We estimate that is will require 100 Part D plan sponsors 30 minutes each to provide the required material to CMS for consideration for a total annual burden of 50 hours.

(d) A Part D sponsor must provide drug claims data to CCIPs for those beneficiaries that are enrolled in CCIPs in a manner specified by CMS and a Part D sponsor must provide CMS with information regarding the procedures and performance of its MTM program, according to guidelines specified by CMS.

The burden associated with this requirement is the time and effort necessary for each Part D sponsor to provide drug claims data to CCIPs for those beneficiaries that are enrolled in CCIPs and to provide CMS information regarding the procedures and performance of its MTM program, according to guidelines specified by CMS.

We estimate that is will require 100 Part D sponsors 60 minutes each to provide the required material to CCIPs and 100 Part D plan sponsors and 30 minutes each to provide the required material to CMS for consideration for a total annual burden of 150 hours.

An applicant to become a Part D plan sponsor must describe in its application how it will take into account the resources used and time required to implement the MTM program it chooses to adopt in establishing fees for pharmacists or others providing MTM services for covered Part D drugs under a prescription drug plan and disclose to CMS upon request the amount of the management and dispensing fees and the portion paid for MTM services to pharmacists and others upon request. Reports of these amounts are protected under the provisions of section 1927(b)(3)(D) of the Act.

The burden associated with this requirement is captured under § 423.265.

• § 423.168 Accreditation organizations.

(c) An accreditation organization approved by CMS must provide to CMS in written form and on a monthly basis all of the information required by this part.

Since CMS expects to contract with less then 10 organizations on an annual basis, this requirement is not subject to the PRA.

• § 423.171 Procedures for approval of accreditation as a basis for deeming compliance.

(a) A private, national accreditation organization applying for approval must furnish to CMS all of the information and materials set forth in this part.

Since CMS expects to less then 10 applicants on an annual basis, this requirement is not subject to the PRA.

Subpart F—Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

• § 423.265 Submission of bids and related information.

(a) An applicant may submit a bid that meets the requirements set forth in this section and related sections of this regulation, to become a Part D sponsor.

The burden associated with this requirement is the time and effort necessary for an entity to submit the required materials to CMS. We estimate we will receive 100 Part D sponsor applications on an annual basis and that it will requires each entity 80 hours to submit the required documentation to CMS for total annual burden of 8,000 hours.

Subpart G—Payments to Part D plan sponsors and MA-PD Plans For All Medicare Beneficiaries For Qualified Prescription Drug Coverage

• § 423.329 Determination of payment.

(b) Part D plan sponsors must submit data regarding drug claims to CMS that can be linked at the individual level to Part A and Part B data in a form and manner similar to the process provided under § 422.310 and other information as CMS determines necessary.

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors submit the required claims data to CMS. We estimate that on an annual basis it will take 100 Part D plan sponsors 52 hours to submit the required documentation to CMS for total annual burden of 5,200 hours.

(ii) MA organizations that offer MA-PD plans to submit data regarding drug claims that can be linked at the individual level to other data that the organizations are required to submit to CMS in a form and manner similar to the process provided under § 422.310 and other information as CMS determines necessary.

The burden associated with this requirement is the time and effort necessary for MA organizations submit the required claims data to CMS. We estimate that on an annual basis it will take 350 MA organizations 15 hours to submit the required documentation to CMS for total annual burden of 5,250 hours.

• § 423.336 Risk-sharing arrangements.

(a) A Part D plan sponsor may submit a bid that requests a decrease in the applicable first or second threshold risk percentages or an increase in the percents applied under paragraph (b) of this section.

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors submit the required bid materials to CMS. We estimate that on an annual basis it will take 10 Part D plan sponsors 20 hours to submit the required documentation to CMS for total annual burden of 200 hours.

(c) Within 6 months of the end of a coverage year, the Part D plan plan must provide the information that CMS requires.

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors submit the required cost data to CMS. We estimate that on an annual basis it will take 100 Part D only sponsors and 350 MA organizations 10 hours to submit the required documentation to CMS for total annual burden of 45,000 hours.

• § 423.343 Retroactive adjustments and reconciliations.

(c) Within 6 months of the end of a coverage year, the Part D plan plan must provide the information that CMS requires.

The burden associated with this requirement is the time and effort necessary for Part D only sponsors to submit the required data to CMS. We estimate that on an annual basis it will take 100 Part D Only sponsors and 350 MA organizations 10 hours to submit the required documentation to CMS for total annual burden of 4,500 hours.

(d) Within 6 months of the end of a coverage year, the Part D plan plan must provide the information that CMS requires.

The burden associated with this requirement is the time and effort necessary for Part only sponsors to submit the required cost data to CMS. We estimate that on an annual basis it will take 100 Part D only sponsors and 350 MA organizations 10 hours to submit the required documentation to CMS for total annual burden of 4,500 hours.

Subpart I—Organization Compliance With State Law and Preemption by Federal Law

• § 423.410 Waiver of certain requirements to expand choice.

(e) Under this section a Part D plan sponsor applicant may submit a waiver application to CMS to waive certain State licensure and fiscal solvency requirements in order to contract with CMS.

The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor applicant to submit a waiver application that meets the requirements of this section. We estimate that on an annual basis it will take 15 applicants 10 hours to submit the required waiver documentation to CMS for total annual burden of 150 hours.

Subpart J—Coordination of Part D Plans with Other Prescription Drug Coverage

• § 423.458 Application of Part D rules to Certain Part D Plans on and after January 1, 2006.

(b) Organizations offering or seeking to offer a MA-PD plan may request from CMS in writing waiver or modification of those requirements under this part that are duplicative of, or that are in conflict with provisions otherwise applicable to the plan under Part C.

The burden associated with this requirement is the time and effort necessary for an organization to submit the required waiver information to CMS for consideration. We estimate on average that we will receive 10 waiver applicants, 20 hours to provide the required material to CMS for consideration for a total annual burden of 200 hours.

(c) Any entity seeking to offer, sponsor, or administer an employer-sponsored group prescription drug plan may request, in writing, a waiver or modification of additional requirements under this Part that hinder its design of, the offering of, or the enrollment in, such employer-sponsored group prescription drug plan.

The burden associated with this requirement is the time and effort necessary for an organization to submit the required waiver information to CMS for consideration.

We estimate on average that we will receive 500 waiver applicants, 20 hours to provide the required material to CMS for consideration for a total annual burden of 10,000 hours. However, it should be noted that the number of respondents is an average for over the initial five year period and over time we expect an increase in the number of applicants.

(d) A cost plan (as defined in 42 CFR 417.401) or PACE organization (as defined in 42 CFR 460.6) that offers qualified prescription drug coverage under Part D may request, in writing, a waiver or modification of those requirements under this part otherwise applicable to cost plans or PACE organizations that are duplicative of, or that are in conflict with, provisions otherwise applicable to cost plans under section 1876 of the Act or PACE organizations or under sections 1894 and 1934 of the Act, or as may be necessary in order to improve coordination of this Part with the benefits offered by cost plans or PACE organizations.

The burden associated with this requirement is the time and effort necessary for a cost plan or PACE organization to submit the required waiver information to CMS for consideration. We estimate we will receive 10 waiver applicants, 20 hours to provide the required material to CMS for consideration for a total annual burden of 200 hours.

• § 423.464 Coordination of benefits with other providers of prescription drug coverage

(f) A Part D plan must exclude expenditures for covered Part D drugs made by insurance or otherwise, a group health plan, or other third party payment arrangements, including expenditures by plans offering other prescription drug coverage for purposes of determining whether a Part D plan enrollee has satisfied the out-of-pocket threshold provided under § 423.104(d)(5)(iii). To ensure that this requirement is met, A Part D enrollee must disclose all these expenditures to a Part D plan in accordance with requirements under § 423.32(b)(ii).

The burden associated with this requirement is the time and effort necessary for a Part D enrollee to disclose all these expenditures to a Part D plan in accordance with requirements under § 423.32(b)(ii). The burden associated with this requirement is captures and discussed above under § 423.32(b).

Subpart K—Application Procedures and Contracts With Part D Plan Sponsors

• § 423.502 Application requirements.

(b) In order to become a Part D sponsor, an entity, or an individual authorized to act for the entity (the applicant), must complete, comply with, and submit a certified application in the form and manner required by CMS that meets the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for Part D sponsors and MA organizations to submit the required application materials to CMS. We estimate that on an annual basis it will take 100 Part D sponsors and 350 MA organizations 10 hours to submit the required documentation to CMS for total annual burden of 4,500 hours.

• § 423.505 Contract provisions

(d) The Part D sponsor agrees must maintain for 10 years books, records, documents, and other evidence of accounting procedures and practices that are sufficient to meet the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for Part D sponsors and MA organizations to maintain the required documentation outlined in this section. We estimate that on an annual basis it will take 100 Part D sponsors and 350 MA organizations 52 hours to maintain the required documentation on an annual basis, for total annual burden of 23,400 hours.

(f) The Part D sponsor must submit to CMS certified financial information that must include the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for Part D sponsors and MA organizations to submit the required certified data to CMS. We estimate that on an annual basis it will take 100 Part D plan sponsors and 350 MA organizations 8 hours to submit the required documentation to CMS for total annual burden of 3,600 hours.

• § 423.507 Nonrenewal of Contract.

(a) If a Part D sponsor does not intend to renew its contract, it must notify CMS in writing by the first Monday of June in the year in which the contract ends and notify, in an manner that meets the requirements of this section, each Medicare enrollee, at least 90 days

before the date on which the nonrenewal is effective.

The burden associated with this requirement is the time and effort necessary for a Part D sponsor to submit a notice of nonrenewal to CMS. Since this requirement affects less than 9 entities per year, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

• § 423.508 Modification or termination of contract by mutual consent.

(b) If the contract is terminated by mutual consent, the Part D sponsor must provide notice to its Medicare enrollees and the general public as provided in paragraph (c) of this section.

Based on our experience with the M+C program CMS does not anticipate that more then 9 of these terminations will occur on an annual basis.

• § 423.509 Termination of Contract by CMS.

(b) If CMS notifies the Part D sponsor in writing 90 days before the intended date of their termination the Part D plan sponsor must notify its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination.

The Part D sponsor must also notify the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D sponsor's service area.

Based on our experience with the M+C program CMS does not anticipate that more then 9 of these terminations will occur on an annual basis.

• § 423.510 Termination of contract by the Part D sponsor.

(b) If a Part D sponsor terminates its contract because CMS fails to substantially carry out the terms of the contract the Part D sponsor must give advance notice to CMS, its Medicare enrollees, and the general public in a manner that meets the requirements set forth in the section.

Based on our experience with the M+C program CMS does not anticipate that more then 9 of these terminations will occur on an annual basis.

• § 423.514 Reporting requirements.

(b) Each Part D sponsor must report to CMS or other Federal agencies, on an annual basis the information necessary to meet the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for 100 Part D sponsors to submit the required document that meets all of the requirements referenced in this section to CMS or other Federal agencies. We estimate that on an annual basis it will take 100 Part D plan sponsors 40 hours to submit the required documentation, for total annual burden of 4,000 hours.

(d) For an employees' health benefits plan that includes a Part D sponsor in its offerings, the Part D plan sponsor must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (for the particular Part D plan sponsor) under the Employee Retirement Income Security Act of 1974 (ERISA). The Part D sponsor must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term ''administrator'' is defined in ERISA.

The burden associated with this requirement is the time and effort necessary for 100 Part D plan sponsors to submit the required document that meets all of the requirements referenced in this section. We estimate that on an annual basis it will take 100 Part D plan sponsors 40 hours to submit the required documentation, for total annual burden of 4,000 hours.

(e) Each Part D plan sponsor must notify CMS of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities.

The burden associated with this requirement is the time and effort necessary for 100 Part D plan sponsors to notify CMS of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities. We estimate that on an annual basis it will take 100 Part D plan sponsors 1 hour to notify the required entities, for total annual burden of 100 hours.

(f) Each Part D plan sponsor must make the information reported to CMS under this section available to its enrollees upon reasonable request.

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors to disclose the required materials that meet all of the requirements referenced in this section to the public upon request. We estimate that on an annual basis it will take 100 Part D plan sponsors 20 hours to submit the required documentation, for total annual burden of 2,000 hours.

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

• § 423.551 General provisions

(c) states that a Part D plan sponsor that has a Medicare contract in effect under § 423.502 of this part and is considering or negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change. The Part D plan sponsor must also provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

The burden associated with this requirement is the time and effort of the Part D plan sponsor considering or negotiating a change in ownership, to notify CMS and provide the information specified in this section. While this requirement is subject to the PRA, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.4.

• § 423.552 Novation agreement requirements

(a) Discusses the conditions for CMS approval of a novation agreement. This paragraph requires the Part D plan sponsor to notify CMS at least 60 days before the date of the proposed change of ownership and requires them to provide CMS with updated financial information and a discussion of the financial solvency impact of the change of ownership on the surviving organization.

The burden associated with this requirement is discussed above in § 423.551 of the PRA section.

This paragraph also requires the Part D plan sponsor to submit to CMS, at least 30 days before the proposed change of ownership date, 3 signed copies of the novation agreement containing the provisions specified in this section, and 1 copy of other relevant documents required by CMS.

The burden associated with this requirement is time and effort of the Part D plan sponsor to provide CMS with the required documentation. While this requirement is subject to the PRA, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

Subpart M—Grievances, Coverage Determinations, and Appeals

• § 423.562 General Provisions

(a) A Part D plan sponsor must ensure that all enrollees receive written information about the grievance, coverage determination, and appeals procedures that are available to them through the Part D plan sponsor and that meet the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for each of the 100 Part D plan sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 Part D plan sponsors 8 hours on an annual

basis to disclose the information for a total annual burden of 800 hours.

• § 423.564 Grievance procedures.

(e) The Part D plan sponsor must notify the enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 days after the date the plan sponsor receives the oral or written grievance.

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors to notify enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 days after the date the plan sponsor receives the oral or written grievance. We estimate that on an annual basis it will take 100 Part D plan sponsors 52 hours to meet the notification requirements of this section an annual basis, for total annual burden of 5200 hours.

(g) The Part D plan sponsor must maintain records on all grievances received both orally and in writing, including, at a minimum, the date of receipt, final disposition of the grievance, and the date that the Part D plan sponsor notified the enrollee of the disposition.

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors to maintain the required documentation outlined in this section. We estimate that on an annual basis it will take 100 Part D plan sponsors 52 hours to maintain the required documentation on an annual basis, for total annual burden of 5,200 hours.

• § 423.568 Standard timeframe and notice requirements for coverage determinations.

(a) When a party makes a request for a drug benefit, the Part D plan sponsor must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request, or, for an exceptions request, the physician's supporting statement.

The burden associated with this requirement is the time and effort necessary for each of the 100 Part D plan sponsors to disclose the necessary information to an enrollee whenever a coverage determination is unfavorable. We estimate the universe of such determinations to be 140,000 (approximately 80 percent of which will be ''exceptions requests'' under § 423.578). We estimate that it will take 30 minutes to prepare a notice of unfavorable decision. The total estimated annual burden is 56,000 hours.

(b) When a party makes a request for payment, the Part D plan sponsor must notify the enrollee of its determination no later than 72 hours after receipt of the request.

The burden associated with this requirement is the time and effort necessary for the 100 Part D plan sponsors to disclose the necessary information to an enrollee. We estimate that approximately 10 percent of coverage determinations will involve payment disputes. Thus, the annual associated burden will be 7000 hours.

(c) The burden associated with requirement is discussed above in § 423.568(a).

• § 423.570 Expediting certain coverage determinations.

(c) The Part D plan sponsor must document all oral requests in writing and maintain written and oral request documentation in the case file.

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors to maintain the required documentation outlined in this section. We estimate that on an annual basis 10 percent of all coverage determinations will be expedited requests. Of the 12,600 requests, we estimate that approximately 90 percent will be oral requests. Thus, it will take 100 Part D plan sponsors 57 hours to maintain the required documentation on an annual basis, for total annual burden of 5700 hours.

(d) If a Part D plan sponsor denies a request for expedited determination, it must give the enrollee prompt oral notice of the denial and subsequently deliver, within 3 calendar days, a written letter that explains the notice requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for each of the 100 Part D plan sponsors to disclose the necessary information to an enrollee. We estimate that 1 percent of the expedited requests will be transferred to the standard process. We estimate that it will take each of the 100 Part D plan sponsors 15 minutes to process each of the 126 cases. Thus, it will take Part D plan sponsors 32 hours an annual basis to disclose the information.

• § 423.572 Timeframes and notice requirements for expedited coverage determinations.

(a) Except as provided in paragraph (b) of this section, a Part D plan sponsor that approves a request for expedited determination must make its determination and notify the enrollee (and the prescribing physician involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request, or, for an exceptions request, the physician's supporting statement.

The burden associated with this requirement is the time and effort necessary for each of the 100 Part D plan sponsors to disclose the necessary information to an enrollee and prescribing physician involved in 11,340. We estimate that it will require each of the 100 Part D plan sponsors 30 minutes to disclose adverse coverage determinations. We estimate that approximately 15 percent of the cases (1700) will involve adverse coverage determinations, for a total annual burden of 850 hours. We estimate that it will take 5 minutes for the Part D plan sponsors to disclose favorable decisions for the remaining 9640 cases for a total annual burden of 803 hours.

(b) The burden associated with this requirement is discussed above in § 423.572(a).

• § 423.578 Exceptions process.

(a) An enrollee, the enrollee's representative, or the enrollee's prescribing physician (on behalf of the enrollee) may file a request for an exception that meets the requirements of this section.

The burden associated with this requirement is the time and effort necessary for an individual to submit a request for exception. We estimate it will require an individual 30 minutes to provide the request and that the 100 Part D plans sponsors will receive 112,000 requests on an annual basis. Therefore, we estimate a total annual burden of 56,000 hours.

(b) An enrollee, the enrollee's representative, or the prescribing physician (on behalf of the enrollee) may file an exception request that meets the requirements of this section.

The burden associated with this requirement is the time and effort necessary for an individual to submit a request for exception. We estimate it will require an individual 30 minutes to provide the request and that that the 100 Part D plan sponsors will receive 112,000 requests on an annual basis. Therefore, we estimate a total annual burden of 56,000 hours.

A Part D plan sponsor may require a written supporting statement from the enrollee's prescribing physician that the requested prescription drug is medically necessary to treat the enrollee's disease or medical condition. The Part D plan sponsor may require the prescribing physician to provide additional supporting medical documentation as part of the written follow-up.

The burden associated with this requirement is the time and effort necessary for a prescribing physician to submit the required documentation to the Part D plan sponsor. We estimate it will require a prescribing physician 15 minutes to provide the supporting documentation and that that the 100 Part D plan sponsors will make 5,600 requests on an annual basis. Therefore, we estimate a total annual burden of 1400 hours.

• § 423.582 Request for a standard redetermination.

(a) An enrollee must ask for a redetermination by making a written request with a Part D plan sponsor that made the coverage determination. The Part D plan sponsor may adopt a policy for accepting oral requests.

The burden associated with this requirement is the time and effort necessary for an individual to submit a request for redetermination. We estimate that approximately 15 percent of the 140,000 coverage determinations will be adverse. Of those 21,000 cases, we estimate that approximately 50 percent will be appealed. We further estimate it will require an individual 30 minutes to provide the request and that the 100 Part D plan sponsors will receive 9,450 standard requests on an annual basis. Therefore, we estimate a total annual burden of 4,725 hours.

(c) If the 60-day period in which to file a request for a redetermination has expired, an enrollee may file a request for redetermination and extension of time frame with the Part D plan sponsor.

The burden associated with this requirement is the time and effort necessary for an individual to submit a request for extension of redetermination. We estimate it will require an individual 15 minutes to provide the request and that each of the 100 Part D plan sponsors will receive 100 requests on an annual basis. Therefore, we estimate a total annual burden of 2500 hours.

(d) The person who files a request for redetermination may withdraw it by filing a written request for withdrawal at the location listed in paragraph (a) of this section.

The burden associated with this requirement is the time and effort necessary for an individual to submit a withdrawal request. We estimate it will require an individual 15 minutes to provide the request and that each of the 100 Part D plan sponsors will receive 5 requests on an annual basis. Therefore, we estimate a total annual burden of 125 hours.

• § 423.584 Expediting certain redeterminations.

(c) The Part D plan sponsor must document all oral requests in writing, and maintain the documentation in the case file.

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors to maintain the required documentation outlined in this section. We estimate that on an annual basis, 10 percent of the 10,500 redeterminations will be expedited requests. Of the 1,050 expedited requests, we estimate that approximately 90 percent will be oral requests. Thus, it will take the 100 Part D plan sponsors approximately 5 hours to maintain the required documentation on an annual basis, for total annual burden of 500 hours.

(d) If a Part D plan sponsor denies a request for expedited redetermination, it must give the enrollee prompt oral notice, and subsequently deliver, within 3 calendar days, a written letter that explains the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for each of the 100 Part D plan sponsors to disclose the necessary information to an enrollee. We estimate that 10 percent of the expedited requests will be transferred to the standard process. We further estimate that it take each of the 100 Part D plan sponsors 15 minutes to process each of the 105 cases to disclose the information for a total annual burden of 26 hours.

• § 423.590 Timeframes and responsibility for making redeterminations.

(a) When a party makes a request for a drug benefit, the Part D plan sponsor must notify the enrollee in writing of its redetermination as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for a standard redetermination.

The burden associated with this requirement is the time and effort necessary for each of the 100 Part D plan sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 Part D plan sponsors 30 minutes to disclose the information for a total annual burden of 4,725 hours.

(b) When a party makes a request for payment, the Part D plan sponsor must issue its redetermination no later than 7 calendar days from the date it receives the request for a standard redetermination. We estimate that 10 percent of the 9,450 standard redetermination requests will involve payment disputes.

The burden associated with this requirement is the time and effort necessary for each of the 100 Part D plan sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 Part D plan sponsors 30 minutes on an annual basis to disclose the information for a total annual burden of 473 hours.

(d) A Part D plan sponsor that approves a request for expedited redetermination must complete its redetermination and give the enrollee (and the prescribing physician involved, as appropriate), notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request for an expedited redetermination.

The burden associated with this requirement is the time and effort necessary for each of the 100 Part D plan sponsors to disclose the necessary information to 895 enrollees (and the prescribing physicians involved, as appropriate). We estimate that it will require each of the 100 Part D plan sponsors 30 minutes on an annual basis to disclose the information for a total annual burden of 448 hours.

Subpart N—Medicare Contract Determinations and Appeals

This Subpart deals with Contract Determinations and Appeals; therefore, the information collection requirements referenced in this Subpart are exempt from the PRA in accordance with 5 CFR 1320.4(a)(2) during the conduct of an administrative action, investigation, or audit.

Subpart O—Intermediate Sanctions

• § 423.756 Procedures for imposing sanctions.

(a) Before imposing the intermediate sanctions specified in this section, CMS will allow the Part D plan sponsor to provide evidence that it has not committed an act or failed to comply with the requirements as described. In addition, CMS may allow additional time for the Part D plan sponsor to provide the evidence if the Part D plan sponsor sends a written request providing a credible explanation of why additional time is necessary.

These information collection requirements are exempt from the PRA in accordance with 5 CFR 1320.4(a)(2) during the conduct of an administrative action, investigation, or audit.

Subpart P—Premiums and Cost-Sharing Subsidies for Low-Income Individuals

• § 423.774 Eligibility determinations, redeterminations, and applications.

Paragraph (d) of this section discusses the application requirements for individuals applying for low-income subsidy. This paragraph states that individuals applying for low-income

subsidy, or a personal representative applying on the individual's behalf, must complete all required elements of the application, provide any statements from financial institutions, as requested, to support information in the application, and certify, as to the accuracy of the information provided on the application form.

The burden associated with this requirement is the time and effort for the individual or personal representative applying on the individual's behalf, to complete the low-income subsidy application, provide financial statements as requested and to certify that the information provided is accurate. These collection requirements are subject to the PRA; however, the burden associated with these requirements is currently approved under OMBı 0938–0467 with a current expiration date of October 31, 2005. We will revise this currently approved PRA package to incorporate the burden being imposed on new enrollees. We estimate that this requirement will impose a burden on 4.5 million new enrollees for a total additional burden of 750,000 hours annually (4.5M X 10 minutes).

• § 423.800 Administration of subsidy program.

Paragraph (b) of this section requires the Part D plan sponsor offering the Part D plan plan, or the MA organization offering the MA-PD plan, to reduce the individual's premiums and cost-sharing as applicable and provide information to CMS on the amount of such reductions, in a manner determined by CMS. This paragraph also requires the Part D plan sponsor offering the Part D plan to maintain documentation to track the application of the low-income cost-sharing subsidies to be applied to the out-of-pocket threshold.

The burden associated with these requirements is the time and effort for the Part D plan sponsor offering the Part D plan to provide information to CMS and to maintain documentation. We estimate that it will take each of the 450 Part D plan or MA-PD sponsors offering the Part D plans or MA-PD approximately 52 hours on an annual basis to provide the information to CMS. We also estimate that it will take approximately 26 hours for each of the 450 entities to maintain the information for tracking purposes. Therefore, we estimate that it will take approximately 35,100 total hours annually to comply with these requirements.

Subpart Q—Guaranteeing Access to a Choice of Coverage

• § 423.859 Assuring access to a choice of coverage.

(c) states that CMS may waive or modify the requirements of this part if an entity seeking to become a prescription drug plan in an area such, as a territory, other than the 50 States or the District of Columbia requirement Part D in order to provide qualified prescription drug.

The burden associated with this requirement is the time and effort for the Part D plan to make a request of waiver or modification to CMS. We estimate that approximately 2 Part D plan s will request a waiver or modification on an annual basis. Since this requirement affects less than 10, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

• § 423.863 Submission and approval of bids.

(a) discusses the process CMS uses for the solicitation and approval of bids. CMS solicits bids from eligible fallback entities for the offering in all fallback service areas in one or more Part D plan regions of a fallback prescription drug plan. CMS specifies the form and manner in which fallback bids are submitted in separate guidance to bidders.

The burden associated with this requirement is the time and effort for the fallback entities to prepare and submit a bid that meets the requirements of the section and related sections.

We estimate as an upper limit that approximately 20 fallback entities will submit a bid every three years. We also estimate that it will take each fallback entity approximately 80 hours to complete and submit the bid to CMS. Therefore, we estimate it will take a total of (20 * 80) /3 = 533.33 hours on an annual basis to comply with this requirement.

(b) Negotiation and Acceptance of Bids discusses the procedures CMS uses to enter into contracts. CMS solicits bids from eligible fallback entities and uses competitive procedures to enter into contracts.

The burden associated with this requirement is the time and effort for the fallback entities to enter into a contract with CMS that meets the requirements of this section and related sections.

We estimate, again as an upper limit, that approximately 5 fallback entities will enter into a contract with CMS on an annual basis. Since this requirement affects less than 10, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

• § 423.871 Contract terms and conditions.

(f) states that each contract for a fallback prescription drug plan requires an eligible fallback entity offering a fallback prescription drug plan to provide CMS with the information CMS determines is necessary to carry out the requirements of this section.

The burden associated with this requirement is the time required of the fallback prescription drug plan to provide CMS with the information CMS determines necessary. We estimate that approximately 5 fallback prescription drug plans will enter into a contract with CMS. Since this requirement affects less than 10, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans

• § 423.884 Requirements for qualified retiree prescription drug plans.

(a),(b), (c),and (d) In order to qualify for the retiree drug subsidy, the employer or union sponsor shall file an annual application with CMS that meets the requirements of this section and related sections, for each qualified retiree prescription drug plan maintained, including an attestation as to actuarial value.

The burden associated with this requirement is the time and effort necessary for an entity to submit the application to CMS. The requirements of this part state that an application must provide sponsor and plan identification information, together with an actuarially-certified attestation that the actuarial value of the retiree prescription drug coverage in each plan (benefit option) is at least equal to the actuarial value of standard Medicare Part D prescription drug coverage in accordance with actuarial guidelines established by CMS in accordance with generally accepted actuarial principles. If there is a change during the year that materially affects the actuarial value of their drug coverage, sponsors will need to submit an updated attestation. Sponsors will also be required to collect identifying information on their qualifying covered retirees and submit this information with their application, along with a signed sponsor agreement. If we determine that a sponsor of a retiree prescription drug program meets all of the requirements of this section, we will send to the sponsor a written notification regarding the sponsor's eligibility to receive a subsidy payment along with a list of qualified retirees that has been verified with the Medicare Beneficiary Database (MBD).

For each entity we estimate an average of 2 hours administrative work to assemble the application, 31 hours for systems changes to extract identifying information on qualifying covered retirees, about 7 hours for preparation of the actuarial attestations, and about 30 minutes to sign the required sponsor

agreement, for a total of approximately 40.5 hours, for each prescription drug plan (benefit option). The 7–hour estimate for preparation of actuarial attestations represents an average and varies substantially across firm size (see the economic impact section of this proposed regulation for the analysis pertaining to the range of time needed for sponsors of various sizes and numbers of plans).

For the number of entities applying for the subsidy, we have used 50,000, our estimate of the total number of public, private, and union sponsors projected to offer retiree prescription drug coverage in 2005. We have estimated on the basis of this figure in order to calculate the highest potential burden.

The total burden for preparation and filing of the 2005 applications for 50,000 sponsors is 2,025,000 hours. We also estimate that 5 percent of the initial applications may have to be re-filed due to mid-year changes to drug coverage that materially affect actuarial value. We estimate 101,250 hours for this activity.

(e) Each entity must disclose the creditable coverage status for each prescription drug plan to CMS in a form and manner described by CMS. We estimate this activity to take about 1 hour each for a total of approximately 50,000 hours. Additionally, in future years, each entity must notify CMS of any changes in creditable coverage status for an average annual burden of 1 hour.

In addition, each entity must notify each Part D eligible individual of the plan's creditable coverage status in a form and manner prescribed by CMS. The burden associated with the sponsor notices is required by § 423.56 of the proposed regulation, as discussed earlier in this analysis.

For the sponsors of retiree drug coverage, we estimate that it will take 50,000 entities approximately 8 hours each to produce a standardized notice for a total of 400,000 burden hours.

Since each entity can include initial disclosure notices in existing beneficiary plan materials, which are already being disseminated to their participants, we estimate that this will involve a negligible amount of time. Additionally, in subsequent years, on average, we estimate that each entity will provide 13 additional separate notices to individuals upon request for an annual burden of about 1 hour. We also estimate that in subsequent years some of these sponsors of retiree coverage will provide notices of a change in creditable coverage for an average annual burden of 8 hours. We estimate that the annual burden associated with providing notices prior to the ACEP in subsequent years will be negligible, since they will be able to include these notices in their existing plan materials with minimal modifications.

If an individual establishes to CMS that he or she was not adequately informed that he or she no longer had creditable prescription drug coverage or the coverage is involuntarily reduced, the individual may apply to CMS to have the coverage treated as creditable coverage so as to not be subject to the late enrollment fee described in § 423.46. The burden associated with this requirement is the time and effort necessary for an individual to apply to CMS to have such coverage treated as creditable coverage. While we have no way of determining how many individuals will apply to CMS, for the purpose of providing an upper bound estimate for public comment we estimate that on an annual basis it will take 100,000 individuals 15 minutes to apply to CMS, for a total of 25,000 hours.

(f) The employer or union sponsor of the plan must maintain the records outlined in this section for 6 years after the expiration of the plan year in which the costs were incurred.

The burden associated with this requirement is the time and effort necessary for an entity to maintain the required documentation for six years. We estimate that on an annual basis it will take 50,000 entities 20 hours in total to retain the required documentation prescribed in this section and in § 423.888(d), for a total of 1,000,000 burden hours. We believe that for a small firm the total number of hours required for record retention will be less than 20 hours, but for purposes of the PRA we assume 20 hours for firms of all sizes.

• § 423.888 Payment methods, including provision of necessary information.

(b) and (c) To receive payment under this section, each qualified entity must submit information in a form and manner and at such times provided in this paragraph and under other guidance specified by CMS, by the sponsor or any party designated the sponsor.

If a sponsor elects to receive monthly or quarterly retiree subsidy payments or an interim annual retiree subsidy payment, the plan sponsor must submit aggregated gross cost data, an estimate of the difference between these gross costs and allowable costs (based on expected rebates and other price concessions), and any other data CMS may require upon submission of data for payment at each of the time intervals elected by the sponsor, with a final reconciliation within 15 months after the end of the plan year. For final reconciliation purposes, sponsors must submit total gross cost data segregated per qualifying covered retiree; actual rebates, discounts or other price concessions received with respect to such costs; and any other data CMS may require, within 15 months after the end of the plan year. In addition, plan sponsors are required to provide on a monthly basis an update to their enrollment file, (for example, accretes and deletes).

The burden associated with this requirement is the time and effort necessary for an entity to submit the required data and information that meets the requirements of this section. We estimate that on an annual basis it will take 50,000 entities 17 hours to provide the required documentation, for a total of 850,000 burden hours. The 17–hour estimate reflects an average across firms of various sizes and reflects our expectation that the time involved in the data submission process will be lessened by the development of automated systems to calculate this information. (See the regulatory impact analysis for more detailed discussion of these estimates.)

(d) Participating entities must maintain the records outlined in this section for 6 years after the expiration of the plan year in which the costs were incurred and fully meets the requirements of this section.

The burden associated with this requirement is the time and effort necessary for an entity to maintain the required documentation for six years. We estimate that on an annual basis it will take 50,000 entities 20 hours to retain the required documentation prescribed in this section and in § 423.884(e), for a total of 1,000,000 burden hours.

• § 423.890 Appeals

The information collection requirements set forth in this section are exempt from the PRA as stipulated in 5 CFR 1320.4.

• § 423.892 Change in Ownership.

(c) A sponsor who is contemplating or negotiating a change of ownership must notify CMS at least 60 days before the anticipated effective date of the change. We estimate that approximately 5 percent of sponsors will fall into this category in a given year.

The burden associated with this requirement is the time and effort necessary for a sponsoring entity to submit the required notification to CMS. On an annual basis it will take 2,500 entities (5 percent of 50,000) about 30

minutes to submit the required notification to CMS, for a total of approximately 1,250 burden hours.

Subpart S—Special Rules for States-Eligibility Determinations for Low-Income Subsidies and General Payment Provisions.

• § 423.904 Eligibility determinations.

Paragraph (b) of this section states the State agency must inform CMS of cases where eligibility is established or redetermined.

The burden associated with the requirement on State agencies to inform CMS of cases where eligibility is established or redetermined is estimated to total approximately 11,220 annual hours. We estimate that there will be approximately 600,000 of these cases on an annual basis. We also estimate that it will take approximately 10 hours per month for the State agency to inform CMS of these cases.

Paragraph (d) of this section requires States to make available—low-income subsidy application forms, information on the nature of, and eligibility requirements for the subsidies under this section, and offer assistance with the completion of the application forms. States must require an individual or personal representative applying for the low-income subsidy to complete all required elements, provide documents as necessary, and certify as to the accuracy of the information provided. In addition, States must provide CMS with other information as specified by CMS that may be needed to carry out the requirements of the Part D prescription drug benefit.

The burden associated with the requirement on States to make available the information specified in this section is subject to the PRA; however, we believe the burden for this requirement to be a reasonable and customary business practice; therefore, imposes no additional burden on the States.

The burden associated with the requirement on States to require the applicant of the low-income subsidy to complete all required elements, to provide documents, and to certify as to the accuracy of the information is subject to the PRA; however, the burden associated with this requirement is discussed in § 423.774 above.

The burden associated with the requirement on States to provide CMS with other information as specified by CMS is estimated to total approximately 1,020 annual hours. Since it is difficult to determine at this time the volume of information CMS will request, we are estimating that it will take on average 20 hours per State on an annual basis to provide CMS with the specified information.

• § 423.907 Treatment of Territories

Paragraph (a) of this section discusses the requirements on territories to submit plans for approval by the Secretary to receive increased grants. This paragraph states that a territory may submit a plan to the Secretary under which medical assistance is to be provided to low-income individuals for the provision of covered Part D drugs. Paragraph (b) of this section describes what a plan must include.

The burden associated with this requirement is the time and effort of territories to prepare and submit a plan for approval. While this requirement is subject to the PRA, we estimate that this requirement would affect only 5 territories; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

• § 423.910 Requirements.

(c) This subpart sets forth the requirements for State contributions for Part D drug benefits based on dual eligible drug expenditures. It requires States to submit MSIS data to provide accurate and complete coding to identify the numbers and types of Medicaid and Medicare dual eligibles in their MSIS data submittals.

The burden associated with the requirement on States to provide accurate and complete coding in their MSIS data submittals is subject to the PRA; however, this requirement is already approved under OMB ı0938–0502 with a current expiration date of January 31, 2006.

(d) The subpart also requires States to submit an electronic file, in a manner specified by the Secretary, identifying each full benefit dual eligible enrolled in the State for each month with Part D drug coverage who is also determined to be full benefit eligible by the State for full Medicaid benefits.

The burden associated with the requirement on States to submit an electronic file identifying each full benefit dual eligible enrolled in the State for each month with Part D drug coverage is estimated to total approximately 120 hours per State on an annual basis. We estimate that it will take approximately 10 hours for each State to submit an electronic file on a monthly basis. Therefore, we estimate a total burden of 6,120 hours on an annual basis. Startup development effort is estimated at 100 hours per State for a total of 5,100 hours.

Subpart T—Financial Relationships Between Physicians and Entities Furnishing Designated Health Services.

Subpart T does not contain any requirements subject to the PRA.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare and Medicaid Services

Office of Strategic Operations and Regulatory Affairs,

Attn: John Burke (CMS–4068–F)

Room C5–13–28, 7500 Security Boulevard,

Baltimore, MD 21244–1850;

and Office of Information and Regulatory Affairs,

Office of Management and Budget,

Room 10235, New Executive Office Building,

Washington, DC 20503,

Attn: Christopher Martin, CMS Desk Officer (CMS–4068–F),

christopher__martin@omb.eop.gov. Fax (202) 395–6974

V. Regulatory Impact Statement

A. Overall Impact

We have examined the impacts of this rulemaking under Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism, and the Congressional Review Act (5 USC 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impact and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). Our estimate is that this rulemaking is ''economically significant'' as measured by the $100 million standard, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a regulatory impact analysis.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amends Title XVIII of the Social Security Act (the Act) to create a voluntary prescription drug benefit within the Medicare program beginning in 2006. The Medicare prescription drug benefit will make prescription drugs more affordable for beneficiaries by offering subsidized Medicare prescription drug coverage to all beneficiaries, with even more generous assistance available to low-income

beneficiaries. We believe that this is an important step in modernizing the Medicare program to better meet beneficiaries' needs. We anticipate that by giving beneficiaries access to affordable insurance coverage that helps them to pay for their outpatient prescription drugs—which have become a critical component in the delivery of comprehensive, quality health care services—the Medicare prescription drug benefit will help beneficiaries to lead healthier, more productive lives, while also helping to improve the effectiveness of the Medicare program.

The MMA also includes provisions to help employers and unions continue to provide drug coverage to their Medicare eligible retirees that is at least as generous as the new Medicare coverage. The MMA authorizes Medicare to make retiree drug subsidy payments to employers and unions that provide qualified retiree prescription drug coverage to beneficiaries who do not enroll in a Part D plan. This retiree drug subsidy provides special tax-favored payments to the sponsors of qualified retiree health plans. The retiree drug subsidy program has highly flexible rules that permit employers and unions to retain their current plan designs that are at least equivalent to the standard Part D benefit while using the drug subsidy to reduce the cost of providing generous coverage.

With the trend toward declining retiree health insurance coverage that has occurred over the past decade, the Medicare retiree drug subsidy is intended to ''help employers [to] retain and enhance their prescription drug coverage so that the current erosion in coverage would plateau or even improve'' (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Conference Report, p. 53).

Medicare Part D also offers employers and unions a variety of other options for continuing to assist their Medicare retirees, and our final regulation reflects comments on how Medicare can best implement all of these approaches to achieve the maximum support for retiree coverage. In addition to having the opportunity to obtain the Medicare retiree drug subsidy, employers and unions can choose to provide additional drug coverage to their Medicare-eligible retirees through or in coordination with Part D by encouraging their Medicare-eligible retirees to enroll in Part D (with Medicare subsidizing the costs of their standard Part D benefits), and providing enhanced or supplemental coverage over and above the standard Part D benefit. This can be achieved by either providing separate supplemental drug coverage that wraps around a Part D plan (similar to policies that wrap around Medicare benefits under Part A and Part B), arranging for a Part D plan (that is, a Part D plan (PDP) or Medicare Advantage Prescription Drug Plan (MA-PD)) to provide enhanced benefits to their retirees, or choosing through waivers to become a Part D plan that offers enhanced benefits to their retirees. In all of these cases, financial support from the new Medicare benefit and retiree drug subsidy can augment contributions by employers and unions to provide a more generous and less costly drug benefit for retirees than is possible through employer/union support alone.

We described this range of employer/union options in our proposed rule and in a subsequent white paper and public meetings, and we received extensive public comments on the key issue of how this combination of employer/union options can be used to achieve maximum support for retiree drug coverage. Based on the public comments and further analysis, we believe that the mechanism for implementing options for strengthening employer and union coverage with Medicare Part D, including the Medicare retiree drug subsidy and the other opportunities it affords employers and unions for providing continued prescription drug assistance to their Medicare retirees, will result in combined aggregate payments by employers/unions and Medicare for drug coverage on behalf of retirees that are significantly greater than they otherwise would have been without the enactment of the MMA. Furthermore, the Medicare prescription drug benefit and retiree drug subsidy represent a particularly important strengthening of health care coverage for future Medicare-eligible retirees, given the erosion in the availability and generosity of employment-based retiree coverage for future Medicare beneficiaries that has already been taking place, as is discussed in further detail subsequently in this impact analysis.

We have updated our impact analysis from what was presented in our August 3, 2004 proposed rule. Our update reflects responses to public comments, changes due to final policy and implementation decisions, improvements to the analysis based on additional information and new research studies (see, for example, our discussion of the financial value of the Part D benefit to beneficiaries), and updated data and actuarial and economic assumptions. A discussion of our updated assumptions and the effects of these various changes is presented subsequently in the impact analysis.

We estimate that in calendar year (CY) 2006 about 39 million Medicare beneficiaries will receive creditable drug coverage either through a Medicare Part D plan (including beneficiaries who receive additional drug coverage or premium assistance from other sources such as a former employer or union), or through an employer/union sponsored retiree plan that is eligible for the Medicare retiree drug subsidy. By CY 2010, with growth in the overall Medicare population, we estimate that about 42 million Medicare beneficiaries will receive such coverage.

The Medicare drug benefit, including the retiree drug subsidy, will lead to an increase in Federal spending on Medicare benefits and a decrease in Federal spending on Medicaid benefits (as dual eligibles' drug coverage is shifted from Medicaid to Medicare). The net effect of these changes on Federal outlays is estimated to be about $49 billion in CY 2006 and about $68 billion in CY 2010, with the total effect estimated to be roughly $293 billion over the period from CY 2006–2010. The vast majority of this Federal spending is on Medicare subsidies that defray the cost of the Medicare drug benefit for beneficiaries, that provide substantial additional cost-sharing and premium assistance to low-income beneficiaries, and that make it more affordable for employers and unions to continue to provide and support high quality retiree drug coverage. We also anticipate that some of the Federal spending will generate savings for States, as responsibility for drug coverage for full-benefit dual eligibles is shifted from Medicaid to Medicare and as State spending on State prescription drug assistance programs is likely to be at least partly displaced by the Medicare drug benefit. We also estimate that more eligible low-income beneficiaries will enroll in Medicaid and other low-income benefits, in addition to the comprehensive Medicare drug benefit, as a result of the additional value of the drug benefit and unprecedented beneficiary outreach activities. Taking together the various State savings and costs related to Medicare Part D, we estimate that the Medicare drug benefit will lead to net State budgetary savings of about $1.0 billion in CY 2006 and $2.2 billion in CY 2010, with total net savings of about $7.9 billion over the period from CY 2006–2010.

As discussed in more detail in section L of the impact analysis, from both an economic and budgetary accounting perspective, Federal spending on the Medicare drug benefit largely represents transfers of Federal budget revenue from taxpayers to Medicare beneficiaries and

retiree plans sponsored by private and public sector employers and unions. Also, from an economic perspective, there is effectively a transfer of Federal budget revenues from taxpayers to State governments, as Medicare pays for some of the costs of drug coverage for full-benefit dual eligibles that had been previously paid for by States and as the Medicare drug benefit displaces some State spending on prescription drug assistance programs. In addition, a portion of the Federal spending on Medicare Part D is for administrative costs incurred by PDPs and MA-PDs to administer the benefit effectively.

B. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. We anticipate that this rule would not impose costs above the $110 million UMRA threshold on State, local, or tribal governments. We have determined that this rule would not impose costs on the private sector exceeding $110 million. We note that the provisions of the Act related to electronic prescribing are dealt with in a separate rule.

1. Private Sector

The provision of this rule related to disclosure notices of creditable coverage represents a mandate on the private sector. As discussed elsewhere in this document, certain private sector entities—Medigap plans and private sector employer or union sponsored health plans that provide drug coverage to Medicare beneficiaries who are retired or who are active workers—are required to provide at certain times disclosure notices on whether the coverage provided equals or exceeds the actuarial value of defined standard Part D coverage. Later in the impact analysis we provide a discussion of the costs expected to be borne in providing such notices. The largest cost for providing these notices is expected to occur in the months preceding the implementation of the drug benefit in January 2006 when the largest volume of notices need to be provided. Following receipt of these notices, beneficiaries will be making choices regarding where they receive their drug coverage.

For private sector employers and unions that provide retiree drug coverage, the implementation of Medicare Part D, including the Medicare retiree drug subsidy program, is expected to produce net savings that far exceed the costs of the disclosure notices. This is true both for employers and unions that choose to obtain the retiree drug subsidy, and for employers and unions that decide to restructure their prescription drug coverage to provide continued assistance by supplementing the Medicare prescription drug benefit and/or paying Medicare Part D premiums.

For those private entities that will not achieve savings—Medigap insurers and employer/union group health plans that offer coverage only to beneficiaries who are active workers, not retirees—as discussed in greater detail later in this analysis, the cost of providing disclosure notices is estimated to be approximately $62 million in 2005 (which translates into an average of roughly $151 per employer/union that offers drug coverage to Medicare beneficiaries who are active workers and about $11,050 per Medigap insurer). Thus, the costs associated with the notice requirements are not expected to reach the $110 million UMRA threshold.

We also note that Section 104 of the MMA, which prohibits the sale of new Medigap policies with drug coverage or the renewal of existing Medigap policies that contain drug coverage for Medicare drug benefit enrollees, is not an unfunded mandate as defined by UMRA. This statutory Medigap prohibition does not result in the ''expenditure'' of funds by the private sector, one part of the statutory test for an unfunded mandate. For a discussion of the effect on Medigap insurers of the MMA prohibition, see section J of the impact analysis.

2. States, Local and Tribal Governments

While States will incur direct costs as a result of this rule, as discussed in greater detail in section H on State impacts, States will achieve net savings under this rulemaking, as now Medicare will be paying for prescription drug costs previously funded under Medicaid, State Pharmacy Assistance Programs (SPAPs), and State sponsored retiree health insurance, or will be providing subsidies for State sponsored qualified retiree prescription drug coverage. There are several sources of the direct costs States will incur. As described below, several of these, taken alone and without consideration of offsetting gains, would reach or exceed the threshold level in UMRA.

In order to defray a portion of the Medicare drug expenditures for full-benefit dual eligibles, States will be responsible for making monthly payments to the Federal government beginning in January 2006. These payments are estimated to be $9.0 billion in CY 2006, reaching $13.0 billion by CY 2010. These payments represent the largest direct cost to States.

States will also incur administrative costs associated with Medicare Part D. The statute gives States, as well as the Social Security Administration, responsibility for eligibility determinations for the Medicare Part D low-income subsidy. States are also responsible for screening and enrolling low-income subsidy applicants in the Medicare Savings Program. While we anticipate that the Social Security Administration will play a substantial role in Part D low-income subsidy eligibility determinations, we anticipate that States will incur some administrative costs related to these activities, including costs associated with refining their data on dual eligibles; developing eligibility determinations systems; training staff; performing eligibility determinations, re-determinations, and appeals; and screening and enrolling for the Medicare Savings program. To the extent allowable under Title XIX, Federal matching payments will be available to assist in paying for these administrative costs. We estimate that the State share of Medicaid administrative costs associated with Medicare Part D will be $39 million in FY 2004, $73 million in FY 2005, and average about $90 million per year over the period 2006 to 2010. We are undertaking collaborations with the Social Security Administration (SSA), the State Health Insurance Assistance Programs (SHIPs), and other groups to assist in outreach and enrollment, and to help minimize administrative burdens for States as much as possible. Furthermore, as discussed in more detail in the State section of the impact analysis, we anticipate that SSA will play a substantial role in the eligibility determinations process for the low-income subsidy, lessening the administrative burden on States.

In addition, States will also have revenue losses associated with the MMA prohibition on States imposing taxes on premiums related to Part D coverage. As a result of the shift of beneficiaries from prescription drug coverage subject to State premium taxes to Part D coverage, we estimate that the loss in premium tax revenue to States will be about $62 million in CY 2006, and $145 million by CY 2010, totaling about $504 million over this period. States will also incur direct costs attributable to required disclosure notices for creditable coverage. Similar to the requirement for private sector

group health plans, State governments that offer retiree health insurance benefits with drug coverage will need to provide disclosure notices to Medicare beneficiaries enrolled in those plans. States will also need to provide disclosure notices to Medicare beneficiaries who receive drug coverage through State Pharmacy Plus programs, and State Pharmacy Assistance Programs. As noted elsewhere in this document, the costs of providing such notices are small and are more than offset by the savings achieved from receiving the Medicare retiree drug subsidy (because States may also qualify for this subsidy) or through the enrollment of beneficiaries in the Part D benefit. As discussed elsewhere in the preamble we will be deeming beneficiaries who are full-benefit duals as eligible for the full low-income subsidy. As part of the notices to these beneficiaries regarding their eligibility for the low-income subsidy we will also inform them of the change to receiving their drug coverage through Medicare and that Medicaid will no longer provide creditable coverage to Medicare beneficiaries. Our notices to beneficiaries will relieve State Medicaid programs of the burden of providing disclosure notices to full-benefit dual eligibles.

As discussed in the State section of the impact analysis, the direct and indirect costs and revenue losses to States are offset by savings States will achieve as a result of the implementation of the Medicare prescription drug benefit and retiree drug subsidy. As noted in that section, the net savings to States increase over time, as the share of drug coverage costs for full-benefit dual eligibles for which States are required to compensate Medicare declines. States do, however, begin incurring administrative costs prior to implementation of Medicare Part D. We estimate that States will incur net administrative costs in FY 2005 of $73 million. These costs do not exceed the UMRA threshold. Furthermore, we estimate that State costs in 2005 will be more than offset by State savings related to Medicare Part D beginning in 2006.

Local governments that offer retiree health insurance benefits that include coverage for prescription drugs also will need to provide disclosure notices to Medicare beneficiaries enrolled in their group health plans related to that coverage. As noted previously, the costs of providing such notices are small, and are more than offset by the savings achieved either from receiving the Medicare retiree drug subsidy (because local governments may also qualify for this subsidy) or through the enrollment of beneficiaries in the Part D benefit.

We have determined that this rule does not mandate any requirements for Tribal governments.

Comment: We received comments from a number of States that asserted that Medicare Part D represents an unfunded mandate on States. Several States asserted that it is an unfunded mandate because the Federal government provides matching payment for State administrative expenses related to Medicare Part D, rather than providing 100 percent reimbursement. A few States asserted that they should not be responsible for auto-enrollment of dual eligibles and asserted that it would represent an unfunded mandate. One State asserted that eligibility determination costs in the initial start-up period would exceed the UMRA threshold.

Response: The statute gives States certain administrative responsibilities related to Medicare Part D enrollment. To the extent allowable under Title XIX, the Federal government will provide Federal matching payments for those activities, which cover at least 50 percent of State costs related to those activities. Within the context of the Unfunded Mandates Reform Act, we are obligated to determine whether this regulation imposes costs on States (as well as local and tribal governments and the private sector) in excess of $110 million in any one year.

As discussed previously, in 2005 prior to implementation of Medicare Part D, we anticipate that States will incur administrative expenses related to Medicare Part D, including refining their data on dual eligibles; developing eligibility determinations systems; training staff; performing eligibility determinations, re-determinations, and appeals; and screening and enrolling for the Medicare Savings program. We estimate that those costs are approximately $73 million in FY 2005, and consequently, do not exceed the UMRA threshold. Furthermore, savings that States achieve in future years once Medicare Part D is implemented will substantially outweigh the administrative costs they incur in 2005. Finally, with respect to the auto-enrollment responsibilities that a few States were concerned would be an unfunded mandate, the final rule indicates that these responsibilities will be handled by CMS.

C. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. Specifically, an agency must act in strict accordance with the governing law, consult with State officials, and address their concerns.

As discussed previously, the MMA and this rule have implications for States. In addition to the provisions addressed in the UMRA discussion, the statute includes specific provisions prohibiting State regulation of PDP plans, except for licensure and solvency, and permitting the Secretary to waive even State licensure and solvency requirements. The majority of these waivers, however, are temporary and may not exceed 36 months, except in the case of a State that does not have a licensing process for PDP sponsors. As specified in the MMA, we have consulted with the National Association of Insurance Commissioners (NAIC) on establishing the financial solvency and capital adequacy standards that will be used in the waiver process. In addition, because of the national nature of the Medicare Part D benefit, the statute prohibits States from limiting the amount that a PDP sponsor can recover from liable third parties under Medicare Secondary Payer provisions. Also, as discussed in the preamble, the statute preempts State any willing pharmacist laws with respect to a plan's Part D business. Finally, the statute permits Federal grievance procedures to preempt State grievance requirements for PDPs and MA-PDs. As discussed in subpart M of the preamble, we have established Federal grievance procedures that preempt State requirements because we believe that one set of grievance standards protects beneficiaries, promotes consistency among plans, and reduces confusion and burden for enrollees and plans. However, enrollees would still have access to various State remedies in cases in which an issue is unrelated to the plan's status as a PDP or MA-PD. We note that State law has been preempted in an identical way for the Medicare Advantage program, through MMA changes expanding a preemption law that had previously applied to that program. The impact analysis for the final Medicare Advantage rule (CMS 4069–F) contains a discussion of the preemption issue as it applies to these Federal programs.

As discussed earlier in this preamble, especially in subpart I, we received a number of comments on preemption issues. Our responses to these comments are included in subpart I and other relevant preamble sections. Although most of these comments

opposed the broad scope of the MMA's preemption clauses, the Congress intended to provide that scope and it is necessary to the operation of the prescription drug program. Should any issues of interpretation arise in any particular State, we would work with that State to resolve these issues.

In addition, we have also consulted extensively with States regarding the numerous provisions related to the Medicare prescription drug benefit that have implications for States. Among these, our Center for Medicaid and State Operations has regular meetings with State Medicaid Directors and has used these opportunities to provide our State partners with information about the MMA. For example, in March 2004, we held conference calls with State representatives to provide them with an overview of the MMA and information on what to expect during implementation, to discuss the provisions in the statute dealing with State payments to the Federal government under Section 103 of the MMA, and to allow States to raise issues about the implementation process. In April and May 2004, we held conference calls with State representatives to discuss the calculation of State phased-down contribution, definition of ''full-benefit dual eligibles'', excluded drugs, enhanced FMAP on family planning drugs, and related State payment issues. We have also organized a group of interested States to work collaboratively on proposals for addressing the managed care adjustment component of the phase-down calculation. We have set up special email addresses for phase-down issues so that States may send questions and communicate specific concerns to the appropriate experts.

We are currently working with State Medicaid Directors, State Pharmaceutical Assistance Program staff, and State Health Insurance Assistance Program (SHIP) counseling staff to raise awareness of the Medicare prescription drug discount card program, and we are building on those efforts for the implementation of the Medicare Part D prescription drug benefit. In August of 2004, we convened the State Issues Workgroup, which includes State Medicaid Directors (including members of the Executive Council of the National Association of State Medicaid Directors), SSA, and CMS. The purpose of this group is to identify all significant issues and concerns related to Medicare Part D (and other MMA changes) that affect States and to identify potential solutions, including providing recommendations for data exchanges and systems processes and developing a protocol for working with SSA on training and outreach associated with the low-income subsidy. Numerous meetings and conference calls of the full workgroup and its five subgroups have already taken place. The efforts of this workgroup are continuing and have been extremely valuable in identifying State issues and concerns and potential solutions. We have also been working with the State Pharmaceutical Assistance Transition Commission, which was established by the statute, to provide support and technical assistance as it develops recommendations for addressing the unique transitional issues facing SPAPs. In addition, we have consulted with the NAIC on Medigap issues.

The Medicare retiree drug subsidy is an optional program that public or private sector employers or unions may choose to participate in if they offer qualified retiree prescription drug coverage. Like other plan sponsors, State and local governments that offer qualified retiree prescription drug coverage and wish to receive Medicare retiree drug subsidy payments will need to comply with the reporting requirements of this rule, such as attestation of actuarial equivalence and certain data reporting necessary for calculating the retiree drug subsidy payments. However, these are not requirements because no public or private employer or union need apply for Medicare retiree drug subsidy payments. Thus, we have determined that the retiree drug subsidy provisions of this rule would not impose direct costs on State and local governments. In addition, we have been conducting outreach to prospective applicants for Medicare retiree drug subsidy payments, including public sector employers, for example through open door forums and an educational web cast, in an effort to better understand the needs of this segment of the employer community, share information about the Medicare retiree drug subsidy program and its implementation. We have also had discussions with representatives of individual State retiree benefit systems, as well as the National Conference on Public Employee Retirement Systems, to hear their concerns about the retiree subsidy program.

D. Limitations of the Analysis

The following analyses present projected effects of this rule on Medicare beneficiaries, the Federal budget, States, private sector organizations that provide drug coverage to Medicare beneficiaries, and small entities. Unless otherwise noted, all estimates in this impact analysis are net budgetary spending based on calendar year data.

We have updated our impact estimates from what was presented in our August 3, 2004 proposed rule. Since publication of the proposed rule, we have continued to refine our assumptions and estimates of Medicare Part D impacts to take into account policy decisions made in the final rule and to incorporate more up-to-date data, additional research, information from industry experts, and public comments on the expected impact of Medicare Part D. The estimates presented in this rule are a result of those efforts and represent our best estimate of the likely effects of Medicare Part D. Discussion of the public comments and the updates made to our estimates is included in the relevant sections of the impact analysis.

While we believe the estimates in this final rule represent our best estimate of the likely impact of Medicare Part D, we emphasize that there is considerable uncertainty in these estimates and the discussion throughout the impact analysis reflects this. Because 2006 will be the first year of the Medicare prescription drug benefit and retiree drug subsidy program, we do not have program experience from prior years. In estimating the impact of a completely new program, there are limited data and considerably greater uncertainty than would be the case with modifications to existing programs. Furthermore, we note that analyses in the 2004 Medicare Trustees Report (currently available) and in future annual Trustees Reports, including the 2005 Medicare Trustees Report (forthcoming in spring 2005), can provide a sense of the range of uncertainty inherent in these types of estimates. (The Trustees Report is available on the CMS website at *http://www.cms.hhs.gov/publications/trusteesreport/*).

E. Enrollment Estimates

1. Summary

Table IV–1A shows for CY 2006–2010 our estimates of the number of beneficiaries projected to receive creditable drug coverage through a Medicare Part D plan (that is, by enrolling in a PDP or MA-PD), or through an employer/union sponsored retiree plan that is eligible for the Medicare retiree drug subsidy. We estimate that in CY 2006 about 39 million Medicare beneficiaries will receive drug coverage either through a Medicare Part D plan or through an employer/union sponsored retiree plan that is eligible for the Medicare retiree drug subsidy. By CY 2010, due to growth in the overall Medicare

population, we estimate that about 42 million Medicare beneficiaries will be receiving such coverage.

Tables IV–1B and 1C provide further details on these estimates. Table IV–1B shows for CY 2006–2010 our estimates of the number of beneficiaries projected to receive drug coverage through a Medicare Part D PDP or MA-PD, and the number of individuals receiving the low-income subsidy. In 2006, we estimate that about 29 million beneficiaries will receive their drug coverage through a Part D plan. We estimate that this number will grow to about 35 million in 2010.

As mentioned previously, Medicare Part D offers additional assistance with Medicare drug benefit cost-sharing and premiums to low-income beneficiaries who meet certain income and assets requirements. We estimate that about 10.9 million beneficiaries will enroll in the Medicare Part D low-income subsidy program in CY 2006. Among low-income subsidy participants, we estimate that in 2006 about 6.3 million would be full-benefit dual eligibles, about 3.0 million would be other beneficiaries with income less than 135 percent of FPL and meeting the lower assets test (including newly enrolled beneficiaries in the Medicare Savings Program), and 1.6 million would be other beneficiaries with income less than 150 percent of FPL and meeting the higher assets test. By 2010, we estimate that 11.8 million beneficiaries will be receiving the low-income subsidy.

Table IV–1C presents estimates related to employment based retiree drug coverage. The table includes an estimate of the number of Medicare beneficiaries who would have employment-based retiree drug coverage absent the law change, including those with access-only coverage where the beneficiary pays the entire premium. For the population with retiree coverage, the table presents estimates of their anticipated sources of drug coverage following implementation of Medicare Part D. Our estimates of drug coverage for these beneficiaries reflect the various options that are available to employers and unions through the Medicare prescription drug benefit and the Medicare retiree drug subsidy for continuing to provide prescription drug assistance to their retirees.

In 2006, we estimate that 11.4 million beneficiaries would have had retiree drug coverage absent the law change.[5] We estimate that 9.8 million of these Medicare beneficiaries will receive creditable drug coverage through an employer/union sponsored retiree plan that is eligible for the Medicare retiree drug subsidy, and that 0.4 million will receive drug coverage through a PDP or MA-PD plan, with their previous employers/unions offering enhanced benefits or providing wraparound or coordinated coverage. We also estimate that 1.3 million beneficiaries will enroll in the standard Part D drug benefit through a PDP or MA-PD, including those who receive additional employer/union premium assistance or other financial assistance and those who will benefit from the more generously subsidized coverage of Medicare Part D (for example, those who would otherwise have had unsubsidized ''access-only'' employer plans that are becoming increasingly common). We note that recent employer surveys suggest significant interest in providing comprehensive drug benefits through additional supplemental or wraparound coverage. Depending upon the amount of time it may take employers/unions to adopt such approaches, it is possible that the provision of wraparound coverage might be more prevalent in the earlier years of Medicare Part D.

In 2010, we estimate that 11.8 million beneficiaries would have had retiree drug coverage absent the law change. By 2010, we estimate that 7.2 million beneficiaries will be receiving creditable drug coverage through an employer/union sponsored plan that is eligible for the Medicare retiree drug subsidy, and 2.4 million will have drug coverage through a PDP or MA-PD plan while also receiving enhanced benefits or wraparound coverage through their former employers or unions, including Part D plans that employers or unions are sponsoring under waivers. We note, however, that there is a great deal of uncertainty in estimating employers' and unions' responses to the various options available under Medicare Part D and the retiree subsidy. As discussed in greater detail subsequently, these estimates do reflect our expectation that, over time, some employers and unions will choose to take advantage of the other opportunities for continuing to provide high quality retiree drug coverage that are available to them under Medicare Part D—by transitioning from providing drug coverage that qualifies for the retiree subsidy to providing their own enhanced Part D plan (through waivers), purchasing enhanced Part D coverage, or providing supplemental drug coverage that wraps around Medicare Part D.

Given the trends in decreasing generosity of employment-based retiree coverage and the increasing provision of ''access-only'' coverage, we also estimate that by 2010 approximately 2.3 million beneficiaries will receive drug coverage through standard Medicare Part D plans, including those receiving additional premium assistance or other financial assistance from their former employers or unions, and those who may benefit from the more generously subsidized coverage of Medicare Part D. For example, recent employer surveys have shown that more new retirees are paying a larger share of the cost of their retirement benefits, with new retirees in about 20 percent of large private-sector firms (1,000 or more employees) having ''access-only'' benefits in which they receive no employer premium subsidy. Assuming this trend continues, increasingly more of the retirees with employer/union coverage would be paying for much or all of the cost of their retiree drug coverage in the absence of the law change. With the availability of Medicare Part D drug coverage these beneficiaries will gain access to a generous subsidized benefit.

These enrollment estimates above have been updated from those that were presented in the August 3, 2004 proposed rule. A discussion of how these estimates have been updated to incorporate policy decisions made in the final rule and to take into account additional information and data is included in the following section on projection assumptions.

[5] This figure includes Federal retirees.

TABLE IV–1A. TOTAL BENEFICIARIES ESTIMATED TO RECEIVE CREDITABLE DRUG COVERAGE, EITHER THROUGH MEDICARE PART D PLANS (PDPS OR MA-PDS), OR THROUGH EMPLOYER/UNION SPONSORED RETIREE PLANS THAT ARE ELIGIBLE FOR THE MEDICARE RETIREE DRUG SUBSIDY, CY 2006–2010

	2006	2007	2008	2009	2010
Total Beneficiaries Receiving Creditable Drug Coverage Through a Medicare Part D Plan or Through an Employer/Union Sponsored Retiree Plan That Is Eligible For the Medicare Retiree Drug Subsidy	39.1	39.8	40.5	41.4	42.2

TABLE IV–1B. BENEFICIARIES ESTIMATED TO RECEIVE PRESCRIPTION DRUG COVERAGE THROUGH MEDICARE PART D PLANS (PDPS OR MA-PDS), CY 2006–2010

	2006	2007	2008	2009	2010
Total Beneficiaries Enrolling in Medicare Part D Plans (including those receiving additional assistance from employers/unions, see Table IV–1C)	29.3	30.6	32.0	33.5	35.1
Subtotal Medicare Part D Enrollees Receiving Low-Income Subsidy	10.9	11.1	11.3	11.6	11.8
—Full-Benefit Dual Eligibles	6.3	6.4	6.6	6.7	6.8
—Other beneficiaries with income less than 135% FPL and meeting the lower assets test*,**	3.0	3.1	3.2	3.2	3.3
—Other beneficiaries with income less than 150% FPL and meeting the higher assets test*	1.6	1.6	1.6	1.7	1.7
Subtotal Medicare Part D Enrollees Not Receiving Low-Income Subsidy	18.4	19.5	20.7	21.9	23.2

* In CY 2006, an individual beneficiary must have assets not in excess of $6,000 ($9,000 per couple) for the lower assets test and $10,000 per individual ($20,000 per couple) for the higher assets test. In years after 2006, these dollar amounts will be indexed to the Consumer Price Index.

** This group includes beneficiaries deemed eligible for the full low-income subsidy based on their status as QMB, SLMB, or QI individuals, or as recipients of SSI benefits, including those beneficiaries who we estimate will newly enroll in the Medicare Savings Program. In 2006, this is estimated to be approximately 2 million individuals.

Note: Numbers may not sum to total due to rounding.

TABLE IV–1C. ESTIMATES RELATED TO EMPLOYER/UNION SPONSORED RETIREE DRUG COVERAGE, CY 2006–2010[1]

Estimated beneficiary counts (in millions)	2006	2007	2008	2009	2010
Total beneficiaries with employment-based retiree drug coverage absent the law change*	11.4	11.5	11.6	11.7	11.8
Beneficiaries receiving creditable drug coverage through an employer/union sponsored retiree plan that is eligible for the Medicare retiree drug subsidy	9.8	9.1	8.5	7.8	7.2
Beneficiaries enrolling in Medicare Part D through PDP or MA-PD plans and receiving enhanced benefits or wraparound coverage through their former employer or union	0.4	0.9	1.4	1.9	2.4
Beneficiaries enrolling in the standard Medicare Part D benefit through PDP or MA-PD plans (including, for example, those receiving additional premium or other financial assistance from their former employer or union, and those previously enrolled in "access only" retiree plans)	1.3	1.5	1.8	2.0	2.3

Note: Numbers may not sum to total due to rounding.

* Includes Federal retirees.

2. Projection assumptions

We project that there will be nearly 43 million beneficiaries entitled to or enrolled in Medicare Part A or enrolled in Medicare Part B in 2006 who will be eligible for Medicare Part D. We estimate that about 91 percent of these beneficiaries, about 39 million, will receive creditable drug coverage either through a Medicare Part D plan (that is, a PDP or MA-PD) or through an employer or union-sponsored retiree plan that is eligible for the Medicare retiree drug subsidy.

First, we assume that Medicare beneficiaries who are active workers (or spouses and dependents of active workers) and who have employment-based insurance as their primary payer with Medicare as a secondary payer (MSP), will not participate in Medicare Part D at this time. Since these beneficiaries receive coverage that is related to active worker employment, and they are not retirees (or spouses/dependents of retirees), their plan sponsors would not be able to claim the Medicare retiree drug subsidy on their behalf. In addition, we believe that it is unlikely that these beneficiaries will enroll in the Medicare drug benefit at this time. These beneficiaries are likely to have creditable drug coverage and that coverage would be the primary payer (if their employer is subject to MSP requirements by virtue of having 20 or more employees, or 100 or more employees in the case of disabled

workers) regardless of enrollment in the Medicare drug benefit. In the future, when these beneficiaries retire, they will have an opportunity to enroll in Medicare Part D without being subject to a late enrollment penalty as long as they had creditable drug coverage through their previous primary group health plan.

Second, we assume that all full-benefit dual eligibles and other beneficiaries who are deemed to be full subsidy eligibles (that is, QMBs, SLMBs, QIs, and beneficiaries with Supplemental Security Income (SSI)) will enroll in the Medicare drug benefit. As discussed in the preamble for subpart B, there will be automatic processes put in place to ensure that full-benefit dual eligibles will be automatically enrolled in a Medicare Part D plan. In addition, we will establish a facilitated enrollment process for non-full-benefit dual eligible individuals who are deemed or determined eligible for the low-income subsidy.

Third, among all other Part D eligible beneficiaries, except those beneficiaries estimated to have retiree drug coverage absent the law change who are discussed later, we assume 95 percent uptake among these beneficiaries, with the exception of beneficiaries who have very low drug spending (that is, beneficiaries with spending in the lowest quintile) for whom we assume about 71 percent uptake. We anticipate somewhat lower uptake among beneficiaries with very low drug spending because some may decide to forgo enrollment in Part D, since there is the possibility that they may pay more in premiums than they realize in savings in a particular year. However, we assume that the majority of beneficiaries with very low drug spending will choose to enroll in Medicare Part D to gain protection against higher drug costs, including catastrophic costs, that they could experience in the future. In addition, given the presence of the late enrollment penalty, we expect that many beneficiaries with low drug spending will enroll in Medicare Part D at the outset of the program, recognizing that they will very likely achieve savings in subsequent years as they age and have increasing drug costs.

Our uptake assumptions for this group of beneficiaries are slightly lower than those used in the proposed rule. In the proposed rule, we assumed that 99 percent of these beneficiaries would enroll in Medicare Part D. While we have lowered our uptake assumptions slightly based on additional research and technical discussions, as well as input from public comments, we continue to believe that there will be very high uptake of Medicare Part D for a number of reasons. This expectation is based in part on the experience of high participation rates in Medicare Part B, but on other factors as well. The standard Medicare Part D benefit shares several similar features with Medicare Part B that encourage enrollment. Both are subsidized benefits, where the beneficiary premium is set at roughly 25 percent of the cost of the insurance, with the government providing a subsidy to cover the remaining 75 percent. In addition, under both Part B and Part D, beneficiaries face a late enrollment penalty or surcharge (in the form of higher premiums) unless they enroll within the initial enrollment period, have met creditable coverage requirements in the case of Medicare Part D, or have met certain other requirements that occur in a limited number of circumstances. We think that beneficiaries' concern about current prescription drug costs and the likelihood that an elderly or disabled individual will have even greater need for prescription drugs as they age, in combination with the late enrollment penalty, will promote high initial enrollment in the Medicare drug benefit.

Other features of the Medicare drug benefit are also likely to encourage high enrollment. In addition to the Federal subsidy of the beneficiary premium (which is a part of the standard benefit), a subset of beneficiaries, specifically those who meet certain income and assets requirements, are eligible for additional low-income subsidies. We along with the Social Security Administration will be conducting aggressive outreach efforts to individuals eligible for the low-income subsidy. In addition, we expect that States will also be doing outreach particularly related to the lower income population. For example, many States have been working with us to facilitate enrollment of beneficiaries participating in State Pharmaceutical Assistance Programs into the Medicare drug discount card program (including auto-enrollment arrangements for some States). In addition, as discussed elsewhere in the preamble, the MMA also provides for transitional grants to States with Pharmaceutical Assistance Programs in each of fiscal years 2005 and 2006 to among other things help facilitate enrollment in Part D. Also as discussed elsewhere in the preamble, to facilitate the enrollment process for low-income beneficiaries our final regulation includes auto-enrollment for the full-benefit dual eligibles and we will also implement steps to facilitate enrollment for other individuals who are determined or deemed eligible for the low-income subsidy. In addition, any beneficiary currently enrolled in an MA plan that offers any prescription drug coverage (as of December 31, 2005) would be deemed to be enrolled in an MA-PD plan offered by that same organization as of January 1, 2006.

Also, in the months preceding the implementation of the Part D benefit, beneficiaries who have drug coverage (other than full-benefit duals, who will be deemed) should receive disclosure notice information from the entities from which they receive that coverage regarding enrollment in the Medicare prescription drug benefit and the applicability of the late enrollment penalty. These notices from other sources are in addition to the extensive outreach efforts that CMS and SSA will conduct.

Fourth, for those beneficiaries who we anticipate would have employer or union sponsored retiree drug coverage (including unsubsidized coverage) absent the law change, we made assumptions about their anticipated sources of drug coverage following implementation of Medicare Part D. We begin by making assumptions about the percent of beneficiaries (excluding those with MSP) that would have employer or union sponsored retiree drug coverage absent the law change. In 2006, we assume that 28 percent of beneficiaries—11.4 million—would have retiree drug coverage from a former employer or union absent the law change. By 2010, we assume that about 27 percent of beneficiaries—11.8 million—would have employer or union sponsored drug coverage absent the law change. Since the availability and generosity of retiree drug coverage has been declining over the last decade, we assume that absent the law change there would be a continuation of this baseline trend. However, the number of beneficiaries that we estimate would receive employer or union sponsored retiree drug coverage absent the law change actually increases due to growth in the Medicare population.

We next make assumptions about sources of future drug coverage for these beneficiaries after the implementation of the Medicare prescription drug benefit and the retiree drug subsidy. In making these assumptions, we took into account that Medicare Part D offers employers and unions a variety of options for continuing to provide high quality retiree drug coverage at a lower cost for both retirees and employers and unions. Employers and unions that offer retiree drug coverage that is at least actuarially

equivalent to Medicare Part D can apply for the tax-free 28 percent Medicare retiree drug subsidy (which is equal to 28 percent of allowable prescription drug costs attributable to the portion of gross prescription drug costs between $250 and $5,000 in 2006). The Medicare retiree drug subsidy lowers the cost of providing drug benefits for employers and unions that sponsor qualified retiree plans, making it more affordable for employers and unions to provide this comprehensive subsidized coverage than it would otherwise be.

In addition to the retiree drug subsidy, Medicare Part D also offers employers and unions other opportunities to continue to provide comprehensive prescription drug coverage at a lower cost. Employers and unions can choose to provide supplemental drug coverage to their Medicare-eligible retirees through or in coordination with Part D by encouraging their retirees to enroll in Part D (with Medicare subsidizing the costs of their standard Part D benefits), and paying for supplemental coverage over and above the standard Part D benefit. This can be achieved by either: 1) arranging for a PDP or MA-PD Part D plan to provide enhanced benefits to their retirees; 2) arranging for a PDP or an MA-PD under a waiver to offer a customized plan that is exclusive to the employer's retirees; 3) choosing through a waiver to become a Part D plan for their retirees that offers enhanced benefits (this is equivalent to offering a self-insured benefit); or 4) providing separate supplemental drug coverage that wraps around a Part D plan. The various options available for providing supplemental drug coverage make it possible for employers/unions to provide coverage that mimics their current benefits package, while achieving cost savings due to the Federal government subsidizing a significant portion of the cost of standard Part D coverage (a subsidy which, not taking into account the value of the reinsurance,[6] is estimated to average about $900 per beneficiary). In other words, employers/unions can offer comprehensive drug coverage by wrapping around standard Medicare Part D coverage for, on average, at least $900 less than it would cost the employer/union to do so absent the new law. This supplementation by employers/unions also results in lower Medicare costs. The supplemental employer coverage results in lower out-pocket-costs for beneficiaries, and thus fewer individuals reaching the catastrophic out-of-pocket threshold, and those that do, having lower catastrophic costs for which the government would provide reinsurance payments to Part D plans.

As discussed in more detail later in this impact analysis, employers' and unions' evaluations of the relative advantages and disadvantages of choosing among the options that are available under the MMA for assisting their retirees with prescription drug coverage (for example, taking the Medicare retiree drug subsidy versus offering enhanced prescription drug benefits through a Part D plan) will be influenced by a number of factors. For example, these include current benefit design, employer/union and retiree contributions and other financial considerations, tax status, labor relations, and contractual agreements. Regardless of whether employers and unions seek to obtain the Medicare retiree drug subsidy or provide drug coverage to their retirees by encouraging them to participate directly in the Medicare prescription drug benefit while providing enhanced benefits or wraparound coverage, Medicare Part D is estimated to significantly lower their cost of providing retiree drug coverage. Thus, the Medicare prescription drug benefit and retiree drug subsidy make the provision of employer/union sponsored retiree benefits much more affordable. The amount of financial support available under each option will vary depending in part on the characteristics of each sponsor and their retiree population. As discussed in more detail subsequently in section F.4 of the impact analysis, we estimate that retiree drug subsidy payments will average about $668 per retiree in 2006. While the tax-free nature of the retiree drug subsidy does not alter the value of the subsidy to firms without taxable income, for plan sponsors with tax liabilities, the tax-free nature of the retiree subsidy increases its value. For example, a tax free subsidy of $668 would be equivalent to a taxable payment of $891 for an employer with a 25 percent marginal tax rate and $1,028 for an employer with a 35 percent marginal tax rate. In comparison, if an employer or union chooses to provide supplemental drug coverage to standard Part D, the indirect subsidy to the employer or union excluding the value of reinsurance is estimated to average about $900 per retiree in 2006. Thus, for plan sponsors that do not have taxable income, the indirect Federal support associated with providing supplemental drug coverage to standard Medicare Part D could be larger than the support they would receive through the Medicare retiree drug subsidy. For plan sponsors that have taxable income, the level of support under the two options may be more comparable, and, depending on a plan sponsor's marginal tax rate and retiree population, could possibly be larger under the Medicare retiree drug subsidy.

In making our assumptions about employer and union sponsored retiree drug coverage, we also took into account that some sponsors currently do not provide drug coverage that has the same or greater actuarial value as Medicare Part D, and many employers provide coverage that (in contrast to Part D) is not subsidized at all. For example, in the Kaiser/Hewitt 2004 survey of large firms with at least 1,000 employees offering retiree health benefits, 5 percent of these firms reported that they believed the actuarial value of their current retiree drug benefit was less than the value of the standard Medicare Part D drug benefit, 4 percent reported that they believed their benefits were equal to Medicare Part D, and 22 percent reported that they did not know how their benefit compared to the standard Part D benefit, while 69 percent reported that they believed their benefits were greater than the standard Part D drug benefit. However, it is important to note that employers responding to the survey could not have been aware of our final approach for comparing the actuarial value of retiree drug coverage with the value of the standard Part D benefit, since the survey was conducted in 2004 before publication of this final rule (''Current Trends and Future Outlook For Retiree Health Benefits: Findings from the Kaiser/Hewitt 2004 Survey on Retiree Health Benefits,'' The Henry J. Kaiser Family Foundation and Hewitt Associates, December 2004, available at *http://www.kff.org*). Furthermore, many employers with coverage that has a high actuarial gross value do not make contributions equal to the Medicare contributions to Part D coverage, so that the employer-based retiree coverage would potentially cost more to the retiree than Part D. For example, the survey found that 19 percent of large firms require new Medicare-age retirees to pay 100 percent of the premium for retiree health insurance and another 11

[6] The relative value of the reinsurance subsidy for catastrophic coverage would be lower for retirees whose employers/unions provide supplemental drug coverage that wraps around the standard Part D benefit. Catastrophic coverage is only available when an individual's true out-of-pocket (TrOOP) expenses exceed a specified threshold, and employers/unions' contributions for supplemental drug coverage would not count toward the TrOOP threshold (thus increasing the total drug spending level at which the retiree would receive catastrophic Part D benefits).

percent require these retirees to pay 61–99 percent—a level of contribution that may not satisfy the ''no windfall'' net test for the retiree subsidy, and thus may be less than the new government subsidy on the Part D benefit. In certain cases, where employers are currently making no premium contribution or a very limited premium contribution for retiree drug coverage, beneficiaries are likely to be better off financially if they enroll in Medicare Part D, since it includes a 75 percent government subsidy of the cost of the insurance coverage. To the extent that beneficiaries without substantial employer/union subsidies enroll in Medicare Part D and to the extent that employers/unions provide additional premium or other financial assistance, the significant financial gain that such retirees would receive by enrolling in the subsidized Medicare Part D benefit would be further increased. Thus, the significant increase in total support (from employers/unions and Medicare) for retiree coverage as a result of the MMA's retiree options in part reflects the fact that many retirees who enroll in Part D plans are likely to obtain significant savings in their drug costs, particularly in future years.

In developing specific numeric assumptions about how employers and unions are likely to respond to the various options Medicare Part D offers for providing prescription drug assistance to retirees, we considered information from a number of experts in the employee benefits consulting industry, as well as recent surveys and studies that have been conducted. Among the 11.4 million beneficiaries we estimate would have retiree drug coverage in 2006 absent the law change, we assume that 86 percent would receive creditable drug coverage from an employer or union plan that is eligible for the Medicare retiree drug subsidy, 3 percent would enroll in a Medicare Part D plan and receive employer or union sponsored enhanced or supplemental drug coverage, and 11 percent would enroll in a standard Part D plan (including those who receive additional premium or other financial assistance from their former employer or union). We note that these assumptions reflect the percentage of beneficiaries whom we estimate will receive drug coverage through the various sources. The percentage of firms choosing the various options will likely be different from the above percentages, as the distribution of beneficiaries across firms that offer retiree drug coverage tends to be concentrated among the largest firms.

Over time, we assume that some employers and unions will transition from providing retiree drug coverage for which they receive the Medicare retiree drug subsidy to providing their own enhanced Part D plan (through waivers), or purchasing enhanced Part D coverage, or offering supplemental drug coverage that wraps around Medicare Part D. Recent surveys suggest significant interest among employers in providing enhanced or supplemental drug coverage that wraps around standard Part D. Employers and unions commonly provide wraparound coverage for Medicare Part A and Part B, either through separate supplemental policies or through arrangements with Medicare Advantage plans, and we anticipate that some employers/unions may prefer using a similar approach with Medicare Part D. In addition, as discussed previously, for some plan sponsors, the indirect subsidy plan sponsors receive by providing enhanced coverage or supplemental drug coverage that wraps around Medicare Part D may be greater in value than the Medicare retiree drug subsidy. While we expect that some employers and unions may want to provide enhanced or supplemental benefits, we anticipate that it may take some time for employers/unions who are interested in doing so to restructure their drug benefits to complement Medicare Part D, and thus these employers and unions may initially elect to obtain the retiree drug subsidy. As discussed in more detail previously, employers and unions that wish to restructure their drug coverage to supplement Medicare Part D have a number of options to consider for providing enhanced or supplemental drug coverage, including the option for an employer or union to obtain a waiver to provide its own enhanced Part D plan. It may take some time for these employers/unions to choose which supplemental coverage option they wish to pursue and make the requisite changes. Consequently, we assume that over time an increasing number of employers/unions would transition from receiving the Medicare retiree drug subsidy to providing their own enhanced Part D plan, purchasing enhanced Part D coverage, or providing separate supplemental drug coverage that wraps around Medicare Part D. Depending upon the amount of time it may take employers/unions to adopt such approaches, it is possible that the provision of wraparound coverage may also be more prevalent in the earlier years of Medicare Part D.

In addition, because some employers have placed caps on their contribution to retiree health benefits, we expect that the number of retiree plans that qualify for the Medicare retiree drug subsidy will decline somewhat over time. Once these plans hit the existing caps that employers have placed on their contributions, the net value of the plans' benefits relative to total drug costs will decline over time and eventually fall below the net value test required to qualify for the Medicare retiree drug subsidy. When this occurs, we anticipate that these employers and unions will likely encourage their retirees to enroll in Medicare Part D and provide either enhanced or supplemental coverage that wraps around Medicare Part D, or additional premium or other financial assistance or some combination of these steps. By doing this, beneficiaries would gain financially since they would receive the more generous Medicare Part D benefit, plus any additional support that the employer or union might offer in terms of wrap around coverage or premium assistance.

Also, due to steps some employers have taken to reduce retiree health benefits for future retirees, such as increasing retiree premium contributions, we anticipate that in future years as new retirees age into the Medicare program, there would be more retirees enrolling in standard Part D (including those with employer or union assistance with the Part D premium). As noted previously, the 2004 Kaiser/Hewitt survey of large employers offering retiree drug coverage found that roughly 20 percent of firms provide new retirees with access only coverage (that is coverage, where the employer makes no financial contribution to the cost of the premium). In situations where employers or unions make no or only a minimal contribution to the cost of retiree drug benefits, beneficiaries would be better off financially if they enrolled in Medicare Part D, since Medicare Part D includes a significant government subsidy. Furthermore, if employers or unions that provide only a very minimal contribution to retiree drug coverage instead offered to put that contribution toward the standard Medicare Part D premium, those retirees would benefit financially from both the subsidized Medicare Part D benefit and their employers/ unions' assistance with premiums. In addition, there has also been a trend toward declining generosity of retiree benefits for current retirees (for example, through increased premiums or cost-sharing), and we expect that this may also result in a slight increase in the number of retirees enrolled in standard Part D.

Due to the various considerations discussed above, among the 11.8 million

beneficiaries that we estimate would have employer or union sponsored retiree drug coverage in 2010 absent the law change, we assume that 61 percent would receive creditable drug coverage from an employer or union plan that is eligible for the Medicare retiree drug subsidy, 20 percent would enroll in Medicare Part D and receive employer or union sponsored enhanced or supplemental drug coverage, and 19 percent would enroll in standard Part D including those who would receive additional premium or other financial assistance from their former employer or union.

Depending on the circumstances of the retiree, all of these types of drug coverage have the potential to reduce retiree lifetime drug costs significantly compared to retiree costs in the absence of the law. Because of the substantial new subsidies and the range of subsidized options available to employers and unions for continuing coverage and enhancing total support for retiree coverage, we conclude that combined payments by employers/unions and Medicare for drug coverage on behalf of retirees will generally be greater—and frequently significantly greater—than they otherwise would have been without the enactment of the MMA. That is, lifetime drugs costs for retirees will generally be lower, and frequently substantially lower, than they otherwise would have been, as a result of strengthened retiree coverage and new assistance with drug costs.

A fifth participation assumption concerns enrollment in the low-income subsidy portion of the program. We estimate that approximately 14.4 million beneficiaries will be eligible for the low-income subsidy in 2006. We assume that a portion of beneficiaries who are eligible for the low-income subsidy (while receiving prescription drug coverage under Part D) will not take up the low-income assistance. We assume 100 percent uptake among full-benefit dual eligibles and 57 percent uptake among all other low-income subsidy eligibles. Among this latter group, we assume 100 percent uptake among those beneficiaries who will be deemed full low-income subsidy eligible and have facilitated enrollment (that is, QMBs, SLMBs, QIs, and beneficiaries with SSI). As noted in the proposed rule, we assume less than full uptake of the low-income subsidy among the remaining low-income beneficiaries based on experience with other means tested programs such as Medicaid and Medicare Savings (QMB/SLMB) programs, which suggests that full take up does not generally occur.

There are several limitations inherent in the assumptions for predicting the specific impacts of a major new program like the Medicare drug benefit. For example, it is difficult to project enrollment rates in this entirely new program, and there is uncertainty about how employers and unions will respond to the retiree drug subsidy or the other approaches available to augment Medicare Part D prescription drug coverage. The assumptions discussed previously reflect our current best estimates, considering the structure of the program, the wide variety of new efforts to educate beneficiaries and facilitate enrollment, and information about participation rates in other types of similar programs where available.

Comment: One commenter asserted that our assumption in the proposed rule that 99 percent of non-low-income and non-actively working beneficiaries would receive drug coverage through a Medicare Part D plan or through an employer or union sponsored health plan that is eligible for the Medicare retiree subsidy was unrealistic, claiming that the late enrollment penalty for Medicare Part D was not sufficient to generate that level of participation. This commenter also asserted that our assumptions did not reflect the potential for selection bias in enrollment in Medicare Part D.

Response: In addition to receiving this comment on our Part D program uptake assumptions, in our efforts to refine our model of Medicare Part D impacts, we also obtained information from industry experts on their expectations of the likely response to Medicare Part D. While we continue to believe that there will be high participation in Medicare Part D, we have revised our uptake assumption downward slightly to reflect what we think is the current best estimate of likely participation in Medicare Part D and we have accounted for selection by assuming graduated uptake rates based on beneficiaries' drug spending levels, as discussed previously.

F. Anticipated Effect of Medicare Part D on Beneficiaries

The Medicare prescription drug benefit is designed to provide all of the nation's Medicare beneficiaries with the opportunity to enroll in a prescription drug benefit that is subsidized by the Medicare program. We believe that giving Medicare beneficiaries access to affordable drug coverage that helps them to pay for their outpatient prescription drugs (which have become an increasingly important component of health care service delivery), and helps beneficiaries to use prescription drugs more effectively, will assist beneficiaries in leading healthier, more productive lives, while improving the effectiveness of the Medicare program. Additionally, we believe that the substantial additional resources that Medicare Part D provides through the retiree drug subsidy and the various opportunities employers and unions have for providing additional coverage that complements the standard Part D drug benefit will make it more affordable for employers and unions to continue providing high quality retiree drug coverage to Medicare-eligible retirees.

The following section contains discussions of: a recap of the Medicare drug benefit's structure, estimates of the average amount of drug spending covered by the Medicare drug benefit and average beneficiary premiums, the anticipated positive effects that the Medicare prescription drug benefit will have on beneficiaries, and a discussion of the anticipated positive effects that the Medicare retiree drug subsidy and other options that are available to employers and unions under Medicare Part D will have on the availability and generosity of retiree drug coverage.

1. Recap of the Structure of the Medicare Part D Drug Benefit

As discussed in more detail in subpart C in the preamble, standard prescription drug coverage under Medicare Part D for 2006 consists of a $250 deductible, 25 percent cost-sharing (or an actuarially equivalent cost-sharing structure) up to an initial coverage limit of $2,250, 100 percent beneficiary cost-sharing after the initial coverage limit until an out-of-pocket threshold of $3,600 is reached, and nominal cost-sharing for expenditures beyond the out-of-pocket threshold (that is, the greater of 5 percent coinsurance or a copayment of $2 for a generic or preferred multiple source drug and $5 for any other drug in 2006, or an actuarial equivalent cost-sharing structure). For each year after 2006, the deductible, initial coverage limit, out-of-pocket threshold, and nominal copayment amounts are indexed to per capita growth in prescription drug expenditures for Part D enrollees, as described in more detail in the preamble.

While we model all of our impact estimates on the defined standard benefit structure, we note that PDP and MA-PD plans have the option of offering actuarially equivalent alternative coverage. In addition, plans may offer enhanced alternative coverage where for an additional premium they offer supplemental drug coverage such as coverage for benefits above the initial coverage limit (that is, coverage of the so-called ''doughnut hole''), and we

anticipate that some plans will offer this coverage.

Beneficiaries who meet certain income and assets requirements qualify for low-income subsidy assistance with cost-sharing and premiums. While the out-of-pocket threshold level is the same for all enrollees, the beneficiary cost-sharing liability covered by the low-income subsidy counts towards the Part D out-of-pocket threshold. Therefore, subsidy-eligible individuals will pay substantially less than all other enrollees before the catastrophic coverage begins. Institutionalized full-benefit dual eligibles pay no cost-sharing. Other full-benefit dual eligibles with income not in excess of 100 percent of the Federal Poverty Level (FPL) face no deductible, have nominal cost sharing of $1 for generic drugs or preferred multiple source drugs and $3 for any other drug up to the out-of-pocket threshold, and receive full coverage for drug costs beyond the out-of-pocket threshold. Other full-benefit dual eligibles with income above 100 percent of FPL and beneficiaries who are not full benefit dual eligibles, but who have income less than 135 percent of FPL and assets up to $6,000 per individual (or $9,000 per couple) in 2006, face no deductible, have nominal cost sharing of $2 and $5 for the respective drugs up to the out-of-pocket threshold, and receive full coverage for costs beyond the out-of-pocket threshold. For other beneficiaries with income less than 150 percent of FPL and assets up to $10,000 per individual (or $20,000 per couple) in 2006, there is a reduced deductible of $50, cost-sharing of 15 percent for costs up to the out-of-pocket threshold, and nominal cost sharing of $2 and $5 for the respective drugs for costs beyond the out-of-pocket threshold. For years after 2006, all aspects of the benefit structure related to the low-income subsidy are indexed to growth in per capita drug spending, except for the nominal copayment amounts for full-benefit dual eligibles with income not in excess of 100 percent of FPL and the low-income assets tests, which are indexed to the Consumer Price Index.

The low-income subsidy also offers beneficiaries substantial help with premiums. Many beneficiaries who receive the low-income subsidy will pay no premium for Medicare drug coverage. Full-benefit dual eligibles and beneficiaries who have incomes up to 135 percent of FPL and who meet the assets test receive a full Federal subsidy of the beneficiary premium—that is, beneficiaries pay no premium as long as they select a PDP or MA-PD that has a premium that does not exceed the greater of the low-income benchmark premium or the lowest PDP premium for basic coverage for the region and as long as they sign up for Medicare Part D within the initial enrollment period or have met creditable coverage requirements. Other beneficiaries receiving a low-income subsidy—those with income between 135 percent and 150 percent of FPL and meeting asset requirements—would face a sliding scale premium based on income.

Medicare Part D also has implications for beneficiaries enrolled in the Program of All Inclusive Care for the Elderly (PACE). PACE programs already provide a comprehensive drug benefit to dual eligible enrollees and to enrollees who only have Medicare coverage. For the dual eligible enrollees, PACE programs will now be receiving funding for prescription drugs through Medicare Part D instead of through the State Medicaid program. PACE enrollees who only have Medicare coverage are today paying the full cost of their drug coverage. As a result of the Federal subsidization of Part D coverage, they will receive substantial premium relief. This lowering of premiums for beneficiaries who only have Medicare coverage may lead to an increase in enrollment in PACE organizations.

2. Estimated total drug spending, spending paid by the Medicare drug benefit, and premiums

a. Summary

Table IV–2 presents estimates for Medicare Part D enrollees of (1) average per capita total drug spending (including spending paid for by the Medicare drug benefit, by the beneficiary, and by any sources of supplemental coverage), (2) average drug spending paid for by the standard Medicare Part D benefit, and (3) the average premium associated with standard Medicare Part D drug coverage. Since beneficiaries who are eligible for the low-income subsidy receive additional assistance with cost-sharing and premiums, we present estimates separately for beneficiaries who do and do not receive the low-income subsidy. A discussion of how these estimates were developed is included in the next section, ''b. Methodology and Assumptions Underlying Estimates.''

For Medicare Part D enrollees who do not receive the low-income subsidy, we estimate that average per capita drug spending in CY 2006 would be $2,260. This projection of drug spending includes cost-management savings discussed in the next subsection, such as price concessions and generic substitution, or utilization effects resulting from the Medicare drug benefit. The Medicare drug benefit would be expected to pay for on average about $1,138 of prescription drug costs, or on average half of total beneficiary drug spending in CY 2006.[7] Beneficiary premiums for defined standard coverage will vary across PDPs and MA-PDs. We estimate that the beneficiary premium to obtain defined standard coverage would be on average about $440 per year in CY 2006. Thus, we estimate that the average monthly premiums would be less than $37. A beneficiary may pay a higher or lower amount depending upon which PDP or MA-PD the beneficiary selects. In CY 2010, drug spending for Part D enrollees who do not receive the low-income subsidy is projected to be $2,945 on average, with the Medicare drug benefit paying for on average $1,490 of prescription drug costs. The average premium in CY 2010 for these beneficiaries is projected to be $580 per year or roughly $48 per month for defined standard coverage.

For enrollees who receive the low-income subsidy, we estimate that average per capita drug spending in 2006 would be $4,359.[8] We estimate that on average the Medicare drug benefit would be expected to pay for about $4,189 of prescription drug costs, or approximately 96 percent of total drug spending. In 2010, these beneficiaries would be expected to spend on average $5,684 per capita on prescription drugs, with the Medicare drug benefit paying for on average about $5,439 of beneficiaries' drug costs. As discussed in the preamble, the low-income cost-sharing amounts vary depending upon a beneficiary's income and assets. Consequently, the share of drug spending paid for by the Medicare drug benefit would vary by subsidy eligibility category, ranging from an average of about 85 percent for the highest-resource subsidy eligibility category (that is, those beneficiaries who qualify for the subsidy under the criteria that they have income less than 150 percent of FPL and assets up to $10,000

[7] We note that $1,138 reflects the average payout of the Medicare drug benefit for non-low-income beneficiaries in 2006. This is different from what the payout would be for a beneficiary with total drug spending equal to average total drug spending for all enrollees. For example, standard coverage under Medicare Part D would payout $1500 for a beneficiary with total spending of $2260. The difference between the average payout versus the payout for a beneficiary with average total drug spending is due to the interaction between the distribution of drug spending and the deductible and cost-sharing structure of the Medicare drug benefit.

[8] Average drug spending for enrollees eligible for the low-income subsidy is higher than for enrollees not eligible for the subsidy because a substantial portion of those eligible for the low-income subsidy are full-benefit dual eligibles, who on average tend to be sicker.

per individual (or $20,000 per couple) in CY 2006) to 98 percent for the most generous subsidy category (that is, full-benefit dual eligibles with income not in excess of 100 percent of FPL). As discussed in the following methodology section, these estimates do not take into account the waiver of cost sharing for institutionalized full-benefit dual eligibles, which further enhances the subsidy for this category of beneficiaries.

As noted previously, many beneficiaries who receive the low-income subsidy receive a full Federal subsidy of the beneficiary premium (that is, the beneficiary pays no premium at all), as long as they enroll in a PDP or MA-PD with a premium that does not exceed the greater of the low-income benchmark premium or the lowest PDP premium for basic coverage for the region and as long as they enroll during the initial enrollment period or have met creditable coverage requirements. For low-income enrollees with income between 135 percent and 150 percent of FPL who face a sliding scale premium based on income, we estimate that the premium will average $220 per year or roughly $18 per month in 2006, and $290 per year or roughly $24 per month in 2010.

Overall, the government is estimated to contribute $1355 to the $1795 cost of standard Part D insurance coverage. In addition, the government will provide further financial assistance for low-income subsidy enrollees—an average of $1863 in low-income cost-sharing subsidies and $420 in premium subsidies.

We note that our total per capita drug spending estimates for the two groups of Part D enrollees—those receiving and those not receiving the low-income subsidy—differ from those presented in the proposed rule. Our current estimate of total per capita drug spending is lower for Part D enrollees not receiving the low-income subsidy and is higher for Part D enrollees receiving the low-income subsidy than our prior proposed rule estimates. The reasons for these changes include use of more recent (2001) Medicare Current Beneficiary Survey (MCBS) data in which spending for non-low-income beneficiaries did not grow as rapidly as predicted using earlier baseline data and benchmarking spending estimates for low-income beneficiaries to Medicaid data.

b. Methodology and Assumptions Underlying Estimates

To estimate beneficiary drug spending for the period CY 2006–2010, we use drug spending data from the 2001 MCBS adjusted for underreporting and trended forward based on projected growth in per capita drug spending based on the National Health Expenditures projections.

In projecting drug spending for enrollees in Medicare Part D, we assume that PDPs and MA-PDs will achieve a certain level of savings due to cost management activities such as negotiation of manufacturer rebates, retail discounts, and other price concessions, and promotion of generic substitution together with other utilization management efforts. We assume discounts and cost-management savings of 15 percent in 2006, 17 percent in 2007, 19 percent in 2008, 21 percent in 2009, and 23 percent in 2010. To take into account that some enrollees in the Medicare Part D drug benefit are likely to have had previous drug coverage from other sources and received some level of discounts and cost-management savings through that coverage, we adjusted the MCBS spending data upward to reflect the full retail price by backing out any assumed discounts and cost management savings and then applied the Part D savings factor. We note that some beneficiaries without drug coverage are currently receiving discounts through the Medicare-approved drug card program. Conceptually, those discounts should also be backed out of drug spending before applying the Part D savings factor; however, because the drug spending data on which our projections are based predate the Medicare-approved drug card program, such an adjustment was not necessary.

Our assumptions related to the cost management savings take into account several factors. Insured products generally obtain lower drug prices than those available to cash paying customers. For example, an April 2000 study prepared by HHS entitled, ''A Report to the President: Prescription Drug Coverage, Spending, Utilization and Prices,'' indicated a significant price differential between individuals paying cash for prescriptions at a retail pharmacy versus individuals with insurance. This difference held true for both the Medicare and non-Medicare populations. According to the study, in 1999 the price paid by cash customers was nearly 15 percent more than the total price paid under prescription drug insurance, including the enrollee cost sharing. For 25 percent of the most commonly prescribed drugs, this price difference was higher—over 20 percent. Such price concessions are envisioned to be an important part of the Medicare drug benefit, as the statute specifically requires PDPs and MA-PDs to provide beneficiaries with access to negotiated prices, which would reflect manufacturer rebates, retail discounts, and other price concessions. Besides these types of price concessions, we also anticipate that PDPs and MA-PDs will achieve savings as a result of other cost management activities such as promotion of generic substitution, which Medicare will help support as well through providing information on opportunities for cost savings to beneficiaries and their health providers. As discussed elsewhere in the preamble, the statute requires PDPs and MA-PDs to put in place a cost-effective drug utilization management program that would include incentives to reduce costs when medically appropriate. We believe that these various efforts are likely to increase use of generics relative to brand-name drugs among Medicare Part D enrollees.

In addition, our drug spending projections assume that changes in beneficiary out-of-pocket costs resulting from the Medicare drug benefit would affect beneficiaries' utilization of drugs. For example, as discussed previously, beneficiaries without drug coverage fill fewer prescriptions and spend less in total on prescription drugs than beneficiaries with drug coverage. Under the Medicare drug benefit, we would expect that drug utilization and spending would increase for beneficiaries without prior drug coverage. Our estimates assume that aggregate beneficiary drug spending (that is, total drug spending for all beneficiaries including those with and without drug coverage prior to 2006) would be 7.2 percent greater in CY 2006 than it otherwise would be, due to reduced out-of-pocket costs resulting from the Medicare drug benefit. Our estimate of the increase in drug spending that results in response to reduced out-of-pocket costs is somewhat lower than our previous proposed rule estimate because we have refined our methodology. For the final rule estimates, we have developed a regression model, where we estimate the demand for prescription drugs as a function of the share of drug costs that are out-of-pocket controlling for the number of physician visits, age, and gender.

Using our estimates of projected drug spending for enrollees in Medicare Part D, we estimate the amount of drug spending that would be paid for by the Medicare drug benefit assuming the defined standard benefit design, separately for enrollees who would and would not receive the low-income subsidy. For enrollees who receive the low-income subsidy, these estimates take into account the differential cost-sharing by income and assets within the

low-income group. However, due to data limitations, our estimates do not take into account the fact that beneficiary cost-sharing is waived entirely for institutionalized full-benefit dual eligibles.

Using the drug spending estimates, we also estimate the statutorily specified share of spending financed through beneficiary premiums for defined standard Part D coverage. For the purpose of this impact analysis, those beneficiaries who are assumed to enroll in Medicare Part D are assumed to do so within their initial enrollment period and face no late enrollment penalty. We also assume that all low-income beneficiaries with income under 135 percent of FPL select PDP and MA-PD plans with a premium that does not exceed the greater of the low-income benchmark premium or the lowest PDP premium for basic coverage for the region, and thus face no beneficiary premium. To estimate the average sliding scale premium, where low-income subsidy enrollees receive a 75 percent premium subsidy (if income is greater than 135 percent of FPL but does not exceed 140 percent of FPL), a 50 percent subsidy (if income is greater than 140 percent of FPL but does not exceed 145 percent of FPL), or a 25 percent subsidy (if income is greater than 145 percent of FPL but less than 150 percent of FPL), we assume a uniform income distribution between 135 percent and 150 percent of FPL. If the income distribution is not uniform, the average sliding scale premium could differ somewhat from our estimates.

We received several comments related to the methodology and estimates in this section.

Comment: One commenter raised concern about the use of Medicare Current Beneficiary Survey data and National Health Expenditure projections to estimate beneficiary drug spending in future years. The commenter questioned the reliability and completeness of self-reported survey data like the MCBS and questioned the use of the NHE projections of per capita prescription drug expenditure growth because these projections are not Medicare specific. The commenter maintained that data from the Federal Employee Health Benefits Program and other public programs that reflect a large number of geographically diverse Medicare beneficiaries should be used for the estimates instead.

Response: We agree with the commenter that there are limitations to the data used to project beneficiary drug spending in future years. We also recognize that data from the Federal Employee Health Benefits Program and other public programs can provide important information about prescription drug spending among Medicare beneficiaries and we have used those data in our other research efforts. However, for the purpose of developing nationally representative costs estimates for Medicare Part D, both CMS and the Congressional Budget Office have relied on the MCBS data. CMS has chosen to use the MCBS because it is the largest nationally representative survey of prescription drug expenditures for Medicare beneficiaries and it has the advantage of being a single data source that provides information on all types of beneficiaries—for example, both beneficiaries with and without prescription drug coverage, beneficiaries with varied income levels, and beneficiaries of different ages and health acuities. The administrators of the survey undertake a number of measures to reduce inaccuracies associated with self-reported data, including supplying respondents with calendars to record drug purchases, requesting that beneficiaries save their drug containers for their next interview, and providing the interviewer with a roster of drugs previously mentioned by the respondent to ensure we are capturing refills. Moreover, we recently completed and published a pharmacy follow-back analysis in which we compared beneficiary-reported drug data to pharmacist-reporting data (''Reporting of Drug Expenditures in the MCBS,'' John A. Poisal, *Health Care Financing Review*, Winter 2003–2004, pp. 23–36). This allowed those who oversee the survey to adjust their estimates to account for survey drug mis-reporting. All of our drug estimates reflect the results from the follow-back study.

With respect to the National Health Expenditures projections, we acknowledge that these projections are national and not specific to the Medicare population. These projections are based on data obtained by our Office of the Actuary (OACT) from a variety of sources, including the National Prescription Audit conducted by IMS Health. OACT adjusts the data from the National Prescription Audit to take into account a number of factors, including benchmarking to the Economic Census and adjusting the data to subtract an estimate of manufacturer rebates provided to health insurers related to insurance coverage for prescription drugs. Since no such projections that take these various factors into account exist specifically for the Medicare population, we believe it is appropriate to use the NHE projections.

Comment: We received a comment from a retiree advocacy group in which they provided independently generated data on the cost of prescription drugs for a group of beneficiaries who currently receive generous drug coverage through large employers and unions. The data were generated by having retirees use the website of an Internet pharmacy to determine the cost of a 90-day supply of the drugs they use. Based on this, the commenter estimated average total drug spending, average drug spending paid for by Medicare Part D, and the average beneficiary premium. The commenter's estimate of average drug spending for its group of retirees was higher than the proposed rule estimate while its estimate of average drug spending paid for by Medicare Part D was lower than in the proposed rule. The commenter's estimate of the beneficiary premium was fairly similar to the proposed rule although the commenter's estimate was slightly lower.

Response: It would not be unexpected that average drug spending for a specific group of beneficiaries may differ from our projections of average drug spending for all Medicare Part D enrollees. However, if on average a specific subgroup of enrollees has higher drug spending, then the average amount of drug spending paid for by the Medicare drug benefit would also be higher for that subgroup of beneficiaries.

As discussed elsewhere, we have based our estimates for Medicare Part D on the MCBS, which is the largest nationally representative survey of prescription drug expenditures for Medicare beneficiaries and which has the advantage of being a single data source that provides information on all types of beneficiaries. The projections based on this data reflect our best estimate of the average impact of Medicare Part D on beneficiaries.

Comment: One commenter took issue with the application of the cost management savings equally to all segments of the Medicare Part D population. The commenter asserted that it is not realistic to expect the same level of savings for low-income subsidy enrollees because their cost-sharing is extremely limited and plans have little ability to incentivize the use of cost effective drugs.

Response: While it is true that low income subsidy enrollees will have minimal cost-sharing, we believe that cost management savings are possible for this population because Part D plans still have other cost management tools available—for example, notably, price concessions for drugs on a plan's formulary, as well as such tools as mandatory generic substitution, step

therapy, and prior authorization. Cost-sharing is only one of many tools available to Part D plans that influence cost management savings.

Comments: Some commenters asserted that they did not believe private price negotiations between Part D plans and drug manufacturers would yield as large savings for beneficiaries as direct government price negotiation (which is prohibited by statute). Some commenters claimed that Medicare Part D plans or PBMs, rather than beneficiaries, would benefit from price concessions negotiated with manufacturers.

Response: We disagree with the commenters. We expect that the private price negotiations between PDP sponsors and drug manufacturers would achieve comparable or better savings than direct price negotiation between the government and manufacturers, as well as coverage options that better reflect beneficiary preferences. This expectation reflects the strong incentives to obtain low prices and pass on the savings to beneficiaries resulting from competition, relevant price and quality information, Medicare oversight, and beneficiary assistance in choosing a drug plan that meets their needs. This is similar to the conclusion of other analyses, for example, CBO's recent statement that ''Most single-source drugs face competition from other drugs that are therapeutic alternatives. CBO believes that there is little, if any, potential savings from negotiations involving those single-source drugs. We expect that risk-bearing private plans will have strong incentives to negotiate price discounts for such drugs and that the Secretary would not be able to negotiate prices that further reduce Federal spending to a significant degree.'' In addition, the provision of relevant price and quality information on each Part D plan through a price comparison website will further promote low prices to beneficiaries.

TABLE IV–2. ESTIMATED AVERAGE ENROLLEE TOTAL DRUG SPENDING, DRUG SPENDING PAID FOR BY MEDICARE DRUG BENEFIT, AND DRUG BENEFIT PREMIUM, CY 2006 AND CY 2010

Estimated Average Annual Drug Spending*	Estimated Average Annual Drug Spending Paid For By the Medicare Drug Benefit**	Estimated	Average Annual
2006			
Enrollees Not Receiving Low-Income Subsidy	$2,260	$1,138	$440
Enrollees Receiving Low-Income Subsidy	$4,359	$4,189	$0 or $220***
2010			
Enrollees Not Receiving Low-Income Subsidy	$2,945	$1,490	$580
Enrollees Receiving Low-Income Subsidy	$5,684	$5,439	$0 or $290***

* Estimated average total drug spending includes spending paid for by the Medicare drug benefit, by the beneficiary, and by any other sources of coverage.

** Average annual drug spending paid for by the Medicare drug benefit reflects on average how much the Medicare drug benefit will payout per beneficiary. This is different from the amount of drug costs the Medicare drug benefit would payout for a beneficiary with average total drug spending, due to the interaction between the distribution of drug spending and the deductible and cost-sharing structure of the Medicare drug benefit. We also note that the average drug spending paid for by the Medicare Part D plan reflects drug costs reimbursed by the plan and does not include PDP or MA-PD administrative costs.

*** These numbers reflect separate premium estimates for two groups of low-income subsidy enrollees. (1) Those low-income subsidy enrollees with income under 135 percent of FPL have a $0 beneficiary premium, as long as they select a PDP or MA-PD with a premium that does not exceed the greater of the low-income benchmark premium or the lowest PDP premium for basic coverage for the region, and as long as they enroll within the initial enrollment period or have met creditable coverage requirements. (2) Low-income subsidy enrollees with income between 135 percent and 150 percent of FPL face a sliding scale premium based on income, which is estimated to average $220 per year in 2006 ($290 in 2010).

2. Qualitative Discussion of Positive Effects of the Medicare Drug Benefit

The purpose of the Medicare prescription drug benefit is to provide all of the nation's Medicare beneficiaries with the opportunity to enroll in a prescription drug benefit that is subsidized by the Medicare program. Outpatient prescription drugs have become an integral component in the delivery of comprehensive, high quality health care services. Giving beneficiaries access to affordable drug coverage, that helps them to pay for their outpatient prescription drugs and helps beneficiaries and their health professionals to use prescription drugs more effectively as part of their overall health care, will enable beneficiaries to lead healthier, more productive lives, while improving the effectiveness of the Medicare program.

a. Enhancement of the Medicare Benefit Package

When the Medicare program was first enacted, outpatient prescription drug coverage was generally not included in private sector health benefit packages. However, over the last two decades, prescription drugs have played an increasingly critical role in health care service delivery. For example, currently, at least one medication is ordered, provided, or continued in approximately 65 percent of all visits to office-based physicians by persons 65 years and over (2001 National Ambulatory Medical Care Survey, National Center for Health Statistics). Prescription drugs have significantly improved the treatment and management of many major conditions—including life-threatening diseases such as stroke (anticoagulant or clot-blocking therapy), heart disease and coronary artery disease (antihypertensive medications, cholesterol-lowering drugs), and cancer (targeted biologics and other agents that modify the course of illness and can be taken orally), as well as disorders that have fundamental impacts on quality of life like psychiatric illnesses (antipsychotics and antidepressants),

osteoporosis (bone-strengthening drugs), and arthritis (anti-inflammatory drugs and other disease-modifying agents)—thereby contributing to longer and healthier lives as well as reductions in other types of medical expenditures such as inpatient admissions and lengths of stay (''The Price of Progress: Prescription Drugs in the Health Care Market,'' J. D. Kleinke, *Health Affairs* 20:5, September/October 2001, available at *www.healthaffairs.org*). Many other significant diseases have also seen improvements in treatment and management, and thus in patient health, as a result of the availability of new medications, including: HIV/AIDS, complex infections, diabetes, asthma and chronic lung diseases, Parkinson's disease, and many less common but serious disorders. With more new medicines in development than ever before, potential future health benefits from better drug therapies are even greater. Medicare Part D will augment the Medicare program's benefit package by making drug coverage, which is currently offered in most private sector health plans, available to all beneficiaries. This represents an important step in modernizing the Medicare program to better meet beneficiaries' needs and respond to changes in health care delivery.

b. Access To Subsidized Prescription Drug Coverage

For the first time in the history of the Medicare program, the Medicare prescription drug benefit will make subsidized prescription drug coverage available to all Medicare beneficiaries. Historically, many Medicare beneficiaries have received prescription drug coverage through a variety of sources, including: employment-based retiree health coverage, Medigap policies with drug coverage, Medicare Advantage plans, Medicaid, and State Pharmaceutical Assistance Programs. These various types of drug coverage have traditionally varied widely in comprehensiveness and cost (for example, many of these policies may not include catastrophic coverage), leaving some beneficiaries at risk for high out-of-pocket costs and related financial access issues even though they have drug coverage. Meanwhile, an estimated 24 percent of Medicare beneficiaries currently do not have any prescription drug coverage at all (based on 2001 Medicare Current Beneficiary Survey data).

In the proposed rule, we stated that by providing substantial additional resources to defray the cost of Medicare drug coverage—including direct subsidy and government reinsurance payments to PDPs and MA-PDs that will cover roughly 75 percent of the total cost of the Medicare drug benefit for all beneficiaries, additional assistance with cost-sharing and premiums for low-income beneficiaries, and new subsidies for the retiree coverage and Medicare Advantage coverage that many beneficiaries receive today—the Medicare prescription drug benefit will make prescription drug coverage more accessible and affordable for beneficiaries. Since we issued the proposed rule, several new independent studies have been published that have examined the financial benefits that are available to beneficiaries through Medicare Part D. In the remainder of this section, we highlight some of the ways that having access to subsidized Part D drug coverage will be helpful to Medicare beneficiaries as a whole, and for specific subgroups within the beneficiary population.

The Medicare prescription drug benefit will provide access to basic subsidized prescription drug coverage for all Medicare beneficiaries, regardless of income, and additional targeted assistance for low-income beneficiaries. We anticipate that beneficiaries who choose to take advantage of the subsidized drug coverage that is available through Medicare Part D by enrolling in a PDP or MA-PD will experience reductions in their out-of-pocket spending for prescription drugs, both in the short-term and over their lifetime, and will also gain generous insurance protection against catastrophic drug costs. Ultimately, we believe that the Medicare prescription drug benefit will significantly reduce the financial burden that beneficiaries may face in obtaining needed outpatient prescription drugs.

Medicare beneficiaries' out-of-pocket spending for prescription drugs has been increasing during the past decade. However, several independent analyses confirm our belief that beneficiaries enrolling in the Medicare drug benefit are likely to receive substantial help through lower out-of-pocket spending. These savings will be associated with Medicare's direct subsidy, low-income subsidy and reinsurance payments (''Estimates of Medicare Beneficiaries' Out-of-Pocket Drug Spending in 2006,'' Jim Mays et. al., Actuarial Research Corporation, and Tricia Neuman et al., The Henry J. Kaiser Family Foundation, November 2004, available at *http://www.kff.org*). Beneficiaries will also achieve savings from the additional price discounts that will be available through the Part D plans (''The Medicare Prescription Drug Benefit: Potential Impact on Beneficiaries,'' Jack Rodgers and John Stell, PricewaterhouseCoopers, prepared for the AARP Public Policy Institute, November 2004, available at *http://research.aarp.org/health/2004_13_rx.pdf*).

These independent analyses suggest that although the level of savings that beneficiaries receive will vary by income and total drug costs, the Medicare drug benefit will enable beneficiaries to achieve savings across all age and health status cohorts. For example, one study consistently found lower out-of-pocket spending for all of the major beneficiary sub-groups analyzed, including age, sex, race, income, place of residence (rural/urban) and health status (Mays, et. al., November 2004).

Although most beneficiaries will experience lower out-of-pocket costs during the first year of the Medicare drug benefit, the available studies suggest that some healthier beneficiaries with low utilization could potentially pay more in premiums than they collect in benefits in 2006 (Mays, et. al., November 2004; King et. al., November 2004; Rodgers et. al., August 2004). However, it is important to note that insurance coverage is purchased to protect against high or unexpected costs. Thus, the value of the Part D benefit should not be measured solely based on savings during any given year; rather, it is more appropriate to compare beneficiaries' out-of-pocket costs with their total lifetime prescription drug expenditures to determine the net savings that beneficiaries will receive through Medicare Part D over their lifetime (King et. al., November 2004). To further illustrate this point, we note that like the existing Medicare Part B benefit, which covers physician care and other outpatient services, the new Medicare drug benefit is voluntary. Under current Medicare Part B coverage, an estimated 30 percent of beneficiaries pay more in premiums than they collect in benefits during any given year; nevertheless, most beneficiaries choose to enroll in Part B when they first become eligible because they know that they will do better over time if they have insurance coverage than if they remain uninsured. The same is true for the new Medicare Part D prescription drug benefit. Younger and healthier beneficiaries who currently have low drug utilization will still be substantially better off over time by enrolling in Medicare Part D. Most beneficiaries who currently have low drug spending will need more costly medicines in the future, as drug utilization and spending tend to increase with age. Moreover, many illnesses can strike unforeseeably, so

that a beneficiary that is healthy during a given year may need an expensive drug the following year. Thus, even if they expect to have no drug spending or modest drug spending in 2006, these beneficiaries will want to join Part D in anticipation of the benefits they will need in the future. This is particularly important because there is a late enrollment penalty for people who do not sign up for Part D, and who do not maintain creditable coverage elsewhere.

Indeed, one study concluded that ''since annual net benefits even for beneficiaries in the youngest age group and in good health exceed the premiums paid, it is readily apparent that over the lifetime of all but the healthiest beneficiaries, benefits will exceed premiums paid for the coverage'' (King et. al., November 2004).

Additionally, millions of beneficiaries who choose to enroll in Medicare Part D will benefit from the availability of catastrophic drug coverage that was lacking in Medigap drug plans, as well as in most Medicare Advantage plans and many employer/union-sponsored plans. A portion of the beneficiary's Part D premium, as well as a portion of the government subsidy, is for this catastrophic protection. In addition to its financial value, this catastrophic coverage also has a psychological value in that even if a given beneficiary's drug spending does not reach the catastrophic coverage threshold during a given year, the beneficiary can still have greater peace of mind in knowing that this valuable catastrophic protection is available to them, should they need it (Mays, et. al., November 2004; Rodgers et. al., August 2004; King et. al., November 2004).

In addition to the Medicare prescription drug benefit, Medicare Part D also provides additional resources to support the continuation of high quality employer and union-sponsored retiree drug coverage. We discuss the anticipated effects of the Medicare retiree drug subsidy and the various other ways that Medicare Part D offers assistance with retiree prescription drug costs to employers and unions in a subsequent section of this impact analysis.

The remainder of this section provides a more detailed description of how different types of Medicare beneficiaries will be helped by the new Medicare prescription drug benefit.

Low-income beneficiaries—As discussed earlier, Medicare Part D makes substantial assistance available to beneficiaries with lower incomes. Altogether, we estimate that more than a third of the Medicare beneficiaries that are expected to enroll in Part D plans in 2006 will receive the low-income subsidy. These 11 million beneficiaries with limited incomes and assets (which includes the full-benefit dual eligibles) will receive substantial additional help from Medicare, with no gaps in coverage and limited or no premiums, deductibles, or co-payments. As discussed elsewhere in this impact analysis, Medicare Part D is estimated to cover on average 96 percent of prescription drug costs for these low-income beneficiaries.

There are three major groups of low-income beneficiaries that will receive additional assistance through the low-income subsidy. About 6.3 million ''dual eligible'' low-income beneficiaries will pay no premium, or a limited premium, no deductible and nominal co-pays of as little as $1 or $3 per prescription. As discussed elsewhere in greater detail, the Medicare drug benefit will pay, on average, 98 percent of dual eligible beneficiaries' drug costs. Additionally, about 1.5 million of these dual eligible beneficiaries are institutionalized, and will be totally exempt from Part D cost sharing, which means that they will not pay any premiums, deductibles, or co-payments. While the nominal cost sharing of the Medicare prescription drug benefit may in some cases be slightly higher than the cost-sharing under a State's Medicaid program, Medicare Part D provides catastrophic drug coverage protection with no cost sharing for all dual eligibles, a benefit that is not currently available in all States. Since this population on average experiences higher drug costs, the catastrophic coverage provided by Part D offers important additional protection to this vulnerable population. We also believe that Medicare Part D is likely to result in more stable prescription drug coverage for low-income Medicare beneficiaries. For many dual eligibles, Medicaid is not a secure source of drug coverage, as eligibility is subject to meeting certain income and resource requirements; as a result, for some dual eligibles, Medicaid only provides intermittent drug coverage. The broader income eligibility criteria for the Medicare Part D low-income subsidy are such that, when compared to Medicaid full-benefit dual eligibility standards, Medicare Part D is likely to result in more stable prescription drug coverage for this population because small income fluctuations will be less likely to jeopardize beneficiaries' eligibility for the subsidized Part D coverage. In addition the duration of eligibility for the low-income subsidy is for one year.

About 3 million Medicare beneficiaries who are not full-benefit dual eligibles, but whose incomes are less than 135 percent of the Federal poverty level ($12,568 for an individual and $16,861 for a couple in 2004) and who have limited assets will also pay only a few dollars per prescription, with no premium, and no deductible under the Part D low-income subsidy. Medicare will also cover 96 percent of these beneficiaries' drug costs, on average.

About 1.6 million beneficiaries with incomes less than 150 percent of the Federal poverty level and assets up to $10,000 (or $20,000 if married) in 2006 will pay 15 percent co-pays with a sliding-scale premium under Medicare Part D, which will cover 85 percent of their drug costs, on average.

Beneficiaries with help from State Pharmaceutical Assistance Programs—States that operate State Pharmaceutical Assistance Programs (SPAPs) have shown a historical commitment to provide the elderly with assistance with prescription drug costs, and are generally showing an interest (for example, through their comments on the proposed rule) in continuing to provide some assistance by working in conjunction with the new Medicare Part D benefit. As noted elsewhere in the preamble, the Act recognized this interest on the part of States through special provisions related to SPAPs. As discussed in greater detail subsequently in this impact analysis, States operating SPAPs which provide subsidized drug coverage to individuals that will be eligible for the Medicare drug benefit will gain substantial savings starting in 2006, when Medicare Part D begins providing very generous coverage for beneficiaries with limited means. As a result of these savings, States may have additional funds, with which they could provide additional coverage that wraps around the Medicare drug benefit if they wish to do so. SPAP assistance with beneficiary cost sharing will count toward the true out-of-pocket cost catastrophic threshold. As a result, this would enable SPAPs to provide as generous or more generous assistance for the beneficiaries who currently receive coverage through these programs, at a lower cost per beneficiary for the States due to the availability of the Medicare drug benefit.

Higher income beneficiaries that do not currently have prescription drug coverage—Non-low income beneficiaries that do not currently have prescription drug coverage will also benefit from the subsidized drug coverage that will be available through Medicare Part D. On average, these beneficiaries will be much better off with Part D coverage than they were

without drug coverage. Indeed, average spending for non-low-income beneficiaries is expected to be about $2,260 in 2006. Compared with not having drug coverage, beneficiaries who spend at least $820 a year (around $70 a month) on prescription drugs in 2006 will see immediate net savings through the Medicare drug benefit. This break-even point actually comes earlier when the discounted prices and other formulary management savings that plans will offer are considered. Beneficiaries spending less than $820 a year on prescription drugs will pay more in premium than they receive in benefits during the first year of the Part D drug benefit. However, a relatively small portion of beneficiaries will fall below the break-even point, largely due to the fact that the Part D premium is highly subsidized, with beneficiaries only paying about a quarter of the total cost of the premium on average. We estimate that about one-fourth (27 percent) of all Medicare beneficiaries will have drug spending below $820 in 2006. However, as discussed earlier, even for these relatively healthy beneficiaries, an unexpected illness could result in large and unanticipated drug costs, and annual prescription drug spending levels are expected to rise as people age, such that these beneficiaries will be much better off enrolling in Part D when they first become eligible to do so, and avoiding the late enrollment penalty. As noted previously, an estimated 30 percent of beneficiaries pay more in premiums under current Medicare Part B coverage than they collect in benefits during any given year. Nevertheless, most beneficiaries choose to enroll in Part B when they first become eligible because of its insurance value—they know that they will do better over time if they have insurance coverage than if they remain uninsured. The same is true for the new Medicare Part D prescription drug benefit.

Beneficiaries that currently have Medicare Advantage—In July 2004, approximately 4.2 million beneficiaries were enrolled in general Medicare Advantage Plans (that is, those not operating under an employer waiver), and about 82 percent of these beneficiaries (3.4 million) had some prescription drug coverage through their Medicare Advantage plan. However, most beneficiaries that currently have drug coverage through Medicare Advantage plans do not have a drug benefit that is as generous as the Medicare Part D standard benefit. For example, around 34 percent had coverage for generic drugs only, about 48 percent had coverage for both brand and generic drugs, and almost all beneficiaries in these plans had annual coverage limits of $2,000 or less, while only about 2 percent of the beneficiaries in Medicare Advantage plans had unlimited brand and generic drug coverage. Medicare Part D will give all beneficiaries access to subsidized brand and generic drug coverage and catastrophic coverage through Part D plans, including MA-PDs, as well as additional assistance for low-income beneficiaries. We expect that the combination of the new Medicare-subsidized Part D drug benefit, as well as the availability of rebates for Medicare Advantage Plans that are related to the provision of Medicare Part A and Part B services, and the attractiveness of drug coverage to beneficiaries will result in Medicare Advantage plans offering prescription drug premiums and benefit designs that are more advantageous to beneficiaries than the existing prescription drug offerings in the current Medicare Advantage market.

Beneficiaries that currently have drug coverage through a Medigap plan—The Medicare Part D prescription drug benefit will also provide savings for beneficiaries in comparison to existing Medigap insurance policies that include drug coverage. The new Medicare prescription drug coverage offers a much better value to beneficiaries than Medigap plans, where the enrollee must pay the full cost of the premium (which is not subsidized by the Federal government) and has no catastrophic protection against high prescription drug costs. By comparison, the Medicare drug benefit provides beneficiaries with comprehensive drug coverage at a lower cost, with the beneficiary paying only about 25 percent of the Part D premium. These savings occur at all spending levels. For example, at a drug spending level of $1,000 a year, beneficiaries who switch from Medigap H and I plans will save over $800 a year in premiums and cost-sharing, and those in plan J will save over $1,300 a year in premiums and cost-sharing by enrolling in Part D. Similarly, a beneficiary who spends $3,000 a year on drugs will typically save about $1,300 a year in premiums and cost sharing by switching to the new Medicare drug benefit from a Medigap H or I plan, and save almost $1,700 a year by switching from a Medigap J plan. Additionally, it is important to note that enrollees who switch from Medigap drug coverage into a Part D prescription drug plan will be able to keep their other Medigap benefits, such as payment of deductibles and coinsurance for doctor and hospital care, while paying lower premiums since their drug coverage will no longer be included in the Medigap plan. They will also be able to switch into two new Medigap benefit packages that will allow purchasers to insure against catastrophic costs for benefits covered under traditional Medicare and, together with the new drug benefit, allow beneficiaries to insure against catastrophic expenses for hospital, doctor, and prescription drug costs. Since all beneficiaries face some risk of catastrophically high bills for these services, these are important additions to the choices available to beneficiaries to manage their costs and potential financial exposure.

Beneficiaries that currently have employer- or union-sponsored coverage—As discussed elsewhere in this impact analysis, for well over a decade the availability and generosity of employment-based retiree health coverage has been eroding, particularly for future retirees. Medicare Part D, including the retiree drug subsidy and the other options it gives employers and unions for providing additional drug coverage that complements the standard Part D drug benefit, will help to counteract this trend by increasing the financial support that is available to employers and unions for retiree drug coverage. We discuss the anticipated effects of the Medicare retiree drug subsidy and the various other ways that Medicare Part D offers assistance with retiree prescription drug costs to employers and unions in a subsequent section of this impact analysis.

Overall, both our analysis and the analyses of several independent researchers have found that the new Medicare drug benefit will provide substantial help to millions of beneficiaries. However, we did receive some comments expressing concerns about how Medicare Part D will affect access to prescription drugs for certain beneficiary subpopulations.

Comment: We received numerous comments from beneficiary advocacy groups, States, and others expressing concern about the potential for dual eligible beneficiaries to experience coverage gaps if they do not enroll in a Part D plan prior to January 1, 2006 (when their primary prescription drug coverage will be transitioned from Medicaid to Medicare). These commenters stated that dual eligibles are particularly vulnerable due to their extensive and complex medical needs and limited financial resources, and that such coverage gaps could interfere with their ability to obtain medically necessary prescription drugs.

Additionally, various commenters noted that it will be particularly difficult to educate the dual eligible population about the relatively complex array of choices that are inherent in the new Part D drug benefit due to a variety of factors, including cognitive impairments (which may make it difficult for some dual eligibles to select a Part D plan, including those who are disabled, mentally ill, and/or institutionalized), limited proficiency with written English, and general poor health status. A few commenters also asserted that the potential for various different actuarially equivalent benefit designs under Part D could contribute to beneficiaries' difficulty in comparing Part D plans and making an informed choice among the options that are available to them. Some commenters expressed concern that dual eligible beneficiaries could be exposed to late enrollment penalties if they enroll in a Part D plan after the initial enrollment period has ended, which could represent an added financial burden for individuals that are on a fixed income. Some commenters also expressed concern that the provision allowing Part D plans to disenroll individuals whose behavior is disruptive could cause additional gaps in drug coverage and exposure to late enrollment penalties that could disproportionately affect beneficiaries with mental illness or cognitive difficulties. Commenters asserted that interruptions in access to needed prescription drugs could ultimately potentially have a negative impact on health outcomes and costs for dual eligibles and other beneficiaries with HIV/AIDS, mental illness, or developmental disabilities, as well as for beneficiaries that are institutionalized in skilled nursing facilities. For this reason, several commenters recommended either delaying implementation of Part D for dual eligibles to ensure a smooth transition; delaying implementation of the late enrollment penalty for dual eligibles; or auto-enrolling dual eligibles into Part D plans by Fall 2005 (with the ability to change plans) to avoid coverage gaps. Additionally, some commenters also suggested auto-enrolling beneficiaries that are enrolled in Medicare Savings Programs, as well as other low-income subsidy-eligible beneficiaries into Part D plans. Finally, some commenters recommended increased funding for SHIPs, AAAs, and States to provide an extensive network of local, face-to-face, culturally and linguistically competent counseling services to notify and educate the dual-eligible population about the low-income subsidy, and improve beneficiaries' overall comprehension of and enrollment into Part D plans.

Response: We share the commenters' concerns about the importance of facilitating a smooth transition to Medicare Part D for dual eligibles, and ensuring access to necessary prescription drug coverage for vulnerable populations. As discussed elsewhere, we have modified the final rule to ensure that auto-enrollment of dual eligibles will begin as soon as the eligible Part D plans are known prior to January 1, 2006. Additionally, given the significant savings that will be available to beneficiaries through the low-income subsidy, our final rule also includes facilitated enrollment provisions for all other beneficiaries who are determined or deemed eligible for the low-income subsidy. It is important to note that for low-income beneficiaries, the Part D benefit design will be fairly standardized due to the cost-sharing subsidies.

Also, as discussed in the preamble, we anticipate making every effort to provide beneficiaries with information to assist them in considering whether they should change Part D plans after they have been auto-enrolled and as part of the facilitated enrollment process. For example, we anticipate working with SHIPs, States and a broad array of public, voluntary, and private community organizations serving Medicare beneficiaries to assist dual eligibles and other beneficiaries (including targeted efforts among historically underserved populations) in understanding the various options that are available to them under Medicare Part D. We also anticipate that the special enrollment period provisions in the final rule will help to ensure that dual eligibles and other beneficiaries are able to change to a PDP or MA-PD that better meets their needs. We have also made additional revisions in the final rule to provide additional protections for vulnerable individuals, such as the mentally ill, who potentially might face involuntary disenrollment from a PDP due to disruptive behavior. Ultimately, as discussed earlier, we believe that Medicare Part D will improve access to and stability of generously subsidized drug coverage for many dual eligibles and lower income beneficiaries due to the broader income eligibility criteria that are associated with the Medicare Part D low-income subsidy, which means that small income fluctuations will be less likely to jeopardize beneficiaries' eligibility for coverage. In addition, the duration of eligibility for the low-income subsidy is for one year.

Comment: We also received numerous comments from beneficiary advocacy groups and others expressing concern that some beneficiaries with extensive and complex medical needs that enroll in PDPs and MA-PDs could be required to switch their medications due to a given Part D plan's formulary restrictions. Several commenters stated that there is a possibility that a beneficiary's current prescription drugs may not be included on their Part D plan's formulary, or may be included in a formulary tier that has higher cost-sharing requirements, because PDPs and MA-PDs will only be required to include at least two drugs from each therapeutic class on their formularies, and will not have any limits on their application of tiered co-payments under Medicare Part D (including the ability to use different tiers for different classes of drugs, and to make changes in tiers during the plan year). These commenters stated that many beneficiaries need immediate and ongoing access to medically necessary and therapeutically appropriate medications, which often may not be interchangeable with other drugs in the same therapeutic class—including dual eligibles; institutionalized beneficiaries; beneficiaries with HIV/AIDS, mental illness, developmental disabilities, or other life-threatening and pharmacologically complex conditions; and beneficiaries in subpopulations where there is data suggesting that specific drugs may be more efficacious than others (for example, based on gender, ethnicity or disease category)—and expressed concern that the Part D appeals process could cause delays in these beneficiaries receiving timely access to needed medications. Commenters also asserted that various other cost-control mechanisms can potentially delay beneficiaries' access to necessary and appropriate treatment, including dispensing limits, prior authorization requirements, therapeutic substitution, step therapy, and fail first provisions. Some commenters also suggested that Part D formulary cost-sharing requirements could be particularly burdensome for certain beneficiaries, including dual eligibles whose States do not currently require co-payments for prescription drugs and institutionalized beneficiaries (who could be subject to out-of-network costs if they obtain their drugs through a long-term care pharmacy that has an exclusive contract with the facility where they reside and provides value-added therapeutic management services, but is not part of their Part D plan's pharmacy network). Some commenters

also expressed concern that Part D plans may not actively solicit the inclusion of I/T/U pharmacies in their networks, noting that in some areas, I/T/U pharmacies may be the only facilities capable of providing medication therapy management services to certain American Indian / Alaska Native beneficiaries due to language and cultural barriers. Additionally, several commenters expressed concern that some mentally ill patients could be switched to less effective medications and experience painful withdrawal symptoms because benzodiazepines and barbiturates are excluded from being Part D drugs. Finally, a substantial number of commenters requested that CMS designate certain groups of beneficiaries—including dual eligibles; institutionalized beneficiaries; and beneficiaries with HIV/AIDS, mental illness, developmental disabilities, or other life-threatening and pharmacologically complex conditions—as special populations that are protected from the potential effects that formulary restrictions could have on their access to medically necessary prescription drugs through the inclusion of alternative or open formularies and other special provisions and exemptions.

Response: We agree with commenters' concerns about the importance of continuity of care and access to medically necessary drugs for vulnerable populations. The preamble considers the various issues that were raised in the comments relating to special populations and Part D plans' formulary restrictions, and discusses the steps we are taking to be responsive to these concerns. For example, although Part D plans will not be required to include every Part D drug on their formularies, we will require Part D plan formularies to include adequate access to a broad range of drugs used to treat diseases for which drugs exist. Additionally, we will comprehensively review Part D plans' proposed benefit designs—including their tiered cost-sharing formulary structures, P&T committee structure and utilization, utilization management policies and processes, and exceptions and appeals processes—to ensure that they provide an adequate benefit that generally complies with all applicable standards under Part D.

As discussed in the preamble, we will also review Part D plan formularies to ensure that plans do not discriminate against certain classes of Part D eligible individuals by adopting a benefit design (including any formulary or tiered formulary structure) that would substantially discourage enrollment by certain beneficiaries. We believe that our review of Part D plans' benefit designs, including their utilization management policies and processes, will address commenters' concerns regarding access to Part D drugs for vulnerable populations and ensure that Part D plans' benefit designs do not discriminate against certain groups of beneficiaries.

In addition to the safeguards noted above, as discussed in the preamble, we have also modified the final rule to include a requirement that Part D plans establish an appropriate transition process for new enrollees whose current drug therapies may not be included in the Part D plan's formulary. We expect that a plan's transition process would address procedures for medical review of non-formulary drug requests and, when appropriate, a process for switching new plan enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination. We will review the Part D plans' proposed transition processes as part of our overall benefit package review process.

We have also modified the final rule to clarify that Part D plans must disclose information about any utilization management procedures that they may use as part of the formulary information that they must disseminate to beneficiaries. We believe that this provision will assist beneficiaries in making informed choices during the enrollment process in determining which Part D plan will best meet their needs.

Additionally, as discussed elsewhere in the preamble, we believe that our approach of providing for any willing pharmacy contracts tailored to long-term care pharmacies that serve institutionalized populations will encourage the participation of long-term care pharmacies in the Part D plans' networks, and thus help to assure that institutionalized beneficiaries will continue to have access to these pharmacies, while also providing for increased competition in this area. Also, in what we anticipate are those limited instances where a beneficiary's Part D plan does not have the long-term care pharmacy servicing the beneficiary's particular long-term care facility in its network, then the beneficiary is eligible for a special enrollment period that will enable them to switch plans. Should such a change in Part D plans be necessary and involve a transition period, our rules also provide that non-routine use of an out-of-network pharmacy is permitted when the beneficiary cannot reasonably access a network pharmacy. We note that the final rule provides that CMS will pay the out-of-network differential for appropriate non-routine use of out-of-network pharmacies on behalf of all full low-income subsidy individuals and will pay amounts above the statutory cost-sharing limit for partial low-income subsidy-eligible Part D enrollees.

We have used a similar approach in addressing concerns relating to access to I/T/U pharmacies. As discussed elsewhere in the preamble, we have added a provision to our final regulations requiring Part D plans to offer contracts to all I/T/U pharmacies in their service areas, and to include a special addendum to their standard contracting terms and conditions in order to account for the special circumstances of I/T/U pharmacies.

Finally, we expect that some Medicare beneficiaries will continue to have access to drugs excluded under Medicare Part D, such as benzodiazepines, through Part D plans or State Medicaid plans. First, Medicare Part D allows PDPs and MA-PDs to provide drugs that are specifically excluded from being Part D drugs if they do so as supplemental benefits through enhanced alternative coverage. We believe that some beneficiaries with chronic conditions will choose to enroll in Part D plans that offer enhanced alternative coverage. Additionally, under Medicaid, States will be able to, at their discretion, provide coverage for a drug that is an excluded Medicare Part D drug.

c. Improved Compliance with Treatment Regimens

Available data suggest that not having drug coverage, combined with high drug expenses, may cause some beneficiaries to either not have their prescriptions filled or have them filled less often because they are not financially able to purchase outpatient prescription drugs. Because the Medicare prescription drug benefit will reduce affordability barriers associated with obtaining outpatient prescription drugs by reducing both the costs of drug treatment and beneficiaries' payments, we believe it will help to improve beneficiaries' compliance with their drug treatment regimens.

There is evidence that some beneficiaries, particularly those without drug coverage, do not fill some prescriptions ordered by their physicians and skip doses to make their drugs last longer due to cost concerns. For example, a study of Medicare beneficiaries in eight States found that among those without drug coverage, 25 percent reported not filling a prescription due to cost, while 27 percent reported skipping doses to make

drugs last longer. These rates of ''noncompliance'' with physician prescribing orders were more than double the rates reported among beneficiaries with drug coverage (Dana G. Safran, et. al., ''Prescription Drug Coverage And Seniors: How Well Are States Closing the Gap?'' Health Affairs Web Exclusive W253, July 2002, *http://content.healthaffairs.org/cgi/reprint/hlthaff.w2.253v1.pdf*).

Furthermore, analysis of data from the 2001 Medicare Current Beneficiary Survey (MCBS), a nationally representative sample of Medicare beneficiaries shows that Medicare beneficiaries without drug coverage fill fewer prescriptions than those with drug coverage. Overall, beneficiaries without drug coverage, on average, self-report filling 37 percent fewer prescriptions (18) than those with drug coverage (29). While some of this difference in utilization likely reflects differences in health status and other beneficiary characteristics, this phenomenon holds true even among groups of beneficiaries with large numbers of chronic conditions. For beneficiaries with five or more chronic conditions, those without drug coverage self-report, on average, filling approximately 38 prescriptions a year compared to beneficiaries with drug coverage, who self-report filling, on average, 50 prescriptions.

Finally, a study in the December 2001 issue of the *Journal of General Internal Medicine* found that certain characteristics, such as minority ethnicity, and low income (defined as income less than $10,000) significantly increase the risk that individuals without drug coverage will restrict their use of medications by, for example, skipping doses or avoiding taking medication altogether. For example, the odds of medication restriction in minority subjects were higher among those with no drug coverage than among those with full drug coverage. Similarly, the odds of medication restriction were higher in low-income subjects with no drug coverage than in those with full drug coverage. (Michael A. Steinman, et al., ''Self-restriction of Medications Due to Cost in Seniors without Prescription Coverage,'' 16 Journal of General Internal Medicine 793–799, Dec. 2001). Thus, comprehensive coverage is particularly likely to have an impact on prescription drug use among disadvantaged populations.

d. Improved Health and Reduction of Adverse Health Effects

Not filling prescriptions, skipping doses, or cutting pills in half are referred to in medical literature as ''medication noncompliance,'' and can have adverse health effects. We believe that by reducing financial barriers associated with obtaining outpatient prescription drugs and encouraging beneficiary compliance with their drug treatment regimens, the Medicare prescription drug benefit will reduce the occurrence of adverse health events and lead to overall improvements in beneficiaries' health.

Medication noncompliance can lead to worsening health problems and the need for additional health care services. For example, a study of prescription drug noncompliance among disabled adults found that about half of the individuals reporting medication noncompliance due to cost reported experiencing one or more health problems as a result, including pain, discomfort, disorientation, change in blood pressure or other vital signs, having to go to a doctor or emergency room, or being hospitalized. (Jae Kennedy and Christopher Erb, ''Prescription Noncompliance Due to Costs Among Adults with Disabilities in the United States,'' American Journal of Public Health, July 2002). This same study cited other research indicating that medication noncompliance is a clinical problem, particularly related to chronic illnesses such as hypertension, and has been found to be a predictor of hospital admissions and emergency room visits in other studies.

Similarly, another study found that limiting access to medications among low-income, elderly Medicaid patients increased rates of admission to nursing homes. The study analyzed Medicaid recipients aged 60 years or older who took three or more medications per month and at least one maintenance drug for chronic diseases. Limiting affordable access to prescription drugs for this population (through a reimbursement cap on medications) increased rates of admission to nursing homes. The authors concluded that for the sicker patients in the study, the limitation on medication more than ''double[d] the rate'' of admission in comparison to a group whose medications were not limited. (Stephen B. Soumerai et al., ''Effects of Medicaid Drug-Payment Limits on Admission to Hospitals and Nursing Homes,'' 325 *New England Journal of Medicine* 1072, 1074, 1991).

There is also evidence suggesting that the use of specific drugs may reduce adverse health events, utilization of other health care services, and related costs for certain groups of patients. For example, a recent study found that the use of statins in cholesterol-lowering drug therapy reduced the incidence of coronary disease-related deaths by 24 percent in elderly men and women (ages 70 to 82) with a history of, or risk factors for, vascular disease, and also reduced the incidence of non-fatal heart attacks and fatal or non-fatal strokes in these patients (''Pravastatin in Elderly Individuals at Risk of Vascular Disease (PROSPER): A Randomised Controlled Trial,'' *Lancet* 2002, 360:9346, 1623–1630).

Similarly, the Heart Outcomes Prevention Evaluation (HOPE) study has found that antihypertensive drug therapy reduced the combined risk of cardiovascular death, heart attack and stroke by 22 percent in approximately 9,000 high-risk middle-aged and elderly patients (ages 55 and older), with $871,000 in net estimated savings associated with direct hospitalization and procedural costs for this cohort of patients over the first 4 years of the study, and also significantly reduced the risk of adverse cardiovascular outcomes by 25 to 30 percent in a broad range of high-risk middle-aged and elderly patients with diabetes mellitus (See ''Drug Therapy and Heart Failure Prevention,'' Editorial, Jennifer V. Linseman, PhD, and Michael R. Bristow, MD PhD, *Circulation* 107:1234, American Heart Association, 2003; ''Economic Impact of Ramipril on Hospitalization of High-Risk Cardiovascular Patients,'' Cathryn A. Carroll, PhD MA MBA BSPharm, *The Annals of Pharmacotherapy*, Volume 37, No. 3, pp. 327–331; and ''Effects of Ramipril on Cardiovascular and Microvascular Outcomes in People With Diabetes Mellitus: Results of the HOPE Study and MICRO-HOPE Substudy, Evaluation (HOPE) Study Investigators, *Lancet* 355 (9200):253–259, 2000).

While there is evidence that the use of certain prescription drugs may be cost-effective for specific groups of patients (in the sense that they result in net health care cost savings or produce health improvements at relatively low cost), thus far it has been difficult to generalize the results of these drug-specific studies more broadly to estimate the potential health care cost savings or morbidity or mortality reductions in the context of an overall Medicare prescription drug benefit. First, the findings from available cost-effectiveness analyses in the literature suggest that while some prescription drugs may lead to short-term or long-term reductions in net health care costs, other prescription drugs may lead to net increases in health costs (for example, as a result of adverse drug reactions which require additional health care services). Second, the Medicare prescription drug benefit will improve access to prescription drugs for a

broader patient population than is typically included in the available studies in the literature, which may affect the potential cost-effectiveness of certain drugs. For example, while the literature suggests that the use of statin drugs for lowering blood cholesterol levels in patients with existing heart disease is relatively cost-effective, using these drugs to preventively lower blood cholesterol levels in patients that do not have heart disease may be less cost-effective (see ''Are Pharmaceuticals Cost-Effective? A Review Of The Evidence,'' Peter J. Neumann, Eileen A. Sandberg, Chaim M. Bell, Patricia W. Stone, and Richard H. Chapman, *Health Affairs* 19:2, March/April 2000; and ''The Price of Progress: Prescription Drugs in the Health Care Market,'' J. D. Kleinke, *Health Affairs* 20:5, September/October 2001 available at *www.healthaffairs.org*).

In addition to the anticipated reductions in adverse health events associated with anticipated improvements in prescription drug compliance, we believe that many elements of the Medicare prescription drug benefit—including quality assurance, electronic prescribing, better beneficiary information on drug costs and ways to reduce drug costs (for example, through generic substitution), and medication therapy management which are designed to improve medication use and reduce the risk of adverse events, including adverse drug interactions—will also improve beneficiaries' health outcomes. We believe that these improvements will occur through enhanced beneficiary education, health literacy and compliance programs; improved prescription drug-related quality and disease management efforts; and ongoing improvements in the information systems that are used to detect various kinds of prescribing errors—including duplicate prescriptions; drug-drug, drug-allergy and drug-food interactions; incorrect dosage calculations, and problems relating to coordination between pharmacies and health providers. We also believe that additional reductions in errors and additional improvements in prescription choices based on the latest available evidence will occur over time as the electronic prescribing provisions of the MMA are implemented (T*o Err is Human: Building A Safer Health System*, Institute of Medicine of the National Academies, 1999, pp. 191–193, *www.iom.edu* or *www.nap.edu*).

Ultimately, we believe that the evidence supports our conclusion that making prescription drugs more available and affordable will help beneficiaries to live healthier, more productive lives. We also believe that expanding prescription drug coverage will reduce adverse health events and Medicare program spending on more costly services for some beneficiaries, and will be particularly important for beneficiaries with limited means who are more likely to forego beneficial prescription drugs when they do not have coverage. However, the effect on aggregate Medicare program spending across all beneficiaries is difficult to ascertain. At this time, there have not been studies that have found evidence that expansions of drug coverage across a large population, as will occur under the Medicare drug benefit, yields aggregate health care cost savings. Furthermore, there have been mixed results on the impact of coverage on the cost-effectiveness of care involving certain individual drugs in general, and in differing patient populations. Thus, the extent to which the Medicare drug benefit may lead to reductions in Medicare spending for other health care services in the aggregate across all beneficiaries is difficult to predict. Additional research will be needed to further examine and quantify these potential effects. For example, we are currently conducting a demonstration study on the extent to which coverage of oral medicines reduces the use of professionally-delivered medicines and the associated physician and health care services that are currently covered in Part B. We are very interested in developing further evidence on the best ways to encourage outcome improvements and overall health care cost reductions through drug coverage. For example, we are currently collaborating with AHRQ and other experts to identify priorities for developing better evidence and increasing value in the use of outpatient medications, and intend to develop further evidence as part of the implementation of the drug benefit.

In the proposed rule, we requested comments related to how outcome improvements and overall health care cost reductions related to drug coverage can be incorporated into the implementation of the drug benefit.

Comment: We received a comment from a quality organization which stated that when administered appropriately, a prescription drug benefit can affect care across the spectrum, from preventing infection or disease to managing or reversing the impact of chronic disease, and controlling the cost of overall care; however, a poorly managed drug benefit can worsen the health of beneficiaries, raise costs, and potentially negatively affect public health. The commenter went on to state that prescription drugs are a critical element of an evidence-based benefit package, and that administration of a drug benefit must simultaneously guard against potential underutilization of needed drugs and over utilization of inappropriate drugs, both of which have the potential to negatively affect quality and costs for the individual and for society as a whole. Another quality organization stated that medication therapy management program services are a vital component for ensuring that Medicare beneficiaries receive their Part D benefits in a safe and effective manner. Several quality organizations provided recommendations relating to Part D plan quality assurance measures and systems, encouraged us to develop quality and performance measures for assessing the services provided by PDPs and MA-PDs, and offered to assist us in developing requirements and performance measures. Additionally, we received a number of comments that included examples of successful medication therapy management programs and described methods for measuring outcomes for asthmatic, diabetic, and hypertensive patients. Additionally, one quality organization commenter urged us to standardize the format, terms, definitions, and types of information that PDP sponsors will use in describing their quality assurance measures and systems and medication therapy management programs in the plan information they disseminate to beneficiaries.

Response: We appreciate the information that commenters provided relating to incorporating quality improvements and potential cost reductions into the implementation of the Medicare drug benefit. We agree that effective medication therapy management programs and quality assurance measures and systems can help to improve beneficiaries' health outcomes, and ultimately reduce health care costs, and will continue to look at this issue closely. As mentioned in the preamble, we intend to work with various stakeholders to develop appropriate quality elements and utilization measures, and incorporate them into Medicare Part D where appropriate.

4. Positive Effects of the Medicare Retiree Drug Subsidy and Other Employer/Union Options for Providing Prescription Drug Assistance

The Medicare prescription drug benefit and retiree drug subsidy represent additional funding sources that can help employers and unions continue to provide high quality drug

coverage for their retirees. In this section, we describe the Medicare retiree drug subsidy and the various other ways that Medicare Part D offers financial assistance with retiree prescription drug costs to employers and unions. We also discuss some of the potential effects that these options will have on the availability and generosity of retiree drug coverage for Medicare-eligible retirees.

We anticipate that these new sources of support will have many important positive benefits for the quality and security of drug coverage for retirees. Overall, we believe that the implementation of Medicare Part D, including the Medicare retiree drug subsidy and the other opportunities it affords employers and unions for providing continued prescription drug assistance to their Medicare retirees, will result in combined aggregate payments by employers/unions and Medicare for drug coverage on behalf of retirees that are significantly greater than they otherwise would have been without the enactment of the MMA. Furthermore, we believe that the Medicare prescription drug benefit and retiree drug subsidy represent a particularly important strengthening of health care coverage for future Medicare-eligible retirees, given the erosion in the availability and generosity of employment-based retiree coverage for future Medicare beneficiaries that has already been taking place.

a. Overview of the Medicare Retiree Drug Subsidy

The positive benefits for retiree coverage from the new retiree drug subsidy program are related to the subsidy payments it will make available to sponsors of employer and union plans that provide high quality retiree drug coverage, the special tax-favored status of the subsidy payments that will be made to the qualified retiree health plan sponsors, and the flexibility in using the subsidy to support retiree coverage. The retiree drug subsidy program has highly flexible rules and stands as an additional option that permits employers and unions to continue providing drug coverage to their Medicare-eligible retirees while retaining their current plan designs that are at least equivalent to the standard Part D benefit, and receiving a Federal subsidy that reduces the cost of providing this coverage. We note that employers and unions that want to participate in the retiree drug subsidy program also retain the option of providing regular supplementation to Medicare Part A and Part B benefits through arrangements with Medicare Advantage organizations offering a MA only plan without the Part D benefit, while still qualifying for the retiree drug subsidy program by arranging for an employer or union-sponsored retiree drug benefit through a separate private contract with the MA organization.

The intent of the Medicare retiree drug subsidy is to offer qualified retiree prescription drug plans financial assistance with a portion of their prescription drug costs and thereby ''help employers [to] retain and enhance their prescription drug coverage so that the current erosion in coverage would plateau or even improve'' (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Conference Report, p. 53). By making a tax-free subsidy for 28 percent of allowable prescription drug costs attributable to the portion of each qualifying retiree's gross prescription drug costs that is between the cost threshold and cost limit (that is, drug spending between $250 and $5,000 for 2006) available to qualified retiree prescription drug plans, the Medicare retiree drug subsidy significantly reduces the financial liabilities associated with employment-based retiree drug coverage and encourages employers and unions to continue assisting their retirees with prescription drug coverage.

To provide a rough estimate of the per capita retiree drug subsidy, we used MCBS data on prescription drug spending for retirees with employment-based coverage, adjusted for under-reporting, and trended these data forward based on the projected growth rate in prescription drug spending from the National Health Expenditures projections. We then applied 28 percent to the drug spending between $250 and $5,000 to approximate the average annual retiree drug subsidy for 2006. This calculation yielded an estimated per capita retiree drug subsidy amount of $668 in 2006. The per capita subsidy amount was calculated across all beneficiaries in qualified retiree prescription drug plans, including both those who do and do not have spending high enough to qualify for a Medicare retiree drug subsidy payment. In the proposed rule, we sought comment on the completeness and accuracy of our MCBS-based projections for valuing the retiree subsidy. While we did not receive any comments specifically relating to the use of MCBS data for valuing the retiree drug subsidy, we did receive comments about the use of MCBS data more generally (see section D of this impact analysis). As discussed in more detail previously, we acknowledge that there are limitations associated with using MCBS data; however, we believe that the MCBS offers the best data available for making these estimates because it is the largest nationally representative survey of prescription drug utilization and costs for Medicare beneficiaries.

The Medicare retiree drug subsidy is excluded from the taxable income of the plan sponsor (just as the Medicare subsidy provided to beneficiaries through the Medicare prescription drug benefit is excluded from the taxable income of the beneficiary). While the tax-free nature of the retiree drug subsidy does not affect the value of the subsidy to firms without taxable income, the tax-free nature of the Medicare retiree drug subsidy generally increases its value to plan sponsors that are subject to taxation. As indicators of the value of this tax subsidy, we provide some estimates of the equivalent values of a taxable subsidy for employers at several corporate income tax rates. For corporations with taxable incomes, marginal tax rates generally range from 15 percent to 35 percent. According to estimates by the Congressional Research Service, the weighted average effective tax rate for corporations that pay taxes is approximately 28.5 percent (Congressional Research Service, ''Weighted Effective Total Tax Rates on the Corporate and Noncorporate Sectors,'' cited in the Congressional Budget Office's letter and report to the Honorable Don Nickles, February 24, 2004, see *www.cbo.gov*). Combining this tax rate and the estimated $668 average per capita subsidy amount for 2006, we estimate that the $668 tax-free retiree drug subsidy amount would be equivalent to a taxable subsidy of $934 for employers subject to taxation. The equivalent taxable subsidy for any particular employer with taxable income would, of course, vary depending on its specific marginal tax rate. For example, the tax-free $668 average retiree drug subsidy amount would be equivalent to about $891 of taxable income for employers with a marginal tax rate of 25 percent and about $1,028 of taxable income for employers with a marginal tax rate of 35 percent.

Our implementation of the retiree drug subsidy program is guided by the following four policy goals: 1) maximizing the number of Medicare-eligible retirees with high quality employer or union-provided retiree drug coverage, and maximizing the generosity of their coverage; 2) avoiding financial windfalls in the retiree drug subsidy program by ensuring that plan sponsors contribute at least as much to retiree drug coverage as Medicare pays them as a subsidy; 3) minimizing

administrative burden while maximizing flexibility for employers and unions; and 4) fulfilling our fiduciary responsibility by limiting overall budgetary costs. We have taken a number of steps to be responsive to the concerns that were raised in the comments relating to the retiree drug subsidy program. We believe that the flexibility that we have provided relating to actuarial equivalence, plan definition, qualifying covered retirees, payment methodology, and data reporting requirements will make it easier for employers and unions to continue offering their existing retiree drug plans to Medicare-eligible retirees, while qualifying for the retiree drug subsidy.

b. Overview of Additional Options Available to Employers and Unions Through Medicare Part D

As indicated earlier, in addition to the ability to obtain Medicare retiree drug subsidy payments for sufficiently generous drug coverage, Medicare Part D also gives employers and unions a variety of other options for continuing to assist their Medicare-eligible retirees in obtaining more generous drug coverage. For example, employers and unions that are supporting retiree coverage now could also choose to provide additional drug coverage by using the new Medicare Part D subsidy directly (that is, encouraging their retirees to enroll in a Medicare Part D plan which includes a significant government subsidy for the standard benefit) with the employer/union providing additional coverage over and above the standard Part D benefit that maintains or exceeds the generosity of their current benefit designs. This can be achieved by either: 1) arranging for a PDP or MA-PD Part D plan to provide enhanced benefits to their retirees; 2) arranging for a PDP or an MA-PD under a waiver to offer a customized plan that is exclusive to the employer or union's retirees; 3) choosing through a waiver to become a Part D plan for their retirees that offers enhanced benefits (this is equivalent to offering a self-insured benefit); or 4) providing separate supplemental drug coverage that wraps around a Part D plan (similar to the typical employer and union policies that wrap around Medicare benefits under Part A and Part B). In addition to the various options that are available for providing additional retiree drug coverage in coordination with a Part D plan, employers and unions also have the opportunity to assist their Medicare-eligible retirees in paying all or part of their Part D premiums.

Under these approaches for coordinating employer or union-sponsored retiree drug coverage with Part D, the employers/unions' costs associated with providing retiree drug benefits are reduced on a dollar-for-dollar basis by the amount that Medicare subsidizes Part D plans. For example, we estimate that employers and unions that choose to provide enhanced or separate supplemental drug coverage that wraps around Part D will achieve, on average, a minimum of $900 per beneficiary of savings in 2006.

For Medicare Advantage Part C, we have broad authority to waive rules that hinder the design, enrollment in, or offering of employer plans to Medicare eligible beneficiaries. We believe that this waiver authority, which has also been extended to Part D, can assist PDPs and MA-PDs in designing prescription drug benefits that are offered exclusively to employers for their retiree populations, and make it easier for employers to contract with (or become) PDPs and MA-PDPs to provide enhanced benefits to their retirees that supplement the standard Part D benefit (for example, additional assistance with cost sharing).

We anticipate providing considerable flexibility in the waiver process for PDPs and MA-PDs that are offered exclusively to employers. As discussed in the preamble, we will be using a streamlined approach for implementing employer group waivers that allows maximum flexibility for employers to retain retiree prescription drug coverage. As part of this process, we will include details on the types of waivers that we will consider in guidelines, and we will address additional waiver requests from specific employers or plans on a flow basis. Additionally, we note that once waivers have been granted, they will be available to all similarly situated employers or unions, thus maximizing the number of employers that will be able to benefit from the flexibility of the waiver process.

We are also committed to easing the transition to employer/union participation in providing separate supplemental coverage that wraps around Part D. Employers and unions that choose this option will need to coordinate their wraparound benefits with the standard Part D benefit, a function that can be performed by the employer or union's insurer or third party administrator. As discussed more fully in the preamble, CMS will play a role in facilitating coordination of benefits and the tracking of TrOOP. We are considering the most efficient way of assisting in coordinating benefits and TrOOP tracking, including through the establishment of a TrOOP facilitation contractor, contractors, or a blend of approaches. We will provide more details of our solution in this regard in CMS guidance to be released before the statutory deadline of July 1, 2005. We believe that the TrOOP facilitation process will make it easier for employers and unions to offer supplemental coverage that wraps around Part D.

Finally, it is important to note that since the final rule includes a two-prong actuarial equivalence test for qualifying for the retiree drug subsidy, as discussed in subpart R of the preamble, there may be some employers or unions that provide retiree drug coverage that is creditable on a gross value basis but, for example, are not making sufficient contributions toward the financing of the benefit to qualify for the retiree drug subsidy on a net value basis. These employers and unions can choose at any time to modify their existing retiree drug benefit designs to supplement Part D. Under this circumstance, as discussed in subpart B of the preamble, the Medicare retirees would be eligible for a special enrollment period for Medicare Part D because their retiree drug coverage no longer meets the criteria for creditable coverage. The special enrollment period provision would enable these employers/unions to work with their retiree populations and the new Part D plans to achieve a smooth transition and ensure that their Medicare-eligible retirees would not be subject to late enrollment penalties when they enroll in Part D. We believe that the availability of special enrollment periods provides important additional flexibility and time to employers and unions as they evaluate the various options that are available to them under the Medicare drug benefit and retiree drug subsidy.

c. How Employers and Unions Are Likely To Respond To The Options That Are Available To Them Under The MMA

While there is considerable uncertainty about the choices that employers and unions will make regarding the form of prescription drug assistance that they may choose to provide for their Medicare-eligible retirees, we believe that employers and unions will generally continue to provide prescription drug assistance to their retirees and that Medicare Part D will make it more affordable for them to do so.

First, as we noted in the proposed rule, with the decline over the years in the number of employers/unions offering retiree health insurance coverage, it is likely that many of the remaining employers and unions who

continue to offer such coverage directly are likely those employers/unions who have a contractual commitment or other interest in maintaining that coverage.

Second, although employers and unions' responses to Medicare Part D and the retiree drug subsidy are expected to play out over the next few years, initial signals suggest that there has been a positive response to the Medicare retiree drug subsidy. Several major employer associations have praised the MMA for giving businesses flexibility in deciding how their retiree health plans will work in relation to the Medicare prescription drug benefit, and for offering employers and unions a 28 percent Medicare retiree drug subsidy payment that would not be taxed for plan sponsors who continue to provide high quality retiree coverage (''ECOM Applauds Historic Passage of Medicare Reform Legislation,'' Employers' Coalition on Medicare press release, November 25, 2003, *www.employersandmedicare.org*; ''Chamber Praises Congressional Action on Medicare Reforms,'' U. S. Chamber of Commerce, November 25, 2003, *www.uschamber.com*).

Additionally, several major corporations issued 2003 annual reports that included estimates suggesting that they will collectively experience an $11.8 billion reduction in their accumulated postretirement benefits obligation that will occur over time due to the Medicare subsidy payments they anticipate receiving under the Medicare retiree drug subsidy program (''Expected Cost Savings From Medicare Act May Top $11.8 Billion'', Lingling Wei, Dow Jones Newswires, The Wall Street Journal, March 22, 2004, available at *www.wsj.com*). Although some of these companies may have needed to revise their initial estimates to reflect the Financial Accounting Standards Board's (FASB) Final Staff Position on accounting for the effects of the Medicare retiree drug subsidy payments, which was effective for financial statements for periods beginning after June 15, 2004 (''FASB Staff Position Number FAS 106–2, Accounting and Disclosure Requirements Related to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,'' posted May 19, 2004, available at *www.fasb.org*) and the provisions of this final rule, these initial reports suggest that some employers are already planning to take advantage of the substantial savings that are available to them under Medicare Part D.

However, given the uncertainty that exists about the future choices that employers and unions will make we requested comments about how employers and unions are likely to view the various options that are available under Medicare Part D for assisting them in continuing or enhancing their retiree health benefits. Specifically, we were interested in comments on the factors that will affect employers' and unions' choices between applying for the retiree drug subsidy, wrapping around Part D coverage, qualifying as an enhanced Part D plan directly, or using an enhanced PDP or MA-PD plan to provide enhanced coverage to their retirees. This information will assist us in understanding how these options can be designed together to maximize the increase in availability of high quality drug benefits for retirees. The following sections summarize the major issues relating to employers and unions' likely responses to the various options available to them under the MMA that we discussed in the proposed rule, as well as the comments that we received relating to these issues.

i. Major Factors That Will Affect Employers And Unions' Responses To The Options That Are Available To Them Under The MMA

In the proposed rule, we identified several factors that could potentially influence employers and unions' responses to the opportunities for continuing to provide high quality retiree drug benefits that are available to them through the retiree drug subsidy and the various options that are available for coordinating their coverage with Part D.

For example, we noted that the Medicare retiree drug subsidy is excluded from the taxable income of the plan sponsor (just as the Medicare subsidy provided to beneficiaries through the Medicare prescription drug benefit is excluded from the taxable income of the beneficiary). While the tax-free nature of the retiree drug subsidy does not affect the value of the subsidy to firms without taxable income, the tax-free nature of the Medicare retiree drug subsidy generally increases its value to private sector employers that are subject to taxation. For example, as noted previously, the tax-free $668 average retiree drug subsidy amount would be equivalent to about $891 of taxable income for employers with a marginal tax rate of 25 percent and about $1,028 of taxable income for employers with a marginal tax rate of 35 percent.

We also stated that based on published employer surveys, reports from employers and benefit consultants, and other available sources of evidence, we expect that some employers and unions will choose to provide prescription drug assistance to their Medicare-eligible retirees in the form of enhanced benefit packages through Part D plans or separate wraparound coverage. In both cases, the employer/union contributions would augment Medicare's subsidized coverage under Part D. We noted that many employers and unions currently do this relative to Medicare Part A and Part B coverage, either through separate supplemental policies or through arrangements with Medicare Advantage plans. In fact, the Medicare retiree drug subsidy represents a new type of arrangement for employers and unions relative to the interaction of their retiree coverage with Medicare. Thus, some employers and unions may prefer to interface with the new Medicare prescription drug benefit in a manner similar to their supplementation of the basic Medicare Part A and Part B benefits. We also stated that we expect that many of the employers and unions that choose to provide drug coverage through or in coordination with Part D will also choose to pay some or all of their retirees' Part D premiums. Since the Medicare Part D drug benefit includes a direct Federal subsidy, these approaches would allow employers and unions to continue to provide a benefit package of similar or greater generosity compared to their existing arrangements while potentially lowering their prescription drug costs.

We also noted that another important factor that will affect whether employers or unions will use the retiree drug subsidy is whether their contribution to the retiree coverage is sufficient to qualify for the retiree drug subsidy, and if it is not currently sufficient, whether they will increase the generosity of their contribution in order to receive the cash and tax value of the subsidy. We suggested that such increased contributions could be in the financial interest of some employers and unions because they could qualify for the value of the full subsidy by making an additional incremental contribution of less than the full value of the subsidy, thereby achieving net savings. However, we also stated that providing enhanced benefits or separate wraparound coverage in coordination with Part D may also be an attractive option to employers and unions that may not be eligible for the Medicare retiree drug subsidy because their retiree drug benefits, as currently structured, are not actuarially equivalent to the standard Medicare Part D drug benefit. In both cases, these employers/unions could use their contributions to augment Medicare's subsidized coverage under

Part D, and thereby provide a more generous benefit to their Medicare-eligible retirees.

Comment: We received several public comments from employers and employer groups that supported the MMA and proposed rule's overall approach of encouraging employers and unions to continue providing retiree health coverage, while providing flexibility and minimizing administrative burdens. Several of these comments indicated that employer and union retiree health plan sponsors' responses to the various options that are available to them under the Medicare drug benefit and retiree drug subsidy will be affected by a variety of factors, including: the timeframe of CMS regulation and guidance; the degree of flexibility in the retiree drug subsidy program (for example, relating to the actuarial equivalence methodology, application process, plan sponsor and qualifying covered retiree definitions, payment methodology and frequency, and subsidy payment allocation requirements); the amount of flexibility in the waiver process for employer-sponsored PDPs and MA-PDs; the financial incentives and degree of administrative burden associated with the various options; the timely availability of feasible PDP and wraparound options in the market; and employers and unions' own internal timeframes and processes required to make benefit design changes.

We also received several comments suggesting that plan sponsors' responses to the various options that are available to them under the MMA, including whether or not they will choose to accept the retiree drug subsidy, may vary according to the type of employer or union plan. For example, one commenter stated that small, self-insured employers might find that the cost of obtaining an actuarial attestation may exceed the value of the retiree drug subsidy payments that they would receive. Similarly, a few commenters stated that employer/union plan sponsors and insurers offering fully-insured retiree health plans might have difficulty tracking claims at the individual plan sponsor level for purposes of meeting the retiree drug subsidy program's data submission and record retention requirements.

Additionally, a few public sector employer commenters stated that the definition of plan sponsor that was being used in the proposed rule did not seem to be broad enough to allow some public retirement systems to qualify for the retiree drug subsidy. Two public sector employer commenters suggested that some governmental entities may be discouraged from obtaining the retiree drug subsidy because its tax-free nature does not provide an additional financial incentive to non-taxable plan sponsors that provide retiree health benefits. Also, one public employer group commenter requested that we assure through final regulations or the waiver process that State and local government plans have the same opportunity to directly sponsor a PDP or MA-PD as other employer/union plan sponsors.

Finally, a few commenters expressed concerns that retiree health plans with limited employer/union contributions—including some State and local government retiree health plans and many church plans that require their retirees to contribute in excess of 50 percent of the cost of prescription drug coverage—might have difficulty qualifying for the retiree drug subsidy if a net-value test is used in determining actuarial equivalence.

Response: In recognition of the considerable diversity that exists within the employer and union community, the MMA gives employers and unions several options for accessing the new financial resources that Medicare Part D makes available for assisting them in continuing to offer high quality retiree drug coverage. For example, employers and unions have the option of continuing to provide drug coverage that is at least actuarially equivalent to the standard Part D benefit for their Medicare-eligible retirees as a primary insurer, and receiving a direct retiree drug subsidy that reduces the cost of providing this coverage. As discussed in more detail in subpart R, to qualify for the retiree subsidy, plans must meet a two-prong test for actuarial equivalence, which includes a net-value test. We chose this definition of actuarial equivalence for the retiree subsidy because we believe it best achieves our goals of maximizing the number of beneficiaries retaining employment-based retiree drug coverage while not creating windfalls to sponsors.

Employers and unions, including those that do not qualify for the subsidy, have several other options under Medicare Part D for providing prescription drug assistance to their retirees. For example, employers and unions can choose to offer drug coverage that maintains or exceeds the generosity of their current benefit designs by providing additional coverage that complements the standard Part D prescription drug benefit, effectively becoming a secondary insurer that uses the Part D benefit to subsidize the costs of their Medicare-eligible retirees' drug coverage. As discussed earlier, this coordination can be achieved by: 1) arranging for a PDP or MA-PD Part D plan to provide enhanced benefits to their retirees; 2) arranging for a PDP or an MA-PD under a waiver to offer a plan that is exclusive to the employer's retirees; 3) choosing through a waiver to become a Part D plan that offers enhanced benefits; or 4) providing separate supplemental drug coverage that wraps around a Part D plan (similar to policies that wrap around Medicare benefits under Parts A and B). We recognize that some of the options that are available through the Medicare drug benefit and retiree drug subsidy may be more attractive to certain employers/unions than other options. However, we believe that these options give employers and unions a wide variety of opportunities for continuing to provide a generous level of retiree coverage.

Our implementation of the various options that are available to employers and unions under the Medicare drug benefit and retiree drug subsidy for continuing to offer high quality prescription drug coverage to Medicare-eligible retirees at a lower cost is guided by four policy goals: 1) maximizing the number of Medicare-eligible retirees with high quality employer or union-provided retiree drug coverage, and maximizing the generosity of their coverage; 2) avoiding financial windfalls in the retiree drug subsidy program by ensuring that plan sponsors contribute at least as much to retiree drug coverage as Medicare pays them as a subsidy; 3) minimizing administrative burden while maximizing flexibility for employers and unions; and 4) fulfilling our fiduciary responsibility by limiting overall budgetary costs. The preamble considers the issues that were raised in the comments from employers, unions, and other related entities and describes the policy decisions that we made relating to these issues, balancing the various policy goals in an effort to achieve the maximum increase in support for retiree health coverage as existing employer and union contributions are augmented by new financial support from the Medicare prescription drug benefit and retiree drug subsidy. We have taken a number of steps to be responsive to the concerns that were raised in the comments. Similarly, we are exploring options for increasing flexibility in employers' and unions' ability to directly sponsor PDPs or MA-PDs. For example, as discussed in the preamble, we have provided flexibility in the payment methodology and data submission requirements related to retiree drug subsidy payments to plan sponsors with insured benefits.

In addition, where appropriate, the potential impact of these various policy decisions has been factored into the projection assumptions for the impact analysis, as discussed elsewhere in this impact analysis.

ii. Potential Effect of Factors Unrelated to Medicare on Employer and Union Behavior

In the proposed rule, we noted that although the Medicare prescription drug benefit and retiree drug subsidy represent additional funding sources for employment-based retiree drug coverage that can help employers and unions to retain drug coverage for their retirees, there are also a number of economic forces unrelated to Medicare that will play a role in employers' and unions' decision making regarding both the availability and the generosity of employment-based retiree health coverage. Many of the economic forces behind the ongoing erosion of retiree health benefits that are discussed subsequently in this impact analysis may continue to give employers and unions a financial incentive to reduce the costs associated with providing retiree health coverage. The Employee Benefit Research Institute (EBRI) has estimated that additional declines in retiree drug coverage could potentially continue to occur, particularly for future retirees, ''due to existing business, accounting, and cost trends,'' regardless of changes in the Medicare program (EBRI Special Analysis prepared for Senator Charles E. Grassley, Dallas L. Salisbury and Paul Fronstin, Employee Benefit Research Institute, July 18, 2003, available at *www.ebri.org*).

Comment: We received one comment from a retiree advocacy group suggesting that the recent Equal Employment Opportunity Commission (EEOC) ruling could significantly affect employer/union behavior relating to retiree health benefits for Medicare-eligible retirees.

Response: As noted above, several economic and non-economic forces that are not related to the Medicare retiree drug subsidy and the other opportunities that are available for coordinating employer/union-sponsored coverage with Part D could potentially influence employers' and unions' decisions about the availability and generosity of retiree health benefits for Medicare-eligible retirees. We agree that the recent EEOC ruling is a non-Medicare related factor that could potentially affect employers' and unions' behavior concerning retiree drug coverage. In that ruling, the EEOC approved a proposed final rule that would allow ''employers and labor organizations to offer retirees a wide range of health plan designs that incorporate Medicare or comparable State health benefit programs without violating the ADEA.'' EEOC states that its proposed final rule would enable employers and unions to supplement a retiree's Medicare coverage or take advantage of the tax-free retiree drug subsidy without having to demonstrate that the drug coverage they provide to their Medicare-eligible retirees is identical to the drug coverage that they offer to their early retirees. There is considerable uncertainty about how the EEOC's ruling will ultimately affect employer and union behavior (see EEOC web site, *http://www.eeoc.gov/policy/regs/retiree_benefits/*).

Similarly, the Governmental Accounting Standards Board (GASB, which develops accounting standards for State and local governments) recently issued Statement No. 43, Financial Reporting for Postemployment Benefit Plans Other Than Pension Plans and Statement No. 45, Accounting and Financial Reporting by Employers for Postemployment Benefits Other Than Pensions, which will require State and local governments to begin reporting the long-term costs of their retiree health benefit liabilities on an accrual basis and will encourage them to begin setting aside money in trust funds to cover the future costs of providing benefits to their retirees (''GASB Issues Standards to Improve Postemployment Benefit Plan Reporting,'' May 11, 2004 and ''GASB Issues Statement That Addresses Employer Reporting of Postemployment Benefits Other Than Pensions,'' August 2, 2004, see GASB web site, *http://www.gasb.org/news/index.html*). Some experts have speculated that the GASB standards could put additional financial pressures on State and local governments to reduce their financial liabilities by making changes in their retiree health benefits; however, others have noted that some State and local governments may find it difficult to make such changes due to legislative and collective bargaining considerations, or may not opt to make such changes due to labor relations considerations.

Additionally, while there is some uncertainty relating to their potential impact on employer and union behavior, factors such as existing caps on retiree health benefits that have been instituted by some plan sponsors, and demographic trends could also potentially influence employer and union decision making concerning retiree health benefits. Furthermore, as discussed elsewhere, the availability and generosity of retiree health coverage had been declining for more than a decade prior to enactment of the MMA, particularly for future retirees, and available evidence suggests that this erosion is continuing to occur (primarily in the form of increasing retirees' share of premiums and increasing eligibility restrictions for future retirees) due to ongoing financial pressures on employers (Comments made during discussion of the Medicare Payment Advisory Commission (MedPAC) Supplement to the Kaiser/HRET Survey, Transcript of MedPAC Public Meeting, November 16, 2004, see MedPAC web site, *http://www.medpac.gov/public_meetings/transcripts/1104_allcombined_transc.pdf*).

iii. Employers And Unions Have Not Yet Decided How They Will Respond

In the proposed rule, we noted that some employers and unions have not yet decided whether they will apply for the Medicare retiree drug subsidy, and are considering the various other options that are available for providing prescription drug assistance to their Medicare-eligible retirees (See Press Releases and Statements, Press Room of the Employers' Coalition on Medicare, available at www.employersandmedicare.org). We also noted that at the time that the proposed rule was published, most publicly traded companies had chosen to defer recognizing the effects of the Medicare retiree drug subsidy payments pending receipt of additional accounting and regulatory guidance. However, we noted that available evidence suggests that numerous large companies that offer employment-based retiree prescription drug coverage anticipate continuing to provide this coverage and accepting the Medicare retiree drug subsidy payments.

Comment: We received comments suggesting that most employers and unions have not yet decided how they will respond to the options that are available to them under the Medicare drug benefit and retiree drug subsidy. However, a few commenters did provide some information about employers' and unions' future plans. For example, two public sector employer commenters expressed a desire to continue providing their current retiree health benefits and receive the retiree drug subsidy. Similarly, a retiree advocacy group comment included information about a private employer that plans to separate its retiree drug coverage from its other retiree health coverage so that its Medicare-eligible retirees can choose between remaining in the employer's retiree drug plan or enrolling in a Part D plan, and plans to stop offering retiree drug coverage in a few years when the value of its retiree drug benefit becomes

lower than the value of the standard Part D benefit due to existing financial caps that the company had placed on its contribution to the costs of retiree coverage.

Response: Recent anecdotal information from various benefit consultants, researchers, and other experts suggests that many employers and unions have not yet determined how they will respond to the options that are available under the Medicare drug benefit and retiree drug subsidy, due to uncertainty about some of the details relating to how these options will be implemented.

However, in spite of employers and unions' uncertainty, some early evidence suggests that many employers and unions are likely to continue providing prescription drug assistance to their Medicare-eligible retirees. Recent surveys that included questions related to the Medicare drug benefit and retiree drug subsidy suggest that the vast majority of current Medicare-age retirees are likely to continue receiving some form of prescription drug assistance from their former employers/unions—either primary drug coverage that qualifies for the retiree drug subsidy, enhanced or supplemental coverage that wraps around the standard Part D benefit, or assistance with paying Part D premiums—and that few beneficiaries with retiree drug coverage were likely to lose their employment-based retiree drug benefits and/or retiree health benefits. The surveys suggest that many employers are likely to continue to assist their retirees by taking advantage of the financial support for retiree drug coverage that is available through the retiree drug subsidy and other options for coordinating with Part D, rather than ceasing to provide prescription drug assistance for their Medicare-eligible retirees (Comments made during discussion of the Medicare Payment Advisory Commission (MedPAC) Supplement to the Kaiser/HRET Survey, Transcript of MedPAC Public Meeting, November 16, 2004, see MedPAC web site, *http://www.medpac.gov/public_meetings/transcripts/1104_allcombined_transc.pdf*; Kaiser/Hewitt 2004 Survey on Retiree Health Benefits).

iv. Employers' And Unions' Responses May Change Over Time

Comment: We received several comments suggesting that employers' and unions' responses to the various options that are available to them under the Medicare drug benefit and retiree drug subsidy may change over time. For example, a benefit consultant stated that many plan sponsors will initially be attracted to accepting the retiree drug subsidy because this decision may be the easiest course administratively; however, as time goes on, it may be more attractive for employers and unions to consider modifying their retiree drug plans to supplement and coordinate with Part D. This benefit consultant also anticipated that the typical employer/union plan will provide retiree drug benefits that are better than Part D in 2006, but suggested that this pattern is likely to reverse over time. This commenter stated that the value of employment-based coverage for future retirees may well be less than the value of the highly-subsidized standard Part D coverage, suggesting that as plan sponsors' retiree populations begin to include more future retirees (who may be disproportionately affected by the economic caps that some companies have placed on their contributions to the cost of retiree coverage), this could result in a gradual shift in the average generosity of employment-based plans, thus making the option of supplementing the Part D benefit a more attractive approach for providing retiree drug coverage.

Similarly, we received a comment suggesting that another factor that may contribute to changes in employer and union behavior over time relates to the effect of financial caps that some employers have placed on their contributions to retiree health benefits in response to rising costs and the implementation of Financial Accounting Statement No. 106 (FAS 106). Specifically, as employers' contribution levels reach these caps, their retiree drug plans may no longer qualify for the retiree drug subsidy, or their retiree drug plans could become less valuable than the new Medicare drug benefit.

In addition, several commenters stated that employers and unions typically require a lead-time of at least one year to implement benefit design changes (and even longer in the case of church plans), and may not have sufficient advance information that would enable them to take full advantage of the various options that are available to them under Medicare Part D by 2006. For example, two commenters indicated that although employers are very interested in the option of wrapping around Medicare Part D coverage, they do not yet see arrangements in the marketplace that they feel would make this option feasible, such as the availability of cross-regional PDP and MA-PD offerings.

Response: In responding to the various options that are available to them under the Medicare drug benefit and retiree drug subsidy, employers and unions have two major choices. They will either need to determine whether they want to continue to offer creditable coverage that qualifies for the retiree drug subsidy and remain the primary insurer for their Medicare-eligible retirees' drug coverage, or whether they want to become a secondary payer that offers additional coverage that complements the Medicare Part D, with Medicare acting as the primary insurer. In developing this final rule, we have sought to provide significant flexibility in implementing the various options that are available to employers and unions under the Medicare drug benefit and retiree drug subsidy. We believe that this approach will help us to maximize the number of employers and unions that are able to take advantage of the various options available under the Medicare prescription drug benefit and retiree drug subsidy for retaining and enhancing their retiree drug coverage.

As discussed earlier, it is also important to note that an employer or union that provides retiree drug coverage that is creditable on a gross value basis but, for example, is not making sufficient contributions toward the financing of the benefit to qualify for the retiree drug subsidy on a net value basis can choose at any time to modify its existing benefit design to supplement Part D. Under this circumstance, as discussed in subpart B of the preamble, the Medicare retirees would be eligible for a special enrollment period for Medicare Part D because their retiree drug coverage no longer meets the criteria for creditable coverage. The special enrollment period provision would enable these employers and unions to work with their retiree populations and the new Part D plans to achieve a smooth transition and ensure that their Medicare-eligible retirees would not be subject to late enrollment penalties when they enroll in Part D. We believe that the availability of special enrollment periods provides important additional flexibility and time to employers and unions as they evaluate the various options that are available to them under the Medicare drug benefit and retiree drug subsidy.

However, we recognize that employers and unions will not be making their decisions in a static environment; rather, many of the environmental factors that will affect their decisions will continue to change over time, including the impact of rising health care costs and financial caps on employer contributions to retiree health coverage, demographic shifts in employers' and unions' retiree populations (as more of the future

retirees who may have less generous benefits than the current retirees begin to retire), and changes in a plan sponsor's financial position. Additionally, as discussed in the proposed rule, we believe that some employers and unions may prefer to provide coverage that interfaces with Medicare Part D in much the same way that they supplement the basic Medicare Part A and Part B benefits, and we acknowledge that they may require some additional lead-time to implement this option. Moreover, anecdotal information from various benefit consultants, researchers, and other experts suggests that some employers/unions that initially choose to accept the retiree drug subsidy may move to a wraparound option a few years later (Comments made during discussion of the Medicare Payment Advisory Commission (MedPAC) Supplement to the Kaiser/HRET Survey, Transcript of MedPAC Public Meeting, November 16, 2004, see MedPAC web site, *http://www.medpac.gov/public_meetings/transcripts/1104_allcombined_transc.pdf*).

For these reasons, we believe that it is likely that some employers' and unions' responses to the various options that are available to assist them in providing high quality drug coverage under the Medicare drug benefit and retiree subsidy may change over time—either in the aggregate or for specific retiree subpopulations. As discussed earlier, we have updated our enrollment estimates to reflect this potential change in employer and union behavior over time. We believe that these enrollment estimates are the best available given the considerable amount of uncertainty surrounding the possible responses of current plans to the many options that are available to them for interacting with Part D.

d. Anticipated Effects of the Medicare Retiree Drug Subsidy Program and Part D Assistance for Retirees on the Availability and Generosity of Retiree Drug Benefits

We also requested comments on how choices by employers and unions relating to the retiree drug subsidy, wrapping around Part D coverage, qualifying as an enhanced Part D plan directly, or using an enhanced PDP or MA-PD plan will affect retirees' net payments for drugs and other health services.

Comment: We received several comments from retiree advocacy groups and unions, which stated that the implementation of Medicare Part D will pose several potential risks for retirees with regard to the availability and generosity of their employment-based coverage, and requested that the final rule include additional retiree protections. Specifically, these commenters stated that Medicare-eligible retirees have a risk of: losing their current generous employer or union-sponsored retiree drug coverage; experiencing significant increases in out-of-pocket costs; not making the best choice for receiving prescription drug coverage due to confusion about the multiple options that are available to them; being exposed to the late enrollment penalty; and experiencing reduced access to newer drugs due to Part D formulary limitations. We also received comments from two employer groups suggesting that there is a risk for disabled beneficiaries in active worker plans (although they are in a non-work status) to receive less generous drug coverage if they are not deemed as being qualifying covered retirees for purposes of the retiree drug subsidy. Finally, one employer group commenter suggested that some retirees that choose to enroll in Part D plans could lose their other retiree health benefits because many employers may require their retirees not to enroll in a Part D plan as a condition of eligibility for the employer's qualified retiree health plan.

Response: A variety of factors will affect employers' and unions' decisions about how to respond to the various options that are available to them under the Medicare drug benefit and retiree drug subsidy. These decisions will ultimately affect the nature of the retiree drug benefits that will be available to current and future Medicare-eligible retirees. As discussed elsewhere, the availability and generosity of retiree health coverage had been declining for more than a decade prior to enactment of the MMA, particularly for future retirees, and available evidence suggests that this erosion is continuing to occur (primarily in the form of increasing retirees' share of premiums and increasing eligibility restrictions for future retirees) due to ongoing financial pressures on employers. For example, according to comments made by a researcher from the Health Research and Educational Trust, the cost of retiree health benefits has increased by 56 percent since 2000, and 27 percent of Medicare-eligible retirees receive their benefits from firms that have more Medicare-eligible retirees than active workers (Comments made during discussion of the Medicare Payment Advisory Commission (MedPAC) Supplement to the Kaiser/HRET Survey, Transcript of MedPAC Public Meeting, November 16, 2004, see MedPAC web site, *http://www.medpac.gov/public_meetings/transcripts/1104_allcombined_transc.pdf*).

In the context of this continuing erosion in the availability and generosity of retiree coverage, the Medicare drug benefit and retiree drug subsidy make considerable new financial resources available to assist employers and unions in continuing to offer high quality retiree health benefits. Employers and unions have considerable latitude in making changes in their existing retiree health benefit designs unless they have made a specific promise to maintain these benefits in their formal written plan documents, collective bargaining agreements, or other contractual commitments; or in the case of public employers, unless they have other statutory or regulatory constraints on their ability to make such changes. This has always been the case, and continues to be the case with the enactment of the MMA. However, we believe that the substantial additional resources that Medicare Part D provides through the retiree drug subsidy and the various options that employers and unions have for coordinating with Part D can help to counteract some of the financial pressures that have been contributing to the trends toward erosion in retiree health benefits by making it more affordable for employers and unions to continue providing high quality retiree drug coverage. Additionally, as discussed earlier, available evidence suggests that the majority of current Medicare-age retirees are likely to continue receiving prescription drug assistance from their former employers and unions—either in the form of primary drug coverage that qualifies for the retiree drug subsidy, enhanced or supplemental coverage that wraps around the standard Part D benefit, or assistance with paying Part D premiums—and that very few beneficiaries are likely to lose their employer or union-sponsored retiree drug benefits altogether.

The preamble describes the policy decisions that we made relating to the various options that are available to employers and unions under Medicare Part D, in an effort to balance our various policy goals and to achieve the maximum increase in support for retiree health coverage. We have taken a number of steps to be responsive to the concerns that were raised in the comments that we received relating to the proposed rule. For example, we believe that the flexibility that we have provided relating to actuarial equivalence, plan definition, qualifying covered retirees, payment methodology, and data reporting requirements will

make it easier for employers and unions to continue offering their existing retiree drug plans to Medicare-eligible retirees, while qualifying for the retiree drug subsidy. In cases where employers and unions choose to provide additional retiree drug benefits through separate wraparound coverage that supplements Part D, or enhanced benefits through Part D plans, they can coordinate this additional coverage with Part D in such a way that they can continue providing generous retiree drug benefits at a lower cost, while ensuring that their retirees do not experience significant changes in their out-of-pocket spending.

Additionally, given that approximately 30 percent of the large private sector firms (that is, firms with 1,000 or more employees) that currently offer retiree health coverage to new Medicare-age retirees require those retirees to pay 61 to 100 percent of the cost of their retiree health premiums, based on findings from the 2004 Kaiser/Hewitt Survey on Retiree Health Benefits, some retirees are likely to experience a significant reduction in their out-of-pocket costs by enrolling in the government-subsidized Part D plans. We also note that many beneficiaries' current employer/union-sponsored coverage includes various features that are similar to Part D, including the use of tiered formularies, which may help to minimize potential disruptions associated with switching from an existing employment-based retiree drug plan to a Part D plan (''Current Trends and Future Outlook For Retiree Health Benefits: Findings from the Kaiser/Hewitt 2004 Survey on Retiree Health Benefits,'' The Henry J. Kaiser Family Foundation and Hewitt Associates, December 2004, available at http://www.kff.org).

Additionally, as discussed earlier, it is also important to note that an employer or union that provides retiree drug coverage that is creditable (on a gross value basis) can choose at any time to modify its existing benefit design to supplement Part D. Under this circumstance, the Medicare retirees would be eligible for a special enrollment period for Medicare Part D because their retiree drug coverage no longer meets the criteria for creditable coverage. Thus, the special enrollment period provision would enable these employers and unions to work with their retiree populations and the new Part D plans to achieve a smooth transition and ensure that their Medicare-eligible retirees would not be subject to late enrollment penalties when they enroll in Part D.

We anticipate working closely with employers, unions, and advocacy groups to assist beneficiaries that have employment-based drug coverage in understanding the various choices that are available to them under Part D and choosing the option that will provide them with the best value, given their particular circumstances. Ultimately, we believe that Medicare Part D, including the retiree drug subsidy and the other options it gives employers and unions for providing drug coverage, will help to counteract the trend toward erosion in retiree health benefits by significantly increasing the amount of financial support that is available to employers and unions for retiree drug coverage, and by providing important support for recent retirees and future retirees that may have less generous employer/union support.

Overall, we believe that the implementation of Medicare Part D, including the Medicare retiree drug subsidy and the other opportunities it affords employers and unions for providing continued prescription drug assistance to their Medicare retirees, will result in combined aggregate payments by employers/unions and Medicare for drug coverage on behalf of retirees that are significantly greater than they otherwise would have been without the enactment of the MMA. Furthermore, we believe that the Medicare prescription drug benefit and retiree drug subsidy represent a particularly important strengthening of health care coverage for future Medicare-eligible retirees, given the erosion in the availability and generosity of employment-based retiree coverage for future Medicare beneficiaries that has already been taking place.

e. Historical Trends in the Availability and Generosity of Retiree Drug Coverage

As additional background, we provide a discussion of trends in the availability and generosity of employer-sponsored retiree drug coverage, based on data from several different sources. We note that there are a limited number of data sources relating to retiree coverage, and some of these data sources may not be directly comparable to one another due to differences in the scope of analysis (for example, overall retiree health benefits versus specific information on retiree drug coverage), unit of analysis (for example, retirees versus firms, or firms versus establishments), as well as differences in the age groups, types of retirees (current versus future), and employer sizes that are being analyzed. For these reasons, caution should be exercised in making comparisons across the various data sources that are cited in this section.

As noted previously, employer-sponsored insurance has been an important source of drug coverage for many Medicare beneficiaries. For example, the trend in retiree health coverage for older Medicare beneficiaries (ages 70 and older) was essentially flat between 1996 and 2000 (''Employer-Sponsored Health Insurance and Prescription Drug Coverage for New Retirees: Dramatic Declines in Five Years,'' Bruce Stuart et al, Health Affairs, July 23, 2003, available at www.healthaffairs.org). However, for well over a decade, the availability and generosity of employer-sponsored retiree health coverage has been eroding, particularly for future retirees. The level of employer-sponsored retiree health coverage has been relatively stable for the nation's current retirees during recent years. However, the apparent stability of benefits has been changing for future retirees. We believe that certainly absent the new law, these trends would have continued. In enacting the law, the Congress hoped that the opportunities available to employers and unions under the Medicare prescription drug benefit and retiree subsidy would help to ameliorate the erosion in retiree health coverage. Overall, we do expect that the implementation of Medicare Part D, including the Medicare retiree drug subsidy and the other opportunities it affords employers and unions for providing continued prescription drug assistance to their Medicare retirees, will result in combined aggregate payments by employers/unions and Medicare for drug coverage on behalf of retirees that are significantly greater than they otherwise would have been without the enactment of the MMA.

From 1988 to 1991, the percentage of firms with 200 or more workers offering health benefits to active workers that also offered retiree health benefits declined substantially from 66 percent to 46 percent (KPMG Survey of Employer-Sponsored Health Benefits: 1988, 1991, cited in Kaiser/HRET 2004 Annual Survey of Employer-Sponsored Health Benefits, available at www.kff.org) due to the implementation of Financial Accounting Statement No. 106 (FAS 106) as well as increasing costs. FAS 106, which was published in December 1990, required companies to make significant changes in the way that they accounted for future retiree health benefits on their balance sheets for fiscal years ending after December 15, 1992 (''Retiree Health Benefits: Trends and Outlook,'' Paul Fronstin, Employee Benefit Research Institute (EBRI) Issue Brief No. 236, August 2001; ''Statement

of Financial Accounting Standards No. 106: Employers' Accounting for Postretirement Benefits Other Than Pensions,'' Financial Accounting Standards Board, December 1990, available at *www.fasb.org/pdf/fas106.pdf*). The percentage of large employers offering retiree health coverage has continued to decline during the past decade (General Accounting Office (GAO), ''Retiree Health Benefits: Employer-Sponsored Benefits May Be Vulnerable To Further Erosion,'' May 2001, available at *www.gao.gov*). However, the recent declines have been more gradual than what occurred during the early 1990s, with less than 40 percent of the nation's large firms with 200 or more workers that offer health benefits to active workers also offering retiree health benefits in 2003 (Kaiser/HRET 2004 Annual Survey of Employer-Sponsored Health Benefits, available at *www.kff.org*).

Many of the changes in availability of retiree health coverage in the past decade have primarily affected future retirees, rather than current retirees. (Fronstin, August 2001). For example, the percentage of large employers with 500 or more employees offering retiree health benefits to new Medicare-age (that is, ages 65 and older) retirees decreased from 40 percent in 1993 to 20 percent in 2004 (data from the National Survey of Employer-Sponsored Health Plans, 2004 cited in a press release entitled ''US health benefit cost rises 7.5 percent in 2004, lowest increase in five years,'' Mercer Human Resource Consulting, November 22, 2004, available at *www.mercerhr.com*). As a result, new retirees are less likely to have employer-sponsored retiree drug coverage than current retirees.

Availability of retiree health coverage varies depending on the type of employer. Employers with union workers are more likely to offer retiree coverage than employers without union workers. Similarly, public sector employers are more likely to offer coverage to retirees than private sector employers. (Kaiser/HRET 2004 Annual Survey of Employer-Sponsored Health Benefits, available at *www.kff.org*; ''How States Are Responding to the Challenge of Financing Health Care for Retirees,'' Jack Hoadley, Henry J. Kaiser Family Foundation, September 2003, available at *www.kff.org*.)

Availability of retiree health coverage also varies according to the size of the employer. Larger employers are more likely to offer retiree health coverage than smaller employers. For example, in 2004, 36 percent of the nation's private sector firms with 200 or more workers that offered health benefits to active workers also offered retiree health coverage to pre-age 65 and/or Medicare-age retirees (Kaiser/HRET, 2004). However, very few smaller employers offer retiree health insurance. Recent surveys have found that only 3 to 10 percent of the nation's smaller private sector firms (3 to 199 workers) that offer health benefits to active workers also offer retiree health coverage (Kaiser/HRET 2001, 2002, 2003 and 2004 Annual Surveys of Employer-Sponsored Health Benefits, available at *www.kff.org*).

Larger employers account for the majority of the beneficiaries with employer-sponsored retiree coverage. In 2001, data from the Medical Expenditures Panel Survey indicate that less than 1 percent of the nation's smallest private establishments (those with a ''firm size,'' or total number of employees for the entire firm, of less than 50 employees) offered health insurance to Medicare-age retirees, compared with 37 percent of the nation's largest private sector establishments (those with a firm size of 1,000 or more employees). As a result, within the private sector, the largest firms (1,000 or more employees) covered approximately 90 percent of the Medicare-age retirees who had employer-sponsored retiree coverage, while smaller firms (fewer than 1,000 employees) covered only 10 percent of these retirees.

In an effort to control costs, many employers have been changing their benefit packages (for example, reducing the benefit that is offered and/or increasing the amount that the retiree has to pay), resulting in gradual erosion in the generosity of this coverage over time. For example, since the mid–1990s, some employers have made changes in eligibility for retiree health coverage (for example, age and service requirements), reduced their subsidization of retiree health costs (by increasing retirees' share of premiums and increasing retirees' co-payments and deductibles), placed caps on the employer contribution to retiree health costs (aggregate or per beneficiary), or changed their health benefit designs to a defined contribution structure (Fronstin, August 2001; GAO, May 2001). Because many employers have identified prescription drug costs as a major contributor to rising retiree health benefit costs, they have adopted cost control measures in an effort to manage their retiree prescription drug costs (Kaiser/HRET, 2004).

The intent of Medicare Part D and the retiree drug subsidy is to provide employers and unions with a set of highly flexible options that are designed to make it more affordable for them to continue providing high quality prescription drug assistance to their Medicare-eligible retirees. As discussed earlier, the MMA Conference Report indicates that by lowering the cost of providing retiree drug benefits and providing financial incentives for employers and unions to maintain this coverage for their Medicare-eligible retirees through Medicare Part D and the retiree drug subsidy, it is hoped that the erosion in the availability of employment-based retiree drug coverage will plateau or even improve.

Overall, we expect that the implementation of Medicare Part D, including the Medicare retiree drug subsidy and the other opportunities it affords employers and unions for providing continued prescription drug assistance to their Medicare retirees, will result in combined aggregate payments by employers/unions and Medicare for drug coverage on behalf of retirees that are significantly greater than they otherwise would have been without the enactment of the MMA. Furthermore, the Medicare prescription drug benefit and retiree drug subsidy represent a particularly important strengthening of health care coverage for future Medicare-eligible retirees, given the erosion in the availability and generosity of employment-based retiree coverage for future Medicare beneficiaries that has been taking place.

G. Anticipated Effect on the Federal Budget

The following section presents estimates of the effect of Medicare Part D on net Federal budgetary spending. As indicated previously, there is a great deal of uncertainty related to making these estimates. However, we believe that these estimates provide a reasonable representation of the likely net Federal budgetary effects of the Medicare Part D program.

We expect that the Medicare drug benefit will affect several components of the Federal budget. Specifically, we anticipate that it will increase Federal spending on Medicare benefits and decrease Federal spending on Medicaid benefits (as dual eligibles' drug coverage is shifted from Medicaid to Medicare). The net effect of these changes on Federal spending is estimated to be about $49 billion in CY 2006 and $68 billion in CY 2010, with the total net effect estimated to be about $293 billion over the period from 2006–2010. We note that these estimates are slightly higher than those presented in the proposed rule due largely to the higher per capita spending estimates for the

low-income subsidy enrollees as discussed in section F.2 of this impact analysis. Table IV–3 provides year-by-year estimates of the net Federal budgetary effects[9] of Medicare and Medicaid benefit spending. We discuss these effects subsequently, as well as the expected impacts of the Medicare drug benefit on Federal administrative costs for Medicare, Medicaid, and the Social Security Administration.

1. Federal Medicare Spending

We estimate that the net Federal budgetary effect of Medicare benefit spending related to Medicare Part D, including the Medicare retiree drug subsidy program, will be nearly $61 billion in CY 2006 and nearly $365 billion over the five-year period from CY 2006–2010. The estimated $365 billion in additional net Federal spending over the five-year period is made up of approximately $419 billion in Federal Medicare spending on direct government subsidies, government reinsurance payments, low-income subsidies, and retiree drug subsidies, with an offset of nearly $55 billion in additional Medicare revenues received from States to partially compensate for Medicare coverage of dual eligibles' drug costs (overall, we estimate States will save due to reduced Medicaid spending, as is explained subsequently).[10]

In addition, CMS expects to incur administrative expenses related to the Medicare drug benefit. Implementing a new program of the size and scope of the Medicare drug benefit requires substantial implementation expenses, including extensive computer and other systems changes. Estimates of CMS administrative costs for these activities will be incorporated in the forthcoming President's Budget.

2. Federal Medicaid Spending

As a result of Medicare Part D, there is expected to be a reduction in net Federal spending on Medicaid benefits for the period CY 2006–2010, with the reduction estimated to be about $11 billion in CY 2006 and about $72 billion over the five-year period from CY 2006–2010.

With the Medicare program providing drug coverage to dual eligibles who had previously received drug coverage through Medicaid, State Medicaid spending on prescription drugs will be reduced, and as a result Federal spending on Medicaid matching payments will also be reduced. We estimate reduced Federal Medicaid spending on prescription drugs for full-benefit dual eligibles of about $13 billion in CY 2006 and about $84 billion during the five-year period from CY 2006–2010.

The reduction in Federal spending for Medicaid prescription drug benefits will be partially offset by an increase in Federal Medicaid spending for newly enrolled dual eligibles. As discussed in more detail in the State impacts section, the additional benefits available to low-income beneficiaries through Medicare Part D and our related outreach activities are likely to raise awareness of other benefits available to such individuals through Medicaid, including Medicare Savings (QMB/SLMB) programs, and lead to higher enrollment in these programs. We assume that 1.1 million more Medicare beneficiaries will enroll in Medicaid, including Medicare Savings (QMB/SLMB) programs, in CY 2006 as a result of the Medicare drug benefit. As discussed later in the State impacts section, we estimate that a larger share of these beneficiaries will receive benefits as QMB/SLMB individuals than will receive full Medicaid benefits. Among beneficiaries that are eligible for, but not enrolled in Medicaid and the Medicare Savings Program, we assume a smaller new enrollment rate among those beneficiaries that are eligible for full Medicaid benefits, because we believe that if these beneficiaries were likely to sign up for the full Medicaid benefits package, most would have done so already. We assume a somewhat higher new enrollment rate for those beneficiaries that are eligible for QMB/SLMB benefits. We estimate Federal matching payments for State Medicaid expenditures for these beneficiaries will be about $2 billion in CY 2006, and total about $12 billion during the five-year period from CY 2006–2010.

In addition, the Medicare drug benefit has implications for Federal spending on Medicaid administrative costs. The statute gives responsibility to State Medicaid programs as well as the Social Security Administration (SSA) for conducting eligibility determinations for low-income benefits under Part D. In addition, States are required to provide us with data for the purpose of calculating the amounts States are required to pay Medicare to compensate for a portion of full-benefit dual eligibles' drug costs. These and other State administrative activities related to Medicare Part D will generate State administrative costs, as discussed in more detail in the State section of the impact analysis. We estimate that the Federal share of these net costs will be $39 million in FY 2004, $73 million in FY 2005, and average $67 million from FY 2006–2010.[11] These net costs reflect savings from reduced State claims processing workload as dual eligibles' drug coverage is shifted from Medicaid to Medicare.

3. SSA Administrative Costs

SSA will incur administrative costs associated with its responsibilities under the MMA. SSA is developing and executing an outreach plan to educate beneficiaries about the low-income subsidy assistance that is available under Medicare Part D. To assist beneficiaries with their requests for subsidy assistance, SSA is developing simplified application, appeal, and redetermination forms. SSA has responsibility for determining eligibility for the low-income subsidy, performing reviews of determinations based on requests for appeal, and redetermining eligibility. To do this, SSA must develop computer systems, regulations, and internal SSA instructions for processing applications, appeals, and re-determinations. In addition, SSA is developing training materials for State employees so that they can use SSA's simplified application form and application process, and is conducting data exchanges with CMS and other Federal Agencies necessary for making eligibility determinations. Estimates for SSA administrative costs for these activities will be incorporated in the forthcoming President's Budget.

[9]–We note that the estimated net Federal budgetary effect of Medicare subsidy payments excludes changes to governmental receipts (that is, tax collections) because we do not have sufficient data to estimate these effects at this time.

[10] For the purpose of this impact analysis, we do not assume any additional Medicare costs or savings related to risk corridors. We also do not assume any savings on Part A and Part B benefits.

[11] For the purpose of this impact analysis, we do not assume any additional Medicare costs or savings related to risk corridors. We also do not assume any savings on Part A and Part B benefits.

TABLE IV–3. ESTIMATED NET FEDERAL BUDGETARY EFFECTS OF MEDICARE AND MEDICAID BENEFIT SPENDING, CY 2006–2010 (BILLIONS OF DOLLARS)

	2006	2007	2008	2009	2010	2006–2010
Net Effect of Medicare Benefit Spending Related to Medicare Part D						
Federal Spending Related to Medicare Part D, Including the Retiree Subsidy	69.7	76.2	83.3	91.0	99.2	419.3
State Payments to Partially Offset Medicare Drug Costs for Dual Eligibles	-9.0	-9.9	-10.9	-11.9	-13.0	-54.7
Subtotal	60.6	66.2	72.5	79.1	86.1	364.6
Net Effect of Medicaid Benefit Spending						
Additional Federal Matching Payments for Newly Enrolled Dual Eligibles	2.0	2.2	2.5	2.7	2.9	12.3
Reduction in Federal Matching Payments for Medicaid Drug Expenditures for Dual Eligibles	-13.3	-14.9	-16.6	-18.5	-20.7	-84.0
Subtotal	-11.3	-12.7	-14.1	-15.8	-17.8	-71.7
Net Federal Budgetary Effects of Medicare and Medicaid Benefit Spending	49.3	53.6	58.4	63.3	68.3	292.9

Note: Positive numbers denote increased spending; negative numbers denote reduced spending (that is, savings). Numbers may not sum to totals due to rounding and exclude effects on Federal tax revenues.

H. States

1. Overall State Budgetary Impacts

We estimate that, as a result of Medicare Part D, States will realize net savings of $7.9 million over the CY 2006–2010 period, as shown in Table IV–4. Estimated State savings range from approximately $1.0 billion in CY 2006, increasing each year during the five-year period, to reach about $2.2 billion by CY 2010. The estimated $7.9 billion in net State savings over the five-year period are made up of $72.6 billion in State savings related to Medicare Part D that are partially offset by $64.8 billion in State costs related to Medicare Part D. We note that our estimates of State savings are slightly lower than those presented in the proposed rule because our current estimate of the overall impact on States includes an estimate of State administrative costs while our previous estimate had not.

We estimate that States will save approximately $73 billion from CY 2006 to 2010 as the Medicare Part D drug benefit and Medicare retiree drug subsidy provide financial support for the prescription drug costs of full-benefit dual eligibles, State retirees, and participants in State prescription drug assistance programs. The vast majority of these State savings ($63.4 billion) are the result of Medicare Part D replacing drug coverage for full benefit dual eligibles that would otherwise be paid for by Medicaid. States offering qualified retiree prescription drug coverage to their own former employees (and their spouses and dependents) will also achieve savings due to the Medicare retiree drug subsidy and the other options Part D offers employers and unions for providing retirees with prescription drug coverage at lower costs. We estimate these savings to be $6.3 billion from CY 2006 to CY 2010. In addition, States that operate prescription drug assistance programs, as well as States with Pharmacy Plus programs, will also realize additional savings as Medicare Part D displaces a portion of their spending on prescription drug coverage for enrollees ($3 billion from CY 2006 to CY 2010). We discuss the estimated savings for State prescription drug programs in more detail in a separate section later in this analysis.

The estimated $73 billion in State savings, discussed previously, will be partially offset by approximately $65 billion in State costs related to Medicare Part D over the period CY 2006–2010. The largest component of these costs are State payments to the Federal government to defray a portion of the Medicare drug expenditures for full-benefit dual eligibles, estimated at about $54.7 billion from CY 2006–2010. As discussed in the preamble, the States and the District of Columbia are required to make these monthly payments beginning January 1, 2006. It is important to note that the data sources and methodology used to estimate these State payments for the purpose of this impact analysis differ somewhat from those that will be used, as stipulated by statute and described in more detail in subpart S of the preamble, to calculate the actual State payment amounts for 2006. The expenditure data that will be used to calculate the actual State payment amounts are not yet available. Thus, for the purpose of this impact analysis, we relied on MCBS as the data source to produce an estimate of aggregate State payments.

Another component of these costs is increased State Medicaid spending due to increased Medicaid enrollment. We anticipate that in the process of outreach and applying for the Part D low-income subsidy, some beneficiaries will learn of their eligibility for other low-income assistance such as Medicaid or Medicare Savings (QMB/SLMB) programs and choose to enroll in these programs. We estimate that about 1.1 million additional beneficiaries will enroll in Medicaid or the Medicare Savings programs in CY 2006. We assume that a larger share of these beneficiaries will receive benefits as QMB/SLMB individuals than will receive full Medicaid benefits, with 21 percent of the new enrollees estimated to receive full Medicaid, 20 percent to receive QMB benefits, and 59 percent to receive SLMB benefits. We assume a smaller new enrollment rate among those beneficiaries that are eligible for

full Medicaid benefits, because we believe that if these beneficiaries were likely to sign up for the full Medicaid benefit package, most would have done so already. We assume a somewhat higher new enrollment rate for those beneficiaries that are eligible for QMB/SLMB benefits. Because there are currently more beneficiaries eligible for but not enrolled in the SLMB program than the QMB program, new enrollees into the SLMB program make up the majority of the estimated 1.1 million new enrollees. We estimate that State Medicaid spending on benefits for these 1.1 million individuals will be about $9.1 billion over the five-year period from CY 2006–2010.

Also included in our estimate of State costs is the effect of the MMA's prohibition on States imposing taxes on premiums related to Part D coverage. As a result of this prohibition, we estimate that States will realize reduced premium tax revenues of approximately $504 million over the period CY 2006–2010.

States will also incur administrative costs related to Medicare Part D. We estimate that these State costs will be $39 million in FY 2004, $73 million in FY 2005 and average $90 million per year from FY 2006–2010 (after receiving Federal matching payments). In FY 2004 and 2005, we anticipate that States will incur costs on data file cleanup (to enable States to provide us with information on dual eligibles). In addition, in FY 2005, we estimate that States will incur costs for development of State eligibility determinations systems for Part D and for processing eligibility determinations for individuals who apply for the low-income subsidy through the State during the early stages of the low-income subsidy application period. In FY 2006–2010, we expect that the bulk of States' administrative costs will be associated with processing Part D applications, re-determinations, and appeals; and State screening of Part D low-income subsidy applicants for eligibility for the Medicare Savings programs. The additional administrative costs during FY 2006–2010 will be partially offset by State savings on claims processing costs, as dual eligibles' prescription drug claims will no longer be processed by States. We note that our estimates of State administrative costs are somewhat lower than those cited in the proposed rule because, as discussed subsequently, we anticipate that SSA will play a substantial role in the eligibility determinations process for the low-income subsidy, lessening the burden on States. We anticipate that prior to implementation of Medicare Part D, States will incur costs related to the data file preparation work necessary to provide us with information on which beneficiaries are full dual eligibles, QMBs, SLMBs, or QIs. States are required, effective with CY 2003 and all subsequent MSIS data submittals, to provide accurate and complete coding to identify the numbers and types of Medicaid and Medicare dual eligibles, with CY 2003 data submittals required to be completed by December 31, 2004. In accordance with the statute, this final rule also requires States to submit an electronic file, beginning effective August 2005, and each subsequent month, that identifies each full benefit dual eligible enrolled in the State for each month.

As discussed in the preamble, we will send notices of eligibility to all deemed low-income subsidy eligible individuals, relieving States of the financial burden of sending notices to these beneficiaries. We will also educate Medicare beneficiaries, including dual eligibles, through a variety of methods about prescription drug coverage under the new Part D benefit, which we expect would eliminate the need for States to carry out this function.

The statute gives responsibility to State Medicaid programs as well as the Social Security Administration for conducting eligibility determinations for low-income benefits under Part D. As a result, States will need to develop an eligibility determinations system for processing Part D low-income subsidy applications. However, States have considerable flexibility in designing the system in a manner that would be most cost-effective given their existing eligibility determination processes and the likelihood that SSA will process a substantial number of applications. We anticipate that SSA will have a substantial role in processing Part D eligibility determinations, which will considerably reduce State costs related to processing Part D applications. SSA will be conducting an extensive outreach campaign to inform low-income Medicare beneficiaries about the Medicare Part D low-income subsidy assistance and inform them that they can apply for the low-income subsidy through SSA. In addition, as discussed in the preamble, we are encouraging States to consider using the SSA application form and process as their default approach for processing low-income subsidy applications. While States would have to develop a process to determine eligibility for an individual who requests a ''State'' determination as opposed to an ''SSA'' determination, States may use the SSA low-income subsidy application in order to reduce the administrative burden associated with sending notices and processing appeals and re-determinations. With SSA performing a substantial role in eligibility-processing, States would also be relieved of a significant burden in verifying information reported on low-income subsidy applications. As a result, States could focus most of their attention on assisting individuals with completing the SSA application, and screening and enrolling individuals in the Medicare Savings Program.

We also note that States are generally responsible for issuing licenses to health insurers. While some new PDP plans will require new licenses, the States charge fees for licensing and the States already have the mechanisms in place to handle these new license applications. Furthermore, licensing would not affect current insurers that want to become PDPs if these insurers are already licensed as insurers in a given State; the PDP would simply be a new line of business for these insurers. Thus, we do not estimate any cost implications for the States associated with licensing insurers.

Comment: Several States noted that they did not believe they would realize net savings as a result of Part D. These States commented that their costs would exceed their savings. In addition, some States pointed out that the characteristics of their situation, in terms of such issues as savings for retirees, existence of a SPAP, administrative costs associated with low-income eligibility determinations, or new Medicaid enrollments, would mean that their particular State costs would exceed savings from Medicare Part D.

Response: Based on our estimates, we believe that, in aggregate, State savings will exceed State costs over the 5 year period, CY 2006–2010. Our best estimate, based on available data, is that generally States will realize net savings from the implementation of Medicare Part D, and these savings will increase over time, as shown in Table IV–4. We estimate that States will save approximately $7.9 billion from CY 2006 to CY 2010 as the Medicare Part D drug benefit and Medicare retiree drug subsidy provide financial support for prescription drug costs of full-benefit dual eligibles, State retirees, and participants in State prescription drug assistance programs. The vast majority of these State savings are the result of Medicare Part D replacing drug coverage for full benefit dual eligibles that would otherwise have been paid for by Medicaid (about $63 billion from CY 2006 to CY 2010).

Comment: Several States asserted that exempting Medicare Part D prices from Medicaid best price will have a negative financial effect on States. In addition, several States also asserted that Medicare Part D will reduce their drug price negotiating power for the non-dual population.

Response: As noted elsewhere in the preamble, we do not have the statutory authority to modify the best price provisions of the Medicaid best price statute and the exemption of Part D under the MMA. However, we do not believe that the exemption of PDP and MA-PD prices from ''best price'' will adversely affect best price compared with what it would have been in the absence of Medicare Part D. We expect that price negotiations by PDPs and MA-PDS with drug manufacturers will lead to price concessions for beneficiaries. Nevertheless, the expected increase in drug use among the Medicare population, due to the expansion of drug coverage, will make it less likely that manufacturers will respond by raising their prices to other lines of business. Consequently, we expect that there would be minimal, if any effect, on best price.

In terms of the impact on States' negotiating power with drug manufacturers, we believe that States would remain large volume purchasers of prescription drugs even after the dual eligible beneficiaries transition to Part D coverage. Furthermore, a number of States have joined purchasing pools to increase their market power in an effort to reduce their Medicaid spending on prescription drugs. As such, we believe that the States would maintain their bargaining power with drug manufacturers and that there would be minimal impact on their ability to negotiate price concessions.

Comment: Two States noted that the estimate of net State savings should include administrative costs.

Response: The estimate of State administrative costs is included in the estimate of net State savings, as shown in Table IV–4.

Comment: One State wanted us to clarify whether we included the estimated fiscal impact of the following programmatic and administrative State costs: (1) additional compliance responsibilities with HIPAA and privacy rule notice of practice provisions; (2) Certificates of Coverage requirements; (3) educating staff; (4) coordinating the State pharmacy programs (and systems) with the PDPs for purposes of medication management programs; and (5) educating dual eligibles on Medicare Part D.

Response: Our estimates of State administrative costs take into account staff training activities. We have not included new costs for HIPAA, the privacy rule notice of practice provisions, or Certificates of Coverage because we do not agree that the MMA imposes additional compliance responsibilities on States in these areas. In terms of the costs of educating beneficiaries, we did not include these costs in our estimate as we believe they will be negligible, for several reasons. First, SSA will be conducting an extensive outreach campaign to inform low-income Medicare beneficiaries about the Medicare Part D low-income subsidy assistance and inform them that they can apply for the low-income subsidy through SSA. Second, CMS will send notices of eligibility to all deemed low-income subsidy eligible individuals, relieving States of the financial burden of sending notices to these beneficiaries. Third, CMS will educate Medicare beneficiaries, including dual eligibles, through a variety of methods about prescription drug coverage under the new Part D benefit, which we expect would lessen the need for States to carry out this function.

As discussed elsewhere in the preamble, we recognize that SPAPs and States have an interest in acquiring access to prescription drug utilization data for purposes of their medical and case management activities. We are continuing to work on means to practically expedite data sharing. As noted previously, although we do not have the authority to require data exchanges between Part D plans and the States, we will strongly encourage Part D plans to independently share data on these shared enrollees with State Medicaid plans consistent with the HIPAA Privacy Rule provisions for the sharing of protected health information with another covered entity for that entity's health care operations.

Comment: Two States noted that we underestimated the administrative cost estimates for States to conduct low eligibility determinations under Part D. One State noted that, due to the complexity of the new drug benefit and the incidence of cognitive impairment in the dual eligible population, the figure of $100 million is underestimated and should be reconsidered. Similarly, another State noted that if the States are required to determine low-income subsidy eligibility for low-income individuals other than Medicaid and Medicare Savings Program recipients, there will be additional costs to the States. The State asserted that the significant costs include system changes necessary to do the eligibility determinations and to issue notices to beneficiaries and notify CMS; the cost of applications, forms, and information material; the cost of writing and maintaining a policy manual; the cost of developing training materials and training staff; and the cost of new positions, space, and supplies for new staff needed to do determinations. This State noted that these costs will be even higher if the States are required to process automatic enrollments and if each State must coordinate subsidy eligibility determination processes with SSA.

Response: We recognize that States will incur costs associated with the eligibility determinations for Medicare Part D benefit. In developing our State administrative cost estimates related to eligibility determinations, we took into account the costs of developing eligibility systems; developing training materials; processing Part D applications, re-determinations, and appeals; screening and enrolling beneficiaries in Medicare Savings programs; and notifying CMS about beneficiaries determined eligible for the Part D low-income subsidy. In estimating these costs we included the cost of staff time, benefits, overhead, and training involved. We did not include State costs for auto-enrollment as CMS will be responsible for that function. We have estimated total State administrative costs (after receiving Federal matching payments) of $39 million in FY 2004, $73 million in FY 2005 and on average $90 million per year from FY 2006–2010. The vast majority of these costs are for the eligibility determinations process described above. While we recognize that States will incur significant costs related to eligibility determinations, we believe that our estimates represent a reasonable assessment of these costs. As noted previously, we anticipate that SSA's role in processing Part D low-income subsidy eligibility determinations will considerably reduce State costs related to processing Part D low-income subsidy applications. SSA will be conducting an extensive outreach campaign to inform low-income beneficiaries about the Medicare Part D low-income subsidy assistance and inform them that they can apply for the low-income subsidy through SSA. In addition, we are encouraging States to consider using the SSA application form and process as their default approach for processing low-income subsidy applications. While States would have to develop a process to determine eligibility for an individual who

requests a ''State'' determination as opposed to an ''SSA'' determination, States may use the SSA low-income subsidy application in order to reduce the administrative burden associated with sending notices and processing appeals and re-determinations. With SSA playing a substantial role in eligibility-processing, States would also be relieved of a significant burden in verifying information reported on low-income subsidy applications. In addition, while States must develop a process to support eligibility determinations when specifically requested of them, States have flexibility in designing the system in a manner that would be most cost-effective given their existing eligibility determination processes and the likelihood that SSA will process a substantial portion of Part D low-income subsidy applications.

2. State Prescription Drug Assistance Programs

As mentioned previously, one of the components of our estimate of net State savings resulting from Medicare Part D is savings on State Pharmaceutical Assistance Programs (SPAPs). We estimate that SPAPs spend roughly $1.45 billion of State only resources on prescription drug assistance for 1.2 million individuals, based largely on FY 2002 data. Five States account for approximately 87 percent of the SPAP spending, and have approximately 77 percent of the enrollment. For Medicare beneficiaries who have income less than 135 percent of the Federal Poverty Level (FPL) and assets valued up to $6,000 per individual (or $9,000 per couple) in 2006, Part D offers comprehensive drug coverage with a full Federal subsidy for the beneficiary premium and only nominal cost-sharing. Thus, SPAP expenditures on this group of Medicare beneficiaries will be mostly displaced by the Medicare prescription drug benefit. We estimate that the savings that will accrue to States as a result of Medicare Part D displacing SPAP expenditures for low-income beneficiaries will be approximately $600 million per year, or about $3 billion over the five-year period from CY 2006–2010.

States with SPAPs have shown a commitment to assisting their low-income residents with drug costs. As of Spring 2004, twenty States were operating SPAPs that provide subsidized drug coverage to individuals who will be eligible for Medicare Part D. We anticipate that many of these States will choose to continue providing financial assistance with drug expenditures, because they can achieve the same or a greater level of assistance for their beneficiaries at a lower cost to the States. Part D provides States with a number of options for continuing their provision of prescription drug assistance to Medicare beneficiaries, if they choose to do so. States, for example, have the flexibility to restructure their SPAP programs to wrap around the Part D benefit and pay deductibles and cost sharing for beneficiaries, with the State's assistance counting toward the Medicare Part D annual out-of-pocket threshold triggering protection against catastrophic drug costs. States can also provide assistance by paying for Part D premiums for beneficiaries. As part of their SPAPs, States also have the flexibility to make arrangements with PDPs and MA-PDs to provide enhanced Part D benefits.

Comments: The comments from States did not indicate a preferred option for restructuring their SPAP benefits in relation to Medicare Part D. One commenter indicated that given the proposed system for coordination of benefits, it seems likely that SPAPs will structure their benefit design to wrap around Medicare Part D. However, another commenter stated that choosing a wraparound benefit design would entail significant administrative and information systems costs.

Response: We are uncertain at this time what actions States will take to structure their SPAP benefits in relation to Part D. Part D provides States with a number of options for continuing their provision of prescription drug assistance to Medicare beneficiaries (for example, wrapping around Medicare Part D, or paying for some portion or all of premiums, including buying enhanced coverage). While we recognize that SPAPs will incur administrative costs in modifying their programs, we do not have enough information to quantify those costs. Currently, SPAPs have varying levels of administrative costs and their choices will influence the size of their future operating costs. For example, if SPAPs choose to provide premium assistance in contrast to a wraparound design, then their administrative costs might be lower than an operational design that would require ongoing processing of claims. We believe that we have provided flexibility for the States to restructure their SPAP programs to best serve the needs of their enrollees. We expect that regardless of how States choose to alter their SPAP benefits to work in relation to Part D, States will achieve savings as Part D coverage replaces benefit spending previously financed by SPAPs. Even though States will incur administrative costs in adapting the structure of their programs in relation to Part D, the benefit savings will far exceed administrative costs as administrative costs represent a small share of expenses associated with providing prescription drug coverage.

In the proposed rule, we invited States to provide specific enrollment and expenditure data by FPL for their State and any State-specific savings estimates they may have developed, as well as comments on improvements in our methodology. However, the public comments did not include estimates of SPAP enrollment and expenditure data by FPL, nor did the comments include State-specific savings estimates. Additionally, we did not receive any comments on our methodology for estimating potential savings from SPAP expenditures. Several States with SPAPs have publicly stated that they are realizing savings from the Medicare approved drug discount card and transitional assistance program. We anticipate that Medicare Part D will bring even larger savings for SPAP programs.

We retain the same methodology for estimating savings related to SPAP programs as we used in the proposed rule. We believe that we are presenting a conservative estimate of the displacement of SPAP expenditures, because our assessment does not include any potential State savings for SPAP enrollees at income levels above 135 percent of FPL. States that choose to restructure their programs to complement Medicare Part D can still achieve savings because of the substantial Medicare displacement of SPAP spending for low-income beneficiaries as well as for individuals who enroll in Part D and do not qualify for the low-income subsidy.

We also note that, as discussed elsewhere in the preamble, Section 1860D–23(d) of the Act provides for the payment of transitional grants to States with Pharmaceutical Assistance Programs of up to $62.5 million in each of fiscal years 2005 and 2006. On October 28, 2004 HHS announced the awards to States for fiscal Year 2005. In addition, the statute provides the authority (Section 1860D–23(a) of the Act) for the Secretary to establish requirements for effective coordination between Part D plans and SPAPs. For further discussion related to coordination of benefits, see the section on coordination of benefits under Administrative Costs.

To estimate potential SPAP savings resulting from Medicare Part D expenditures, we focus our analysis on SPAP expenditures that may be spent on individuals with income below 135

percent of FPL. We are primarily relying on State-published data that describe SPAPs and their eligibility standards (sources such as State government websites, program annual reports, and Governor's budget documents). Our ongoing work with States also provides us with certain information regarding enrollment and expenditures under SPAPs. Unless we have adequately detailed State-published data on SPAP expenditures for enrollees by income, we use the Census Bureau's Current Population Survey (CPS) data to help us estimate SPAP spending on beneficiaries with income under 135 percent of FPL.

We recognize that our methodology has significant limitations and that our estimates are imprecise. For example, our analysis does not take into account the effect of the Medicare Part D assets test and does not include an estimate of potential savings for SPAP enrollees with income greater than 135 percent of FPL. We believe that States, with their own internal data and resources, are in the best position to project individual State-level impacts.

3. Pharmacy Plus Waiver Programs

Four States under Medicaid section 1115 waivers operate Pharmacy Plus demonstration programs that provide assistance to Medicare beneficiaries with the cost of prescription drugs. Expenditures for these services receive Federal matching payments in the same manner as do services for full benefit Medicaid beneficiaries. In the proposed rule, we noted that due to the special treatment SPAPs receive relative to the TrOOP, States that operate Pharmacy Plus programs and beneficiaries enrolled in those programs could benefit financially by States restructuring their Pharmacy Plus programs to use a State only SPAP design to wrap around Medicare Part D. We sought comments on this issue and welcomed further data and analyses from States.

Comment: One State that operates a Pharmacy Plus waiver program responded to our request for comments. The State indicated that it does not plan to restructure its Pharmacy Plus program as a SPAP. The State commented that its pharmaceutical assistance programs provide its residents with benefits that are more generous than Medicare Part D. It provided comparative scenarios based on illustrative beneficiary spending levels and stated that beneficiaries in its State would be better off financially under the current arrangement. One beneficiary advocacy group agreed with the State's point-of-view. The public comments did not contain any other data or analysis on the issues we raised in the proposed rule regarding Pharmacy Plus Waiver programs.

Response: The State's comments compare a current benefit design with the structure of the standard Medicare Part D benefit, which will be implemented in January 2006, but assumes no State supplementation to the Medicare benefit nor does it include the special Medicare low-income subsidies that will be available to certain populations. Medicare Part D will provide a generous package of prescription drug coverage. While State Medicaid programs will no longer be able to claim Federal financial participation for those drugs after January 1st, 2006, we assume that States that developed special pharmaceutical assistance programs may be interested in continuing to provide financial assistance to these beneficiaries. The final rule provides that Pharmacy Plus programs can continue with Federal match after January 1, 2006, under certain circumstances. As indicated elsewhere in the Preamble, any State that operates a Pharmacy Plus demonstration program must determine whether it is feasible to continue that Pharmacy Plus program by submitting a revised budget neutrality calculation for the demonstration. We will review the revised budget neutrality calculation and approve or disapprove the continuation of the Pharmacy Plus demonstration for the period when Part D is effective.

Under the Statute, there is a financial incentive favoring States that provide Medicare beneficiaries direct financial assistance for the purchase of prescription drugs. As noted elsewhere in the preamble, Section 1860D–2(b)(4)(C)(ii) of the Act only allows a person or a SPAP to make payments that will count toward TrOOP for an individual Part D enrollee. However, as previously discussed, Pharmacy Plus waiver programs are not considered to be SPAPs. Therefore, Pharmacy Plus program expenditures cannot be counted towards the calculation of TrOOP. As noted earlier, the Pharmacy Plus Waiver Programs could be modified to take advantage of the incentive set by statute.

Given these considerations, we continue to believe that generally States would benefit by restructuring their prescription drug programs using a State-only SPAP design that wraps around Medicare Part D, rather than continuing their Pharmacy Plus programs. Depending on the State and the nature of the population, we believe that generally States could realize savings relative to their current Pharmacy Plus spending levels while protecting program participants from higher out-of-pocket costs. To be conservative, State savings estimates for these four Pharmacy Plus programs have not been included in our estimates of overall State savings, and would be in addition to net State savings presented in this analysis.

TABLE IV–4. PROJECTED STATE SAVINGS AND COSTS DUE TO THE MEDICARE DRUG BENEFIT AND RETIREE DRUG SUBSIDY, CY 2006–2010 (BILLIONS OF DOLLARS)

	2006	2007	2008	2009	2010	2006–2010
Savings						
Reduction in State Medicaid Spending	-10.0	-11.2	-12.5	-14.0	-15.6	-63.4
State Savings on Drug Costs for Retired State Workers	-1.0	-1.2	-1.3	-1.4	-1.5	-6.3
Savings for State Pharmacy Assistance Programs	-0.6	-0.6	-0.6	-0.6	-0.6	-3.0
Costs						
State Payments to the Federal Government for Full-Benefit Dual Eligibles	9.0	9.9	10.9	11.9	13.0	54.7
State Spending for New Medicaid Enrollees	1.5	1.6	1.8	2.0	2.2	9.1

TABLE IV–4. PROJECTED STATE SAVINGS AND COSTS DUE TO THE MEDICARE DRUG BENEFIT AND RETIREE DRUG SUBSIDY, CY 2006–2010 (BILLIONS OF DOLLARS)—Continued

	2006	2007	2008	2009	2010	2006–2010
Lost Revenue from Prohibition on Taxes on Premiums for Part D Coverage	0.06	0.08	0.10	0.12	0.14	0.50
State Administrative Costs*	0.09	0.09	0.09	0.09	0.09	0.45
Net Savings/Costs	-1.0	-1.3	-1.5	-1.8	-2.2	-7.9

Note: Positive numbers denote increased spending; negative numbers denote reduced spending (that is, savings). Numbers may not sum to total due to rounding.

*Prior to 2006, States are estimated to incur administrative costs related to Medicare Part D of $39 million in FY 2004 and $73 million in FY 2005.

I. Administrative Costs

There are four major areas of administrative costs associated with Medicare Part D that will be incurred by the private and public sector that merit separate discussion. These areas include the costs of PDPs and MA-PDs administering the Medicare prescription drug benefit, the cost of creditable coverage disclosure notices that the MMA requires be provided to Medicare beneficiaries and to CMS, the administrative costs associated with certain coordination of benefits as required by the MMA, and the administrative costs for employers and unions associated with obtaining the Medicare retiree drug subsidy. The following provides a detailed discussion of each of these areas.

1. Prescription Drug Plans and MA-PD Plans

The administrative cost estimates are based on taking into account the normal fixed costs associated with administering a prescription drug benefit, for example, such functions as claims processing, responding to customer inquiries, information dissemination, appeals processes, pharmacy network negotiations and contracting, and drug manufacturer negotiations and contracting. In addition, we assume ''risk-premium'' costs associated with risk-based insurance products that require companies to maintain certain levels of financial reserves. The other factor taken into account when developing our estimate is that PDPs and MA-PDs will likely incur slightly higher administrative costs during the initial few years of the Part D benefit due to start-up costs related to implementation and initial operations for a new benefit, for example more marketing and enrollment activities. We also assume that entities that will participate as PDPs will have already made the necessary changes to be HIPAA compliant because of the other business arrangements they will have been functioning in prior to choosing to participate as a PDP under the Medicare drug benefit program.

As is typically done with insurance products, we express the average administrative costs as a percentage relative to net standard benefit expenses. This percentage is commonly referred to as the ''administrative load.'' We estimate that the average administrative load will be 12.7 percent in CY 2006, with this declining slightly over time, and reaching 11.9 percent in CY 2010. The administrative load is expected to decline slightly over the period for two reasons: (1) administrative costs are expected to grow at a somewhat slower rate than PDP and MA-PD plans' prescription drug costs and (2) initial administrative start-up costs associated with implementation are expected to phase out in the first few years of operations.

Our estimates for administrative costs are similar to those seen in the general health insurance market. Our administrative load of 12.7 percent in 2006 translates into administrative costs being about 11.2 percent of total Part D plan expenditures (including both benefits and administrative costs). This is similar to the share of total health plan spending accounted for by administrative costs in the private sector. For example, as CMS reported in its ''Health Care Industry Market Update on Managed Care,'' Blue Cross Blue Shield health plans had average sales, general and administrative (SG&A) expenses ranging from 12 percent in 1999, 11.7 percent in 2000, 11.3 percent in 2001, and 10.9 percent in the first half of 2002. Similarly, in examining our Medicare Advantage plans data we see variation in administrative costs, for example newer plans (less than 5 years) seem to have higher administrative costs (11 percent) than older plans (7 percent).

The MMA also requires PDPs and MA-PDs to pay a user fee to help offset ongoing beneficiary education and enrollment costs relating to the Medicare prescription drug benefit, which represents an expansion of the user fees that are currently required of MA plans. As discussed earlier in this preamble, the MMA authorizes up to $200 million for beneficiary education and enrollment activities in FY 2006 and thereafter, reduced by the fees that will be collected from MA organizations and PDP sponsors in that fiscal year. Our rough estimates of the user fees for beneficiary education and enrollment costs in CY 2006 are approximately $21 million for PDPs and $34 million for MA organizations, with the remainder (approximately $144 million) being the government's share. These estimates are slightly different from those presented in the proposed rule and reflect our updated estimates for the Medicare Advantage program and Part D. While the user fees will actually be collected on a fiscal year basis, we believe that these estimates, which are based on calendar year data, provide a reasonable estimate of what the magnitude of these user fees will be during a given fiscal year. We assume that the cost of these user fees will be built into the administrative cost structure of the PDPs and MA-PDs, and will therefore be reflected in bids. We note that these user fees represent a minuscule percentage of the estimated total payments to MA organizations and PDP sponsors under the Medicare program.

2. Disclosure Notice Requirements

A number of entities that provide prescription drug coverage to Medicare beneficiaries such as Medigap plans, private and public sector employer or union sponsored plans that provide drug coverage to Medicare beneficiaries who are retired or who are active workers, State Medicaid Pharmacy Plus programs, State Pharmacy Assistance programs (SPAPs), and the Indian Health Service—are required to provide at certain times disclosure notices to beneficiaries on whether the drug coverage they provide equals or exceeds the actuarial value of standard Part D coverage. As discussed in the preamble,

certain entities that provide Part D coverage that is by definition creditable coverage (that is, PDPs and MA-PDs) will not be required to provide disclosure notices. Additionally, as discussed previously, States will not need to provide disclosure notices to full-benefit dual eligibles, as this will be handled through our process of deeming these beneficiaries as being eligible for the low-income subsidy.

The largest cost for providing these disclosure notices is expected to occur in the months preceding the implementation of the drug benefit in January 2006. Thereafter, notices will need to be provided by these entities prior to each subsequent Part D annual coordinated election period (AEP), if there is a change in creditable coverage status, or upon request by the individual. Also, firms that provide drug coverage to active workers will have to provide disclosure notices in the future to those active workers who become new Medicare beneficiaries. In an effort to reduce the burden associated with providing these notices, we have revised our final regulations to allow notices of creditable and non-creditable status to be provided with other information materials that these entities distribute to beneficiaries (rather than separately) and, as discussed in the preamble, we anticipate providing model language for both types of notices.

With the exception of Medigap insurers and group health plans that provide drug coverage only to Medicare beneficiaries who are active workers (and not retirees), implementation of the Medicare prescription drug benefit and the retiree drug subsidy is expected to produce net savings to public and private sector entities that provide drug coverage to Medicare beneficiaries. For SPAPs, State Pharmacy Plus programs, the Indian Health Service (IHS), and private sector and State/local government group health plans that provide retiree drug coverage, we estimate that the cost of creditable coverage disclosure notices will be about $18 million in CY 2005, with anticipated savings from the implementation of Medicare Part D expected to far exceed the disclosure notice costs for each of these entities. We note that the estimated disclosure notice cost for these entities has decreased from our previous estimate in the proposed rule because we are allowing most entities (with the exception of Medigap plans) to include disclosure notices with other existing plan materials (instead of requiring a separate notice) and CMS will be handling the disclosure notices for full-benefit dual eligibles through our process of deeming these beneficiaries as being eligible for the low-income subsidy.

For Medigap insurers and employer/union group health plans that offer coverage only to beneficiaries who are active workers, not retirees, the cost of providing disclosure notices is estimated to be approximately $62 million in CY 2005 (which translates into an average of roughly $151 per employer/union that offers drug coverage to Medicare beneficiaries who are active workers and about $11,050 per Medigap insurer).

We anticipate that annual disclosure notice costs in years after 2005 will generally be significantly lower. For example, while entities will be required to provide disclosure notices prior to each Part D annual coordinated election period, they will be able to include these notices in their existing plan materials with minimal modifications unless there has been a change in their creditable coverage status. Similarly, while group health plans that provide drug coverage to active workers will also need to provide disclosure notices to the more limited number of new beneficiaries who age into the Medicare program, they will also be able to include these notices in their existing plan materials at minimal cost.

We anticipate that most of the disclosure notice costs in years after 2005 will be related to changes in benefit design and/or creditable coverage status among employer and/or union-sponsored plans providing coverage to active workers and retirees. For example, we estimate that some group health plans providing coverage to active workers will incur costs in the event that their plan has a substantial change in its benefit structure that makes a reconfirmation of their creditable coverage status appropriate, as well as in the event of a change in their creditable coverage status. Similarly, we anticipate that there will be some disclosure notice costs associated with changes in creditable coverage status among employer/union-sponsored retiree plans that choose to transition from providing coverage that qualifies for the retiree subsidy to providing coverage that complements the Medicare drug benefit. Additionally, we anticipate that a small number of beneficiaries will request an additional copy of their creditable coverage disclosure notice during any given year, which may need to be sent separately from the other plan materials that the various entities normally provide to their participants.

We estimate maximum costs of roughly $8 million to $9 million per year for disclosure notices during the period CY 2006–2010. We note that the estimated disclosure notice cost for years after 2005 has increased somewhat from our previous estimate in the proposed rule because in addition to the estimated costs associated with creditable coverage status changes and reconfirmations relating to active worker plans, we have also included costs associated with plan sponsors providing notices to Medicare retirees in the event of a change in status and costs associated with providing additional copies of notices to a small number of individual beneficiaries upon request. For private sector and State/local government group health plans that provide retiree drug coverage, we estimate that the maximum cost of creditable coverage disclosure notices will be about $3 million per year during the period CY 2006–2010 (including costs associated with change of creditable coverage status notices and costs associated with providing additional notices to individuals upon request). For Medigap insurers and employer/union group health plans that offer coverage only to beneficiaries who are active workers, the cost of providing disclosure notices is estimated to be approximately $5 to $6 million per year during the period CY 2006–2010.

In brief, we take the following approach to estimate the cost of disclosure notices. For the various entities that are required to provide disclosure notices, the circumstances of these different types of coverage and how they will relate to the new Medicare prescription drug benefit differ. Consequently the nature of the disclosure notice and any associated actuarial valuation will vary. Beyond the cost of the actuarial valuation are the costs of preparing and mailing the notices. We generally base our cost estimates on wage data from the Department of Labor for an actuary and for administrative personnel, adjusted to 2005 and loaded for compensation, overhead, general administration and fee, with additional adjustments for wage growth in subsequent years.

In terms of the basic costs of preparing and mailing the disclosure notices, we assume that each entity required to provide these notices expends 8 hours for developing the notice (with one exception described below), 1 hour for providing a copy of the notice to CMS, 1 hour per 60 notices for providing separate notices to beneficiaries in the case of Medigap plans, approximately 5 minutes per notice for providing separate additional

copies of the notices to individual beneficiaries upon request, and negligible costs for incorporating notices into existing plan materials that are provided to beneficiaries (since these plan materials are already being disseminated to their participants). The one exception to this relates to group health plans that provide drug coverage only to Medicare beneficiaries who are active workers, not retirees. We assume these entities expend less time developing the notice (2 hours) because we expect that this service is likely to be provided to them by insurers or health plan administrators, who we anticipate will spread the cost of this service across many plan sponsors.

In terms of the time involved in performing the actuarial valuation that forms the basis of the disclosure notices, we anticipate that it will vary somewhat by the type of entity providing the notice. As discussed subsequently in the section on administrative costs for the retiree drug subsidy, our estimates of the time involved in doing actuarial valuations were informed by discussions held with actuaries in our Office of the Actuary and other industry experts. With respect to SPAPs and State Pharmacy Plus programs, we expect that the actuarial assessment is not likely to be complex, and that the disclosure notice will likely focus on how the State program will work with the new Medicare drug benefit. We assume that each SPAP and State Pharmacy Plus program would expend on average 2 hours for actuarial work. With respect to the Indian Health Service, we expect that the actuarial assessment is not likely to be complex since the coverage is likely to be creditable; we assume that the IHS would expend less than 6 hours for actuarial work.

We believe that the notice requirement related to Medigap drug policies will be relatively straightforward. In accordance with section 104 of the MMA, we are developing a model disclosure notice for Medigap insurers in consultation with the NAIC. For standardized Medigap plans, we anticipate that the actuarial work involved in developing these notices will be minimal. As discussed elsewhere in the preamble, we believe that standard Medigap plans H and I are not creditable and that it is very unlikely that plan J would be creditable. In the case of the pre-standardized policies, the nature of the actuarial valuation and the level of effort involved will likely vary with the nature of the benefit package. For the purpose of this analysis, we assume 6 hours on average per Medigap insurer for actuarial valuations, taking into account that those with pre-standardized plans may do more extensive actuarial valuations.

Employer or union-sponsored retiree health plans that apply for the Medicare retiree drug subsidy will have to perform an actuarial valuation for the purpose of their application. We assume that those plans will simply use the actuarial valuation that was developed for the retiree subsidy application for the disclosure notices. We note that the first prong of the retiree drug subsidy program's actuarial equivalence test requires plan sponsors to compare the gross value of their drug benefit with the value of the standard Part D benefit (which is the same comparison that they will need to make for disclosure notice purposes). Thus, we assume nominal costs for the actuarial valuation related to the disclosure notices. Estimates of the administrative costs related to applying for the Medicare retiree subsidy, including the actuarial valuation, are discussed elsewhere in this document.

We anticipate that employer or union-sponsored retiree health plans that do not choose to apply for the retiree drug subsidy will need a minimal amount of time to compare the value of their drug benefit with the value of the standard Part D benefit, and expect that these employers/unions will be able to use the simplified actuarial methods that we anticipate developing and publishing for comparing a sponsor's plan with the standard Part D benefit, as discussed in subpart R of the preamble, in making this comparison. For these reasons, we assume that each of these plan sponsors will on average incur expenses for one-quarter of an hour of actuarial time. As discussed in more detail subsequently, this relatively low number reflects our assumption that the insurers and PBMs will build actuarial models that can determine creditable coverage status for multiple plans with similar benefit designs in a relatively automated fashion, and that they will spread the associated costs across many plan sponsors.

In addition, in future years, employer or union sponsored plans that offer retiree coverage may incur costs associated with changes in creditable coverage status. For those entities that experience such changes, we use the same assumptions relating to the time involved in doing the actuarial valuation, developing the notice, and notifying CMS and beneficiaries as for the initial creditable coverage notices, with adjustments for future growth in wages. It is important to note that there is uncertainty relating to the number of firms that will apply for the retiree drug subsidy versus providing enhanced or supplemental prescription drug coverage that complements Medicare Part D, especially since approximately 90 percent of the retirees with employment-based coverage are concentrated in 10 percent of the firms that provide this coverage. Given this uncertainty, we take the approach of estimating the maximum possible cost associated with disclosure notice activities for these firms.

Disclosure notices are also required of group health plans that provide drug coverage to active workers who are Medicare beneficiaries (that is, beneficiaries for whom Medicare is the secondary payer). It is very difficult to know how many firms that provide health insurance to their active workers have a Medicare beneficiary in their workforce. We have estimated roughly as an upper bound that there may be as many as 400,000 firms that provide drug coverage to at least one Medicare beneficiary who is an active worker. We emphasize that this is a very rough estimate that extrapolates from data from a number of sources (including an IRS, SSA, CMS data match, Census data, BLS data, and a Kaiser survey). We note that our rough estimate of the number of employers that may be providing coverage to Medicare beneficiaries that are active workers has decreased from our previous estimate that was included in the proposed rule, because we had inadvertently included employers with fewer than 20 employees who are exempt from Medicare Secondary Payer requirements in the prior estimate.

We anticipate that many of these employers that provide drug coverage to beneficiaries who are active workers are purchasing standard health insurance products from insurers that sell these plans to numerous purchasers, and that the cost of the actuarial valuation for purposes of confirming that this coverage is creditable will be spread across a relatively large number of employers or third party purchasers. While self-insured employers may have more distinct health plan benefit structures, we believe that it is likely that their health plan administrators would be able to achieve economies of scale by building actuarial models that can serve multiple clients. In addition, the cost of the valuation for those employers and unions that also offer retiree drug coverage could potentially be incorporated into the costs required to do an actuarial valuation for both types of coverage and thus there may be some economies of scale (particularly since some employers and unions' retiree plans provide coverage that is

similar to the coverage that is available in their active worker plans). Additionally, we expect that these employers/unions and their insurers or plan administrators will be able to use the simplified actuarial methods described above in comparing their drug coverage to the standard Part D benefit. For these reasons, we assume that each of these employers/unions will on average incur expenses for one-quarter of an hour of actuarial time. This relatively low number reflects our assumption that insurers and PBMs will build actuarial models for determining creditable coverage in an automated fashion that will be able to accommodate different cost-sharing structures with minor modification, and that they will spread the fixed cost associated with building these models across many employers and unions. Consequently, the estimated one-quarter of an hour of actuarial time represents the estimated share of the cost for those systems that will be passed on to each employer.

In years after 2005, employers that provide drug coverage to Medicare beneficiaries who are active workers are likely to expend some additional time related to disclosure notices, but we anticipate this time will be substantially less than in 2005. In subsequent years, we anticipate that these employers will provide disclosure notices to their workers who age into the Medicare program and continue working. In addition, it is possible that a portion of these employers may alter their drug benefit design to such an extent that a reconfirmation of their creditable coverage status may be appropriate. We assume that those active workers who become new Medicare beneficiaries each year will receive disclosure notices as part of existing plan materials that these employers normally provide to their employees, that about 25 percent of the firms providing coverage to beneficiaries who are active workers will need to obtain a new actuarial valuation on their benefit design per year, and that about 1 percent of the firms providing coverage to beneficiaries who active workers will have a change in creditable coverage status that requires them to provide a notice to CMS as well as a notice to beneficiaries in their plan materials in any given year. As discussed previously, we anticipate that the disclosure notice cost per employer that offers drug coverage to Medicare beneficiaries who are active workers (and not retirees) will be relatively small—$151 per employer on average in CY 2005 and we expect less in future years.

Finally, we anticipate that a minimal number of beneficiaries will request an additional copy of a creditable coverage disclosure notice in any given year. Specifically, we estimate that approximately 5 percent of the beneficiaries receiving coverage through group health plans for active workers, and retiree health plans that participate in the retiree drug subsidy program will request an additional copy of their disclosure notice in any given year. Similarly, we estimate that approximately 5 percent of the beneficiaries that choose to continue receiving creditable drug coverage through Medigap plans will request an additional copy of their disclosure notice in any given year (we assume that most beneficiaries that have Medigap drug coverage will enroll in Part D because most Medigap coverage is not creditable). Finally, we estimate that a smaller percentage (1 percent) of the beneficiaries in retiree health plans that choose not to participate in the retiree drug subsidy program will request an additional copy of their disclosure notice in any given year because we anticipate that most of the beneficiaries in these plans will already be enrolled in Part D (since many of these employers/unions are likely to have drug coverage that complements the standard Part D benefit). In cases where individuals request an additional copy of the creditable coverage disclosure notice, we assume that the entity will give the beneficiary a copy of the same disclosure notice that it has already incorporated into its plan materials. Therefore, we do not assume that these entities will incur an additional cost associated with developing a new disclosure notice for this purpose; however, as discussed previously, we conservatively estimate that these entities will incur a nominal cost in disseminating this information to beneficiaries upon request.

We believe that the changes that we have made in the final rule related to allowing various entities to provide notices of creditable and non-creditable coverage status with other existing plan materials that are distributed to beneficiaries (rather than separately), providing model language for both types of notices, and allowing employers and unions to use simplified actuarial methods to determine the actuarial equivalence of their drug coverage to the Part D benefit will help to reduce the administrative burden associated with the disclosure notice requirements, while also ensuring that beneficiaries receive the information they will need to make an informed decision about enrolling in Part D.

3. Coordination of Benefits Under Employer And Union-Sponsored Plans and SPAPs

We are required under the statute to establish requirements for coordination of benefits between Medicare PDPs and MA-PDs and other insurers including SPAPs, Medicaid programs, group health plans, FEHBP, military coverage including TRICARE, and other coverage CMS may specify. Ensuring accurate and timely coordination of benefits is important for tracking the true out-of-pocket limit, a cornerstone of the benefit design. This will necessitate that an efficient and effective operational framework be established to track beneficiary out-of-pocket expenditures.

Section 1860D–23(a) of the Act authorizes the Secretary to establish procedures and requirements to promote the effective coordination of benefits between a Part D plan and an SPAP with respect to payment of premiums and coverage, and payment for supplemental prescription drug benefits. In addition, as specified at section 1860D–24(a) of the Act, we will apply coordination of benefit requirements to other prescription drug plans including group health plans, the Federal Employees Health Benefits Program (FEHBP), military coverage (including TRICARE), Medicaid (including a plan operating under a waiver under section 1115 of the Act), and other coverage that we specify.

The elements to be coordinated include enrollment file sharing, claims processing, payment of premiums for both basic and supplemental drug benefits, third-party reimbursement of out-of-pocket costs, application of protection against high out-of-pocket expenditures (defined in section 1860D–2(b)(4) of the Act), and other administrative processes and requirements that we specify. As required by the statute, we will establish procedures before July 1, 2005, to ensure the effective coordination of benefits between Part D plans and SPAPs and third party coverage.

As discussed more fully in the Preamble, we plan to play a role in ensuring that benefits are coordinated and TrOOP is tracked. We intend to establish an efficient and effective process for handling coordination of benefits and tracking of the TrOOP by the Part D plans, consistent with the statute and the guidance we will issue. We are considering how best to facilitate these processes, including through the establishment of a TrOOP facilitation contractor, contractors, or some type of blended approach. We also plan to

facilitate TrOOP by leveraging coordination of benefits processes currently in place under Medicare, and by creating an on-line eligibility file query to assist pharmacies in directing claims to the correct payer. As discussed, we will provide guidance on the specific processes for coordinating claims prior to July 1, 2005. We believe the coordination effort will reduce the confusion that could result for multiple payers being involved in payment of an individual claim. We believe that a coordination of benefits and TrOOP facilitation effort will ease the burden on Part D plans especially, but also on pharmacists and ultimately on beneficiaries since it will help ensure that claims involving multiple payers are paid correctly, accurately, and as timely as possible.

Section 1860D–24(a)(3) of the Act permits the Secretary to impose user fees on plans (but not on SPAPs) for the transmittal of benefit coordination information under Part D. We are also provided authority to retain a portion of these user fees to offset costs we incur in providing for the coordination of benefits. Costs incurred may include items such as the necessary infrastructure, system security, and outreach and education activities related to TrOOP. We plan to provide more detailed information regarding the user fee, including the amount and collection processes in CMS guidance to be issued prior to July 1, 2005. However, we plan to charge no more than $1 per annum in 2006 for each beneficiary enrolled in a Part D plan to provide for funding of a Part D coordination of benefits and TrOOP facilitation process, and we expect that the fee will be considerably less. This cost is expected to be collected from plans at a rate of 1/12 of $1 per month for each enrolled beneficiary. We expect that these small costs will be reflected in plan administrative costs as part of their bids.

We believe that a maximum of $1 per year per enrolled beneficiary is a relatively modest sum, given the value of the coordination of benefits function to Part D plans, beneficiaries, pharmacists, and secondary payers. The user fee represents a small fraction of the total expense of administering the Part D benefit. Indeed, the $1 per enrollee per year maximum user fee amount is quite small when considered on a per claim basis, given the sheer volume of Part D claims expected in 2006. We believe that imposing a user fee to cover the expenses involved in coordinating benefits and facilitating accurate TrOOP tracking is more cost effective and convenient for Part D plans than having the plans plan for, implement, and perform these functions independently.

Pharmacies have much to gain by having a coordination of benefits effort as described more fully in the Preamble. Pharmacies have a great interest in ensuring that claims are paid correctly and quickly at the point of sale. We expect that pharmacies will have an on-line eligibility file query capability to facilitate situations where the pharmacy is lacking information in order to bill the appropriate payer. Having an electronic source of payer information on customers with multiple insurances will be a valuable service to pharmacies. While the advent of the Part D benefit will require pharmacies to electronically submit a portion of claims to more than one insurer, the cost of doing so will be quite small in comparison to the positive effect on pharmacies of the Part D benefit (including increased sales of prescriptions and increased foot traffic in the ''front end'' of the store).

The majority of commenters supported the option of having a TrOOP facilitator assist us in ensuring that benefits coordination and TrOOP facilitation is performed. We believe that this support underscores the value of the function to plans, pharmacies, and beneficiaries. We are currently considering the best approach for all parties concerned. We are prepared to have a role in coordinating benefits and tracking TrOOP, as explained more fully in the Preamble, since this approach is effective and is supported by commenters. CMS is considering facilitating TrOOP in many ways, including through the establishment of a TrOOP facilitation contractor, contractors, or a blended approach. We will continue to work with the parties involved to pursue an approach that makes the most sense for plans, pharmacies, and beneficiaries. We will continue discussions and will issue details and guidance prior to July 1, 2005.

4. Estimated Administrative Costs in Applying for Retiree Drug Subsidy

Qualified retiree prescription drug plans that choose to accept the Medicare retiree subsidy will incur some administrative costs associated with obtaining the subsidy.

As discussed earlier in the preamble, sponsors will have to submit to CMS an application for the Medicare retiree drug subsidy, including an attestation that the actuarial value of the prescription drug coverage under their retiree plan or plans is at least equal to the actuarial value of defined standard prescription drug coverage under Medicare Part D. The attestation must be certified by the attesting actuary, and the application must be signed by the plan sponsor (or a plan administrator designated by the sponsor). As part of this application, employers and unions are also required to provide other information including data about the eligible covered Medicare retirees in their plan or plans, as well as a signed sponsor agreement. In addition, entities accepting the Medicare retiree drug subsidy payments will have to report certain prescription drug cost data for the purpose of receiving subsidy payments and maintain records for purposes of audit and oversight by CMS. We also note that employer and union sponsored health plans that provide drug coverage to beneficiaries are required to provide, at certain times, creditable coverage disclosure notices to beneficiaries. These notices are required regardless of whether the plan sponsor applies for a subsidy, and consequently the costs of these notices are discussed in the section of this analysis on disclosure notices.

In developing the rule, we have tried to minimize the administrative burden associated with the operation of the retiree subsidy program. We want to establish an efficient administrative structure that provides maximum flexibility for qualified retiree prescription drug plans, while at the same time providing for an appropriate level of financial accountability that assures the accuracy of payments and safeguards the interests of beneficiaries, consistent with our fiduciary responsibility.

For purposes of the ''Collection of Information Requirements'' section and the accounting statement in this rule, we have developed an estimate of the time and aggregate employer/union costs involved in the various administrative functions associated with employers and unions obtaining the Medicare retiree subsidy including: subsidy application requirements, including performing the actuarial valuation; preparing and coordinating the plan(s)' enrollment files and other information databases to identify the eligible Medicare retiree population and other relevant information; assembling the application; reporting data and information (for example, data on prescription drug costs for the purpose of receiving subsidy payments); and record retention. We base our cost estimates on 2005 wage data for an actuary, computer programmer, and administrative personnel loaded for compensation, overhead, general administration, and fee.

a. Application for Retiree Drug Subsidy Including Actuarial Attestation

In applying for the subsidy, sponsors of qualified retiree prescription drug

plans are required to provide to us an attestation that the actuarial value of the prescription drug coverage in each such plan is at least equal to the actuarial value of defined standard Medicare Part D prescription drug coverage. Sponsors of qualified retiree prescription drug plans will need to submit this attestation on an annual basis, and submit an updated attestation if there is a change during the year that materially affects actuarial value of their drug coverage. As discussed earlier in the preamble, a material change means any change that potentially causes a plan to no longer meet the actuarial equivalence test (these submissions would not be required when non-material changes are made to the coverage).

One factor in the cost of actuarial attestation is that one actuarial model can potentially be used to analyze multiple plans' benefit designs that, for example, are similar in design but use different co-payments or have different levels of beneficiary premium contributions. We believe it is likely that various entities that work with employer/union sponsored group health plans (such as employee benefit consultants, actuarial firms, insurance companies, or PBMs) are likely to develop such models and spread the development costs across numerous clients, lessening the cost to any one employer/union. In addition, we believe it is likely the entities that develop actuarial models and pass the costs onto employers/unions will likely amortize over time the fixed costs of model development.

Besides the fixed costs of developing an actuarial model, each actuarial valuation will likely require some individual time by an actuary. That analysis time may vary depending on the complexity of the plan offered by the employer/union. Given that some employers (particularly large employers) may often offer multiple plans (benefit options) which may involve multiple valuations, we expect that the actuarial time would vary across employers.

To develop assumptions about the time and costs involved, we had discussions with actuaries in our Office of the Actuary and other industry experts. From these discussions, we developed a range of time estimates for preparing actuarial models, taking into consideration: the use of actual plan data if it is available and credible, the time to conduct the analyses, the issue of economies of scale in the use of one model to analyze multiple plans, and the time involved in preparing the written attestation report. Based on these discussions, our preliminary estimate is that total time involved in developing one actuarial model and preparing an analysis and report on one plan could generally range from 6 to 40 hours. For the purpose of this analysis, we assume that on average employer/union sponsored retiree health plans incur costs for the actuarial valuation in the initial year ranging from 2 hours of actuarial time for very small firms (assuming that the entity that performs the actuarial valuation spreads the cost of developing an actuarial model across a large number of clients and amortizes the costs over time) to 60 hours for very large firms that offer multiple plans (benefit options) and require significant specialized analysis. Based on these assumptions and taking into account the time involved for firms of different sizes, we estimate that the cost of the actuarial valuation would on average be in the range of about 1.8 percent of the value of the retiree subsidy.

In addition to the actuarial valuation, plan sponsors applying for the retiree subsidy will need to prepare the application and related enrollment data and information on retirees, and sign the sponsor agreement. We anticipate that the time involved in preparing the application and required enrollment information will vary by firm size, with the average time ranging from 5 hours for the smallest firms with 6 retirees on average to 382 hours for the largest firms with more than 1,500 retirees on average. In addition, we assume a half hour for signing the sponsor agreement. As discussed elsewhere, some of the information needed on eligible beneficiaries may not be routinely available to plan sponsors and consequently for initial start-up some level of effort may be needed to obtain this information. We have been conservative in our assumptions to reflect this possibility. It is important to note that a significant portion of the time involved would be a one-time expense. Based on these assumptions, we estimate that on average across large and small firms, the cost involved in preparing the application and related enrollment information (excluding the actuarial work) and signing the agreement would be in the range of about 2.9 percent of the value of the subsidy. It is important to note that after the first year, we believe these costs will decline as the initial work associated with identifying the eligible population will have been accomplished and as employers/unions and their agents gain more experience with the program.

b. Reporting

In order to obtain the subsidy, sponsors of qualified retiree prescription drug plans will need to submit certain data to CMS and maintain certain records. If a sponsor elects to receive monthly or quarterly retiree subsidy payments or an interim annual retiree subsidy payment, the plan sponsor must submit aggregated gross cost data, an estimate of the difference between these gross costs and allowable costs (based on expected rebates and other price concessions), and any other data CMS may require upon submission of data for payment at each of the time intervals elected by the sponsor, with a final reconciliation within 15 months after the end of the plan year. For final reconciliation purposes, sponsors must submit total gross cost data segregated per qualifying covered retiree; actual rebates, discounts or other price concessions received for such costs; and any other data CMS may require, within 15 months after the end of the plan year. In addition, plans sponsors are required to provide on a monthly basis an update to their enrollment file (for example, accretes and deletes). Because prescription drug data and records are highly automated, there are significant economies of scale related to data reporting requirements, which we believe will lessen the cost to any one employer/union group health plan. We anticipate that insurers, PBMs, and third-party administrators will incur initial fixed costs in modifying their current claims processing systems to track prescription spending data in the required format to be submitted for payment purposes. We believe there would be substantial economies of scale in making these systems changes, as we anticipate that an entity (such as a third party administrator or insurer) could generally use the same approach for numerous clients. We also anticipate that entities that work with group health plans (such as insurers, PBMs, third-party administrators, actuarial firms, and employee benefit consultants) will incur fixed costs associated with developing a methodology for rebate allocation and modifying their systems to allocate rebates accordingly. We believe that it is likely that these entities would generally use a similar approach for allocating rebates and making systems modifications for its clients and would spread the fixed development costs across those clients. While we recognize that there will be some individual client specific work necessary for rebate allocation, we believe it is likely that certain aspects of this process such as developing a general rebate allocation method and general approach to systems changes would provide economies of scale. In addition, since some of these same entities will likely be developing

systems to track costs and allocate rebates for both the Medicare retiree drug subsidy and the Medicare Part D program, we believe it is likely that there may be some overlap in the initial development phases of this work for some of these entities that may provide additional economies of scale.

In the initial year, we estimate that plan sponsors will incur costs equal to about 0.8 percent of their expected subsidy payments due to the fixed costs associated with developing methodologies and modifying systems to generate the required cost data and allocate rebates. As noted previously, we assume a relatively low amount of cost per plan sponsor because we anticipate that entities that work with group health plans (such as insurers, PBMs, actuarial firms, and employee benefits consultants) will spread the fixed costs associated with this work across many clients. With respect to costs associated with developing the infrastructure to provide a monthly enrollment update, we believe that the systems and procedures needed to do this would have already been developed as part of the plans sponsors work identifying qualified retirees during the initial application process, and consequently, those costs have been included in our prior cost estimate in that area. In terms of the costs associated with generating the required cost data and enrollment data (once the systems have been developed and tested), we assume that the average number of hours of staff time involved in submitting the drug cost data and enrollment data will range from 12 hours (for a very small firm that we assume submits cost data annually) to 56 (for a very large firm that we assume submits cost data monthly). Based on these assumptions and taking into account the time involved for firms of different sizes, we estimate that the cost associated with submitting drug cost data and enrollment data would on average be in the range of about 0.9 percent of the value of the retiree subsidy.

In addition to data reporting, employers that receive the subsidy will also be required to retain data and records for six years. For the purpose of this analysis, we assume that the time involved in record retention would vary by firm size, with the average time ranging from 4 hours for the smallest firms to 20 hours for the largest firms. Based on these assumptions and taking into account the varied time involved across firms of different sizes, we estimate that on average the record retention would be in the range of about 0.4 percent of the value of the subsidy.

c. Conclusion

Based on our analyses, we estimate that the administrative costs associated with obtaining the retiree subsidy will represent on average in the range of about 6.8 percent of the value of the subsidy in 2006 and are expected to decline significantly in subsequent years. After the first year, we believe these costs will decline as the initial work associated with identifying the eligible population will have been accomplished and as employers/unions and their agents gain more experience with the program.

J. Medigap Provisions

The MMA prohibits Medigap insurers from selling new Medigap policies that cover prescription drugs after December 31, 2005 and prohibits the renewal of existing Medigap policies with drug coverage for beneficiaries who enroll in Medicare Part D. Part D enrollees with current Medigap drug coverage have the choice of renewing their existing Medigap policy without drug coverage or buying certain other Medigap plans that do not have drug coverage if they enroll in a Part D plan in the initial enrollment period. We emphasize that the MMA itself directly restructures the role of Medigap insurance, and that it is not the result of this rulemaking.

We estimate that about 1.9 million beneficiaries would be enrolled in Medigap plans with drug coverage in 2006, absent the law change. As discussed elsewhere in this analysis, we estimate that the vast majority of these beneficiaries will enroll in Medicare Part D. However, we note that these estimates do not take into account the possibility that a small portion of beneficiaries with pre-standardized Medigap plans may have creditable drug coverage. To the extent that such situations exist and beneficiaries, who have had these policies for a long period of time (that is, prior to standardization in the early 1990s), choose to remain in them, our estimates of the number of beneficiaries shifting from Medigap drug coverage to Medicare Part D may be slightly overstated.

As a result of the statutory prohibition on the sale of Medigap policies with drug coverage to Part D enrollees, we expect these beneficiaries will move from Medigap policies that contain prescription drug coverage to Medigap policies that do not contain such coverage. We expect that the policies without drug coverage will have lower premiums. We estimate that the resulting reduction in Medigap insurers revenues associated with the MMA prohibition on the sale or renewal of policies with drug coverage would be approximately $2.4 billion in 2006, $2.5 billion in 2007, $2.7 billion in 2008, $2.9 billion in 2009, and $3.1 billion in 2010. We note, however, that some Medigap insurers may choose to enter the PDP or MA-PD market and offer those products. As discussed elsewhere in the impact analysis, the Medicare prescription drug benefit is subsidized and expected to attract substantial enrollment, which may provide new business opportunities for Medigap insurers. In addition, we believe that the movement of beneficiaries from Medigap drug coverage to Medicare Part D will generate substantial savings for these beneficiaries on prescription drug costs. The standard Medicare Part D benefit provides a 75 percent government-subsidized benefit, catastrophic coverage, and cost savings from discounts and other cost management activities. It also is not likely to suffer from the substantial adverse selection, and resulting increased premiums, that are seen in Medigap plans with drug coverage.

Our projections of Medigap enrollment in policies with drug coverage and the premiums associated with that drug coverage were developed using data from NAIC on standardized Medigap plans, and information gathered by a CMS contractor on pre-standardized Medigap plans and waiver State plans. Our current estimates of the revenue impact on Medigap insurers are slightly lower than those presented in the proposed rule because the analysis assumes a slightly lower rate of enrollment in Medicare Part D. While our estimates do not take into account standalone Medigap drug policies, these policies represent substantially less than 1 percent of the Medigap market and would not affect the estimates.

K. Small Business Analysis

The Regulatory Flexibility Act (RFA) requires agencies to determine whether a rule will have a ''significant economic impact on a substantial number of small entities.''

If a rule is expected to have a significant economic impact on a substantial number of small entities the RFA requires that a Regulatory Flexibility Analysis be performed. Under the RFA, a ''small entity'' is defined as a small business (as determined by the Small Business Administration (SBA)), a non-profit entity of any size that is not dominant in its field, or a small government jurisdiction. HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

With respect to the Medicare prescription drug benefit and retiree drug subsidy, there are four areas that we believe merit discussion related to small business impacts: (1) retail pharmacies, (2) long-term care pharmacies,(3) insurers and PBMs, and (4) employers. We anticipate that the retail pharmacy industry, which is comprised of both chains and a large number of independent pharmacies, will play a critical role in the Medicare drug benefit as it furnishes prescription medicines and pharmacy services to beneficiaries enrolled in Medicare Part D. While the Medicare prescription drug benefit is expected to have several effects on retail pharmacy revenues, both positive and negative, our estimate is that the impact on the overall retail pharmacy industry, including small pharmacies, generally will be positive.

In addition to retail pharmacies, long-term care pharmacies will play an important role in the Medicare Part D drug benefit. The long-term care (LTC) pharmacy industry is dominated by four large corporations. Because of significant data limitations related to the remainder of the market, we are unable to predict with certainty either the presence or absence of ''a significant economic impact on a substantial number'' of small LTC pharmacies. We believe that a more competitive market under Medicare Part D will reward LTC pharmacies offering the lowest prices and highest quality service; it may also open the door for new entrants into the market as LTC facilities restructure their existing contracts with LTC pharmacies. We anticipate that there may be changes in market share among the pharmacies that service LTC facilities. The competitive results we expect are likely to impact many small LTC pharmacies positively, while some will likely experience a negative effect. This changing market will be the result of the competitive situation under Medicare Part D.

Since PDPs and MA-PDs are the principal vehicles through which the Medicare prescription drug benefit is administered, we also examine whether there are any small business impacts on the types of businesses expected to apply to be prescription drug plans—that is, insurers and PBMs. The effects of the statute and regulation promulgating the Medicare Part D program would increase drug utilization and thus be favorable to many insurers and PBMs. Furthermore, in considering how the regulations could be made more flexible, we have analyzed the regulatory provisions of this rule over which we have discretion and concluded that they have little overall effect on the insurance and PBM industry, and certainly not a significant adverse impact.

In the case of the small employers who continue to provide qualified prescription drug coverage for their retirees, we estimate that savings obtained from the Medicare retiree drug subsidy will greatly exceed the employer's administrative costs associated with obtaining the subsidy, and thus the result of the retiree drug subsidy provision is a net positive impact. We would like to make participation in the retiree drug subsidy program as simple as possible for small entities. As discussed elsewhere in the preamble we have made the retiree drug subsidy as flexible as possible for employers by giving them the option to use either a calendar year or plan year cycle for purposes of obtaining the retiree subsidy, and to elect the payment frequency (that is, monthly, quarterly, or annually) that best meets their needs. For example, small employers may find receiving payment only on an annual basis as the least burdensome approach given the size of their retiree population and associated Medicare retiree prescription drug payments, and our final rule provides for this option.

While we believe that we could certify that this rule will not have a significant economic impact on a substantial number of small retail pharmacies, employers, or insurers/PBMs, we provide a Regulatory Flexibility Analysis for each. In addition, since we are unable to predict with certainty either the presence or absence of a significant economic impact on a substantial number of small long-term care pharmacies, we also provide an analysis for these entities.

In addition, in accordance with Section 1102(b) of the Social Security Act, we also address whether this rule will have an impact on the operations of small rural hospitals.

1. Retail pharmacies

The RFA requires us to determine whether this rule will have a significant economic impact on a substantial number of small retail pharmacies. SBA considers pharmacies with firm revenues of less than $6 million to be small businesses. The 1997 Economic Census (the latest available detailed data) indicates that there were about 21,000 firms operating about 41,000 retail pharmacies and drug store establishments (NAICS code 44661) continuously through 1997. Of these firms, about 20,000 had revenues under $5 million (which was the small business size standard in 1997) and operated a total of about 21,000 establishments. Since over 95 percent of retail pharmacy firms are small businesses (as defined by the SBA size standards), we do expect that the statutorily-created Medicare prescription drug benefit will have some effect on a substantial number of small retail pharmacies. However, we estimate that overall the revenue effect on the retail pharmacy industry, including small pharmacies, will generally be positive.

We anticipate that, although the Medicare prescription drug benefit will lead to both revenue increases and decreases for retail pharmacies, the increase in revenues is estimated to more than offset the decrease in revenues. First, we expect that the vast majority of beneficiaries currently without prescription drug coverage will choose to enroll in Medicare Part D. The extension of drug coverage to these individuals, and the resulting lower out-of-pocket costs they face when purchasing prescription drugs, is expected to lead to higher drug utilization and total expenditures, and consequently higher revenues for retail pharmacies. At the same time, some of these beneficiaries without prior drug coverage, as well as some beneficiaries with Medigap drug coverage, would be expected to realize new pharmacy discounts under Medicare Part D that they otherwise would not obtain. We note that the Medicare prescription drug benefit would not lead to any additional pharmacy discounts for the majority of beneficiaries who currently have drug coverage as they already obtain pharmacy discounts through their current insurers (for example, employer-sponsored health plans, Medicare Advantage plans, and State plans). In addition, we have examined the potential for increased use of mail order pharmacies among some beneficiaries, and its potential impact on retail pharmacies. As described in more detail in the subsequent methodological discussion, we estimate that the complex set of countervailing effects of increased utilization and new pharmacy discounts and possibly new use of mail order pharmacies among some beneficiaries would result in a net increase in retail pharmacy revenues ranging from a lower bound of 1.5 percent to an upper bound of 2.7 percent. This estimated increase in retail pharmacy revenues will be partially offset by a reduction in retail pharmacy revenues for dual eligibles as discussed subsequently.

Since State Medicaid programs typically pay higher reimbursement rates to retail pharmacies than private sector insurers, we expect that retail pharmacies would experience some

reduction in revenues due to the movement of full-benefit dual eligibles from Medicaid drug coverage to Medicare drug coverage (through PDPs and MA-PDs). As discussed in more detail subsequently, our upper bound estimate of the average reduction in retail pharmacy revenues that could result from full-benefit dual eligibles receiving drug coverage from Medicare is 1.0 percent. We believe this is an overestimate of the revenue reduction because it does not take into account the effect of the Federal Upper Payment Limit on reducing Medicaid reimbursement rates for many multi-source drugs. Also, to the extent that a State Medicaid program has adopted managed care arrangements to lower the cost of drugs for dual eligibles, our estimate of the revenue impact of pharmacy reimbursement changes for full-benefit dual eligibles would be overstated.

Considering together the effect of increased utilization, new pharmacy discounts and possibly new use of mail order pharmacies among some beneficiaries, and reimbursement changes for full-benefit dual eligibles, we estimate that retail pharmacy revenues would experience a net increase ranging from 0.5 percent to 1.6 percent, as a result of the Medicare prescription drug benefit. Furthermore, while we are not able to provide a quantitative estimate at this time, we expect that retail pharmacies may realize additional revenues from the MMA requirement that PDPs and MA-PDs offer medication therapy management programs to targeted enrollees, which may be furnished by retail pharmacists. Our estimates also do not take into account that increased use of prescription drugs resulting from the Medicare drug benefit may lead to increased foot traffic in retail pharmacies and increased sales for pharmacies' other goods in addition to prescription medicines.

We note that our estimate of the overall impact on small retail pharmacies represents the average effect. We recognize that the effect on any specific retail pharmacy will likely vary to some extent around the average. While we have estimated that the average effect on small retail pharmacies would range from 0.5 percent to 1.6 percent, it is possible that some individual retail pharmacies could experience smaller positive effects and even in some cases negative revenue effects. While it is possible that a specific retail pharmacy because of unique circumstances could experience a negative revenue impact, we believe that this will generally be uncommon. While we cannot predict with full certainty the dynamic effects of this new program for individual pharmacies, we will monitor program and plan performance related to beneficiary access and periodically solicit views on ways we can improve the program.

It is important to note that our estimates of the revenue effect of Medicare Part D on retail pharmacies differ slightly from those presented in the proposed rule. We have revised our analysis to reflect the slightly lower uptake assumption for Medicare Part D assumed throughout the final rule impact analysis. Because retail pharmacies are estimated to experience increased revenues due to the increased utilization of drugs among beneficiaries who gain drug coverage under Medicare Part D, our assumption of slightly lower enrollment in Medicare Part D results in our finding a slightly smaller positive revenue impact on retail pharmacies. In the proposed rule, we estimated that the average impact of Medicare Part D on retail pharmacies would be a revenue increase of 0.6 percent to 1.9 percent. Due to our revised Part D uptake assumptions, we now estimate that the average impact of Medicare Part D on retail pharmacies will be a revenue increase of 0.5 to 1.6 percent.

Comment: In the proposed rule, we sought comments on several issues related to small pharmacies, including comments on our conclusion that retail pharmacy revenues would be positively impacted by Medicare Part D, comments and data related to the distributional impact of Medicare Part D on small retail pharmacies, and comments on any aspect of the rule that may affect adversely affect pharmacies of any size.

We received several comments that questioned our conclusion that Medicare Part D would have a positive revenue impact on small retail pharmacies. One commenter asserted that the proposed rule's analysis overstated the degree of certainty about the revenue impact on retail pharmacies and failed to acknowledge that some retail pharmacies may lose revenue. The commenter also asserted that the impact on retail pharmacies would depend on the degree to which its business model is based on prescription drug sales, the proportion of its customer base that is made up of Medicare beneficiaries and dual eligibles, and whether the pharmacy is preferred or non-preferred. This commenter also took issue with the assertion that small retail pharmacies will share in the positive revenue effects of Medicare Part D because the commenter claimed that the any willing pharmacy provision was of limited effectiveness due to the preferred pharmacy provisions, the special provisions for MA-PD plans that own their own pharmacies to meet network adequacy standards, and the provisions for Part D plans to meet network adequacy standards through accreditation from a Medicare-approved accrediting organization.

We also received several comments that asserted that small retail pharmacies and in some cases regional chains would be hurt by the preferred pharmacy provision because they cannot collectively negotiate contracts with plans. The commenters asserted that plans could designate large retail pharmacy chains as preferred, and leave out small pharmacies. The commenters claimed that even if small retail pharmacies are allowed access to preferred pharmacy networks, if the fees negotiated by the large corporations are very low, smaller pharmacies can not afford to participate. Another commenter wanted us to mandate that plans solicit inner city and rural pharmacies that meet SBA small business standard for their pharmacy network and give them access to any terms that the plan offers to a subset of pharmacies.

A number of commenters asserted that small, independent, or rural pharmacies would be hurt unless steps were taken to avert plans from steering beneficiaries to mail order, implement TRICARE standards at a smaller geographic level (many urged implementation at the local level, some supported the State level), eliminate the preferred provider provisions, and provide guidelines for plans on dispensing fees. One commenter wanted dispensing fees for non-profit entities to reflect their preferred acquisition costs, arguing that without this Medicare would be assisting tax-exempt non-profit competitors of small business pharmacies.

Response: Our analysis estimated that on average retail pharmacy revenues will increase by 0.5 percent to 1.6 percent as a result of Medicare Part D. We believe these estimates are conservative because they do not take into account the effect of the Federal Upper Payment limit on current Medicaid reimbursement, the additional revenues that retail pharmacies are likely to receive from medication therapy management, and the additional revenues that retail pharmacies that sell non-prescription drug products will gain from additional foot traffic.

As noted in the proposed rule, we recognize that our estimates represent an average impact and that the effect on individual retail pharmacies will vary around this average. While we believe

that we have conservatively estimated an average revenue increase ranging from 0.5 percent to 1.6 percent, it is possible that some individual retail pharmacies could experience smaller positive effects and even in some cases negative revenue impacts, while others may experience larger positive effects. While a specific retail pharmacy because of its individual circumstances could experience a negative revenue impact we believe this will generally be uncommon for several reasons.

While we agree with the commenter that retail pharmacies with a disproportionate customer base made up of Medicare beneficiaries and dual eligibles will be more heavily impacted by Medicare Part D, we believe this is unlikely to translate into a negative impact for retail pharmacies. The effect of Medicare Part D on retail pharmacy revenues is largely driven by increased utilization of drugs among beneficiaries without prior drug coverage and reduced revenues for beneficiaries who are dual eligibles (as well as increased revenues from medication therapy management for targeted beneficiaries with chronic illnesses, which is not reflected in our estimates). If a retail pharmacy had an unrepresentative customer base, with substantially more dual eligibles and fewer uninsured beneficiaries than average, then it is possible that the pharmacy might experience a negative revenue impact from Medicare Part D. However, as mentioned in the proposed rule, we believe it is likely that retail pharmacies that serve large populations of dual eligibles will be located in low-income areas that also have a large population of beneficiaries without prior drug coverage, and consequently, larger revenue declines associated dual eligibles would be offset by larger revenue increases associated with beneficiaries that lacked prior drug coverage. We sought comment on this in the proposed rule and received no specific data or information on this issue.

We also agree that Medicare Part D will generally have a greater impact on those retail pharmacies that depend on prescription drug revenues for a larger portion of their sales. We note, however, that since the average impact on retail pharmacies' prescription drug revenues is estimated to be positive, the impact on retail pharmacies' overall revenues would also be expected to be positive regardless of the extent to which a pharmacy relies on prescription drug revenues.

A number of commenters voiced concern that the preferred pharmacy provision would disadvantage small retail pharmacies. As discussed in the preamble, the preferred pharmacy provision is stipulated by statute. This provision would allow plans the option of offering differential cost-sharing in preferred versus non-preferred pharmacies provided that this does not increase government costs. While we acknowledge that preferred pharmacies may have some competitive advantage over non-preferred pharmacies, we believe a number of factors mitigate this. Importantly, our policy decision in the final rule to strengthen the network adequacy requirements by implementing the TRICARE access standard at the State (rather than regional) level provides pharmacies with more leverage in negotiating with Part D plans. In addition, the final rule requirement that plans offer reasonable and relevant standard terms and conditions for network participation to all similarly situated pharmacies promotes retail pharmacy access to Part D networks. In addition, the estimated 11 million Part D low-income subsidy enrollees—which account for more than one-third of all Part D enrollees in 2006—would not face a difference in cost-sharing between preferred and non-preferred pharmacies because of the nominal cost-sharing levels guaranteed by the low-income subsidy. Also, as indicated in the preamble, plans cannot use the preferred pharmacy provision in a discriminatory manner, for example related to rural areas. Finally, the statutory requirement that any differential cost-sharing not effect the Government cost when combined with the final rule requirement that plans offer standard terms and conditions for participation to any willing pharmacy, we believe mitigates against large differentials in cost sharing between preferred and non-preferred pharmacies.

With respect to the commenter requesting that we require plans to offer preferred terms to small pharmacies in rural and inner city areas, we believe that we have used the available statutory authority to the fullest extent possible to promote the participation of small pharmacies. We have done this through our requirement that plans offer reasonable and relevant standard terms and conditions for network participation. We also modified our access standard to be measured on a State basis rather than a regional basis, which necessitates plans providing adequate access to rural areas and strengthens pharmacies bargaining power.

We disagree with the comment that allowing special network adequacy standards for MA-PD plans that provide retail prescription drugs through pharmacies owned by the plan would impact retail pharmacies negatively, as we do not think that these types of arrangements are very common. We also believe that the provision that Part D plans could meet the network adequacy standards through accreditation from a Medicare-approved accrediting body, would not in any way jeopardize network adequacy or retail pharmacies' ability to participate in networks. As discussed in the preamble, the accreditation standards used by the organizations would have to be determined by CMS to be no less stringent than our own requirements and we would retain the authority to initiate enforcement action against any Part D plan sponsor that we determine, on the basis of our own survey or the results of the accreditation survey, no longer meets the Medicare requirements with regard to network adequacy.

With respect to mail order, as discussed in the preamble, the statute allows plans to offer lower cost-sharing at preferred pharmacies, including mail order pharmacies. Consequently, we cannot, as some commenters urged, require plans to offer similar coinsurance in both retail and mail order settings. However, this is similar to what currently occurs in the commercial insurance market today. We have included in our impact estimates the effect of beneficiaries using mail order at the same rate as individuals in the commercial market. Even taking into account this possible increased use of mail order among beneficiaries, our analysis finds an overall positive impact of Medicare Part D on retail pharmacy revenues. In addition, there are some aspects of Medicare Part D, which are not as typical of the commercial market, which put retail pharmacies on a more level playing field with mail order. As noted in the proposed rule, the nearly 11 million beneficiaries who are estimated to enroll in the low-income subsidy face nominal cost-sharing, and consequently we believe there will be little, if any, difference in these beneficiaries' out-of-pocket costs between retail and mail order pharmacies. Our regulation also requires that plans allow retail pharmacies to dispense the same quantity of a prescription (for example, a 90-day supply) as mail order pharmacies, provided it is allowed by State pharmacy law. Also under Medicare Part D, plans are required to have medication therapy management programs which represent an additional service that pharmacists will be able to provide and receive reimbursement.

As noted previously, a number of commenters expressed concern that

dispensing fees to retail pharmacies may not be adequate and urged us to provide guidance to Part D plans to ensure adequate dispensing fees, including one commenter who requested that dispensing fees for non-profit pharmacies reflect their preferred acquisition costs so as to not to disadvantage for-profit pharmacies that compete with these entities. Given plans' need to secure a network of providers (especially in light of the final rule decision to strengthen the network adequacy standards by implementing the TRICARE standard at the State, rather than regional, level), we believe plans will have every incentive to adequately reimburse retail pharmacies for the costs involved with providing covered Part D drugs to plan enrollees.

Comment: One commenter stated that retail pharmacies will receive additional revenues from medication therapy management and fees paid by plans for providing drug utilization review and quality assurance. Another commenter wrote that the lack of detail in the proposed rule on medication therapy management makes it difficult to estimate its economic impact.

Response: While it is difficult to quantify the revenue impact on retail pharmacies of medication therapy management at this time, we believe, as one of the commenters indicates, that plan payments to pharmacies for medication therapy management will generate additional retail pharmacy revenues. As noted elsewhere, the positive revenue effect from these types of payments to retail pharmacies is not included in our impact estimates, making our estimate of a positive revenue impact on retail pharmacies conservative.

Comment: One commenter asserted that additional foot traffic in retail pharmacies would not offset what it claimed was an adverse impact of Medicare Part D on retail pharmacies because more than 90 percent of small retail pharmacy revenues are derived from prescription drugs.

Response: Our analysis in the proposed rule found that on average retail pharmacy revenues would increase as a result of Medicare Part D because the increased utilization of prescription drugs associated with Medicare beneficiaries acquiring drug coverage is estimated to more than offset decreased revenues from new pharmacy discounts and new use of mail order among some beneficiaries. We indicated in the proposed rule that our estimate of the revenue impact on retail pharmacies was conservative since it did not take into account several issues, including the possibility that pharmacy revenues may increase to some extent due to additional foot traffic generating increased sales of non-prescription drug products for pharmacies. We agree with the commenter that small retail pharmacies typically derive more of their revenues from prescription drugs than large pharmacies. Consequently, while small retail pharmacies would likely experience some increase in their non-drug revenues due to additional foot traffic, the increase would be less significant for small pharmacies than large pharmacies. However, since our revenue estimates conservatively assume no revenue increase resulting from additional foot traffic, our estimate of the average revenue impact on retail pharmacies is unaffected by this issue.

Comment: One pharmacy association commenter criticized our definition of significant economic impact as a revenue impact of 3 to 5 percent. The commenter claimed that this does not take into account pharmacy profit margins, which they assert have ranged in past decade from 2.9 percent to 3.8 percent (on a net, pre-tax basis).

Response: HHS uses revenues rather than profit margins to estimate the economic impact of a rule on small entities because in our experience reliable data on profit margins are very difficult to obtain, while reliable data on revenues are much more readily available and straightforward.

One example of the difficulties in obtaining reliable profit margin data and in how to interpret those data in the case of small businesses relates to how owners' salaries are treated. Profit margin estimates can vary substantially depending on how one considers the owner's salary relative to the profits of the business. For example, a 2002 study on the pharmacy industry conducted by Booz Allen Hamilton for us cites data from the National Community Pharmacist Association (NCPA), which indicate that independent retail pharmacies had average profit margins, in 2000, of nearly 8 percent when owners' salaries were included and about 3 percent when owners' salaries were excluded. Furthermore, when the Internal Revenue Service (IRS) determines income tax liability for sole proprietorships, it considers the businesses' incomes to be profits plus the owners' salaries. In the case of pharmacies and drug stores, IRS data on sole proprietorships show fairly similar profit margin levels with NCPA—about 7 percent including owners' salaries in the late 1990s. Thus, if profit margins were used to determine the economic impact of rules on small businesses, how the owners' salaries are treated could significantly alter findings. Furthermore, data are generally not available to separate the portion of an owner's salary that compensates for labor versus the portion that reflects profit taking in the form of salary, which makes developing an accurate estimate of small businesses' profit margins very difficult.

Even if these difficulties were not present, changes in sales levels do not translate directly into proportional changes in profits. One commenter, discussed later in this analysis, claims that higher sales levels can reduce profits. In fact, retailers have many possible responses to changes in their sales levels in terms of management, staffing, inventory levels, and other aspects of their business models, and which responses they choose are likely to determine whether, and to what extent, profits rise or fall. We have no way to predict these responses' precise effects on profits, but of course would expect decisions to be profit maximizing.

Regardless of whether the HHS standard for significant economic impact focuses on revenues rather than profit margins, as stated elsewhere in the preamble, we have taken a number of steps to mitigate the financial impact on small retail pharmacies and drug stores.

Comment: One commenter asserted that the regulatory impact analysis should estimate collectively the effect of both the implementation of Medicare Part D and changes in Medicare Part B on pharmacies.

Response: Changes to Medicare Part B are not the subject of this rule, and as such are not within the scope of this regulatory impact analysis.

a. Expansion of Drug Coverage and Increased Access to Pharmacy Discounts Among Beneficiaries Previously Lacking Such Coverage or Discounts

A substantial portion of beneficiaries (about 24 percent as of 2001) lack drug coverage. As discussed in Section E, we project that generally 95 percent of beneficiaries without drug coverage will enroll in the Medicare drug benefit (with somewhat lower uptake—71 percent—assumed among beneficiaries with drug spending in the lowest quintile). The expansion of drug coverage to these individuals is likely to have countervailing effects on pharmacy revenues. First, it is likely to lead to increased drug utilization and spending among beneficiaries without prior drug coverage, and thus increased pharmacy revenues. Second, it is likely to lead to increased access to pharmacy discounts for some beneficiaries who previously did not receive such discounts (specifically, many beneficiaries

without drug coverage and beneficiaries with Medigap drug coverage), and thus decreased revenues for pharmacies. Because many beneficiaries that currently have prescription drug coverage (for example, those in employer sponsored retiree health plans or Medicare Advantage plans) already receive pharmacy discounts through those insurers, we do not expect the Medicare prescription drug benefit to generate any new pharmacy discounts for these beneficiaries. In addition, it is possible that the Medicare drug benefit may lead to new use of mail order pharmacies among beneficiaries without prior drug coverage and beneficiaries with Medigap drug coverage, potentially having some effect on retail pharmacy revenues. Overall, we estimate that increased utilization for beneficiaries without prior drug coverage and new pharmacy discounts and possible new use of mail order pharmacies among some beneficiaries will result in a net positive revenue impact for retail pharmacies.

Medicare beneficiaries without prior drug coverage who enroll in the Medicare drug benefit will face a substantial reduction in out-of-pocket costs for prescription medicines, and consequently we expect that their drug utilization and expenditures will increase. Beneficiaries with drug coverage fill more prescriptions and have higher total drug spending than beneficiaries without drug coverage. Based on 2001 MCBS data, beneficiaries with drug coverage have average total drug spending that is 109 percent greater than beneficiaries without drug coverage. These spending differences hold true even among beneficiaries with similar numbers of chronic conditions. For example, average spending for beneficiaries with drug coverage was higher than for beneficiaries without drug coverage among beneficiaries with no chronic conditions (247 percent higher), 1–2 chronic conditions (107 percent higher), 3–4 chronic conditions (76 percent higher), and 5 or more chronic conditions (53 percent higher). Thus, we expect that the expansion of drug coverage to beneficiaries who previously did not have such coverage will lead to increased drug utilization and spending, and thus higher pharmacy revenues. For the purpose of this analysis, we assume that beneficiaries without prior drug coverage who enroll in the Medicare drug benefit will experience a 76 percent increase in total drug spending. We base this assumption on the fact that most beneficiaries without drug coverage fall into the category of having 1–2 chronic conditions or 3–4 chronic conditions, and we have chosen the more modest use difference seen in the 3–4 chronic condition group. Furthermore, we believe that this is a conservative assumption because the average difference across the population in drug spending for beneficiaries with and without coverage is 109 percent. Beneficiaries without drug coverage whom we project would enroll in Medicare Part D account for about 12 percent of all drug spending by Medicare beneficiaries (based on 2001 MCBS data). If we assume that these previously uninsured Part D enrollees experience a 76 percent increase in drug expenditures due to a use effect, this would represent about an 8.9 percent increase in total drug spending by Medicare beneficiaries.

At the same time, to the extent that beneficiaries without drug coverage did not receive pharmacy discounts prior to Medicare Part D, we would expect that pharmacy discounts negotiated by PDPs and MA-PDs could result in some reduction in pharmacy revenues. While the vast majority of beneficiaries who currently have drug coverage are likely to already be receiving pharmacy discounts, and thus the Medicare drug benefit would not result in any change in pharmacy discounts for these beneficiaries, this may not be the case for beneficiaries without drug coverage. As mentioned previously, the April 2000 HHS Report ''Prescription Drug Coverage, Spending, Utilization, and Prices'' found that on average individuals with drug coverage paid a 15 percent lower price for prescription drugs at the point of sale than individuals without drug coverage. The discount insured individuals receive at the point of sale reflects a combination of pharmacy and manufacturer discounts. However, to take a conservative approach, we assume that Medicare Part D enrollees without prior drug coverage realize 15 percent price discounts at the point of sale, all of which reflect pharmacy discounts. This assumption is conservative not only because it assumes that the entire 15 percent discount comes from pharmacies, but also because some of these beneficiaries are likely to have received pharmacy discounts previously through the Medicare drug discount card, which began offering discounts in June 2004 and which includes substantial discounts from drug manufacturers, and through senior pharmacy discounts previously offered by many pharmacies. Thus, our assumption that all Part D enrollees without prior drug coverage would receive new pharmacy discounts of 15 percent under Medicare Part D overstates the negative revenue impact on pharmacies. With these beneficiaries accounting for about 12 percent of all drug spending by Medicare beneficiaries, we estimate that extending a 15 percent discount to these beneficiaries would result in about a 1.8 percent decrease in total drug spending by Medicare beneficiaries.

Another group of beneficiaries who we believe may obtain new pharmacy discounts under Medicare Part D are beneficiaries with Medigap drug coverage. Few Medigap plans actively negotiate prescription drug discounts for enrollees. Consequently, we assume that all beneficiaries with previous Medigap drug coverage who are projected to enroll in Medicare Part D obtain new pharmacy discounts. With these enrollees accounting for about 4 percent of prescription drug spending by all beneficiaries, we estimate that extending pharmacy discounts to these beneficiaries could result in about a 0.6 percent decline in total Medicare drug spending by beneficiaries.

It is also possible that the Medicare prescription drug benefit may result in new use of mail order pharmacies by some beneficiaries. We believe that the new Medicare benefit is unlikely to affect the use of mail order pharmacies among beneficiaries currently with employer sponsored or Medicare Advantage drug coverage as mail order is an option currently available to these beneficiaries and the implementation of Medicare Part D makes no changes in this regard. We also believe that there is likely to be no effect on mail order use by beneficiaries who qualify for the low-income subsidy because nominal cost sharing exists regardless of where the beneficiary purchases the prescriptions (and as noted above, for those without prior drug coverage or less generous prior drug coverage, we expect that these beneficiaries will fill significantly more prescriptions). The two groups where it is possible that mail order usage may increase are beneficiaries without prior drug coverage and beneficiaries with Medigap drug coverage. The effect of Medicare Part D on mail order use by these beneficiaries, however, is uncertain. For example, Medicare Part D includes a provision that allows retail pharmacies (subject to State pharmacy laws) to provide a 90-day supply, putting them on equal footing with mail order pharmacies in this regard.

To estimate the potential effect of new mail order use among beneficiaries without prior drug coverage and beneficiaries with prior Medigap drug

coverage, we take the approach of making estimates based on two alternate assumptions. As a lower bound, we assume that there is no additional mail order use. As an upper bound, we assume that the percent of beneficiaries using mail order pharmacies among these two groups of beneficiaries increases to be similar to the rate of use among beneficiaries with private employer-based drug coverage. There is limited publicly available data related to mail order utilization. To supplement publicly available data we tried to obtain information from proprietary sources to help inform our upper bound estimates. For our upper bound assumptions, we use data from the Medical Expenditure Panel Survey (MEPS) to assign higher rates of mail order use (that is, the percentage of population that fills at least one prescription through mail order) to the population that gains drug coverage and to beneficiaries with prior Medigap drug coverage. We also tried to obtain data on the share of drug spending through mail order pharmacies that occurs among individuals who use these pharmacies. However, we were unable to obtain this type of information. We were able to obtain some proprietary information regarding the share of total plan spending occurring through mail order and retail pharmacies for a commercially insured over 65 population. Using this information in combination with the recognition that a number of prescriptions are unlikely to be filled through mail order (for example such as antibiotics and pain medication used to treat acute conditions, or newly prescribed medications), we developed an upper bound assumption that as much as 50 percent of drug spending among new users of mail order might occur through mail order pharmacies. We do not expect mail order use to approach this level; we use it simply for purposes of estimating the maximum potential impact. Under this upper bound assumption, we estimate that as a result of mail order effects, aggregate Medicare drug spending in retail pharmacies could decrease by as much as 2.0 percent. Thus, based on our lower bound and upper bound assumptions, we estimate that possible new use of mail order pharmacies among some beneficiaries could result in a decrease in retail pharmacy revenues of somewhere between 0 to 2.0 percent. If a shift in mail order use were to occur, our prior estimates of utilization and discount effects would be altered slightly since they are based on the assumption of no change in mail order use. We estimate that under our upper bound assumptions related to mail order, our previous estimates of the combined effect of utilization increases and new pharmacy discounts for some beneficiaries would need to be adjusted downward by as much as 1.1 percentage points. We note that even with these adjustments based on a very high upper bound assumption, the net effect for retail pharmacies remains positive. In the proposed rule, we requested additional data that could help inform our assumptions and analysis related to new mail order use by beneficiaries without prior drug coverage, but we did not receive any comments providing data on this issue.

Taken together, we estimate that the effect of expanding access to prescription drug coverage among beneficiaries without prior drug coverage and the effect of new pharmacy discounts and possibly new use of mail order pharmacies by some beneficiaries will result in a net increase in total prescription drug spending by Medicare beneficiaries at retail pharmacies of between 3.8 percent and 6.6 percent. We estimate that this would represent an average increase in retail pharmacy revenues of between 1.5 percent and 2.7 percent, as Medicare beneficiaries account for about 40.5 percent of outpatient prescription drug spending for the non-institutionalized population according to 1999 MEPS data (Stagnitti MN et al., AHRQ, ''Outpatient Prescription Drug Expenses, 1999'', 2003). Furthermore, while not quantifiable at this time, we expect that pharmacies may realize additional revenues from the MMA requirement that PDPs and MA-PDs offer medication therapy management programs to targeted enrollees, which may be furnished by pharmacists. In addition, it is likely that increased use of prescription drugs by Medicare beneficiaries will lead to increased foot traffic in pharmacies and increased pharmacy revenues from non-pharmaceutical products as well.

b. Medicare's Assumption of Drug Coverage for Full-Benefit Dual Eligibles

Because State Medicaid programs typically pay higher reimbursement rates to pharmacies than private sector insurers, the movement of full-benefit dual eligibles from Medicaid drug coverage to Medicare drug coverage (through PDPs and MA-PDs) has potential implications for pharmacy revenues. Our upper bound estimate of the average reduction in pharmacy revenues that could result from full-benefit dual eligibles receiving drug coverage from Medicare is 1.0 percent.[12] We believe that this is an overestimate because it does not take into account the effect the Federal Upper Payment Limit has in reducing Medicaid reimbursement rates for multi-source drugs with at least three generic equivalents. Also, to the extent that a State Medicaid program has adopted managed care arrangements to lower the cost of drugs for dual eligibles, our estimate of the revenue impact of pharmacy reimbursement changes for full-benefit dual eligibles would be overstated.

We conducted the following analysis to estimate how the transfer of dual-eligibles' drug coverage from Medicaid to Medicare would affect pharmacy revenues. First, we developed an estimate of the average Medicaid drug reimbursement rate across States. To begin, we considered how Medicaid reimburses pharmacies for drugs. Medicaid reimburses pharmacies for drugs based on the estimated acquisition costs (EAC) plus a dispensing fee. There is variation across States in how they define and the level at which they set EAC and the dispensing fee. The vast majority of States define EAC as the average wholesale price (AWP) less a certain percentage discount, while a small number define it as wholesale acquisition cost (WAC) plus a certain percentage or the lower of an AWP-based or WAC-based payment amount. Dispensing fees also vary by State and typically range from $3 to $5. Some States use the same reimbursement formula for brand and generic drugs, while others institute a greater discount off of AWP for generic drugs or a higher dispensing fee for generic drugs, and in some cases both. In addition, Medicaid reimbursement rates for multi-source drugs with 3 or more generic equivalents are generally capped by the Federal Upper Payment Limit.

Based on information on the Medicaid EAC and dispensing fee for each State for brand and generic drugs as of fourth quarter 2004, we estimated the overall drug reimbursement rate (EAC plus dispensing fee) as a percent of AWP separately for brand and generic drugs. We did this by estimating the dispensing fee as a percent of the average AWP, using unpublished

[12] This is slightly lower than our proposed rule estimate of a 1.1 percent revenue effect because we have updated our analysis to take into account the most recently available Medicaid pharmacy reimbursement rates. Because a few States have reduced their current Medicaid pharmacy reimbursement rates, the effect on pharmacy revenues of shifting dual eligibles' drug coverage from Medicaid to Medicare is slightly less.

Express Scripts data on the average AWP for brand drugs ($77.42) and generic drugs ($32.57) in 2002.[13] (It should be noted that under this methodology the total reimbursement rate for generic drugs (including the ingredient cost and the dispensing fee) as a percent of AWP is much greater than the reimbursement rate as a percent of AWP for the ingredient cost alone, because the dispensing fee represents a fairly high percentage of AWP for low cost generic drugs.) For States that set EAC based on WAC rather than AWP, we express their reimbursement formula in AWP terms by assuming that WAC is equivalent to roughly 20 percent of AWP, based on information about the typical relationship between WAC and AWP in the 2000 HHS Prescription Drug study. After estimating an overall Medicaid reimbursement amount for brand and generic drugs for each State, we estimate the weighted average reimbursement rate across States, using the number of full-benefit dual eligibles with drug coverage in each State for weights. Based on this method, we estimate that average Medicaid reimbursement to pharmacies (for ingredient cost and dispensing fee combined) is roughly equivalent to AWP minus 7 percent for brand drugs and AWP for generic drugs. It should be noted that this likely overstates current Medicaid reimbursement rates for generic drugs because it does not take into account that Medicaid reimbursement for multi-source drugs with 3 or more generic equivalents is generally capped by the Federal upper payment limit.

We then estimated an average Medicaid reimbursement rate across all drugs (brand and generic) by weighting the average reimbursement estimates for brand and generic drugs by the percent of Medicaid expenditures we assume they comprise. According to a survey of State Medicaid programs by the Kaiser Family Foundation, States estimate that 80 percent of State Medicaid drug expenditures are on brand drugs and 20 percent on generics. Using these figures for weights, we estimate an overall average Medicaid drug reimbursement rate (including dispensing fee) of roughly 5 percent off of AWP.

The revenue impact on pharmacies of transitioning dual eligibles from Medicaid to Medicare Part D is measured by taking pharmacies' current revenues for dual eligibles minus their expected revenues for this population under Medicare Part D. Consequently, by overstating current Medicaid pharmacy revenues, our analysis overstates (rather than understates) the adverse impact on pharmacies from transitioning dual eligibles to Medicare Part D.

Second, for the purpose of this analysis, we make assumptions about the average pharmacy reimbursement rate for brand and generic drugs under PDPs and MA-PDs. We base these assumptions on available literature about typical pharmacy reimbursement rates under private sector insured products. It must be noted that these assumptions are not meant to convey our expectation of the actual pharmacy reimbursement rates negotiated by PDPs and MA-PDs with pharmacies under the Medicare drug. Instead, they are assumptions made solely for this regulatory flexibility analysis. According to a survey sponsored by Takeda Lilly of employer sponsored insurance plans covering more than 17 million lives, the average reimbursement for ingredient cost for a brand drug in 2002 was about 14 percent off of AWP (Takeda, ''The Prescription Drug Benefit Cost and Plan Design Survey Report,'' 2003). In addition, according to a report by Express Scripts, there tends to be about a three times greater discount off of AWP for generic drug ingredient cost than for brand drug ingredient cost (Express Scripts, ''Drug Trends 2002 Report,'' June 2003). Based on these studies, we assume reimbursement for ingredient costs of 14 percent off of AWP for brand drugs and 42 percent off of AWP for generic drugs. In terms of dispensing fees, the Novartis Pharmacy Benefit Reports, which is a survey of HMO plans, finds an average dispensing fee of $1.79 for brand drugs and $2.08 for generic drugs as of 2002 (Novartis, ''Pharmacy Benefit Report: Facts and Figures,'' 2003). The Takeda Lilly survey of employer-sponsored plans indicates an average dispensing fee of $2.13 for brand and $2.22 for generic drugs. For the purpose of this analysis, we average the findings from the two studies and assume a dispensing fee of $1.96 for brand drugs and $2.15 for generic.[14] Similar to the Medicaid reimbursement analysis, we estimate these dispensing fees as a percent of average AWP for brand and generic drugs and then add them to our ingredient cost reimbursement assumptions to arrive at average reimbursement estimates—11 percent off of AWP for brand drugs and 35 percent off of AWP for generic drugs. We then weight the average reimbursement estimates for brand and generic drugs by the percent of expenditures they are assumed to comprise to arrive at an overall average reimbursement estimate (including dispensing fee) of 16 percent off AWP for all drugs.

Third, we estimated the share of national retail prescription drug spending accounted for by Medicaid drug expenditures on dual eligibles. According to a special analysis by the Kaiser Commission on Medicaid and the Uninsured, Medicaid prescription drug spending on dual eligibles was $9.5 billion in 2000, including fee-for-service and managed care and netting out manufacturer rebates (Kaiser Commission on Medicaid and the Uninsured, ''The Proposed Medicare Prescription Drug Benefit: A Detailed Review of Implications for Dual Eligibles and Other Low-Income Medicare Beneficiaries,'' September 2003). In addition, national retail prescription drug spending, net of manufacturer rebates, was $121.5 billion in 2000 according to National Health Expenditures projections by our Office of the Actuary. (*http://www.cms.hhs.gov/statistics/nhe/projections–2003/t11.asp*). Based on the above figures, we estimate Medicaid drug spending on dual eligibles comprised about 7.8 percent of total national retail prescription drug spending net of rebates in 2000. While this estimate is based on drug spending adjusted for rebates, drug spending without adjustments for rebates would be a better measure of the actual amount of revenues flowing through pharmacies. Manufacturer rebates typically occur on the back end between manufacturers and third party insurers and do not impact pharmacy revenues. Therefore, we adjust our estimate to pre-rebate levels of drug spending using the following method. We take national retail prescription drug spending net of rebates and inflate it based on our Office of the Actuary's estimate that national retail prescription drug spending in 2000 would be 6 percent higher without the adjustments for rebates. We also take our estimate of Medicaid prescription drug spending for dual eligibles and inflate it based on information from the Kaiser Study, which indicates that

[13] These unpublished Express Scripts estimates of average AWP for brand and generic drugs in 2002 reflect the average AWP for a 30-day equivalent weighted by the number of scripts, based on utilization data from a commercially insured population age 65 and older, with employer sponsored insurance and with an integrated benefit (network and mail prescription coverage).

[14] There was a typographical error in the text of the proposed rule describing our dispensing fee assumption for generic drugs. Our model and findings in the proposed rule were based on an assumed generic dispensing fee of $2.15. The proposed rule text should have read $2.15, not $2.11.

rebates reduced Medicaid fee-for-service drug spending in 2000 by an average of about 19 percent. Absent information on the percent of Medicaid drug spending for dual eligibles that is under fee-for-service versus managed care, we take an extremely conservative approach and inflate Medicaid drug spending to pre-rebate as though all spending had been fee-for-service. It should be noted that we strongly believe this overstates the amount of Medicaid drug spending on dual eligibles, and thus overstates any negative revenue impact on pharmacies. Based on the above, we estimate that Medicaid drug spending on dual eligibles is about 9.1 percent of total national retail prescription drug spending. Finally, we estimate the potential impact on pharmacy revenues of transferring responsibility for drug coverage of full benefit dual eligibles from Medicaid to Medicare.

Based on our previous estimates of average pharmacy drug reimbursement rates under Medicaid and private insurers, we estimate that prescription drug spending on dual eligibles would account for about 8.1 percent of national retail prescription drug spending if drugs were reimbursed at rates typical of private sector insurer rates rather than Medicaid.[15] Thus, our upper bound estimate of the average reduction in pharmacy revenues that could result from full-benefit dual eligibles receiving drug coverage from Medicare is about 1.0 percent. As mentioned previously, we believe that this is an overestimate of the impact on pharmacies because it does not take into account existing policies that reduce Medicaid reimbursement rates such as the Federal Upper Payment limit for multi-source drugs with at least three generic equivalents.

Comment: Another commenter asserted that if pharmacy revenues increase as predicted in the proposed rule then pharmacies will lose money because business expenses (more claims transmissions, more inventory, higher paychecks) will be more than 3 percent.

Response: Due to the expansion of prescription drug coverage among Medicare beneficiaries, prescription drug utilization is expected to increase moderately among beneficiaries, which will result in more scripts being dispensed by pharmacies. To accommodate a modest increase in the demand for prescription drugs, pharmacies will turn over more inventory to sell to beneficiaries and may also, depending on their current capacity, respond by increasing their staff hours. Similarly, pharmacies are likely to experience some increase in the number of claims transmissions they submit due to increased utilization of drugs among beneficiaries and due to the submission of claims transmissions for beneficiaries with Medicare Part D drug coverage who previously lacked any coverage. Part D plans will be paying pharmacies for the cost of dispensing these drugs through fees plans negotiate with pharmacies for ingredient cost and dispensing. In addition, some pharmacists may receive additional payments from plans for medication management services. We believe that the need for plans to maintain an adequate pharmacy network provides a strong incentive for plans to compensate pharmacies adequately for their costs.

In addition to the increased claims transmissions discussed above, pharmacies may also have additional claims transmissions for those Part D enrollees who have supplemental drug coverage (for example, from an employer or SPAP) that is coordinated with, but not integrated with, Medicare Part D. Since it is unknown how prevalent supplemental drug coverage will be, and whether it will more commonly take the form of enhanced coverage that is integrated with Part D or supplemental drug coverage that is coordinated with Part D, it is difficult to make an estimate of the additional claims transmission volume that may be generated. However, because of the efficiency of arranging for additional coverage through the PDP or MA-PD, we think the incentive is to arrange for or provide enhanced coverage rather than utilize claims based coordination of benefits. Furthermore, since claims transmissions costs are generally a very small fraction of the cost of dispensing a prescription to a beneficiary, and even smaller fraction of the average price of a prescription, we believe that these costs would not be substantial, especially in comparison to the additional pharmacies revenues generated by Medicare Part D. In addition, as discussed elsewhere, we will be arranging for a TrOOP facilitation process to minimize the level of effort involved for pharmacies in dealing with coverage that supplement Medicare Part D.

Comment: One commenter voiced concern about the private sector dispensing estimates used in the impact analysis, arguing that the generic fee was not sufficiently greater than the brand fee to provide incentives for use of generic drugs. In addition the commenter asserted that these fees were below a pharmacy's average cost for dispensing a prescription, which it claimed was $7.50 to $8.00 depending on the geographic location.

Response: We indicated in the proposed rule that the assumptions we made about the average pharmacy reimbursement rate, including dispensing fees, for brand and generic drugs under PDPs and MA-PDs were not meant to convey our expectation of the actual pharmacy reimbursement rates negotiated by PDPs and MA-PDs with pharmacies. Instead, they were assumptions made in order to estimate the potential impact of Medicare Part D on pharmacies for the purpose of a regulatory flexibility analysis. These assumptions were based on available literature about typical pharmacy reimbursement rates under private sector insured products.

Dispensing fees paid to pharmacies will depend on the outcome of the negotiations between pharmacies and plans. Given plans' need to secure a network of providers, we believe plans will have every incentive to adequately reimburse pharmacies for the costs involved with providing covered Part D drugs to plan enrollees. Furthermore, as discussed in the preamble plans have the flexibility to provide higher dispensing fees for generic drugs to encourage utilization if they wish to do so.

Comment: One commenter asserted that the analysis overstates the current Medicaid revenues to pharmacies because the commenter claims that 20 percent of all Medicaid prescriptions are paid at the pharmacy's usual and customary rate, not the estimated acquisition cost, and because there are higher costs of business in Medicaid that do not exist in private programs. They assert that this means that the transfer to Medicare Part D of the dual eligibles could have a greater effect on pharmacies than estimated.

Response: As discussed elsewhere, we believe that our analysis overstates the revenues pharmacies currently receive from Medicaid because it does not take into account the effect of the Federal Upper Payment Limit in capping Medicaid reimbursement for multi-source drugs with 3 or more generic equivalents. Due to data limitations, our analysis also overstates current pharmacy revenues from Medicaid because we inflate Medicaid drug spending for dual eligibles to pre-rebate levels as though all spending had been fee-for-service. In addition, to the extent

[15] The 8.1 percent figure is computed by multiplying our estimate of drug spending for dual eligibles as a percent of NHE (9.1 percent) by our estimate of pharmacy reimbursement rates typical of private sector insurers (AWP–16 percent, or 84 percent of AWP) and dividing by our estimate of average Medicaid pharmacy reimbursement (AWP-5 percent, or 95 percent of AWP).

that Medicaid reimbursement is further limited by pharmacies' usual and customary price, as the commenter asserts, our estimates of current pharmacy revenues from Medicaid would be further overstated.

c. Overall Effect

Considering together the effect of increased utilization, new pharmacy discounts and possibly new use of mail order pharmacies among some beneficiaries, and reimbursement changes for full-benefit dual eligibles, we estimate that retail pharmacy revenues would increase on average by between 0.5 percent and 1.6 percent as a result of the Medicare prescription drug benefit. This is the result of an increase in prescription drug revenues ranging from 1.5 percent to 2.7 percent due to the net effect of increased utilization, new pharmacy discounts, and possibly new use of mail order pharmacies among some beneficiaries, and a 1.0 percent decrease in pharmacy revenues (upper bound estimate) due to drug coverage for full-benefit dual eligibles shifting from Medicaid to Medicare.

In addition, we believe that these estimates understate the degree to which pharmacy revenues increase as a result of the Medicare prescription drug benefit for several reasons. Our estimate of the revenue reduction resulting from the transfer of drug coverage for full benefit dual eligibles from Medicaid to Medicare is likely to be overstated because it does not take into account the effect of the Medicaid upper payment limit on reducing Medicaid reimbursement rates for some multi-source drugs. In addition to revenue effects we have estimated, the Medicare prescription drug benefit is likely to provide other sources of revenue increases for pharmacies; for example, through targeted medication therapy management programs under Medicare Part D which may be furnished by pharmacists, or through increased foot traffic in pharmacies leading to increased pharmacy sales of other goods in addition to prescription medicines. For these reasons, we estimate that the Medicare prescription drug benefit will have a positive revenue impact on the pharmacy industry overall.

We believe that the program's effect on small pharmacies will also be positive. We expect that small pharmacies will participate in the networks of Medicare Part D plans and consequently will share in the positive revenue impacts. Given the current industry practice of broad pharmacy networks and given Medicare Part D's any willing pharmacy provision, which includes the requirement that plans offer reasonable and relevant standard terms and conditions for network participation to all similarly situated pharmacies, we anticipate that all pharmacies that wish to participate in Medicare Part D will be able do so. Furthermore, we believe that the strengthening of the network adequacy standard in the final rule to be implemented at the State level provides pharmacies more bargaining leverage with plans. For these reasons, we would expect the great majority of small business pharmacies to share in the increased business created by the Part D drug benefit.

d. Other Pharmacy Issues

Requirements related to reporting, recordkeeping, and other compliance activities for small pharmacies under this program are minimal. The statute requires that network pharmacies notify a Part D enrollee at the point of sale of the differential between the price of a drug and the lowest priced generic drug under the program that is therapeutically equivalent and bioequivalent and available at the pharmacy. While it is possible that this requirement could represent some burden, we anticipate that the burden would be at most marginal. The pharmacy community routinely indicates that it is common practice for pharmacies to promote the use of generic drugs. Thus, this requirement is unlikely to represent a change in current practice for most pharmacies. We anticipate that the costs of the systems infrastructure required to furnish this pricing information will be borne by the Part D plan. The only cost to pharmacies would be the time involved in conveying the information to the beneficiary, which we anticipated would be small.

2. Long-Term Care (LTC) Pharmacies

a. LTC Pharmacy Access

As discussed in subpart C of the preamble, the Act provides that, in establishing rules for convenient access to network pharmacies, we may include standards with respect to access to long-term care pharmacies for Part D enrollees who reside in long-term care facilities. As discussed previously in the preamble, we believe that the Medicare drug benefit can improve competition in the long-term care pharmacy market, while Medicare's requirements for participation preserve the relationships and levels of service that long-term care facilities now enjoy vis-à-vis their contracted long-term care pharmacies.

To that end, our final rule requires that Part D plans offer standard contracting terms and conditions for long-term care pharmacies. In other words, we are establishing a specific ''any willing pharmacy'' requirement for long-term care pharmacies. Part D plans would be expected to develop standard contracting terms and conditions for long-term care pharmacies, such that any pharmacy in a service area could become an eligible long-term care pharmacy by certifying that it meets certain performance and service criteria for providing pharmacy services to long-term care facilities, which will reflect widely used best practices and will be detailed through guidance. Plans in a region would be required to contract with any willing long-term care pharmacy in that region, provided those pharmacies were able to reach agreement with plans on all standard contract terms and conditions—including payment rates.

As discussed, we will require Part D plans to demonstrate that they have contracts with a sufficient number of LTC pharmacies to ensure ''convenient access'' to prescription drugs for institutionalized beneficiaries within the service area. As noted in the subpart C preamble, we do not think we have the statutory authority to establish access requirements related to the routine use of out-of-network pharmacies. Thus, in the context of beneficiaries residing in LTC facilities, Part D plans will therefore have to demonstrate that they have an adequate plan network for beneficiaries who may reside in LTC facilities. We would also expect that LTC facilities, in choosing LTC pharmacies, will want pharmacies who are participating in all Part D plans in which their residents are enrolled within their area. We will provide more detailed information in CMS guidance regarding what constitutes ''convenient access,'' but we expect that plans will demonstrate convenient access based in part on the number of enrollees in their service areas and the geographic distribution, capacity, and contracting relationships between long-term care facilities and long-term care pharmacies in those service areas. We note that these LTC pharmacy access requirements are in addition to the retail pharmacy access standards.

In formulating our policies for LTC pharmacy access, we have relied on information provided by all stakeholders through the proposed rule comment process. Through these comments and follow-up discussions, we have listened to specific concerns of pharmacies (chains and independents, including small pharmacies), trade associations representing for profit and non-profit nursing facilities, trade associations representing LTC pharmacies, LTC and independent pharmacists, State Medicaid pharmacy

directors, pharmacy benefit managers (PBMs) and plans, and beneficiary advocates. We considered a number of policy alternatives and have discussed those considerations fully in the preamble for subpart C and in Section M., Alternatives Considered, of this Impact Analysis. Taking into consideration the feedback we received from the various stakeholders, we believe our final regulations for the Part D benefit will ensure LTC facility residents' access to prescription drugs in a way that balances greater competition in the LTC pharmacy market with the preservation of relationships and levels of service that LTC facilities currently receive from their contracted LTC pharmacies. We also believe that the policy approach we are taking provides new opportunities for small LTC pharmacies.

b. Impacts on the Current LTC Pharmacy Market

We estimate from the National Health Expenditures data previously mentioned that prescription drug spending in the LTC sector of nursing homes and nursing home providers was about $12.5 billion in 2003. Clearly, the implementation of Part D will influence the LTC pharmacy market. We have actively sought information on the LTC pharmacy market and the role of small pharmacies in that market. From our stakeholder outreach and research, we have determined that four large national corporations claim a majority of the market's revenue (about 60 percent). None of these four corporations is a small business; their revenues range from hundreds of millions of dollars to billions of dollars. As a group these four corporations do business in all but 4 States, and in the aggregate operate hundreds of pharmacies.

There are very limited data sources related to the rest of the LTC pharmacy industry. Consequently, we present the information we are able to obtain and provide a qualitative discussion of our assessment of impacts on the LTC pharmacy market. We obtained through the Economics Department of the National Association of Chain Drug Stores (NACDS) information indicating that in the aggregate there are approximately 1,760 LTC pharmacies, of which approximately 1,360 do not appear to be establishments of the four large corporations. Based on information from a financial analyst report, some of these pharmacies may be part of smaller regional chains. Information from financial analysts indicate that the remaining approximately 40 percent of the LTC pharmacy market is handled by smaller regional or individual market LTC pharmacies. We were not able to locate publicly available data which would inform us of the revenues for all LTC pharmacies. We were able to obtain one financial analyst report indicating that some of the smaller regional or individual entities have revenues greater than the $6 million small business threshold established by the Small Business Administration for pharmacies. In addition, industry sources indicate that some of the entities in the LTC pharmacy market are also in the retail pharmacy market.

We were also able to learn from NACDS that there are differences in the geographic distribution of LTC pharmacies between the larger corporate LTC pharmacies and other LTC pharmacies. For example, 85 percent of corporate pharmacy facilities are in urban areas (MSAs), whereas approximately 77 percent of the regional or individual LTC pharmacies are in urban areas. Conversely, the regional and individual pharmacies appear to have a relatively larger physical presence in rural (non-MSA) areas. For example, the smaller regional and individual LTC pharmacies outnumber the national corporate pharmacies 5–1 in rural (non-MSA) areas, whereas in urban areas this ratio is lower.

Some stakeholders believe that the size of the independently-owned pharmacies may make it more difficult for them to compete in certain geographic locations. We believe the data on market presence in rural versus urban locations supports this. From financial analysts, we learned that the chains that own LTC pharmacies typically view the density of LTC facilities (that is, number of facilities within a geographic area) and Medicaid pharmacy reimbursement rates as some of the key factors in determining interest in ownership and geographic market entry.

As discussed in greater detail subsequently, we believe that the changed competitive market under Part D will likely make it possible for new players to enter the LTC pharmacy market, and will likely also create better incentives for price competition for the provision of drugs and pharmacy services to LTC facility residents. The National Community Pharmacists Association (NCPA) has indicated that LTC pharmacy is the fastest growing segment of the independent pharmacy business. NCPA has stated that if competition is injected into this marketplace, independent pharmacies will compete on price and win on service. We have received similar information from independent and chain pharmacies, as well as pharmacy wholesalers who are currently in or contemplating entry into the LTC pharmacy market.

Part D plans will be required to offer a standard contract to ''any willing'' LTC pharmacy. Once a pharmacy has negotiated its agreement with a plan and becomes a network provider, the LTC pharmacy is eligible for selection by a LTC facility to serve the pharmacy needs of the residents of that facility that are members of that plan. We expect that each long-term care facility will select one or more eligible network pharmacies to provide a plan's long-term care drug benefits to its residents. In order to minimize the number of pharmacy suppliers and maintain patient safety, long-term care facilities will likely select long-term care pharmacies that meet Part D standards and participate in the largest number of plans' long-term care networks.

The competitive design of Medicare Part D provides several benefits. First, Part D plans, depending on the level of competition, may be able to negotiate more favorable market rates due to the incentive pharmacies have to be in as many networks as possible. This potentially means that LTC facility residents may receive better pricing on their prescription drugs. Second, if a LTC pharmacy is participating in as many plans as possible, it is likely that a LTC facility will be able to select only one pharmacy to serve all of its residents. This would help to preserve the ''one pharmacy—one nursing home relationship'' priority cited in comments by LTC facility and LTC pharmacy representatives.

Another impact of this competitive model may be a change in who receives and manages manufacturer rebates. Currently, large LTC pharmacy chains maintain their own formularies and have contracts with pharmaceutical manufacturers for performance payments or rebates (that is, price concessions based on volume, formulary and market share movement). Under Part D, with the LTC pharmacy subject to the formulary of the Part D plan, it is unlikely that manufacturers would continue to pay LTC pharmacies for the same rebates they will likely be paying Part D plans. In this more competitive system, the Part D plan would have to pass on the rebate in the form of lower beneficiary premiums and better benefits, in contrast to all of these rebate dollars generally accruing to LTC pharmacies under the current system. As discussed subsequently, this movement of management of formulary and related rebates from LTC pharmacies in the less competitive current environment through Part D

plans and on to beneficiaries and the Medicare program in the more competitive Part D environment may mean that the competitive pricing advantage that the large LTC pharmacy corporations had over smaller LTC pharmacies is lessened.

While LTC facilities may use a particular pharmacy for all of their residents and payers (including Medicaid prescription drug and LTC benefits, Medicare Part A drugs and services, and private pay pharmacy services), some contracts may need to be revised because payments from Medicare Part D plans will replace Medicaid payments on behalf of beneficiaries dually eligible for both programs. Currently, for LTC pharmacies, Medicaid is the largest single payer for prescription drugs and associated dispensing fees, providing for approximately 60 to 65 percent of their revenue. Dually eligible beneficiaries are a large portion of the Medicaid nursing home population. Thus, we would expect that a shift from Medicaid to Part D plan payment could have an impact on LTC pharmacies. Over time, we anticipate that the drug payments negotiated by Part D plans may be lower than Medicaid rates in some geographic areas, as a result of market competition. In support of this view, our analysis of data supplied by IMS Health for commonly used drugs provided through LTC pharmacies suggests an existing payment differential between Medicaid and third party payers, on the order of approximately 7 percent on average.

We expect over time in some geographic areas where there is healthy competition among Part D plans and among LTC pharmacies (including large corporations, regional and independent entities) to supply LTC facilities that payment rates may become more similar to those currently achieved by third party payers. In other markets where there is less competition (that is, independent entities but few or no large national corporate or regional chains), Part D plans may be less able to negotiate lower rates.

In the current market, some LTC pharmacies bundle a range of additional services along with the cost of the drugs and related dispensing fees that are offered to LTC facilities. Payment for these added services is often not segregated by service offering. Part D allowable costs do not include some of the non-dispensing services currently bundled into LTC pharmacy (for example, the Part D dispensing fee may not include costs associated with drug administration or other professional fees). With the implementation of Part D there will be a need to price these services separately, creating more transparency for the costs and charges paid by LTC facilities.

We recognize that some LTC pharmacies in more competitive markets may face both demand for a lower cost structure from Part D plans and simultaneous pressure from LTC facilities for value-added services that were previously bundled. As indicated by one commenter (not a small business), the demands of the market can produce stress on the participants; the commenter strongly suggested that without adequate reimbursement, LTC pharmacies will either reduce service levels or cease doing business. We believe that market competition in combination with our access requirements should result in effective negotiations between Part D plans and LTC pharmacies. Furthermore, the greater transparency in pricing and competition for value-added LTC pharmacy services to be provided to LTC facilities should result in more competitive pricing for these services. This transparency and competition may also provide more opportunities for small LTC pharmacies to compete on the basis of quality and service against larger players for LTC facility business. In addition, Part D plan payments under medication therapy management programs, described in further detail elsewhere in this preamble, may represent an additional revenue stream to long-term care pharmacies for some of the special services provided by these pharmacies but not reimbursed through dispensing fees.

While there is uncertainty related to the market behavior of the various players, we believe that under Part D, greater competition in the LTC pharmacy market may result over time in lower average Part D drug prices for beneficiaries and the Medicare program, and that it also may have the potential to reduce drug prices for non-Part D enrollees (private pay residents, as well as those covered under the Part A skilled nursing facility benefit). These changes would come as a result of competitive market forces.

Under Part D, small LTC pharmacies in rural areas are more likely to have a greater ability in their local markets to compete effectively compared to the larger LTC pharmacy chains. In non-rural areas, smaller regional and individual LTC pharmacies will benefit from the shift of manufacturer rebates and the leveling of the field upon which price is decided. However, structural efficiencies may be a key determinant of long-term success in areas in which there are more LTC pharmacies competing for business.

A more competitive market will reward pharmacies offering the lowest prices and highest quality service; it may also open the door for new entrants into the market as LTC facilities restructure their existing contracts. Because of the competition there may also be changes in the LTC facilities' negotiation of rates and services with LTC pharmacies. We anticipate that there may be changes in market share among the pharmacies that service LTC facilities. This changing market will be the result of the competitive situation afforded LTC facilities in choosing LTC pharmacies.

Although these changes may adversely affect some LTC pharmacies, large or small, we would note that as a result of the growth in the aged population, with the aging of the large cohort of the ''boomer'' generation, financial analysts predict significant growth in the LTC facility and pharmacy sector, and the changes associated with Part D implementation would not be expected to deter that growth.

As shown by our analysis, we are unable to predict with certainty either the presence or absence of ''a significant economic impact on a substantial number'' of small LTC pharmacies. In accordance with longstanding HHS policy, we therefore treat our regulatory provisions as having such an effect. Under the Regulatory Flexibility Act, we must present the following information. The need for and objectives of our final rule provisions on long term care pharmacy are described earlier in the preamble under subpart C. As indicated there and in this analysis, we have gone to great lengths (including an Open Door Forum and other types of outreach) to consult with the LTC pharmacy community, to identify alternatives, and to assess issues in reaching our final decision. Unfortunately, we have been unable to find authoritative data on the number of ''small'' LTC pharmacies affected in this fast-evolving field of business. Based on the previously mentioned data from NACDS and from a proprietary source serving this market, we believe there may be at least several hundred but probably less than 1,000 ''small'' LTC pharmacies, but we do not have specific data on either overall counts or on the number of small pharmacies that will have new access to serving LTC facilities as a result of the competitive changes outlined here. We are not imposing any new reporting or recordkeeping requirements, other than the statutory requirement related to providing beneficiaries with information on generic alternatives. We

have tried to reduce the burden for LTC pharmacies associated with this requirement and recognizing the unique situation for beneficiaries in LTC facilities, by modifying the timing of the requirement from a point of service basis. Long term care pharmacies will have to provide information about differential price information to Part D plans, which will in turn, provide that information to their institutionalized beneficiaries through an explanation of benefits statement. In addition, the performance and service criteria that we expect will be included in the standard contracts between Part D plans and LTC pharmacies will be those that simply reflect existing community practices with respect to LTC pharmacy service delivery. It is important to note that we have taken a significant step in terms of assuring business opportunity for small pharmacies by requiring that plan sponsors contract on equal terms with ''any willing'' pharmacy to assure broad access to nursing home residents. In practice, we believe that this means that many existing LTC pharmacies as well as new market entrants in certain areas will have a substantial competitive opportunity, in most instances broader than at present. As discussed under subpart C of this preamble and in the analysis above, the factual, legal, and policy reasons for this decision are compelling. Nonetheless there is inherent uncertainty related to the specific impact on any single entity. The competitive results we expect are likely to impact many small LTC pharmacies positively, while some will likely experience a negative effect.

3. Insurers and Pharmacy Benefit Managers (PBMs)

This rule sets forth the terms and conditions that must be met by firms to be approved to offer the Medicare prescription drug benefit. Organizations sponsoring the Medicare prescription drug benefit can be either stand alone Prescription Drug Plans (PDPs) or Medicare Advantage Prescription Drug Plans (MA-PDs). The requirements for Medicare Advantage are discussed in our separate rule. That rule includes a regulatory flexibility analysis specific to the Medicare Advantage program. Consequently the discussion here will focus on PDP sponsors. As discussed previously in the preamble, in order to be approved to offer the Medicare prescription drug benefit as a PDP an entity must be organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan, or have secured a time-limited Federal waiver. The SBA size standard for ''small entity'' health insurance firms is annual revenue of $6 million or less.

Our regulatory flexibility analysis for the Medicare Advantage rule includes an extensive discussion related to insurance firms that might potentially be eligible to be MA plans. That analysis is also applicable to insurance firms that might be interested in being a PDP. As noted for the MA market and equally applicable to the PDP market, essentially all of the insurance firms affected by the statute and our rule exceed size standards for ''small entities'' within the meaning of the RFA and implementing SBA guidelines, which State that an insurance firm is ''small'' only if its revenues are below $6 million annually. Stand-alone drug insurance policies are not a typical product in the insurance market today. Thus, the range of insurance companies that may choose to enter this market is uncertain. However, a portion of the insurance firms that might be interested in being a PDP and thus affected by these rules are ''small entities'' by virtue of their non-profit status.

PDP eligibility provisions in the MMA rely on the Medicare Advantage enrollment provision (unchanged from prior law) that no health insurance plan is normally eligible to participate unless it already serves at least 5,000 enrollees. Section 1860D–12(b)(3) of the Act provides that this minimum shall be waived during the first contract year in a region, since PDPs in the context of Part D are new entities. While there is also a 1,500 minimum standard enrollment for plans that predominantly serve rural populations, in the context of PDP services areas designed on a regional basis, we do not believe a predominantly rural situation would occur. In the proposed rule we sought comment on this question and received no response. Consequently, we have not considered this level of enrollment in our analysis. At the 5,000–enrollee level, no insurance plan would fall below the SBA revenue cutoff assuming estimated average per enrollee revenue of approximately $1,675 in 2006, a revenue level similar to that of prescription drug plans under the standard Medicare Part D benefit. Therefore, the statutory limits generally prevent any insurance firm defined as ''small'' pursuant to the RFA's size standards from participating in the program. It is also important to note that PDPs will only operate on a regional basis. We have established 34 PDP regions, not including territories, and the average population in these exceeds one million Medicare beneficiaries.

In our RFA for the Medicare Advantage program, we include a detailed analysis on regional Medicare Advantage markets and small entities. That discussion is applicable to the PDP market, and therefore we are not repeating that discussion here. That analysis also reviews the local Medicare Advantage market. As is noted in that analysis the option to be a local MA-PD plan provides opportunity for health insurance entities of all types and sizes (but probably not below the ''small'' insurance entity cutoff level defined by the SBA, which is lower than appears viable for a Part D risk-bearing insurance plan) to participate in offering the Medicare prescription drug benefit, albeit as part of a comprehensive benefit offered on a local basis. We point out that many HMOs are non-profit entities, as are several dozen Blue Cross and Blue Shield plans, and conclude that on balance Medicare Advantage provide favorable opportunities for them. We note that a number of HMOs and other insurers including a number of Blue Cross plans are sponsoring Medicare-endorsed drug discount cards under that new program, which suggests their future ability to participate as PDP or MA-PD participants, regardless of profit status. While this rule extends certain requirements related to the provision of Part D benefits to Medicare Advantage plans (for example, network adequacy standards and any willing pharmacy provisions), we believe that these requirements will not result in consequential additional costs for MA-PD plans. We believe that any well-designed plan would already meet or readily be able to accommodate these standards. For example, we believe that competition among plans for enrollees will necessitate that they have a pharmacy network that is at least as broad as those stipulated by our network adequacy standards.

The other organizations that we think potentially may be interested in being PDP sponsors, or most certainly working closely with PDP and MA-PD sponsors to administer all or part of their drug programs, are pharmacy benefit managers (PBMs). PBMs are a relatively new player in the health care market. A major limitation on PBMs being PDP sponsors, however, is the statutory requirement for State licensure as a risk bearing entity, a status PBMs have not historically achieved. As discussed in section C (Federalism) of this Regulatory Impact Analysis, the MMA provides for a time-limited waiver to obtain State licensure, during which an organization can be approved by CMS to be a PDP sponsor. Since the Part D benefit is new, we sought information in the proposed rule on whether PBMs are considering

becoming PDP sponsors. While we received no specific comments indicating PBMs' intentions with regard to Medicare Part D, we note that we did receive comments on the proposed rule from several PBMs.

There are basically two types of PBMs in the market today. Some are subsidiaries of health plans (that is, managed care organizations or insurance companies), and others are independent PBMs. PBMs have evolved over time in the nature of services they provide. In the late 1970s and early 1980s they offered claims processing services. In the late 1980s and early 1990s their services evolved to include pharmacy network design and management, formulary design and manufacturer rebate negotiations, mail order pharmacy services, drug utilization review, and enrollee services (for example, call centers). During the 1990s, PBMs generally expanded to become managers of a wide array of pharmacy services as plan sponsors sought to control drug costs. For example, some PBMs now also provide clinical services such as disease management, and physician and patient education.

Under the ''carve-out'' trend by which pharmacy benefits are administered separately from medical benefits in employer-sponsored insurance, PBMs are now believed to administer roughly half of all pharmacy benefits for employer health plans, and this share is rising rapidly. The primary reasons are analyzed in a 2003 General Accounting Office report (''Federal Employees Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies'' available at *www.gao.gov*; see also the CMS study on PBMs cited above). These reports and others conclude that PBMs help insurance plans achieve significant savings in their drug coverage, for example, through use of discounts and rebates to lower prices, through drug utilization review, and through shifting sales from name brands to generics. Obviously, insurance plans can do these things for themselves, but most find that PBMs substantially improve their ability to achieve savings.

Because PBMs rely heavily on computerized systems to manage pharmacy records, they also provide safeguards against many kinds of medication errors through drug utilization review. Which services a PBM provides to a particular plan sponsor is negotiated between the PBM and the sponsor. Selection of a PBM (usually one, but sometimes two, one for mail order and one for retail) by plan sponsors is strongly influenced by the expected cost of drug benefits, with PBMs gaining a competitive advantage in contractual negotiations by offering lower average costs per prescription.

There are believed to be about one hundred PBM firms. Some are stand-alone companies, but most are subsidiaries of health insurance firms (for example, Wellpoint and Anthem) or owned by drug store chains (for example, Walgreens). Although a handful of particularly large firms account for most of the ''covered lives'' and industry revenue, the industry is regarded by analysts as highly competitive. We have no information on the size of the smaller firms in the industry, but it is likely that none of them, or at most a very small number, would fall below the $6 million annual revenue threshold used by the SBA for defining ''small entities'' in the insurance industry. (The smallest companies are in any event most likely to be subsidiaries or components of health insurance companies and other large firms.) This is an industry in which there appear to be marked advantages to larger size, through both economies of scale and bargaining power. Nor do we believe that a substantial number, if any, are non-profit entities. In the proposed rule we requested additional information on the characteristics of this industry and its firms, but we did not receive comments on this issue.

The MMA will expand PBM business in two ways. First, assuming that all or most PDPs and many MA-PDs will use PBMs, and that nearly all beneficiaries without drug coverage will enroll in a plan providing drug coverage, we anticipate that millions of beneficiaries will start purchasing their drugs using PBM-managed benefits. Second, all or most of those currently enrolled in plans that cover drug purchases on an indemnity basis (rather than through PBMs), and who sign up for PDP or MA-PD plans, will start using PBM services. This latter group includes most of the 1.9 million persons we estimate are currently enrolled in Medigap plans that offer drug coverage. Thus, drug insurance plans using PBMs are likely to enroll millions of new covered lives. Because these enrollees are on average much higher utilizers of drugs than most covered lives in the private sector, this will create positive and significant economic impact on the future volume of business for these firms.

Obviously, the scope, timing, and nature of additional PBM business will depend on the future decisions of PDP and MA-PD sponsors, and the PBMs themselves, and ultimately on the decisions of Medicare beneficiaries as they make choices among their various insurance options. Nothing in this rule directly regulates PBMs, positively or negatively, or directly encourages or discourages their use over alternative methods of managing drug benefits. Furthermore, there are many other influences on the role of PBMs and on the amount of drug spending that they manage. Chief among these is the continuing growth in spending on prescription drugs and the incentives this creates to control costs.

It is possible that the regional boundaries could affect the ability of some PBM firms to compete for PDP contracts. However, we believe that the regional boundaries are unlikely to be an issue for PBMs or PDP sponsors more generally due to our decision announced on December 6, 2004 to designate 34 PDP regions—25 regions made up of a single State, 6 regions made up of two States, with the remaining 3 regions made up of 3 States, 4 States and 7 States respectively. We believe that most if not all PBMs are not plan-specific, and thus would be able to compete in single State regions, multi-State regions, or nationally. In addition, in developing the regional boundaries, we were cognizant that the regions need to have a large enough Medicare population to assure PDP viability, while not being so large as to cause plans to have difficulty enrolling and providing services to beneficiaries especially in the start-up year. The 34 regions were designed to strike that balance.

For all the reasons given above, we conclude that while the statutorily-created Part D and Medicare Advantage programs will be largely favorable to PBMs, this rule as such will not significantly adversely effect a substantial number of small entity PBMs. In the proposed rule we sought comment on this conclusion and on any provisions that might adversely affect small firms; however, we received no comments on this issue.

4. Small Employers

In the case of the small employers, public and private, who provide qualified prescription drug coverage for their retirees, we estimate that savings obtained from the Medicare retiree drug subsidy will exceed the employer's administrative costs associated with obtaining the subsidy, and thus the result of the retiree drug subsidy provision is a net positive impact. We would like to make participation in the retiree drug subsidy program as simple as possible for small entities.

In the proposed rule we requested comments on any provisions of this proposed rule that may be particularly

difficult for small entities, and on any alternatives that might lessen such burdens. One of the particular areas of concern was the burden related to the payment timing, that is, monthly, quarterly, or annually. As noted previously, we want to make the retiree drug subsidy process as flexible as possible to encourage employers, including small employers, to participate. In particular, we think our provision allowing plan sponsors to voluntarily elect to use an annual or quarterly payment process, rather than requiring a monthly process, will significantly reduce the burden for small employers that wish to apply for the retiree drug subsidy.

In addition, as discussed in greater detail in subpart R of the preamble, given statutory provisions, we think our alternative approach for dealing with sponsors of insured plans helps to address concerns that were raised in the comments we received related to such retiree plan products. As discussed in the subpart R preamble and in the final regulation, the quarterly or monthly interim subsidy payments can be based on a determination by the insurer—using reasonable actuarial principles—that allocates a portion of the premium costs to the gross covered prescription drug costs incurred for a sponsor's qualifying covered retirees between the cost threshold and the cost limit. If the insurer determines premiums based on the pooling of employer/union experience in a given policy, the insurer will be permitted to make such determination based on the aggregate experience incurred under such policy for all employers'/unions' qualifying covered retirees. Thus, we think our decisions to provide the options for quarterly or annual payments, in addition to a monthly process, and to provide a simplified method for dealing with premium allocation for fully-insured retiree benefit arrangements, recognizing statutory payment provisions for the retiree drug subsidy, facilitates the participation of small employers in the retiree drug subsidy program.

Another area of concern for small employers was actuarial attestation. We received several comments from small employers stating that we should accept attestations of actuaries with the insurance carriers or with third party administrators who can attest on behalf of the sponsor that the sponsor's retiree drug coverage is actuarially equivalent to Part D. As indicated in the subpart R preamble, sponsors can submit attestations of actuaries employed by insurance carriers or the third party administrators of their retiree drug plans.

One health care plan administrator raised concerns about the burden of actuarial equivalence on small employers and requested streamlined processes. The commenter asserted that small self-insured retiree plans operated by third party administrators are unlikely to have an actuary on staff, and that even if a group of plans is operated through the same PBM they would still need separate actuarial studies. The commenter requested that due to the cost of an annual attestation, we allow small employers to submit an application, their eligibility list and plan benefit descriptions and provide CMS with two years of experience or premium data and have CMS actuaries perform the attestation on behalf of their plan.

As we noted previously, the statute does not permit us to perform the attestation on behalf of a plan sponsor. However, as discussed elsewhere, since many small employers are likely to purchase retiree coverage through insurance companies who offer similar policies to many employers, we expect that the costs of the actuarial attestation would be spread across these employers. In addition, we would expect that, in order to offer health insurance and develop a benefits package, a self-insured plan sponsored by a small employer would have access to actuarial information through a third party administrator or through the entity that assisted the employer in designing the insurance offering, and that the simplified computation methods that we are developing would lessen the complexity and time involved in the actuarial valuation.

At the same time, we acknowledge that there are administrative costs associated with obtaining the retiree drug subsidy. We believe that the revenues from the subsidy would outweigh the costs. As noted earlier, we estimate that the administrative costs associated with obtaining the Medicare retiree drug subsidy will represent on average about 6.8 percent of the Medicare retiree drug subsidy payments in 2006 (declining in subsequent years after initial start-up costs), and that the bulk of these costs will be associated with preparing the actuarial valuation, retiree drug subsidy application, related enrollment information, and reporting data on prescription drug costs for the purpose of receiving subsidy payments. It is important to note that this estimate reflects an average across all plan sponsors. While administrative costs for small employers as a percent of retiree subsidy dollars are likely to be higher than the average, we believe that subsidy payments are likely to exceed the administrative costs of obtaining the subsidy for many small employers. Although smaller employers will spread their administrative costs across fewer qualifying retirees for whom they will be receiving Medicare retiree drug subsidy payments than larger employers, they are expected to have lower costs associated with identifying their Medicare retirees and related enrollment information than large employers. Additionally, we expect that among small employers that purchase retiree coverage from insurance companies, much of the costs associated with the actuarial valuation and data reporting would generally be spread across many employers that are purchasing the same or similar insurance products.

However, it is important to note that under Medicare Part D, employers have several options for providing prescription drug assistance to their retirees at a lower cost. For example, employers that purchase enhanced benefits or provide supplemental wraparound coverage for their retirees who are enrolled in Part D plans will also achieve savings because the Federal government provides a significant subsidy for the cost of standard Medicare Part D. We recognize that the relative benefits to employers of one option versus another will depend on an employer's individual circumstances. In developing all of the employer/union options described in this final rule, we have sought to provide employers and unions with maximum flexibility while minimizing employer/union burden as much as possible.

We believe that affected small businesses are unlikely to experience increased revenues of the magnitude that would approach 3 to 5 percent of revenues due to the Medicare retiree drug subsidy payments. We arrive at this conclusion as follows. First, we estimate the number of covered lives per firm offering retiree coverage. To make this estimate, we use 2001 data from the Medical Expenditure Panel Survey (MEPS) on the number of establishments (by firm size), with retiree coverage for the over 65 population, and the number of retirees covered by these establishments. As a conservative approach, we assume two covered lives per retiree to estimate the number of covered lives in these establishments. This assumption overstates the number of covered lives as not all Medicare beneficiaries are married, or are married to an individual who is also a Medicare beneficiary. Second, we convert the number of

establishments offering age 65 and over retiree coverage to a firm based count using the ratio of the number of establishments to the number of firms, based on the U.S. Census Bureau's Statistics on U.S. Businesses for 2001 (see *http://www.census.gov/epcd/www/smallbus.htm#EmpSize*). Using this firm based count we then estimate the average number of age 65 and over covered lives per firm. For firms with fewer than 100 employees our estimated average number of 65 and older covered lives was 6.15; the corresponding figure for firms with a firm size of 100 to 999 employees was 44.7. Data for 2001 on the overall number of establishments, the overall estimated number of firms, the number of estimated firms with retiree coverage for retirees aged 65 and over, the number of covered retirees, and the estimated number of retirees and covered lives per firm, are shown in Table IV–5.

As an extreme example, we assume the absolute maximum subsidy per person that an employer/union can receive in 2006 is $1,330 (that is, 28 percent of the difference between $250 and $5,000, and assuming no further adjustment related to netting out discounts, chargebacks or rebates). As discussed earlier, we estimated an average per capita Medicare retiree drug subsidy amount at $668 in 2006 (which, for example, would be equivalent to about $891 of taxable income for employers with a marginal tax rate of 25 percent and about $1,028 of taxable income for employers with a marginal tax rate of 35 percent). Using the $1,330 value, the retiree drug subsidy payments would be about $8,178 per firm with less than 100 employees and $59,456 for firms with 100 to 999 employees. These amounts almost certainly are overstated because they assume that every qualifying covered retiree would have annual allowable prescription drug costs of at least $5,000 in 2006, and that each firm would thus receive the maximum retiree drug subsidy payment for every covered individual, which is unlikely.

We compare these estimates with revenues for firms of these respective sizes. We trend forward 1997 revenue data by firm size, from the U.S. Census, to 2001 based on the annual change in the average Consumer Price Index (CPI). While revenues would likely grow at a faster rate than the CPI due to increases in the quantity of items and/or services sold, we take a conservative approach by only accounting for increases in prices from 1997 to 2001 via the annual changes in the average CPI. The most recent year that data on revenues are available is for 1997. We used U.S. Census Bureau data for 2001 for estimating the number of firms. The estimated per firm average revenues for 2001 are about $1.2 million for firms with a firm size of less than 100 employees and $28 million for firms with a firm size of 100 to 499 employees.

The Medicare retiree drug subsidy payments, therefore, represent only 0.7 percent of total revenues for firms with a firm size of less than 100 employees, and 0.2 percent for firms with a firm size of 100 to 999 employees. Because revenue data are not available for firms with 100 to 999 employees, we conservatively use the per-firm revenues for firms with a firm size of 100 to 499 employees to represent the per-firm revenues for firms with a firm size of 100 to 999 employees. For further illustrative purposes, Table IV–6 shows by different firm sizes the revenue impacts using the maximum assumption on retiree drug subsidy payments. Even for the smallest firms, the revenue impacts of the subsidy would be less than 2 percent. The table shows that, as the firm size increases, the percentage of the revenues accounted for by the subsidy decreases. We therefore conclude that this rule will not have a significant economic impact on a substantial number of small employers. This conclusion applies equally to non-profit employers and small local government employers, though we do not have detailed data on these groups (had we the data, the comparison would have been on a cost rather than revenue basis, but the relationships of retirees to active employees would have been similar.) Because of the likely interest in the Medicare retiree drug subsidy program, however, we present some additional background information related to the number of small entities that might potentially be eligible to receive the Medicare retiree drug subsidy payments.

To estimate the number of potentially eligible small businesses for RFA purposes, we need to determine the appropriate standards for identifying a small business. In general, the SBA has size standards that define small businesses within a given industry based on either the average annual receipts (millions of dollars) or average employment (number of employees) of a firm (''Table of Size Standards Matched To North American Industry Classification System Codes, January 28, 2004,'' U.S. Small Business Administration, available at *www.sba.gov*). However, we did not have data available on retiree coverage among either establishments or firms by annual revenues, but these data are available by employee size. We used an alternative size standard for RFA purposes based on our consultation with the Office of Advocacy at the SBA. The alternative size standards are based on the number of the firm's employees, rather than the firm's annual revenues.

Because our data from the Medical Expenditure Panel Survey (MEPS) on the number of establishments providing retiree drug coverage are at the 2-digit North American Industry Classification System (NAICS) code level and the MEPS industry group level (which is based on rolling-up 2-digit NAICS codes), while the SBA size standards are at the 6-digit NAICS code level, we developed an approach for rolling up the size standards to the 2-digit NAICS code level. For the purpose of our analysis, we classified a business within a 2-digit NAICS code as a small business based on the largest SBA employment size standard among all the six-digit NAICS codes that comprised that two-digit NAICS code. It is likely that this methodology overstates the number of small businesses because some large businesses are likely counted as small businesses. Our employee firm size standards ranged from 150 to 1,500 employees.[16]

We estimate the number of small businesses who offer retiree drug coverage based on an analysis of 2001 MEPS data. We mapped the 19 two-digit NAICS codes to nine MEPS industry groups. Where the MEPS industry group consisted of two or more two-digit NAICS codes, we defined a small business using the largest employee size standard among the two-digit NAICS codes that cross-walked to the MEPS industry code. However, for each of nine MEPS industry groups, the MEPS data do have the number of establishments offering retiree health insurance coverage by the number of employees in the firm. We estimate that in 2001, there were 399,751 establishments offering retiree coverage to their retirees age 65 and older. Of this total, 65,208 (not shown in Table IV–5) were small businesses, based on the small business size standards (that is, 150 to 1,500 as noted earlier). These businesses represented 1.3 percent of all small establishments. These businesses also accounted for 16 percent of all establishments offering retiree coverage to their retirees that were age 65 and over.

[16] We used the following alternative size standards for the purpose of this RFA: less than 150 employees (NAICS codes 42 and 44), less than 500 employees (NAICS codes 11, 23, 56, 71, 72, and 81), and less than 1,500 employees (NAICS codes 21, 22, 31, 48, 51, 52, 53, 54, 55, 61, and 62).

While in the case of small businesses the number of establishments is very similar to our estimate of number of firms, this relationship is not the case for the largest firms; that is, those firms with more than 1,000 employees. As a result, from a firm perspective, we estimate that firms with less than 1,000 employees account for 93 percent of all private sector firms offering coverage to retirees age 65 and over, but account for only 10 percent of all retirees with employer-sponsored coverage.

While we have data on the number of small employers who offer retiree coverage, by industry sector, we do not have data on the number of retirees covered by small employers by industry sector. The only analysis we are able to do is the distribution of age 65 and over retirees between large firms with 1,000 or more employees and firms with less than 1,000 employees that offer retiree health coverage to this population. Most covered retirees receive their drug coverage from large employers and unions, both because these large employers/unions are more likely to provide coverage, and large employers/unions have a large number of retirees. According to data from MEPS, in 2001 the largest private sector firms (1,000 or more employees) covered 90 percent of all the retirees who had employer-sponsored retiree coverage, with only 10 percent of retirees being covered in firms of less than 1,000 employees.

As discussed previously, we expect that Medicare Part D will also positively impact those small employers that had provided retiree drug coverage prior to implementation of the Medicare prescription drug benefit but choose not to obtain the Medicare retiree drug subsidy payments. For example, some of these employers may choose to provide alternate forms of prescription drug coverage by either offering enhanced Medicare Part D benefits for their retirees or providing wraparound coverage. These employers would see reductions in their spending on retiree drug coverage, as the Medicare prescription drug benefit would partially offset their spending on drug coverage.

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Table IV-5
Estimated Number of Covered Retirees in Private Sector Establishments and Firms, 2001

Firm Size	Number of Private Sector Establishments, 2001*	Number of Private Sector Firms, 2001*	Ratio of Number of Establishments to Number of Firms	Number of Private Sector Establishments that Offer Coverage to Retirees Age 65 and Over, 2001**	Estimated Number of Private Sector Firms that Offer Coverage to Retirees Age 65 and Over, 2001	Number of Covered Retirees Age 65 and Over**, 2001	Estimated Average Number of Retirees per Private Sector Firm	Estimated Number of Covered Lives, per Private Sector Firm (assuming 2 covered lives per retiree)
Less than 100 employees	5,058,525	4,851,266	1.04	39,308	37,697	115,899	3.1	6.15
100 to 999 employees	418,085	93,876	4.45	29,438	6,610	147,745	22.4	44.70
1,000 or more employees	913,080	8,795	103.82	331,006	3,188	2,432,542	763.0	1,525.91
Total	6,389,690	4,953,937	n/a	399,751	47,496	2,696,186	56.8	113.53

Sources: *U.S. Census Bureau, Statistics of U.S. Businesses, 2001, http://www.census.gov/epcd/www/smallbus.htm#EmpSize
** Medical Expenditure Panel Survey (MEPS), 2001

Table IV-6
Analysis of Medicare Retiree Drug Subsidy Impacts for Different Private Sector Firm Sizes

Firm Size	Number of Private Sector Firms, 2001	Total Revenues, 2001 (in 000s)	Estimated Per Firm Revenues, 2001	Estimated Number of Covered Lives per Firm	Maximum Per Person Subsidy	Total Estimated Retiree Drug Subsidy Amount	Estimated Subsidy as Percent of Revenues
1 to 9 employees	3,716,934	$1,815,857,996	$488,535	6.15	$1,330	$8,178	1.7%
10 to 19 employees	616,064	$1,049,691,336	$1,703,867	6.15	$1,330	$8,178	0.5%
20 to 99 employees	518,258	$2,781,101,533	$5,366,249	6.15	$1,330	$8,178	0.2%
100 to 499 employees	85,304	$2,385,814,720	$27,968,380	44.70	$1,330	$59,456	0.1%

Sources: Number of Firms, Revenues: U.S. Census Bureau, Statistics of U.S. Businesses, http://www.census.gov/epcd/www/smallbus.htm#EmpSize

5. Rural Hospitals

Section 1102(b) of the Social Security Act requires us to prepare a regulatory flexibility impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. This rule will not affect small rural hospitals since the program will be directed at outpatient prescription drugs, not drugs provided during a hospital stay. As required by law, prescription drugs provided during hospital stays are covered under a separate Medicare payment system. Therefore, we are not providing an analysis.

6. Other Requirements in the Regulatory Flexibility Act

The RFA requires that a Final Regulatory Flexibility Analysis (FRFA) meet certain requirements, including responsiveness to public comments, estimates of small entities affected, a description of compliance requirements, a description of steps to minimize impact on small entities, and a statement of the factual, legal, and policy reasons for selecting the adopted alternatives. This impact analysis, taken together with the preamble as a whole, meets all of these requirements. Since the overall effects of the final rule are generally positive on small entities (with the exception of small long-term care pharmacies for which the effect is uncertain), and since we have consistently chosen the least burdensome compliance options legally available to us, we believe we have met or exceeded all expectations.

L. Accounting Statement

In accordance with the OMB A–4 circular on regulatory impact analyses, we have included an accounting statement in Table IV–7. The Medicare prescription drug benefit and retiree drug subsidy represent a transfer of revenues from taxpayers to Medicare beneficiaries, States, and retiree plans sponsored by employers and unions. The table provides an estimate of the annualized amount of transfers from taxpayers to these entities over the five-year period from CY 2006–2010. For the purpose of the accounting statement, these estimates are shown separately with a 3 percent and 7 percent discount rate in 2001 dollars.

The table also indicates that there will be some administrative costs associated with the Medicare prescription drug benefit, specifically the costs associated with disclosure notices, coordination of benefits, and the Medicare retiree drug subsidy. Costs associated with these activities are discussed in the respective sections of this impact analysis.

The accounting statement also provides a summary of the effects of the rule on State and local governments and small businesses, as discussed in the relevant sections of the analysis.

Table IV-7
Accounting Statement
Annualized Estimates for Medicare Prescription Drug Benefit and Retiree Drug Subsidy, CY 2006-2010
(2001 dollars in billions)

	3 percent discount rate	7 percent discount rate
Monetized Transfers		
From Taxpayers to Beneficiaries, States, and Employers/Unions	$51.2*	$51.0*
Administrative Costs		
Notice Requirement	$0.02**	$0.02**
Coordination of Benefits	Not fully quantifiable at this time	Not fully quantifiable at this time
Administrative Costs Incurred by Employers and Unions to Obtain the Medicare Retiree Drug Subsidy	6.8 percent of subsidy in 2006 and declining in subsequent years	6.8 percent of subsidy in 2006 and declining in subsequent years

Category	Effects
Effect on State and Local Governments	Estimated net positive revenue impact for the period CY 2006-2010 in current dollars: State governments ($7.9 billion); Local governments ($4.3 billion)
Effect on small business	**Small Retail Pharmacies:** Positive impact. Estimated economic impact is not expected to reach the threshold for significant (3 to 5 percent of revenues). **Small Long-Term Care Pharmacies:** Impact uncertain. Not able to predict with certainty either the presence or absence of a significant economic impact on a substantial number of small long-term care pharmacies. **Small PBMs:** Impact favorable for PBM industry, and no significant adverse impact on a substantial number of small entities. **Small Insurers:** Impact favorable on insurance industry, and no significant adverse impact on a substantial number of small entities as defined by SBA. **Small Employers:** Positive impact. Estimated economic impact is not expected to reach the threshold for significant (3 to 5 percent of revenues).

* This estimate differs from the one presented in the proposed rule due to use of a corrected method for calculating annualized cost.

** Estimate covers CY 2005-2010.

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M. Alternatives Considered

1. Designation of Regions

The MMA requires that we establish between 10 to 50 PDP regions within the 50 States and the District of Columbia, and at least one PDP region covering the territories. These regions will define PDP service areas. PDPs that provide service in a particular region must cover that region entirely. PDPs can submit bids to provide services in anywhere from one to all regions.

The MMA stipulates that, to the extent practicable, PDP regions must be consistent with MA regions. However, if we determine that access to Part D benefits would be improved by establishing PDP regions that are different than MA regions, we may do so. In developing the PDP and MA-PD regions, we relied on a market survey (conducted for us by Research Triangle Incorporated), obtained input from a series of public meetings and calls, and reviewed hundreds of written comments.

On December 6, 2004, we announced the 34 PDP regions and 26 Medicare Advantage PPO regions. The decision on the regional configuration for PDPs, per se, is not a subject of this rule, although our authority from the Act to designate different regions is included in the final rule. Therefore, as part of alternatives considered we are including background related to our decision to designate PDP regions that differ somewhat from the MA regions. In designating PDP regions, our primary objective is to ensure that all beneficiaries have reliable access to PDP plans at the lowest possible cost. The law requires that beneficiaries have a choice of enrolling in at least two qualifying plans, at least one of which is a PDP. If it is not possible to achieve that with PDP plans undertaking the standard level of risk, the law makes provision for limited risk PDPs, and in cases where that does not occur a fallback plan that is paid based on cost.

For several reasons, we believe it is beneficial to have several PDP plans operating in a region. Most importantly, more plans means greater beneficiary ability to obtain coverage that meets their needs and greater competitive pressure to provide high quality and low costs. We also believe that PDPs that assume some financial risk, as opposed to a fallback plan that is paid based on cost, are likely to negotiate larger price concessions for beneficiaries. In addition, more competition for enrollees between PDPs, as well as MA-PDs, is likely to generate higher quality service for beneficiaries.

Given the goal of providing beneficiary access to risk-bearing PDP plans in as many areas as possible, we considered the need to configure the PDP regions that are different from MA regions, and whether a different configuration would contribute to this goal. One of the principal questions we needed to consider is whether regions should be comprised of the largest possible number (the 50 States, or a close approximation), or a smaller number of regions covering larger geographic areas. Designating a smaller number of regions that cover large geographic areas might be desirable in the sense that areas that might be less likely to attract market interest could be grouped with other more sought after areas. Large regions might also offer PDPs a larger potential enrollee market that would provide more leverage in negotiating rebates and discounts with manufacturers. On the other hand, regions of too large a size could deter participation if there are concerns by PDPs about providing uniform benefits and bearing financial risk across large and possibly diverse health care markets. Furthermore, an important consideration, which we received comment on, is the administrative capacity of PDPs to handle a large volume of initial enrollees in the start-up year, including distribution of plan information, enrollment cards, and answering beneficiaries' inquiries through call centers. Because of the differences in enrollment expectations between regional PPOs and PDPs, from an administrative capacity standpoint it is possible to design somewhat larger geographic areas covering larger populations for PPO regions than for PDP regions. At the same time, to the extent possible, having consistent or at least very similar regions for the MA-PDs and the PDPs will facilitate beneficiary choice and Medicare program administration. As was announced on December 6, 2004, we have established in the vast majority of areas identical PDP and PPO regions. In a limited set of situations, (that is, for 8 PPO multi-state regions), the regions have been further subdivided to contain a smaller number of States, and consequently population sized PDP regions. We have used our authority to create PDP regions that are different from the MA regions in those circumstances where we believed it was necessary to create a reasonably sized potential population enrollment in order to attract sufficient PDPs into the region. While there are PDP regions with larger populations, those regions are typically a single State region.

2. Bid Level Negotiations

As mentioned previously, the FEHBP standard in 5 USC 8902(i) requires us to ascertain that a PDP's or MA-PD's bid ''reasonably and equitably reflects the costs of benefits provided.'' In addition, we note that section 1860D–11(e)(2)(c) of the Act requires that the portion of the bid attributable to basic prescription drug coverage must ''reasonably and equitably'' reflect revenue requirements . . . for benefits provided under that plan, less the sum . . . of the actuarial value of reinsurance payments.'' Analogous to the manner in which the Office of Personnel Management views its FEHBP management responsibilities, we see this requirement as imposing the fiduciary responsibility to evaluate the appropriateness of the overall bid amount.

In general, we expect to evaluate the reasonableness of bids submitted by at-risk plans by means of the actuarial valuation analysis. This would require evaluating the plan's assumptions regarding the expected distribution of costs, including average utilization and cost by drug coverage tier, for example, in the case of standard coverage—(1) those with no claims; (2) those with claims up to deductible; (3) those with claims between the deductible and the initial coverage limit; (4) those with claims between the initial coverage limit and the catastrophic limit; and (5) those with claims in excess of the catastrophic limit. We could test these assumptions for reasonableness through actuarial analysis and comparison to industry standards and other comparable bids. Bid negotiation could take the form of negotiating changes upward or downward in the utilization and cost per script assumptions underlying the bid's actuarial basis.

As discussed in greater detail in the preamble, we considered the circumstances and manner under which we would need to use our authority to carry out bid level negotiations. We anticipate that market forces will generally lead to efficient and appropriate bid prices. In areas where there is competition for enrollees among a number of PDPs and MA-PDs that are at-risk for the provision of Part D drug coverage to beneficiaries, our strong expectation is that we will be able to rely on the incentives provided by competitive bidding, and we would use our authority for bid level negotiations only on the rare occasion we find that a plan's data differs significantly from its peers without any indication as to the factors accounting for this result. If there are any regions with minimal competition (for example, just two Part D plans) or less financial risk (for

example, just limited risk PDPs), we anticipate that it is possible that bid-level negotiations might be slightly more common.

A second issue we considered is to what extent we could negotiate aggregate bid prices with fallback plans. As mentioned elsewhere in the preamble, similar to at-risk and limited-risk plans, we will evaluate whether a fallback plan bid is reasonably justified, and if the price reference points appear too high or low, we may request an explanation of the bidder's pricing structure and the nature of their arrangements with manufacturers. We would also ensure that there is no conflict of interest leading to higher bids.

In addition, since fallback plans are paid on a cost basis, there is significantly less incentive for them to negotiate lower drug prices and take other steps to reduce drug expenditures. Consequently, we also considered options through the contracting process to provide fallback plans with some incentives to control cost. We expect to tie fallback plan performance payments to the plan's ability to keep drug costs below a certain level. We believe that this carries out the Congress' requirement under 1860D–11(g)(5)(B)(i) of the Act that payments to fallback plans take into account the plan's ability to contain costs through mechanisms such as generic substitution or price discounts. Under this approach, we might include performance incentives similar to those used in many pharmacy benefit management contracts today, such as the plan achieving certain targets such as an average discount (including manufacturer discounts) off of AWP (or other pricing reference points chosen by CMS), average cost per script, average generic substitution rate, average dispensing fee per script, or average administrative fee per script. However, because these incentives would apply only to fallback plan performance fees, they would not provide as strong incentives for drug cost control as the incentives faced by risk-bearing plans to keep overall costs down.

3. HSAs, FSAs, MSAs, and HRAs and TrOOP

As discussed in the preamble of subpart C, we considered how health savings accounts (HSAs), flexible savings arrangements (FSAs), health reimbursement arrangements (HRAs), and Archer MSAs should be treated relative to beneficiary spending against the annual out-of-pocket limit. Costs that are paid by a Part D enrollee will count as incurred, or true out-of-pocket (TrOOP) costs, while costs that are paid by a ''group health plan,'' ''insurance or otherwise,'' or ''third party payment arrangements'' through which Part D enrollees may be reimbursed will not count as TrOOP expenditures. The issue we considered was whether expenditures from an HSA, FSA, Archer MSA, or HRA are to be exempted from the definition of ''group health plan'' and treated as expenditures that are incurred by a beneficiary.

The statute provides that the Secretary may establish procedures ''for determining whether costs for Part D eligible individuals are being reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement..'' We believe the statute thus grants us discretion to decide whether personal savings vehicles are equivalent to such plans for the purpose of applying the incurred costs rule.

As noted previously, we agree with the majority of commenters that HSAs, FSAs, and Archer MSAs are similar to beneficiaries' bank accounts in the sense that such accounts consist of funds set aside by a beneficiary for his or her personal use, as opposed to group health plan contributions which are essentially pooled for the benefit of numerous enrollees in a structured benefit plan.

We do not think, as previously summarized, that allowing HSA, FSA, and Archer MSA expenditures to count toward the TrOOP would create a double taxpayer subsidy. Because a beneficiary's own savings, when not in the context of an HSA, FSA, or Archer MSA, will be counted as incurred costs for the purpose of meeting the true-out-of-pocket threshold, there will be no differential treatment of funds on the expenditure side. In contrast, we believe that to not except HSAs, FSAs, and Archer MSAs from our definition of ''group health coverage'' would create an unjustifiable penalty on beneficiaries for the use of personal health savings vehicles. We have determined that the action most consistent with the intent to count an individual eligible's contributions toward incurred costs is to exempt personal savings vehicles (HSAs, FSAs, and Archer MSAs) from our definition of ''group health plan.≥

However, we think that health reimbursement arrangements (HRAs) differ from HSAs, FSAs, and Archer MSAs because HRAs are solely employer-funded; therefore, we considered them separately. HRAs are fundamentally different from HSAs, FSAs, and Archer MSAs, which are funded at least in part by the individual. Due to this distinction, we have determined that HRA contributions should not count toward the true-out-of-pocket threshold. To reflect this distinction, we have added a definition to the regulation that defines ''personal savings vehicles'' to include HSAs, FSAs, and Archer MSAs; the definition does not include HRAs.

4. Actuarial Equivalence of Retiree Drug Subsidy and Interactions with Other Means of Enhancing Retiree Drug Coverage

As discussed previously, the MMA requires that plans qualifying for the retiree drug subsidy must offer retiree drug benefits that are at least actuarially equivalent to those available under the standard Part D benefit. The MMA also provides the Secretary with the authority to determine the standards and methods for specific actuarial equivalence requirements associated with qualifying for the retiree drug subsidy.

In considering the issues related to actuarial equivalence, we have been very cognizant that the Congress has clearly and repeatedly articulated four key policy objectives for the Medicare retiree drug subsidy program created by Section 1860D–22 of the Act and for securing and enhancing retiree drug coverage more generally through the other means of assuring high quality retiree drug coverage that are provided by the Act (including, as described above, employer/union wraparound coverage and employer/union support for enhanced Part D plans). As discussed previously, our consideration of the various alternatives for determining actuarial equivalence in the context of the retiree drug subsidy reflects these four policy objectives: 1) maximizing the number of Medicare-eligible retirees with high quality employment-based retiree drug coverage, and maximizing the generosity of their coverage; 2) avoiding financial windfalls in the retiree drug subsidy program by ensuring that plan sponsors contribute at least as much to retiree drug coverage as Medicare pays them as a subsidy; 3) minimizing administrative burden while maximizing flexibility for employers and unions; and 4) fulfilling our fiduciary responsibility by limiting overall budgetary costs.

As discussed elsewhere in this document, for more than a decade prior to enactment of the MMA, employers have been systematically reducing the availability and generosity of the level of retiree drug coverage offered, particularly for future retirees. The MMA provisions creating Part D provide multiple options for assisting plan sponsors in continuing to provide high

quality retiree drug benefits. Sponsor options range from participating in the retiree drug subsidy program to taking advantage of various mechanisms for complementing the drug coverage that their retirees receive through Part D plans by providing additional coverage over and above the standard Part D benefit that, in combination with standard Part D coverage, maintains or exceeds the generosity of their current benefit designs. As discussed earlier in this impact analysis, there is considerable uncertainty about how plan sponsors will respond to the various options that are available to them under Medicare Part D. In the proposed rule, we sought comments on how best to use the Secretary's statutory authority in setting the specific actuarial equivalence requirements related to qualifying for the retiree drug subsidy, while balancing the various tradeoffs and interactions among our key policy objectives. Our ultimate goal in implementing these MMA provisions is not only to protect but also to enhance the availability of high quality drug benefits for retirees.

a. Options for Determining Actuarial Equivalence

In the proposed rule, we discussed various possible options for determining actuarial equivalence, and sought comments on desirability and legal bases for the different options, as well as on plan sponsors' likely responses to the different approaches for determining actuarial equivalence. We received a substantial number of comments encouraging flexibility in the methodology for determining actuarial equivalence. The preamble considers the issues that were raised in the various comments that we received, and describes the policy decisions that we made relating to these issues. A discussion of the options that we considered relating to the actuarial equivalence standard and plan definition that will be used in determining actuarial equivalence for the purpose of qualifying for the retiree drug subsidy program follows.

i. Actuarial Equivalence Standard

One important factor that will affect how employers and unions respond to the retiree drug subsidy relates to the actuarial equivalence standard. As discussed earlier in this impact analysis, while we believe that most of the employment-based retiree drug coverage that is currently available in the marketplace is at least as generous as the standard Part D benefit on a gross value basis, there is considerable variation in employers' and unions' contributions to the cost of retiree coverage (for example, approximately 30 percent of the large private sector firms with 1,000 or more employees that currently offer retiree health coverage to new Medicare-age retirees require those retirees to pay 61 to 100 percent of the cost of their retiree health premiums, according to the 2004 Kaiser/Hewitt Survey on Retiree Health Benefits). Thus, the actuarial equivalence standard that is selected will affect the number of employers and unions that are able to qualify for the substantial assistance that is available through the retiree subsidy. As noted previously, however, the retiree drug subsidy is one of several options available to employers and unions for continuing to provide assistance with drug costs.

As discussed in the preamble, our proposed rule described three potential standards for determining actuarial equivalence in the context of the retiree drug subsidy: 1) a single prong ''gross value'' test in which the value of the sponsor's retiree drug plan design is compared with the value of the standard Part D plan design, without taking the financing of the coverage into account (the same test as for ''creditable coverage,'' which would generally require that the expected amount of paid claims under the sponsor's retiree drug coverage be at least equal to the expected amount of paid claims under the standard Part D benefit); 2) a gross value test as in the first option, with an additional stipulation restricting the subsidy payment that a plan sponsor receives to no more than what the sponsor contributed to the cost of the retiree drug coverage on behalf of its retirees; and 3) a two-prong test in which the first prong is the ''gross value'' test as in the first option, and the second prong is a ''net value'' test which takes into account the sponsor's contribution toward the financing of the retiree prescription drug coverage. We also discussed several variants for determining the threshold value of the second prong in the third option, the ''net value'' test, including: a) the average per capita amount that Medicare will expect to pay for the retiree drug subsidy (the lowest variant); b) the after-tax value of the retiree drug subsidy (since the retiree subsidy payments are not subject to Federal income tax); and c) the expected value of paid claims under standard Part D coverage minus the retiree's expected monthly beneficiary premiums for such coverage (the highest variant).

In the proposed rule, we stated that the first option (single-prong gross value test) could not by itself preclude the existence of windfalls because unless financing is considered, an employer or union could theoretically impose as much as the full cost of the retiree drug coverage on the retiree through retiree premiums, and still be eligible for a subsidy payment if the value of the drug benefit that the employee was paying for was at least equal to the value of the standard Part D benefit. We also noted that the second option (single-prong gross value test with a requirement that the retiree drug subsidy payment amount could not exceed the amount paid by a plan sponsor on behalf of its retirees) would preclude windfalls and be relatively easy to operationalize, but stated that we had questions about the adequacy of the legal basis underpinning this option. Similarly, we stated that the third option (two-prong test of the gross value and net value of the sponsor's retiree drug coverage) would preclude windfalls, and that each of the three potential variants of the second prong of the two-prong test (that is, the net value test) would also preclude windfalls. However, we noted that each of these variants provides a different balance between the potentially competing objectives of maximizing the number of plan sponsors that participate in the retiree drug subsidy and providing greater protection to beneficiaries.

The vast majority of comments that we received from both business groups and beneficiary advocacy groups supported the two-prong test (the third option) as best serving our stated goals of maximizing the number of retirees that retain their employer or union-sponsored retiree drug coverage while not creating windfalls to plan sponsors. However, we did receive several comments that supported the gross value test (the first option) because they felt there was no legislative authority to require any other test, or because they were concerned that they would not be able to qualify for the retiree drug subsidy based on a net value test (due to relatively high retiree premium contribution levels in their plans).

We received a variety of comments relating to the threshold value for the second prong of the two-prong test, with beneficiary advocacy and union groups generally supporting the highest variant that was identified in the proposed rule (that is, the expected value of paid claims under standard Part D coverage minus the retiree's expected monthly beneficiary premiums for such coverage) due to concerns about the potential for cost-shifting, and employer groups supporting the lowest variant that was identified in the proposed rule (that is, the average per capita amount that Medicare expects to pay for the retiree drug subsidy in a given year) due to concerns about maximizing employer

and union eligibility for the retiree drug subsidy. Additionally, several employer groups proposed that we consider an additional variant for the net value test, which would involve either: 1) determining the expected value of claims paid under Part D by adjusting for the impact that the true-out-of-pocket (TrOOP) provision would have on the value of the reinsurance subsidy portion of the standard Part D benefit if an employer or union chose to provide their retirees with additional coverage that supplemented the standard Part D benefit; or 2) allowing plan sponsors to use the expected per capita value of the retiree drug subsidy that they would receive (based on their own claims experience) as a proxy for this test since, by their calculation, both of these approaches would result in approximately the same value. These employer groups asserted that their proposed alternative variant would provide a more appropriate comparison because the relative value of the standard Part D benefit would be lower for their retirees since catastrophic coverage is only available when an individual's TrOOP expenses exceed a specified threshold, and employers/unions' contributions for supplemental drug coverage would not count toward the beneficiary's true out-of-pocket spending for purposes of TrOOP.

As discussed in the preamble, the approach that we have taken in the final rule with regard to the actuarial equivalence standard seeks to balance our various policy goals within the context of our statutory authority. We agree with the majority of commenters that the two-prong test best accomplishes our goals of maximizing the number of beneficiaries retaining employment-based retiree drug coverage while not creating windfalls to sponsors. We also believe that the MMA statutory provisions impose some constraints on the methods that can be used in determining actuarial values for the purpose of qualifying for the retiree drug subsidy.

For these reasons, we have decided to require the use of a two-prong test for determining actuarial equivalence in the contest of the retiree drug subsidy, with the first prong of the test (the gross value test) generally requiring that the expected amount of paid claims under the sponsor's retiree drug coverage be at least equal to the expected amount of paid claims under the standard Part D benefit. We have also decided to establish that employment-based retiree drug coverage satisfies the net value portion of the actuarial equivalence test if its actuarial value (as determined after reducing the gross value of the benefit by expected retiree premiums) is at least equal to the net value of defined standard prescription drug coverage under Part D (as determined after reducing the gross value of the benefit by the expected monthly beneficiary premiums), with the net value of the defined standard prescription drug coverage reflecting the impact of having an employer's or union's coverage supplement a retiree's Part D coverage and thus increase the point at which the retiree would receive catastrophic Part D benefits. We will require sponsors to calculate the value of the drug coverage provided under the sponsor's plan and the defined standard prescription drug coverage under Part D based upon their own claims experience for plan participants (or their spouses or dependents) who are Part D eligible individuals because we believe that the plan sponsors' claims experience for these individuals best reflects the true value of the prescription drug coverage under the plan. However, we will allow plan sponsors that do not have sufficient claims data to support a reasonable calculation based on actual claims data to utilize alternative normative databases in accordance with our guidance. Our guidelines on the appropriate methodology for applying this two-prong actuarial equivalence test will also include simplified actuarial methods that could be used by plan sponsors that may have difficulty measuring the TrOOP impact associated with their benefit design.

We believe that this approach effectively balances our policy objectives of maximizing the number of beneficiaries who receive high quality retiree drug coverage while avoiding the creation of windfalls. We agree that employers and unions are likely to consider the effects that TrOOP will have on the value of the Part D benefit for their retirees (that is, reducing the value of the reinsurance subsidy for catastrophic coverage) as one of the factors in their decision making. In this context, we agree with the commenters who stated that employers and unions will be deciding among several options, including continuing to sponsor a plan for retiree drug coverage by electing the retiree drug subsidy, sponsoring or becoming a PDP, or providing wraparound coverage that supplements Part D. While we understand the concerns of some commenters relating to the potential for cost-shifting to occur if a lower threshold value is used for the net value test, we note that the ongoing erosion that has occurred in the generosity of retiree health coverage in recent years, through increases in retirees' premium contributions and cost-sharing arrangements, indicates that many plan sponsors already had an incentive to restructure the costs of their retiree health benefits prior to the enactment of the MMA. We do not believe that the Medicare retiree drug subsidy program, in and of itself, creates any additional incentives for plan sponsors to shift costs than what already exists; indeed, as discussed elsewhere in this impact analysis and in the proposed rule, employer survey results suggest that prior to the MMA many plan sponsors were already planning on making additional increases in retirees' premiums and cost-sharing within the next few years in an effort to manage the cost of retiree health coverage. Rather, we believe that the presence of the additional resources that are available through the retiree drug subsidy program, as well as the use of the two-prong actuarial equivalence test, will provide an incentive for more employers and unions to retain the generosity of their existing retiree drug coverage than would have occurred absent the law change. Thus, we believe that accounting for the effect of TrOOP in the net value portion of the two-prong actuarial equivalence test will assist in maximizing the number of employers and unions that will qualify for and choose to apply for the retiree drug subsidy, thereby helping to maximize the number of Medicare beneficiaries that will be able to retain their employment-based retiree drug coverage.

ii. Plan Definition

Another important factor that will affect employers' and unions' responses to the retiree drug subsidy program relates to plan definition that will be used for the purpose of determining actuarial equivalence in the context of the retiree drug subsidy. In this case, the primary issue relates to whether employers and unions that offer multiple benefit designs within a given retiree health plan (for example, with differing retiree contribution levels and/or cost-sharing arrangements) will be required to apply the actuarial equivalence test across all of the beneficiaries in the plan, or if these employers and unions should be allowed to apply the actuarial equivalence test to subgroups of beneficiaries and/or benefit designs within a given plan, if they choose to do so.

As discussed in the preamble, in the proposed rule, we proposed to adopt the rules in COBRA regulations for determining the number of group health plans an employer or union sponsor provides. Under those rules, all benefits

offered by a plan sponsor would be treated as one group health plan unless the sponsor treats them as separate plans through its plan documents and operations. The proposed rule also stated that plan sponsors would be required to determine actuarial equivalence for each plan ''as a whole.'' That is, a given plan would be determined to be actuarially equivalent if, on average, the actuarial value of the retiree drug coverage under the plan is at least equal to the actuarial standards described above.

While several employer groups agreed with our use of the COBRA plan definition, they also indicated that plan sponsors need additional flexibility to distinguish among retirees with differing arrangements within a single plan when establishing actuarial equivalence (such as groups of retirees with different benefit arrangements characterized by contribution or benefit levels based on years of service, date of retirement, collectively bargained status, status as a member of a ''grandfathered'' group of retirees, or other factors). These commenters stated that many plan sponsors may use a single administrative system to administer multiple benefit designs, and it is not uncommon that a given retiree health plan would include both a grandfathered group of retirees for whom the employer makes a substantial contribution and a non-grandfathered group with limited or no employer contributions. These commenters also expressed concern that it is possible that such a plan might not be able to qualify for the retiree drug subsidy based on its average actuarial value due to the averaging of the generous benefits of the grandfathered retirees with the less generous benefits of the non-grandfathered retirees that are in the same plan. For this reason, they recommended that sponsors should be given the discretion to aggregate all retirees in a single plan as a whole or to apply the actuarial equivalence test to each individual ''benefit option'' within a plan in order to maximize the number of employers and unions that are able to qualify to receive retiree drug subsidy payments. However, a few commenters expressed concern that the plan definition that is used for the purpose of the retiree drug subsidy should minimize the extent to which some classes of retirees are offered, and employers/unions receive subsidy payments for, retiree drug coverage that is inferior to the standard Part D benefit.

We believe the MMA provisions give CMS the authority to provide for the actuarial attestation to be submitted for the plan as a whole or to require that separate actuarial attestations be provided for each benefit option within a single plan. We also believe that by providing increased flexibility in the requirements for qualifying for the retiree drug subsidy, we can increase the incentive to plan sponsors to maintain their retiree drug coverage, and thereby maximize the number of Medicare retirees that retain their employment-based retiree drug coverage. However, we also believe that the MMA requires us to insure that all beneficiaries in plans that are receiving the retiree drug subsidy have creditable drug coverage that is at least equal in value to the standard Part D benefit.

In an effort to balance these concerns, we have added provisions in the final rule to allow plan sponsors the flexibility of choosing whether to apply the net prong of the actuarial equivalence test to their plan as a whole, or to apply the net prong of the actuarial equivalence test to each individual benefit option within a plan. In this context, a sponsor will only be allowed to apply the net prong of the actuarial equivalence test to a given retiree drug plan on an aggregate basis if each benefit option in that plan qualifies as creditable coverage (that is, each benefit design under the plan must meet the gross value test, which is the first prong of the two-prong actuarial equivalence test). A plan sponsor that fails to meet that standard for a given plan will be required to apply the net prong of the actuarial equivalence test to each individual benefit option within that plan for the purpose of qualifying for the retiree drug subsidy. However, sponsors may aggregate together the benefit options within the plan that meet the creditable coverage standard (that is, the gross value test) for purposes of the net prong of the actuarial equivalence test. We believe that these requirements will maximize plan sponsors' flexibility, protect beneficiaries, and reduce the chance of windfalls being created.

b. Interaction With Other Means of Enhancing Retiree Drug Coverage

We recognize that employers' and unions' decisions about choosing between obtaining the retiree drug subsidy versus using other means to provide additional retiree drug coverage that complements the standard Part D benefit (for example, by offering supplemental drug coverage that wraps around a Part D plan, or providing enhanced coverage through a PDP or MA-PD) will depend on the relative attractiveness of each of these options, given their particular circumstances. We believe that the flexibility that we have provided in this final rule with regard to the actuarial equivalence requirements related to qualifying for the Medicare retiree drug subsidy will help to make the retiree drug subsidy an attractive and feasible option for many employers and unions.

Additionally, as discussed earlier, we note that in addition to the retiree drug subsidy, Medicare Part D also gives employers and unions a variety of other options for continuing to provide prescription drug assistance to their Medicare-eligible retirees. We believe that these additional approaches to providing generous retiree coverage will be attractive to employers and unions who may not make sufficient contributions or provide sufficiently generous coverage on their own to qualify for the retiree drug subsidy. Ultimately, we believe that this combination of approaches will maximize the number of beneficiaries who continue to receive employment-based assistance with their drug coverage as a result of combining the additional resources for supporting retiree health coverage that are available through Medicare Part D with contributions from employers and unions.

5. Retiree Subsidy—Payment Methodology and Data Reporting

a. Method and Frequency of Medicare Retiree Drug Subsidy Payments

We believe that the statute gives us broad discretion to determine the methodology and timing for distributing the Medicare retiree drug subsidy payments. The proposed rule covered in detail the various options for calculating and making these payments. Specifically, we presented several alternatives for the method and frequency of subsidy payments and rebates, and included a discussion of whether payments should be based on an employer or union's plan year or calendar year.

Regarding the method and frequency of payments, we described four options in the proposed rule: (1) monthly payments based on actual experience with monthly adjustments for price concessions; (2) a single end-of-year payment based on plan sponsors' submission of actual cost data including rebate data at the close of the plan year; (3) multiple payments at interims throughout the year based on estimates of claims, rebates, chargebacks, and discounts, with an end-of-year reconciliation; or (4) periodic lagged payments throughout the year based on actual claims experience and estimates of discounts, chargebacks, and rebates, with an end-of-year reconciliation. A detailed discussion of these four options can be found in the proposed rule. In

short, annual retroactive payments would have the greatest administrative simplicity compared to interim or monthly payments; however, more frequent payments would provide a more even cash flow for sponsors. In addition, making payments based on estimates rather than actual costs would allow for faster payments to sponsors, but would require additional work to produce actuarially sound estimates and later to reconcile estimates with actual experience, and would potentially have a greater risk that substantial overpayments or underpayments could occur.

In the proposed rule, we stated that option one was our preferred approach. Under this option, the plan sponsor would submit the amount of beneficiary spending eligible for the retiree subsidy by the 15th of the month following each monthly payment period. Sponsors would also submit the amount of any rebates, discounts, other price concessions received, and any adjustments to actual expenditures from prior months. By the 30th of each month, Medicare would make a subsidy payment based on the certified amount for the preceding month and adjusted for price concessions recognized for prior months. At the end of the calendar year, there would be a final reconciliation of actual costs except for any outstanding price concessions, which would be accounted for when they are received or recognized, and reconciled as an offset of a future monthly payment.

The responses to our proposed alternatives were mixed. While recognizing that plan sponsors may prefer different methods and frequency of payments based on their unique situations, we proposed option one as our preferred approach because we wanted to balance employers' and unions' perceived preference for frequent payments with a desire to avoid overly complex administrative procedures. Although we felt that this solution reasonably balanced various concerns, the comments we received indicated that flexibility is needed to reflect different circumstances of individual sponsors.

Thus, our final decision was to create a flexible payment system in which employers and unions could choose among multiple methods of receiving payment. We will allow a sponsor to receive payments on a monthly, quarterly, or annual basis. Under the monthly or quarterly option a sponsor will provide the aggregated actual gross covered retiree plan-related prescription drug costs incurred for all of its qualifying covered retirees during the payment period for which it is claiming a subsidy payment, an estimate of the difference between these gross costs and allowable costs (based on expected rebates and other price concessions), and any other data CMS may require. Sponsors choosing the monthly or quarterly payment options would then be required to provide within 15 months after the end of the plan year the total gross covered retiree plan-related prescription drug costs for the plan year segregated by each qualifying covered retiree; actual rebate/discount/other price concession data for the plan year in question; and any other data CMS may require.

Under the annual payment approach, we will offer two payment options: (1) a one-time final annual payment, in which a sponsor will submit actual cost and rebate/discount/other price concession data per retiree within 15 months after the end of the plan year; or (2) an interim annual payment, in which a sponsor after the end of the plan year will submit the aggregated actual gross drug costs incurred for all of its qualifying covered retirees for which it is claiming a subsidy payment; an estimate of the difference between these gross costs and allowable costs (based on expected rebates and other price concessions); and any other data CMS may require after the end of the plan year. Sponsors choosing the interim annual payment option would then be required to provide within 15 months after the end of the plan year the total gross covered retiree plan-related prescription drug costs for the plan year segregated by each qualifying covered retiree; actual rebate/discount/other price concession data for the plan year in question; and any other data CMS may require. In cases where manufacturer rebates, discounts, and other price concessions are not specifically allocated to the drug spending of a particular qualifying covered retiree, we will permit the plan sponsor (or its agent) to assign these rebates/discounts/other price concessions to their qualifying covered retirees based on reasonable actuarial principles.

b. Plan Year Versus Calendar Year

The proposed rule included a discussion of whether to use a plan year or calendar year in determining the retiree drug subsidy amount. As with the method and frequency of payments, commenters' preferences were mixed with respect to this issue. We had originally proposed the calendar year approach because it would be the least burdensome method for us to administer. This approach is most straightforward since the cost threshold and cost limit levels are determined on a calendar year basis. However, we recognize that using a plan year approach would be more consistent with the administrative practices of plan sponsors whose plan operations are based on a non-calendar year. In response to numerous comments requesting flexibility in this area, we have determined that a plan-year approach should be used. Using a plan-year approach, we will be able to accommodate employer or union-sponsored plans that are structured around either a calendar-based plan year or a non-calendar plan year.

A non-calendar year approach to retiree subsidy payments requires the creation of rules for: (1) determining whether a sponsor's plan is actuarially equivalent to Part D for purposes of qualifying for the retiree subsidy; (2) applying the cost threshold and cost limit, which function on a calendar-year basis, to the plan year; and (3) determining retiree subsidy payments for employers/unions with a plan year that straddles 2005 and 2006 when the Medicare retiree drug subsidy begins. In subpart R of the preamble we present the options for calculating subsidy payments using a plan year approach with respect to each of these factors. In summary, we determined that the cost threshold and cost limit for the calendar year in which the plan year ends will be used for determining subsidy payments. For the purpose of determining actuarial equivalence, a plan sponsor may use the elements of the defined standard prescription drug coverage from the calendar year before the year in which the plan year ends, provided that the attestation of actuarial equivalence is submitted no later than 60 days after the publication of the new coverage limits for the upcoming calendar year. During the transition to the retiree subsidy program for employers/unions with a plan year beginning in 2005 but ending in 2006, subsidy amounts will be determined on a monthly basis for the entire plan year (2005–2006), but will only be paid for claims incurred in 2006.

c. Retiree Subsidy Data Collection

Another issue we considered related to the retiree drug subsidy is what type of data should be collected from plan sponsors. Our objectives in making this decision were to minimize the burden on plan sponsors while ensuring that we receive adequate data to correctly determine subsidy payments to plan sponsors. Regardless of the method that is used to make the retiree subsidy payments, we will need data from plan sponsors to calculate the appropriate payment levels. The question is whether

actual cost data should be submitted by plan sponsors on an individual retiree basis or in an aggregated format.

We considered several alternatives in this area. CMS could require that plan sponsors submit: (1) aggregate allowable costs of all eligible retirees in the plan for the relevant time period; (2) costs aggregated over the relevant time period for each individual in the plan; (3) a combination of individual and aggregate data; or (4) actual claims data for each individual retiree in the plan.

Many commenters favored option one, aggregated reporting of allowable retiree costs, because employers and unions may not currently keep records of individual costs for some of the elements that must be submitted to CMS. However, it is important that the data submissions are sufficiently detailed to ensure that we can make accurate payments to plan sponsors. We ultimately determined that data aggregated across all plan enrollees would not be sufficient to fulfill this purpose.

As described in the proposed rule, we previously ruled out the fourth option because we believe requiring submissions of enrollee level claims data would be overly burdensome for plan sponsors taking the subsidy and raise privacy concerns. Option two—aggregate per enrollee data—would create some administrative burdens and privacy concerns, but to a lesser and more reasonable degree than a claims level data requirement.

A combination approach to data collection would diminish the negative effects of individual level data submissions while providing for sufficient assurance of payment accuracy. For instance, we could require the type of submission described in option two for the first two years of the subsidy, and require the type of submission described in option one thereafter. Alternatively, the format of data we require might vary depending on the timing of the plan sponsor's submission within a plan year.

We determined that the latter of these two combinations is better aligned with the various payment methodologies that will be used under the retiree subsidy program. If a sponsor elects to receive monthly or quarterly retiree subsidy payments or an interim annual retiree subsidy payment, the plan sponsor will be required to submit aggregated gross cost data, an estimate of the difference between these gross costs and allowable costs (based on expected rebates and other price concessions), and any other data CMS may require upon submission of data for payment at each of the time intervals elected by the sponsor, with a final reconciliation within 15 months after the end of the plan year. Using aggregated data for interim monthly, quarterly or annual payments will allow plan sponsors to receive more frequent payments without a disproportionate administrative burden.

Regardless of the payment method chosen, for final reconciliation purposes all sponsors will be required to submit total gross cost data segregated per qualifying covered retiree; actual rebates, discounts, or other price concessions received for such costs; and any other data CMS may require, within 15 months after the end of the plan year. This requirement will provide assurance that subsidy payments are appropriate for the actual costs incurred. If rebates and other price concessions for a plan are not specifically allocated by a manufacturer to the drug spending of a particular qualifying covered retiree, a sponsor will be permitted to assign such price concessions to qualifying covered retirees using reasonable actuarial principles. For sponsors who choose the monthly, quarterly, or interim annual payment option, the final data submission will serve as the basis for the reconciliation process, in which we will adjust the payments made for the plan year in question in a manner that we will specify in separate guidance. For sponsors who choose the one-time final annual payment method, this will be the primary submission of cost data required for payment. However, as discussed in the preamble, plan sponsors who choose either of the annual payment options will still be required to provide us with updates of their enrollment information on a monthly basis.

6. Beneficiary Access to Drugs in Long-Term Care Facilities

Section 1860D–4(b)(1)(C)(iv) of the Act provides that, in establishing rules for convenient access to network pharmacies, we may include standards with respect to access to long-term care pharmacies for Part D enrollees who reside in skilled nursing facilities and nursing facilities (hereinafter referred to as ''long-term care facilities''). While we do not directly regulate long-term care pharmacies, this rule will indirectly influence their operations. Long-term care facilities generally contract with one long-term care pharmacy to supply the prescription drugs needed by the residents. With the implementation of Part D, in order to serve Medicare Part D enrollees as a network pharmacy, these long-term care pharmacies will have to contract with both the facility and the Part D plans serving the region. In the proposed rule, we stated our goal of balancing convenient access to long-term care pharmacies with appropriate payment to long-term care pharmacies under the provisions of the MMA. We proposed two potential options to meet this goal and requested public comment.

Under one option, we would use the authority provided under section 1860D–4(b)(1)(C)(iv) of the Act to require prescription drug plans and MA-PD plans to approach some or all long-term care pharmacies in their service areas with at least the same terms available under their plans' standard pharmacy contracts. Alternatively, we would not require that plans contract with long-term care pharmacies and would, instead, strongly encourage PDP sponsors and MA organizations offering MA-PD plans to negotiate with and include long-term care pharmacies in their plans' pharmacy networks.

To the extent that we require Part D plans to solicit long-term care pharmacies in their service areas to join their networks, plans may be forced to negotiate preferential contracting terms and conditions (relative to the terms they would offer any other pharmacy willing to participate in its network) for long-term care pharmacy-specific packaging and services with a number of long-term care pharmacies in order to meet our requirement. If we require Part D plans to contract with any long-term care pharmacy in a service area, we cannot compel long-term care pharmacies to accept the plans' terms and conditions. Yet, given the additional risk associated with institutionalized beneficiaries, it may not be sufficient to rely on the market alone to ensure that Part D plans include a sufficient number of long-term care pharmacies in their networks. Absent a contracting mandate, Part D plans may view contracting with long-term care pharmacies—given the risk associated with institutionalized beneficiaries—as too risky.

If we do not require Part D Plans to contract with long term care pharmacies, some Part D enrollees in long-term care facilities may be served by plans whose networks do not include the long-term care pharmacy under contract with their long-term care facility. As a result, long-term care facilities could face an additional administrative burden-managing covered Part D drugs supplied by multiple sources (such as other long-term care pharmacies, and mail-order pharmacies). This scenario differs from current industry practices of most long-term care facilities. In the absence of direct collaboration between a plan and a Part D enrollee's long-term care pharmacy, it would be difficult for long-

term care facilities to meet Federal pharmacy management standards.

The second option (that is, do not require but encourage Part D plans to negotiate with and include long-term care pharmacies in their networks) would allow for the long-term care pharmacies to maintain their existing one-on-one relationships with long term care facilities. However, for beneficiaries whose Part D plan networks do not include the long-term care pharmacy under contract with their long-term care facility, accessing out-of-network pharmacies could remain a problem. However, it is important to note that the Final Rule provides a special enrollment period for PDP enrollment and disenrollment for beneficiaries entering in, living in, or leaving an institution. In addition, individuals enrolled in MA-PD plans have an unlimited open enrollment period for institutionalized individuals. In addition, we believe that relying on the pharmacy access standards in § 423.120(a) of our final rule will not assure sufficient access to long-term care pharmacies, since many of these pharmacies are not retail pharmacies and therefore would not count toward those requirements.

We believe it is essential to inject competition into the long-term care pharmacy market while preserving the relationships and levels of service that long-term care facilities now enjoy vis-à-vis their contracted long-term care pharmacies. As discussed in greater detail in the preamble for subpart C, our Final Rule will require that Part D plans offer standard contracting terms and conditions, including product performance and delivery and packaging requirements to all long-term care pharmacies in their service areas. We will also require Part D plans to demonstrate that they have contracts with a sufficient number of long-term care pharmacies to ensure ''convenient access'' to prescription drugs for institutionalized beneficiaries within the region.

To further assure ''convenient access'' to a pharmacy for long-term care residents, we will allow each long-term care facility to select one or more eligible network pharmacies to provide a plan's long-term care drug benefits to its Medicare residents. In order to minimize the number of pharmacy suppliers and maintain patient safety, long-term care facilities will likely select long-term care pharmacies meeting Part D standards that participate in the largest number of plan networks. To maintain convenient access and minimize out-of-pocket expenditures, plan beneficiaries would obtain Part D benefits from the eligible long-term care pharmacy selected by the facility. As noted previously, beneficiaries in long-term care facilities are eligible for special enrollment periods. In order to preserve their existing relationships with long-term care facilities, all long-term care pharmacies will likely have to accept the terms and conditions (and network pricing) offered by the Part D plan or lose the plan's entire book of business to another long-term care pharmacy. We believe that our long-term care pharmacy access rules will align incentives for competition while maintaining beneficiary access to the necessary services.

7. Coordination of Benefits and TrOOP

We also considered options regarding implementing provisions in the statute related to coordination of benefits between PDP and MA-PDs and SPAPs and other insurance coverage. Under Option 1, the PDPs and MA-PD plans would be solely responsible for tracking TrOOP costs. Under Option 2, we would be involved, hiring a TrOOP facilitation contractor to establish a single point of contact between primary and secondary payers.

The overwhelming majority of commenters supported the second option, with us having a role in ensuring coordination of benefits and facilitating accurate TrOOP tracking. Given this preference, we are prepared to assume a role in ensuring these important functions occur, and that they occur in as real-time as possible. While plans ultimately are responsible for tracking TrOOP consistent with the statute as discussed elsewhere in the preamble, we will facilitate the coordination of benefits and participate in other processes to help ensure that the plan are in a position to do so. We continue to fully develop the specifications of such assistance, and the operational details involved in bringing it about. In accordance with the statute, we will establish procedures before July 1, 2005 to ensure the effective coordination of benefits.

N. Conclusion

We estimate that about 39 million Medicare beneficiaries will receive drug coverage either through a Medicare Part D plan (that is, by enrolling in a PDP or a MA-PD) or through an employer or union sponsored retiree plan that is eligible for the Medicare retiree drug subsidy in CY 2006. By CY 2010, due to growth in the overall Medicare population, we estimate that about 42 million Medicare beneficiaries will be receiving drug coverage through a Medicare Part D plan or through an employer or union sponsored retiree plan that is eligible for the Medicare retiree drug subsidy. The net Federal budgetary effect of the Medicare prescription drug benefit and retiree drug subsidy is estimated to be about $293 billion during CY 2006–2010. Medicare Part D is estimated to generate about $7.9 billion in net savings for States over the five-year period from CY 2006–2010.

All Medicare beneficiaries will have access to a benefit that protects against catastrophic drug costs. On average, for non-low-income beneficiaries the benefit will cover half their costs, and for beneficiaries with very high drug costs it will cover substantially more. For low-income beneficiaries coverage is comprehensive, covering on average about 96 percent of their prescription drug costs.

Medicare beneficiaries who have no drug coverage today will now be able to obtain an affordable benefit that provides substantial assistance with prescription drug costs. Those beneficiaries with existing private coverage through retirement benefits and Medicare Advantage plans will receive the benefits of new Medicare subsidies to maintain and enhance their coverage. Beneficiaries with public coverage through Medicaid and State programs will have more secure (and potentially more generous) benefits because of the comprehensive low-income Medicare benefit. Beneficiaries who pay the full costs for limited Medigap drug coverage will now be able to obtain highly-subsidized, more generous coverage.

Overall, we anticipate that by giving beneficiaries access to affordable insurance coverage that helps them to pay for their outpatient prescription drugs—which have become a critical component in the delivery of comprehensive, quality health care services—the Medicare prescription drug benefit will help beneficiaries to lead healthier, more productive lives.

List of Subjects

42 CFR Part 400

Grant programs-health, Health facilities, Health maintenance organizations (HMO), Medicaid, Medicare Reporting and recordkeeping requirements

42 CFR Part 403

Grant programs-health, Health insurance, Hospitals

42 CFR Part 411

Kidney diseases, Medicare, Reporting and recordkeeping requirements

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, Reporting and recordkeeping requirements

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping

■ For reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amend 42 CFR chapter IV as follows:

PART–400 INTRODUCTION; DEFINITIONS

■ 1. The authority citation for part 400 continues to read as follows:

Authority: (Secs. 1102 and 1971 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. Chapter 35.

Subpart B—Definitions

■ 2. Section 400.202 is amended by—

A. Adding in alphabetical order the definition of Medicare Part C.

B. Adding in alphabetical order the definition of Medicare Part D.

■ The additions read as follows:

§ 400.202 Definitions specific to Medicare.

* * * * *

Medicare Part C means the choice of Medicare benefits through Medicare Advantage plans authorized under Part C of the title XVIII of the Act.

Medicare Part D means the voluntary prescription drug benefit program authorized under Part D of title XVIII of the Act.

* * * * *

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 3. The authority citation for part 403 continues to read as follows:

Authority: 42 U.S.C. 1359b–3 and secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395 hh).

Subpart B—Medicare Supplemental Policies

■ 4. Section 403.205 is revised to read as follows:

§ 403.205 Medicare supplemental policy.

(a) Except as specified in paragraph (e) of this section, Medicare supplemental (or Medigap) policy means a health insurance policy or other health benefit plan that—

(1) A private entity offers to a Medicare beneficiary; and

(2) Is primarily designed, or is advertised, marketed, or otherwise purported to provide payment for expenses incurred for services and items that are not reimbursed under the Medicare program because of deductibles, coinsurance, or other limitations under Medicare.

(b) The term policy includes both policy form and policy as specified in paragraphs (b)(1) and (b)(2) of this section.

(1) *Policy form*. Policy form is the form of health insurance contract that is approved by and on file with the State agency for the regulation of insurance.

(2) *Policy*. Policy is the contract—

(i) Issued under the policy form; and

(ii) Held by the policy holder.

(c) If the policy otherwise meets the definition in this section, a Medicare supplemental policy includes-

(1) An individual policy;

(2) A group policy;

(3) A rider attached to an individual or group policy; or

(4) As of January 1, 2006, a stand-alone limited health benefit plan or policy that supplements Medicare benefits and is sold primarily to Medicare beneficiaries.

(d) Any rider attached to a Medicare supplemental policy becomes an integral part of the basic policy.

(e) Medicare supplemental policy does not include a Medicare Advantage plan, a Prescription Drug Plan under Part D, or any of the other types of health insurance policies or health benefit plans that are excluded from the definition of a Medicare supplemental policy in section 1882(g)(1) of the Act.

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 5. The authority citation for part 411 is revised to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395 w–101 through 1395w–152, and 1395hh).

Subpart J—Financial Relationships Between Physicians and Entities Furnishing Designated Health Services

■ 6. In § 411.351, the definition of ''Outpatient prescription drugs'' is revised to read as follows:

§ 411.351 Definitions.

* * * * *

Outpatient prescription drugs mean all drugs covered by Medicare Part B or Part D.

* * * * *

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLAN

■ 7. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9), and 31 U.S.C. 9701.

■ 8. In § 417.440, revise paragraph (b)(2) to read as follows:

§ 417.440 Entitlement to health care services from an HMO or CMP.

* * * * *

(b) * * *

(2) *Supplemental services elected by an enrollee*. (i) Except as provided under paragraph (b)(2)(ii) of this section, a Medicare enrollee of an HMO or CMP may elect to pay for optional services that are offered by the HMO or CMP in addition to the covered Part A and Part B services.

(ii) An HMO or CMP may elect to provide qualified prescription drug coverage (as defined at § 423.104 of this chapter) as an optional supplemental service in accordance with the applicable requirements under part 423 of this chapter, including § 423.104(f)(4) of this chapter.

(iii) The HMO or CMP may not set health status standards for those enrollees whom it accepts for these optional supplemental services.

* * * * *

■ 9. In § 417.534, add paragraph (c) to read as follows:

§ 417.534 Allowable costs.

* * * * *

(c) *Medicare Part D program costs*. To the extent that an HMO or CMP provides qualified prescription drug coverage to enrollees under Part D, no costs related to the offering or provision of Part D benefits are reimbursed under this part. These costs are reimbursed solely under the applicable provisions of part 423 of this chapter.

■ 10. Part 423 is added as set forth below:

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

Subpart A—General Provisions

423.1 Basis and scope.
423.4 Definitions.
423.6 Cost-Sharing in beneficiary education and enrollment-related costs.

Subpart B—Eligibility and Enrollment

423.30 Eligibility and enrollment.
423.32 Enrollment process.
423.34 Enrollment of full-benefit dual eligibles
423.36 Disenrollment process

423.38 Enrollment periods.
423.40 Effective dates.
423.44 Involuntary disenrollment by PDP.
423.46 Late enrollment penalty.
423.48 Information about Part D.
423.50 Approval of marketing materials and enrollment forms.
423.56 Procedures to determine and document creditable status of prescription drug coverage.

Subpart C—Benefits and Beneficiary Protections

423.100 Definitions.
423.104 Requirements related to qualified prescription drug coverage.
423.112 Establishment of prescription drug plan service areas.
423.120 Access to covered Part D drugs.
423.124 Special rules for out-of-network access to covered Part D drugs at out-of-network pharmacies.
423.128 Dissemination of Part D plan information.
423.132 Public disclosure of pharmaceutical prices for equivalent drugs.
423.136 Privacy, confidentiality, and accuracy of enrollee records.

Subpart D—Cost Control and Quality Improvement Requirements for Part D Plans

423.150 Scope.
423.153 Drug utilization management, quality assurance, and medication therapy management programs (MTMPs).
423.156 Consumer satisfaction surveys.
423.159 Electronic prescription program.
423.162 Quality improvement organization activities.
423.165 Compliance deemed on the basis of accreditation.
423.168 Accreditation organizations.
423.171 Procedures for approval of accreditation as a basis for deeming compliance.

Subpart E—[Reserved]

Subpart F—Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

423.251 Scope.
423.258 Definitions.
423.265 Submission of bids and related information.
423.272 Review and negotiation of bid and approval of plans submitted by potential Part D sponsors .
423.279 National average monthly bid amount.
423.286 Rules regarding premiums.
423.293 Collection of monthly beneficiary premium.

Subpart G— Payments to Part D Plan Sponsors For Qualified Prescription Drug Coverage

423.301 Scope.
423.308 Definitions and terminology.
423.315 General payment provisions.
423.322 Requirement for disclosure of information.
423.329 Determination of payments.
423.336 Risk-sharing arrangements.
423.343 Retroactive adjustments and reconciliations.
423.346 Reopening.
423.350 Payment appeals.

Subpart H—[Reserved]

Subpart I—Organization Compliance with State Law and Preemption by Federal Law

423.401 General requirements for PDP sponsors.
423.410 Waiver of certain requirements in order to expand choice.
423.415 Temporary waivers for entities seeking to offer a prescription drug plan in more than one State in a region
423.420 Solvency standards for non-licensed entities.
423.425 Licensure does not substitute for or constitute certification.
423.440 Prohibition of State imposition of premium taxes; relation to State laws.

Subpart J—Coordination under Part D Plans with Other Prescription Drug Coverage

423.452 Scope.
423.453 Definitions.
423.458 Application of Part D rules to certain Part D plans on and after January 1, 2006.
423.462 Medicare secondary payer procedures.
423.464 Coordination of benefits with other providers of prescription drug coverage.

Subpart K—Application Procedures and Contracts with PDP Sponsors

423.500 Scope and basis.
423.501 Definitions.
423.502 Application requirements.
423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.
423.504 General provisions.
423.505 Contract provisions.
423.506 Effective date and term of contract.
423.507 Nonrenewal of contract.
423.508 Modification or termination of contract by mutual consent.
423.509 Termination of contract by CMS.
423.510 Termination of contract by Part D sponsor.
423.512 Minimum enrollment requirements.
423.514 Reporting requirements.
423.516 Prohibition of midyear implementation of significant new regulatory requirements.

Subpart L—Effect of Change of Ownership or Leasing of Facilities during Term of Contract

423.551 General provisions.
423.552 Novation agreement requirements.
423.553 Effect of leasing a PDP sponsor's facilities.

Subpart M—Grievances, Coverage Determinations, and Appeals

423.560 Definitions.
423.562 General provisions.
423.564 Grievance procedures
423.566 Coverage determinations.
423.568 Standard timeframe and notice requirements for coverage determinations.
423.570 Expediting certain coverage determinations.
423.572 Timeframes and notice requirements for expedited coverage determinations.
423.576 Effect of a coverage determination.
423.578 Exceptions process.
423.580 Right to a redetermination.
423.582 Request for a standard redetermination.
423.584 Expediting certain redeterminations.
423.586 Opportunity to submit evidence.
423.590 Timeframes and responsibility for making redeterminations.
423.600 Reconsideration by an independent review entity (IRE).
423.602 Notice of reconsideration determination by the independent review entity.
423.604 Effect of a reconsideration determination.
423.610 Right to an ALJ hearing.
423.612 Request for an ALJ hearing.
423.620 Medicare Appeals Council (MAC) review.
423.630 Judicial review.
423.634 Reopening and revising determinations and decisions.
423.636 How a Part D plan sponsor must effectuate standard redeterminations or reconsiderations, or decisions.
423.638 How a Part D plan sponsor must effectuate expedited redeterminations or reconsiderations.

Subpart N—Medicare Contract Determinations and Appeals

423.641 Contract determinations.
423.642 Notice of contract determination.
423.643 Effect of contract determination.
423.644 Reconsideration: Applicability.
423.645 Request for reconsideration.
423.646 Opportunity to submit evidence.
423.647 Reconsidered determination.
423.648 Notice of reconsidered determination.
423.649 Effect of reconsidered determination.
423.650 Right to a hearing.
423.651 Request for hearing.
423.652 Postponement of effective date of a contract determination when a request for a hearing for a contract determination is filed timely.
423.653 Designation of hearing officer.
423.654 Disqualification of hearing officer.
423.655 Time and place of hearing.
423.656 Appointment of representatives.
423.657 Authority of representatives.
423.658 Conduct of hearing.
423.659 Evidence.
423.660 Witnesses.
423.661 Discovery.
423.662 Preearing.
423.663 Record of hearing.
423.664 Authority of hearing officer.
423.665 Notice and effect of hearing decision.
423.666 Review by the Administrator.
423.667 Effect of Administrator's decision.
423.668 Reopening of contract or reconsidered determination or decision of a hearing officer or the Administrator.
423.669 Effect of revised determination.

Subpart O—Intermediate Sanctions

423.750 Kinds of sanctions.

423.752 Basis for imposing sanctions.
423.756 Procedures for imposing sanctions.
423.758 Maximum amount of civil money penalties imposed by CMS.
423.760 Other applicable provisions.

Subpart P—Premium and Cost-Sharing Subsidies for Low-Income Individuals

423.771 Basis and Scope.
423.772 Definitions.
423.773 Requirements for eligibility.
423.774 Eligibility determinations, redeterminations, and applications.
423.780 Premium subsidy.
423.782 Cost-sharing subsidy.
423.800 Administration of subsidy program.

Subpart Q—Guaranteeing Access to a Choice of Coverage (Fallback prescription drug plans)

423.851 Scope.
423.855 Definitions.
423.859 Assuring access to a choice of coverage.
423.863 Submission and approval of bids.
423.867 Rules regarding premiums.
423.871 Contract terms and conditions.
423.875 Payments to fallback prescription drug plans.

Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans

423.880 Basis and scope.
423.882 Definitions.
423.884 Requirements for qualified retiree prescription drug plans.
423.886 Retiree drug subsidy amounts.
423.888 Payment methods, including provision of necessary information.
423.890 Appeals.
423.892 Change of Ownership.
423.894 Construction.

Subpart S—Special Rules for States-Eligibility Determinations for Subsidies and General Payment Provisions

423.900 Basis and scope.
423.902 Definitions.
423.904 Eligibility determinations for low-income subsidies.
423.906 General payment provisions.
423.907 Treatment of territories.
423.908 Phased-down State contribution to drug benefit costs assumed by Medicare.
423.910 Requirements.

Authority: Secs 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

Subpart A—General Provisions

§ 423.1 Basis and scope.

(a) Basis. (1) This part is based on the indicated provisions of the following sections of the Social Security Act:

1860D–1. Eligibility, enrollment, and information.

1860D–2. Prescription drug benefits.

1860D–3. Access to a choice of qualified prescription drug coverage.

1860D–4. Beneficiary protections for qualified prescription drug coverage.

1860D–11. PDP regions; submission of bids; plan approval.

1860D–12. Requirements for and contracts with prescription drug plan (PDP) sponsors.

1860D–13. Premiums; late enrollment penalty.

1860D–14. Premium and cost-sharing subsidies for low-income individuals.

1860D–15. Subsidies for Part D eligible individuals for qualified prescription drug coverage.

1860D–16. Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

1860D–21. Application to Medicare Advantage program and related managed care programs.

1860D–22. Special rules for Employer-Sponsored Programs

1860D–23. State pharmaceutical assistance programs.

1860D–24. Coordination requirements for plans providing prescription drug coverage.

1860D–31. Medicare prescription drug discount card and transitional assistance program.

1860D–41. Definitions; treatment of references to provisions in Part C.

1860D–42. Miscellaneous provisions.

(2) The following specific sections of the Medicare Modernization Act also address the prescription drug benefit program:

Sec. 102 Medicare Advantage conforming amendments.

Sec. 103 Medicaid amendments.

Sec. 104 Medigap.

Sec. 109 Expanding the work of Medicare Quality Improvement Organizations to include Parts C and D.

(b) *Scope.* This part establishes standards for beneficiary eligibility, access, benefits, protections, and low-income subsidies in Part D, as well as establishes standards and sets forth requirements, limitations, procedures and payments for organizations participating in the Voluntary Medicare Prescription Drug Program.

§ 423.4 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Actuarial equivalence means a state of equivalent value demonstrated through the use of generally accepted actuarial principles and in accordance with section 1860D–11(c) of the Act and with CMS actuarial guidelines.

Brand name drug means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(c)), including an application referred to in section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 USC 355(b)(2)).

Cost plan means a plan operated by a Health Maintenance Organization (HMO) or Competitive Medical Plan (CMP) in accordance with a cost-reimbursement contract under section 1876(h) of the Act.

Eligible fallback entity or fallback entity is defined at § 423.855.

Fallback prescription drug plan is defined at § 423.855.

Formulary means the entire list of Part D drugs covered by a Part D plan.

Full-benefit dual eligible individual has the meaning given the term at § 423.772, except where otherwise provided.

Generic drug means a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(j)) is approved.

Group health plan is defined at § 423.882.

Insurance risk means, for a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitutions, nor does it include elements potentially in the control of the pharmacy (for example, labor costs or productivity).

MA stands for Medicare Advantage, which refers to the program authorized under Part C of title XVIII of the Act.

MA plan has the meaning given the term in § 422.2 of this chapter.

MA-PD plan means an MA plan that provides qualified prescription drug coverage.

Medicare prescription drug account means the account created within the Federal Supplementary Medical Insurance Trust Fund for purposes of Medicare Part D.

Monthly beneficiary premium means the amount calculated under § 423.286 for Part D plans other than fallback prescription drug plans, and § 423.867(a) for fallback prescription drug plans.

PACE Plan means a plan offered by a PACE organization.

PACE organization is defined in § 460.6 of this chapter.

Part D eligible individual means an individual who meets the requirements at § 423.30(a).

Part D plan (or Medicare Part D plan) means a prescription drug plan, an MA-PD plan, a PACE Plan offering qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage.

Part D plan sponsor or Part D sponsor refers to a PDP sponsor, MA

organization offering a MA-PD plan, a PACE organization offering a PACE plan including qualified prescription drug coverage, and a cost plan offering qualified prescription drug coverage.

PDP region means a prescription drug plan region as determined by CMS under § 423.112.

PDP sponsor means a nongovernmental entity that is certified under this part as meeting the requirements and standards of this part that apply to entities that offer prescription drug plans. This includes fallback entities.

Prescription drug plan or PDP means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in § 423.272 and that is offered by a PDP sponsor that has a contract with CMS that meets the contract requirements under subpart K of this part. This includes fallback prescription drug plans.

Service area (Service area does not include facilities in which individuals are incarcerated.) means for —

(1) A prescription drug plan, an area established in § 423.112(a) within which access standards under § 423.120(a) are met;

(2) An MA-PD plan, an area that meets the definition of MA service area as described in § 422.2 of this chapter, and within which access standards under § 423.120(a) are met;

(3) A fallback prescription drug plan, the service area described in § 423.859(b);

(4) A PACE plan offering qualified prescription drug coverage, the service area described in § 460.22 of this chapter; and

(5) A cost plan offering qualified prescription drug coverage, the service area defined in § 417.1 of this chapter.

Subsidy-eligible individual means a full subsidy eligible individual (as defined at § 423.772) or other subsidy eligible individual (as defined at § 423.772).

Tiered cost-sharing means a process of grouping Part D drugs into different cost sharing levels within a Part D sponsor's formulary.

§ 423.6 Cost-sharing in beneficiary education and enrollment-related costs.

The requirements of section 1857(e)(2) of the Act and § 422.6 of this chapter with regard to the payment of fees established by CMS for cost sharing of enrollment related costs apply to PDP sponsors under Part D.

Subpart B—Eligibility and Enrollment.

§ 423.30 Eligibility and enrollment.

(a) *General rule.* (1) An individual is eligible for Part D if he or she:

(i) Is entitled to Medicare benefits under Part A or enrolled in Medicare Part B; and

(ii) Lives in the service area of a Part D plan, as defined under § 423.4.

(2) Except as provided in paragraphs (b), (c), and (d) of this section, an individual is eligible to enroll in a PDP if:

(i) The individual is eligible for Part D in accordance with paragraph (a)(1) of this section;

(ii) The individual resides in the PDP's service area; and

(iii) The individual is not enrolled in another Part D plan.

(3) Retroactive Part A or Part B determinations. Individuals who become entitled to Medicare Part A or enrolled in Medicare Part B for a retroactive effective date are Part D eligible as of the month in which a notice of entitlement Part A or enrollment in Part B is provided.

(b) *Coordination with MA plans.* A Part D eligible individual enrolled in a MA-PD plan must obtain qualified prescription drug coverage through that plan. MA enrollees are not eligible to enroll in a PDP, except as follows:

(1) A Part D eligible individual is eligible to enroll in a PDP if the individual is enrolled in a MA private fee-for-service plan (as defined in section 1859(b)(2) of the Act) that does not provide qualified prescription drug coverage; and

(2) A Part D eligible individual is eligible to enroll in a PDP if the individual is enrolled in a MSA plan (as defined in section 1859(b)(3) of the Act).

(c) *Enrollment in a PACE plan.* A Part D eligible individual enrolled in a PACE plan that offers qualified prescription drug coverage under this Part must obtain such coverage through that plan.

(d) *Enrollment in a cost-based HMO or CMP.* A Part D eligible individual enrolled in a cost-based HMO or CMP (as defined under part 417 of this chapter) that elects to receive qualified prescription drug coverage under such plan is ineligible to enroll in another Part D plan. A Part D eligible individual enrolled in a cost-based HMO or CMP offering qualified prescription drug coverage is eligible to enroll in a PDP if the individual does not elect to receive qualified prescription drug coverage under the cost-based HMO or CMP and otherwise meets the requirements of paragraph (a)(2) of this section.

§ 423.32 Enrollment process.

(a) *General rule.* A Part D eligible individual who wishes to enroll in a PDP may enroll during the enrollment periods specified in § 423.38, by filing the appropriate enrollment form with the PDP or through other mechanisms CMS determines are appropriate.

(b) *Enrollment form or CMS-approved enrollment mechanism.* The enrollment form or CMS-approved enrollment mechanism must comply with CMS instructions regarding content and format and must have been approved by CMS as described in § 423.50.

(i) The enrollment must be completed by the individual and include an acknowledgement by the beneficiary for disclosure and exchange of necessary information between the U.S. Department of Health and Human Services (or its designees) and the PDP sponsor. Individuals who assist beneficiaries in completing the enrollment, including authorized representatives, must indicate they have provided assistance and their relationship to the beneficiary.

(ii) Part D eligible individuals enrolling or enrolled in a Part D plan must provide information regarding reimbursement for Part D costs through other insurance, group health plan or other third-party payment arrangement, and consent to the release of the information provided by the individual on other insurance, group health plan or other third-party payment arrangements, as well as any other information on reimbursement of Part D costs collected or obtained from other sources, in a form and manner approved by CMS.

(c) *Timely process an individual's enrollment request.* A PDP sponsor must timely process an individual's enrollment request in accordance with CMS enrollment guidelines and enroll Part D eligible individuals who are eligible to enroll in its plan under § 423.30(a) and who elect to enroll or are enrolled in the plan during the periods specified in § 423.38.

(d) *Notice requirement.* The PDP sponsor must provide the individual with prompt notice of acceptance or denial of the individual's enrollment request, in a format and manner specified by CMS.

(e) *Maintenance of enrollment.* An individual who is

enrolled in a PDP remains enrolled in that PDP until one of the following occurs:

(i) The individual successfully enrolls in another PDP or MA-PD plan;

(ii) The individual voluntarily disenrolls from the PDP;

(iii) The individual is involuntary disenrolled from the PDP in accordance with § 423.44(b)(2);

(iv) The PDP is discontinued within the area in which the individual resides; or

(iv) The individual is enrolled after the initial enrollment, in accordance with § 423.34(c).

(f) *Enrollees of cost-based HMOs or CMPs and PACE*. Individuals enrolled in a cost-based HMO or CMP plan (as defined in part 417 of this chapter) or PACE (as defined in § 460.6 of this chapter) that offers prescription drug coverage under this part as of December 31, 2005, remain enrolled in that plan as of January 1, 2006, and receive Part D benefits offered by that plan until one of the conditions in § 423.32(e) are met.

§ 423.34 Enrollment of full-benefit dual eligible individuals.

(a) *General rule*. CMS must ensure the enrollment into Part D plans full-benefit dual eligible individuals who fail to enroll in a Part D plan.

(b) *Definition of full-benefit dual eligible individual*. For purposes of this section, a full-benefit dual eligible individual means an individual who is:

(1) Determined eligible by the State for—

(i) Medical assistance for full-benefits under title XIX of the Act for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. ; or

(ii) Medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) for any month if the individual was eligible for medical assistance in any part of the month.

(2) Eligible for Part D in accordance with § 423.30(a).

(c) *Enrolling a full-benefit duel eligible individual*. Notwithstanding § 423.32(e), during the annual coordinated election period, CMS may enroll a full-benefit dual eligible individual in another PDP if CMS determines that the further enrollment is warranted.

(d) *Automatic enrollment rules*. (1) *General rule*. CMS must automatically enroll full-benefit dual eligible individuals who fail to enroll in a Part D plan into a PDP offering basic prescription drug coverage in the area where the individual resides that has a monthly beneficiary premium that does not exceed the low-income premium subsidy amount (as defined in § 423.780(b)). In the event that there is more than one PDP in an area with a monthly beneficiary premium at or below the low-income premium subsidy amount, individuals must be enrolled in such PDPs on a random basis.

(2) Individuals enrolled in an MSA plan or one of the following that does not offer a Part D benefit. Full-benefit dual eligible individuals enrolled in an MA Private Fee For Service (PFFS) plan or cost-based HMO or CMP that does not offer qualified prescription drug coverage or an MSA plan and who fail to enroll in a Part D plan must be automatically enrolled into a PDP plan as described in paragraph (d)(1) of this section.

(e) *Declining enrollment and disenrollment*. Nothing in this section prevents a full-benefit dual eligible individual from—

(1) Affirmatively declining enrollment in Part D; or

(2) Disenrolling from the Part D plan in which the individual is enrolled and electing to enroll in another Part D plan during the special enrollment period provided under § 423.38.

(f) *Effective date of enrollment*. Enrollment of full-benefit dual eligible individuals under this section must be effective as follows:

(1) January 1, 2006 for individuals who are full-benefit dual eligible individuals as of December 31, 2005;

(2) The first day of the month the individual is eligible for Part D under § 423.30(a)(1) for individuals who are Medicaid eligible and subsequently become newly eligible for Part D under § 423.30(a)(1) on or after January 1, 2006; and

(3) For individuals who are eligible for Part D under § 423.30(a)(1) and subsequently become newly eligible for Medicaid on or after January 1, 2006, enrollment is effective as soon as practicable after being identified as a newly full-benefit dual eligible individual, in a process to be determined by CMS.

§ 423.36 Disenrollment process.

(a) *General rule*. An individual may disenroll from a PDP during the periods specified in § 423.38 by enrolling in a different PDP plan, submitting a disenrollment request to the PDP in the form and manner prescribed by CMS, or filing the appropriate disenrollment request through other mechanisms as determined by CMS.

(b) *Responsibilities of the PDP sponsor*. The PDP sponsor must—

(1) Submit a disenrollment notice to CMS within timeframes CMS specifies;

(2) Provide the enrollee with a notice of disenrollment as CMS determines and approves; and

(3) File and retain disenrollment requests for the period specified in CMS instructions.

(c) *Retroactive disenrollment*. CMS may grant retroactive disenrollment in the following cases:

(1) There never was a legally valid enrollment; or

(2) A valid request for disenrollment was properly made but not processed or acted upon.

§ 423.38 Enrollment periods.

(a) *Initial enrollment period for Part D—Basic rule*. The initial enrollment period is the period during which an individual is first eligible to enroll in a Part D plan.

(1) *In 2005*. An individual who is first eligible to enroll in a Part D plan on or prior to January 31, 2006, has an initial enrollment period from November 15, 2005 through May 15, 2006.

(2) *February 2006*. An individual who is first eligible to enroll in a Part D plan in February 2006 has an initial enrollment period from November 15, 2005 through May 31, 2006.

(3) *March 2006 and subsequent months*. (i) Except as provided in paragraph (a)(3)(ii) and (a)(3)(iii) of this section, the initial enrollment period for an individual who is first eligible to enroll in a Part D plan on or after March 2006 is the same as the initial enrollment period for Medicare Part B under § 407.14 of this chapter.

(ii) Exception. For those individuals who are not eligible to enroll in a Part D plan at any time during their initial enrollment period for Medicare Part B, their initial enrollment period under this Part is the 3 months before becoming eligible for Part D, the month of eligibility, and the three months following eligibility to Part D.

(iii) An individual who becomes entitled to Medicare Part A or enrolled in Part B for a retroactive effective date has an initial enrollment period under this Part beginning with the month in which notification of the Medicare determination is received and ending on the last day of the third month following the month in which the notification was received.

(b) *Annual coordinated election period*. (1) *For 2006*. This period begins on November 15, 2005 and ends on May 15, 2006.

(2) *For 2007 and subsequent years*. For coverage beginning 2007 or any subsequent year, the annual coordinated election period is November 15th through December 31st for coverage beginning the following calendar year.

(c) *Special enrollment periods*. A Part D eligible individual may enroll in a PDP or disenroll from a PDP and enroll

in another PDP or MA-PD plan (as provided at § 422.62(b) of this chapter), as applicable, at any time under any of the following circumstances:

(1) The individual involuntarily loses creditable prescription drug coverage or such coverage is involuntarily reduced so that it is no longer creditable coverage as defined under § 423.56(a). Loss of credible prescription drug coverage due to failure to pay any required premium is not considered involuntary loss of the coverage.

(2) The individual was not adequately informed, as required by standards established by CMS under § 423.56, that he or she has lost his or her creditable prescription drug coverage, that he or she never had credible prescription drug coverage, or the coverage is involuntarily reduced so that it is no longer creditable prescription drug coverage.

(3) The individual's enrollment or non-enrollment in a Part D plan is unintentional, inadvertent, or erroneous because of the error, misrepresentation, or inaction of a Federal employee, or any person authorized by the Federal government to act on its behalf.

(4) The individual is a full-benefit dual eligible individual as defined under section 1935(c)(6) of the Act.

(5) The individual elects to disenroll from a MA-PD plan and elects coverage under Medicare Part A and Part B in accordance with § 422.62(c) of this chapter.

(6) The PDP sponsor's contract is terminated by the PDP sponsor or by CMS, as provided under § 423.507 through § 423.510, or the PDP plan is no longer offered in the area when the individual resides.

(7) The individual is no longer eligible for the PDP because of a change in his or her place of residence to a location outside of the PDP region(s) in which the PDP is offered.

(8) The individual demonstrates to CMS, in accordance with guidelines issued by CMS, that—

(i) The PDP sponsor offering the PDP substantially violated a material provision of its contract under this part in relation to the individual, including, but not limited to the following—

(A) Failure to provide the individual on a timely basis benefits available under the plan;

(B) Failure to provide benefits in accordance with applicable quality standards; or

(C) The PDP (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in marketing the plan to the individual.

(ii) The individual meets other exceptional circumstances as CMS may provide.

§ 423.40 Effective dates.

(a) *Initial enrollment period.* (1) An enrollment made prior to the month of entitlement to Part A or enrollment in Part B is effective the first day of the month the individual is entitled to or enrolled in Part A or enrolled in Part B.

(2) Except as otherwise provided under § 423.34(f), an enrollment made during or after the month of entitlement to Part A or enrollment in Part B is effective the first day of the calendar month following the month in which the enrollment in Part D is made.

(3) If the individual is not eligible to enroll in Part D on the first day of the calendar month following the month in which the election to enroll in Part D is made, the enrollment in Part D is effective the first day of the month the individual is eligible for Part D.

(4) In no case is an enrollment in Part D effective before January 1, 2006 or before entitlement to Part A or enrollment Part B.

(b) *Annual coordinated election periods.* (1) *General rule.* Except as provided under paragraph (b)(2) of this section, for an enrollment or change of enrollment in Part D made during an annual coordinated election period as described in § 423.38(b), the coverage or change in coverage is effective as of the first day of the following calendar year.

(2) *Exception for January 1, 2006 through May 15, 2006.* Enrollment elections made during the annual coordinated election period between January 1, 2006 and May 15, 2006 are effective the first day of the calendar month following the month in which the enrollment in Part D is made.

(c) *Special enrollment periods.* For an enrollment or change of enrollment in Part D made during a special enrollment period specified in § 423.38(c), the effective date is determined by CMS, which, to the extent practicable, is determined in a manner consistent with protecting the continuity of health benefits coverage.

§ 423.44 Involuntary disenrollment by the PDP.

(a) *General rule.* Except as provided in paragraphs (b) through (d) of this section, a PDP sponsor may not—

(1) Involuntarily disenroll an individual from any PDP it offers; or

(2) Orally or in writing, or by any action or inaction, request or encourage an individual to disenroll.

(b) *Basis for disenrollment.* (1) *Optional involuntary disenrollment.* A PDP sponsor may disenroll an individual from a PDP it offers in any of the following circumstances:

(i) Any monthly premium is not paid on a timely basis, as specified under paragraph (d)(1) of this section; or

(ii) The individual has engaged in disruptive behavior, as specified under paragraph (d)(2) of this section.

(2) *Required involuntary disenrollment.* A PDP sponsor must disenroll an individual from a PDP it offers in any of the following circumstances:

(i) The individual no longer resides in the PDP's service area.

(ii) The individual loses eligibility for Part D.

(iii) Death of the individual.

(iv) The PDP sponsor's contract is terminated by CMS

or by a PDP or through mutual consent. The PDP sponsor must disenroll affected enrollees in accordance with the procedures for disenrollment set forth at § 423.507 through § 423.510.

(v) The individual materially misrepresents

information, as determined by CMS, to the PDP sponsor that the individual has or expects to receive reimbursement for third-party coverage.

(c) *Notice requirement.* (1) If the disenrollment is for any of the reasons specified in paragraphs (b)(1), (b)(2)(i), or (b)(2)(iv) of this section (that is, other than death or loss of Part D eligibility, the PDP sponsor must give the individual timely notice of the disenrollment with an explanation of why the PDP is planning to disenroll the individual.

(2) Notices for reasons specified in paragraphs (b)(1) through (b)(2)(i) and (b)(2)(iii) of this section must—

(i) Be provided to the individual before submission of the disenrollment notice to CMS; and

(ii) Include an explanation of the individual's right to file a grievance under the PDP's grievance procedures.

(d) *Process for disenrollment.* (1) *Monthly PDP premiums that are not paid timely.* A PDP sponsor may disenroll an individual from the PDP for failure to pay any monthly premium under the following circumstances:

(i) The PDP sponsor can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount.

(ii) The PDP sponsor gives the enrollee notice of

disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) Reenrollment in the PDP. If an individual is

disenrolled from the PDP for failure to pay monthly PDP premiums, the PDP

sponsor has the option to decline future enrollment by the individual in any of its PDPs until the individual has paid any past premiums due to the PDP sponsor.

(2) *Disruptive behavior.* (i) *Definition.* A PDP enrollee is disruptive if his or her behavior substantially impairs the plans ability to arrange or provide for services to the individual or other plan members. An individual cannot be considered disruptive if the behavior is related to the use of medical services or compliance (or noncompliance) with medical advice or treatment.

(ii) *Basis of disenrollment for disruptive behavior.* A PDP may disenroll an individual whose behavior is disruptive as defined in § 423.44(d)(2)(i) only after the PDP sponsor meets the requirements described in this section and after CMS has reviewed and approved the request.

(iii) *Effort to resolve the problem.* The PDP sponsor must make a serious effort to resolve the problems presented by the individual, including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness, Alzheimers disease, and developmental disabilities. In addition, the PDP sponsor must inform the individual of the right to use the PDP's grievance procedures. The individual has a right to submit any information or explanation that he or she may wish to the PDP.

(iv) *Documentation.* The PDP sponsor must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraph (d)(2)(iii) of this section, and any extenuating circumstances. The PDP sponsor may request from CMS the ability to decline future enrollment by the individual. The PDP sponsor must submit this information and any documentation received by the individual to CMS.

(v) *CMS review of the proposed disenrollment.* CMS reviews the information submitted by the PDP sponsor and any information submitted by the individual (which the PDP sponsor has submitted to CMS) to determine if the PDP sponsor has fulfilled the requirements to request disenrollment for disruptive behavior. If the PDP sponsor has fulfilled the necessary requirements, CMS reviews the information and make a decision to approve or deny the request for disenrollment, including conditions on future enrollment, within 20 working days. During the review, CMS ensures that staff with appropriate clinical or medical expertise reviews the case before making a final decision. The PDP sponsor is required to provide a reasonable accommodation, as determined by CMS, for the individual in exceptional circumstances that CMS deems necessary. CMS notifies the PDP sponsor within 5 working days after making its decision.

(vi) *Exception for fallback prescription drug plans.* CMS reserves the right to deny a request from a fallback prescription drug plan as defined in § 423.855 to disenroll an individual for disruptive behavior.

(vii) *Effective date of disenrollment.* If CMS permits a PDP to disenroll an individual for disruptive behavior, the termination is effective the first day of the calendar month after the month in which the PDP gives the individual written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(3) *Loss of Part D eligiblity.* If an individual is no longer eligible for Part D, CMS notifies the PDP that the disenrollment is effective the first day of the calendar month following the last month of Part D eligibility.

(4) *Death of the individual.* If the individual dies,

disenrollment is effective the first day of the calendar month following the month of death.

(5) *Individual no longer resides in the PDP service area—Basis for disenrollment.* The PDP must disenroll an individual if the individual notifies the PDP that he or she has permanently moved out of the PDP service area.

(6) *Plan termination.* (i) When a PDP contract terminates as provided in § 423.507 through § 423.510, the PDP sponsor must give each affected PDP enrollee notice of the effective date of the plan termination and a description of alternatives for obtaining prescription drug coverage under Part D, as specified by CMS.

(ii) The notice must be sent before the effective date of the plan termination or area reduction, and in the timeframes specified by CMS.

(7) *Misrepresentation of third-party reimbursement.*

(i) If CMS determines an individual has materially misrepresented information to the PDP sponsor as described under § 423.44(b)(2)(v), the termination is effective the first day of the calendar month after the month in which the PDP sponsor gives the individual written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(ii) *Reenrollment in the PDP.* Once an individual is disenrolled from the PDP for misrepresentation of third party reimbursement, the PDP sponsor has the option to decline future enrollment by the individual in any of its PDPs for a period of time CMS specifies.

§ 423.46 Late enrollment penalty.

(a) *General.* A Part D eligible individual must pay the late penalty described under § 423.286(d)(3) if there is a continuous period of 63 days or longer at any time after the end of the individual's initial enrollment period during which the individual meets all of the following conditions:

(1) The individual was eligible to enroll in a Part D plan;

(2) The individual was not covered under any

creditable prescription drug coverage; and

(3) The individual was not enrolled in a Part D plan.

(b) [Reserved]

§ 423.48 Information about Part D.

Each Part D plan must provide, on an annual basis, and in a format and using standard terminology that CMS may specify in guidance, the information necessary to enable CMS to provide to current and potential Part D eligible individuals the information they need to make informed decisions among the available choices for Part D coverage.

§ 423.50 Approval of marketing materials and enrollment forms.

(a) *CMS review of marketing materials.* (1) Except as provided in paragraph (a)(2) and (a)(3) of this section, a Part D plan may not distribute any marketing materials (as defined in paragraph (b) of this section), or enrollment forms, or make such materials or forms available to Part D eligible individuals, unless—

(i) At least 45 days (or 10 days if using certain types of marketing materials that use, without modification, proposed model language as specified by CMS) before the date of distribution, the Part D sponsor submits the material or form to CMS for review under the guidelines in paragraph (c) of this section; and

(ii) CMS does not disapprove the distribution of the material or form.

(2) If the Part D sponsor is deemed by CMS to meet certain performance requirements established by CMS, the Part D sponsor may distribute designated marketing materials 5 days following their submission to CMS.

(3) Prior to distribution, the Part D sponsor submits and certifies that for certain types of marketing materials it followed all applicable marketing guidelines, or for certain other marketing materials that it used, without modification, proposed model language as specified by CMS.

(b) *Definition of marketing materials.* Marketing materials include any

informational materials targeted to Medicare beneficiaries which—

(1) Promote the Part D plan.

(2) Inform Medicare beneficiaries that they may enroll, or remain enrolled in a Part D plan.

(3) Explain the benefits of enrollment in a Part D plan, or rules that apply to enrollees.

(4) Explain how Medicare services are covered under a Part D plan, including conditions that apply to such coverage.

(c) *Examples of marketing materials*. Examples of marketing materials include, but are not limited to—

(1) General audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the Internet.

(2) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.

(3) Presentation materials such as slides and charts.

(4) Promotional materials such as brochures or leaflets, including materials for circulation by third parties (for example, physicians or other providers).

(5) Membership communication materials such as membership rules, subscriber agreements, member handbooks and wallet card instructions to enrollees.

(6) Letters to members about contractual changes; changes in providers, premiums, benefits, plan procedures etc.

(7) Membership or claims processing activities.

(d) *Guidelines for CMS review*. In reviewing marketing material or enrollment forms under paragraph (a) of this section, CMS determines (unless otherwise specified in additional guidance) that the marketing materials—

(1) Provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling—

(i) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges.

(ii) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each.

(iii) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(2) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service area.

(3) Include in the written materials notice that the Part D plan is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the Part D plan. In addition, the Part D plan may reduce its service area and no longer be offered in the area where a beneficiary resides.

(4) Are not materially inaccurate or misleading or otherwise make material misrepresentations.

(5) For markets with a significant non-English speaking population, provide materials in the language of these individuals.

(e) *Deemed approval*. If CMS has not disapproved the distribution of a marketing materials or form submitted by a Part D sponsor for a Part D plan in a Part D region, CMS is deemed to not have disapproved the distribution of the marketing material or form in all other Part D regions covered by the Part D plan, with the exception of any portion of the material or form that is specific to the Part D region.

(f) *Standards for Part D marketing*. (1) In conducting

marketing activities, a Part D plan may not—

(i) Provide for cash or other remuneration as an inducement for enrollment or otherwise. This does not prohibit explanation of any legitimate benefits the beneficiary might obtain as an enrollee of the Part D plan.

(ii) Engage in any discriminatory activity such as, including targeted marketing to Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(iii) Solicit Medicare beneficiaries door-to-door.

(iv) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the Part D sponsor or its Part D plan. The Part D organization may not claim that it is recommended or endorsed by CMS or Medicare or the Department of Health and Human Services or that CMS or Medicare or the Department of Health and Human Services recommends that the beneficiary enroll in the Part D plan. The Part D organization may explain that the organization is approved for participation in Medicare.

(v) Use providers, provider groups, or pharmacies to distribute printed information comparing the benefits of different Part D plans unless providers, provider groups or pharmacies accept and display materials from all Part D plan sponsors.

(vi) Accept Part D plan enrollment forms in provider offices, pharmacies or other places where health care is delivered.

(vii) Employ Part D plan names that suggest that a plan is not available to all Medicare beneficiaries.

(viii) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

(2) In its marketing, the Part D organization must—

(i) Demonstrate to CMS's satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(ii) Establish and maintain a system for confirming that enrolled beneficiaries have in fact enrolled in the PDP and understand the rules applicable under the plan.

§ 423.56 Procedures to determine and document creditable status of prescription drug coverage.

(a) *Definition*. Creditable prescription drug coverage means any of the following types of coverage listed in paragraph (b) of this section only if the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage as demonstrated through the use of generally accepted actuarial principles and in accordance with CMS actuarial guidelines.

(b) *Types of coverage*. The following coverage is considered creditable if it meets the definition provided in paragraph (a) of this section:

(1) Prescription drug coverage under a PDP or MA-PD plan.

(2) Medicaid coverage under title XIX of the Act or under a waiver under section 1115 of the Act.

(3) Coverage under a group health plan, including the Federal employees health benefits program, and qualified retiree prescription drug plans as defined in section 1860D–22(a)(2) of the Act.

(4) Coverage under State Pharmaceutical

Assistance Programs (SPAP) as defined at § 423.454.

(5) Coverage of prescription drugs for veterans, survivors and dependents under chapter 17 of title 38, U.S.C.

(6) Coverage under a Medicare supplemental policy (Medigap policy) as defined at § 423.205.

(7) Military coverage under chapter 55 of title 10,

U.S.C., including TRICARE.

(8) Individual health insurance coverage (as defined in section 2791(b)(5) of the Public Health Service Act) that includes coverage for

outpatient prescription drugs and that does not meet the definition of an excepted benefit (as defined in section 2791(c) of the Public Health Service Act).

(9) Coverage provided by the medical care program of the Indian Health Service, Tribe or Tribal organization, or Urban Indian organization (I/T/U).

(10) Coverage provided by a PACE organization.

(11) Coverage provided by a cost-based HMO or CMP under part 417 of this chapter.

(12) Coverage provided through a State High-Risk Pool as defined under 42 CFR 146.113(a)(1)(vii).

(13) Other coverage as the Secretary may determine appropriate.

(c) *General disclosure requirements*. With the exception of PDPs and MA-PD plans under § 423.56(b)(1) and PACE or cost-based HMO or CMP that provide qualified prescription drug coverage under this Part, each entity that offers prescription drug coverage under any of the types described in § 423.56(b), must disclose to all Part D eligible individuals enrolled in or seeking to enroll in the coverage whether the coverage is creditable prescription drug coverage.

(d) *Disclosure of non-creditable coverage*. In the case that the coverage of the type described in § 423.56(b) is not creditable prescription drug, the disclosure described in paragraph (c) of this section to Part D eligible individuals must also include:

(1) The fact that the coverage is not creditable prescription drug coverage, as provided by CMS;

(2) That there are limitations on the periods in a year in which the individual may enroll in Part D plans; and

(3) That the individual may be subject to a late enrollment penalty, as described under § 423.46.

(e) *Disclosure to CMS*. With the exception of PDPs and MA-PD plans under § 423.56(b)(1) and PACE or cost-based HMO or CMP that provide qualified prescription drug coverage under this Part, all other entities listed under paragraph (b) of this section must disclose whether the coverage they provide is creditable prescription drug coverage to CMS in a form and manner described by CMS.

(f) *Notification content and timing requirements*. The disclosure notification to Part-D eligible individuals required in § 423.56(c) and (d) must be provided in a form and manner prescribed by CMS. Notices must be provided, at minimum, at the following times:

(1) Prior to an individual's initial enrollment period for Part D, as described under § 423.38(a);

(2) Prior to the effective date of enrollment in the prescription drug coverage and upon any change that affects whether the coverage is creditable prescription drug coverage;

(3) Prior to the commencement of the Annual Coordinated Election Period that begins on November 15 of each year, as defined in § 423.38(b); and

(4) Upon request by the individual.

(g) *When an individual is not adequately informed of coverage*. If an individual establishes to CMS that he or she was not adequately informed that his or her prescription drug coverage was not creditable prescription drug coverage, the individual may apply to CMS to have the coverage treated as creditable prescription drug coverage for purposes of applying the late penalty described in § 423.46.

Subpart C—Benefits and Beneficiary Protections.

§ 423.100 Definitions.

As used in this part, unless otherwise specified-

Actual cost means the negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out-of-network pharmacy consistent with § 423.124(a).

Affected enrollee means a Part D enrollee who is currently taking a covered Part D drug that is either being removed from a Part D plan's formulary, or whose preferred or tiered cost-sharing status is changing.

Alternative prescription drug coverage means coverage of Part D drugs, other than standard prescription drug coverage that meets the requirements of § 423.104(e). The term alternative prescription drug coverage must be either—

(1) *Basic alternative coverage* (alternative coverage that is actuarially equivalent to defined standard coverage, as determined through processes and methods established under § 423.265(d)(2)); or

(2) *Enhanced alternative coverage* (alternative coverage that meets the requirements of § 423.104(f)(1)).

Basic prescription drug coverage means coverage of Part D drugs that is either standard prescription drug coverage or basic alternative coverage.

Bioequivalent has the meaning given such term in section 505(j)(8) of the Food, Drug, and Cosmetic Act.

Contracted pharmacy network means pharmacies, including retail, mail-order, and institutional pharmacies, under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to Part D enrollees.

Covered Part D drug means a Part D drug that is included in a Part D plan's formulary, or treated as being included in a Part D plan's formulary as a result of a coverage determination or appeal under § 423.566, § 423.580, and § 423.600, § 423.610, § 423,620, and § 423.630, and obtained at a network pharmacy or an out-of-network pharmacy in accordance with § 423.124.

Dispensing fees means costs that-

(1) Are incurred at the point of sale and pay for costs in excess of the ingredient cost of a covered Part D drug each time a covered Part D drug is dispensed;

(2) Include only pharmacy costs associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee. Pharmacy costs include, but are not limited to, any reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing quality assurance activities consistent with § 423.153(c)(2), measurement or mixing of the covered Part D drug, filling the container, physically providing the completed prescription to the Part D enrollee, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy. In the case of pharmacies owned and operated by a Part D plan itself, notwithstanding number (3) of this definition, dispensing fees are understood to be the equivalent of all reasonable costs discussed in the previous sentence, including the salaries of pharmacists and other pharmacy workers as well as the costs associated with maintaining the pharmacy facility and equipment necessary to operate the pharmacy; and

(3) Do not include administrative costs incurred by the Part D plan in the operation of the Part D benefit, including systems costs for interfacing with pharmacies.

Government-funded health program means any program established, maintained, or funded, in whole or in part, by the Government of the United States, by the government of any State or political subdivision of a State, or by any agency or instrumentality of any of the foregoing, which uses public funds, in whole or in part, to provide to, or pay on behalf of, an individual the cost of Part D drugs, including any of the following:

(1) An approved State child health plan under title XXI of the Act

providing benefits for child health assistance that meets the requirements of section 2103 of the Act;

(2) The Medicaid program under title XIX of the Act or a waiver under section 1115 of the Act;

(3) The veterans' health care program under Chapter 17 of title 38 of the United States Code;

(4) The Indian Health Service program under the Indian Health Care Improvement Act under Chapter 18 of title 25 of the United States Code; and

(5) Any other government-funded program whose principal activity is the direct provision of health care to persons.

Group health plan, for purposes of applying the definition of incurred costs in § 423.100, has the meaning given such term in 29 U.S.C. 1167(1), but specifically excludes a personal health savings vehicle, as used in this subpart.

Incurred costs means costs incurred by a Part D enrollee for covered Part D drugs —

(1) That are not paid for under the Part D plan as a result of application of any annual deductible or other cost-sharing rules for covered Part D drugs prior to the Part D enrollee satisfying the out-of-pocket threshold under § 423.104(d)(5)(iii), including any price differential for which the Part D enrollee is responsible under § 423.124(b); and

(2) That are paid for—

(i) By the Part D enrollee or on behalf of the Part D enrollee by another person, and the Part D enrollee (or person paying on behalf of the Part D enrollee) is not reimbursed through insurance or otherwise, a group health plan, or other third party payment arrangement, or the person paying on behalf of the Part D enrollee is not paying under insurance or otherwise, a group health plan, or third party payment arrangement;

(ii) Under a State Pharmaceutical Assistance Program (as defined in § 423.454); or

(iii) Under § 423.782.

Insurance means a health plan that provides, or pays the cost of Part D drugs, including, but not limited to, any of the following:

(1) Health insurance coverage (as defined in 42 U.S.C. 300gg–91(b)(1));

(2) A Medicare Advantage plan (as described under section 1851(a)(2) of the Act); and

(3) A PACE organization (as defined under sections 1894(a)(3) and 1934(a)(13) of the Act)

but specifically excluding a personal health savings vehicle.

I/T/U pharmacy means a pharmacy operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603.

Long-term care facility means a skilled nursing facility as defined in section 1819(a) of the Act, or a medical institution or nursing facility for which payment is made for an institutionalized individual under section 1902(q)(1)(B) of the Act.

Long-term care pharmacy means a pharmacy owned by or under contract with a long-term care facility to provide prescription drugs to the facility's residents.

Long-term care network pharmacy means a long-term care pharmacy that is a network pharmacy.

Negotiated prices means prices for covered Part D drugs that-

(1) Are available to beneficiaries at the point of sale at network pharmacies;

(2) Are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remunerations that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale; and

(3) Includes any dispensing fees.

Network pharmacy means a licensed pharmacy that is under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to its Part D plan enrollees.

Non-preferred pharmacy means a network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at higher cost-sharing levels than apply at a preferred pharmacy.

Or otherwise means through a government-funded health program.

Out-of-network pharmacy means a licensed pharmacy that is not under contract with a Part D sponsor to provide negotiated prices to Part D plan enrollees.

Part D drug means—

(1) Unless excluded under number (2) of this definition, any of the following if used for a medically accepted indication (as defined in section 1927(k)(6) of the Act)—

(i) A drug that may be dispensed only upon a prescription and that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act;

(ii) A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act;

(iii) Insulin described in section 1927(k)(2)(C) of the Act;

(iv) Medical supplies associated with the injection of insulin, including syringes, needles, alcohol swabs, and gauze; or

(v) A vaccine licensed under section 351 of the Public Health Service Act.

(2) Does not include—

(i) Drugs for which payment as so prescribed and dispensed or administered to an individual is available for that individual under Part A or Part B (even though a deductible may apply, or even though the individual is eligible for coverage under Part A or Part B but has declined to enroll in Part A or Part B); and

(ii) Drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents.

Person means a natural person, corporation, mutual company, unincorporated association, partnership, joint venture, limited liability company, trust, estate, foundation, not-for-profit corporation, unincorporated organization, government or governmental subdivision or agency.

Personal health savings vehicle means a vehicle through which individuals can set aside their own funds to pay for health care expenses, including covered Part D drugs, on a tax-free basis including any of the following—

(1) A Health Savings Account (as defined under section 220 of the Internal Revenue Code);

(2) A Flexible Spending Account (as defined in section 106(c)(2) of the Internal Revenue Code) offered in conjunction with a cafeteria plan under section 125 of the Internal Revenue Code; and

(3) An Archer Medical Savings Account (as defined under section 223 of the Internal Revenue Code);

but specifically excluding a Health Reimbursement Arrangement (as described under Internal Revenue Ruling 2002–41 and Internal Revenue Notice 2002–45)

Plan allowance means the amount Part D plans that offer coverage other than defined standard coverage may use to determine their payment and Part D enrollees' cost-sharing for covered Part D drugs purchased at an out-of-network pharmacy or in a physician's office in accordance with the requirements of § 423.124(b).

Preferred drug means a covered Part D drug on a Part D plan's formulary for which beneficiary cost-sharing is lower than for a non-preferred drug in the plan's formulary.

Preferred pharmacy means a network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at lower levels of cost-sharing than apply at a non-preferred pharmacy under its pharmacy network contract with a Part D plan.

Qualified prescription drug coverage means any standard prescription drug coverage or alternative prescription drug coverage

Retail pharmacy means any licensed pharmacy that is not a mail order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.

Required prescription drug coverage means coverage of Part D drugs under an MA-PD plan that consists of either—

(1) Basic prescription drug coverage; or

(2) Enhanced alternative coverage, provided there is no MA monthly supplemental beneficiary premium (as defined under section 1854(b)(2)(C) of the Act) applied under the plan due to the application of a credit against the premium of a rebate under § 422.266(b) of this chapter.

Rural means a five-digit ZIP code in which the population density is less than 1,000 individuals per square mile.

Standard prescription drug coverage means coverage of Part D drugs that meets the requirements of § 423.104(d). The term standard prescription drug coverage must be either—

(1) *Defined standard coverage* (standard prescription drug coverage that provides for cost-sharing as described in § 423.104(d)(2)(i)(A) and (d)(5)(i)); or

(2) *Actuarially equivalent standard coverage* (standard prescription drug coverage that provides for cost-sharing as described in § 423.104(d)(2)(i)(B) or cost-sharing as described in § 423.104(d)(5)(ii), or both).

Suburban means a five-digit ZIP code in which the population density is between 1,000 and 3,000 individuals per square mile.

Supplemental benefits means benefits that meet the requirements of § 423.104(f)(1)(ii).

Therapeutically equivalent refers to drugs that are rated as therapeutic equivalents under the Food and Drug Administration's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations.''

Third party payment arrangement means any contractual or similar arrangement under which a person has a legal obligation to pay for covered Part D drugs.

Urban means a five-digit ZIP code in which the population density is greater than 3,000 individuals per square mile.

Usual and customary (U&C) price means the price that an out-of-network pharmacy or a physician's office charges a customer who does not have any form of prescription drug coverage for a covered Part D drug.

§ 423.104 Requirements related to qualified prescription drug coverage.

(a) *General*. Subject to the conditions and limitations set forth in this subpart, a Part D sponsor must provide enrollees with coverage of the benefits described in paragraph (c) of this section. The benefits may be provided directly by the Part D sponsor or through arrangements with other entities. CMS reviews and approves these benefits consistent with § 423.272, and using written policy guidelines and requirements in this part and other CMS instructions.

(b) *Availability of prescription drug plans*. A PDP sponsor offering a prescription drug plan must offer that plan to all Part D eligible beneficiaries residing in the plan's service area.

(c) *Types of benefits*. The coverage provided by a Part D plan must be qualified prescription drug coverage.

(d) *Standard prescription drug coverage*. Standard prescription drug coverage includes access to negotiated prices as described under paragraph (g)(1) of this section, provides coverage of Part D drugs, and must meet the following requirements

(1) *Deductible*. An annual deductible equal to—

(i) *For 2006*. $250; or

(ii) *For years subsequent to 2006*. The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of $5.

(2) *Cost-sharing under the initial coverage limit*.

(i) *25 Percent coinsurance*. Coinsurance for actual costs for covered Part D drugs covered under the Part D plan above the annual deductible specified in paragraph (d)(1) of this section, and up to the initial coverage limit under paragraph (d)(3) of this section, that is—

(A) Equal to 25 percent of actual cost; or

(B) Actuarially equivalent to an average expected coinsurance of no more than 25 percent of actual cost, as determined through processes and methods established under § 423.265(c) and (d).

(ii) *Tiered copayments*. A Part D plan providing actuarially equivalent standard coverage may apply tiered copayments, provided that any tiered copayments are consistent with paragraph (d)(2)(i)(B) of this section and are approved as described in § 423.272(b)(2).

(3) *Initial coverage limit*. The initial coverage limit is equal to—

(i) *For 2006*. $2,250.

(ii) *For years subsequent to 2006*. The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of $10.

(4) *Cost-sharing between the initial coverage limit and the annual out-of-pocket threshold*. Coinsurance for costs for covered Part D drugs above the initial coverage limit described in paragraph (d)(3) of this section and annual out-of-pocket threshold described in paragraph (d)(5)(iii) of this section that is equal to 100 percent of actual costs.

(5) *Protection against high out-of-pocket expenditures*. (i) After an enrollee's incurred costs exceed the annual out-of-pocket threshold described in paragraph (d)(5)(iii) of this section, cost-sharing equal to the greater of—

(A) *Copayments*. (1) In 2006, $2 for a generic drug or preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i) of the Act) and $5 for any other drug; and

(2) For subsequent years, the copayment amounts specified in this paragraph for the previous year increased by the annual percentage increase described in paragraph (d)(5)(iv) of this section and rounded to the nearest multiple of 5 cents; or

(B) *Coinsurance*. Coinsurance of five percent of actual cost.

(ii) As determined through processes and methods established under § 423.265(c) and (d), a Part D plan may substitute for cost-sharing under paragraph (d)(5)(i) of this section an amount that is actuarially equivalent to expected cost-sharing under paragraph (d)(5)(i) of this section.

(iii) *Annual out-of-pocket threshold*. For purposes of this part, the annual out-of-pocket threshold equals—

(A) *For 2006*. $3,600.

(B) *For years subsequent to 2006*. The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of $50.

(iv) *Annual percentage increase*. The annual percentage increase for each year is equal to the annual percentage increase in average per capita aggregate expenditures for Part D drugs in the United States for Part D eligible individuals and is based on data for the 12-month period ending in July of the previous year.

(e) *Alternative prescription drug coverage*. Alternative prescription drug coverage includes access to negotiated prices as described under paragraph (g)(1) of this section, provides coverage of Part D drugs, and must meet the following requirements—

(1) Has an annual deductible that does not exceed the annual deductible specified in paragraph (d)(1) of this section;

(2) Imposes cost-sharing no greater than that specified in paragraphs (d)(5)(i) or (ii) of this section once the annual out-of-pocket threshold described in paragraph (d)(5)(iii) of this section is met;

(3) Has a total or gross value that is at least equal to the total or gross value of defined standard coverage.

(4) Has an unsubsidized value that is at least equal to the unsubsidized value of standard prescription drug coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage exceeds the actuarial value of the subsidy payments under § 423.782 for the coverage; and

(5) Provides coverage that is designed, based upon an actuarially representative pattern of utilization, to provide for the payment, for costs incurred for covered Part D drugs, that are equal to the initial coverage limit under paragraph (d)(3) of this section, of an amount equal to at least the product of -

(i) The amount by which the initial coverage limit described in paragraph (d)(3) of this section for the year exceeds the deductible described in paragraph (d)(1) of this section; and

(ii) 100 percent minus the coinsurance percentage specified in paragraph (d)(2)(i) of this section.

(f) *Enhanced alternative coverage*. (1) Enhanced alternative coverage must meet the requirements under paragraph (e) of this section and includes-

(i) Basic prescription drug coverage, as defined in § 423.100; and

(ii) Supplemental benefits, which include-

(A) Coverage of drugs that are specifically excluded as Part D drugs under paragraph (2)(ii) of the definition of Part D drug under § 423.100; or

(B) Any of the following changes or combination of changes that increase the actuarial value of benefits under the Part D plan above the actuarial value of defined standard prescription drug coverage, as determined through processes and methods established under § 423.265—

(*1*) A reduction in the annual deductible described in paragraph (d)(1) of this section;

(*2*) A reduction in the cost-sharing described in paragraphs (d)(2) or (d)(5) of this section, or

(*3*) An increase in the initial coverage limit described in paragraph (d)(3) of this section.

(C) Both the coverage described in paragraph (f)(1)(ii)(A) of this section and the changes or combination of changes described in paragraph (f)(1)(ii)(B) of this section.

(2) *Restrictions on the offering of enhanced alternative coverage by PDP sponsors*. A PDP sponsor may not offer enhanced alternative coverage in a service area unless the PDP sponsor also offers a prescription drug plan in that service area that provides basic prescription drug coverage.

(3) *Restrictions on the offering of enhanced alternative coverage by MA organizations*. Effective January 1, 2006, an MA organization—

(i) May not offer an MA coordinated care plan, as defined in § 422.4 of this chapter, in an area unless either that plan (or another MA plan offered by the MA organization in that same service area) includes required prescription drug coverage; and

(ii) May not offer prescription drug coverage (other than that required under Parts A and B of title XVIII of the Act) to an enrollee—

(A) Under an MSA plan, as defined in § 422.2 of this chapter; or

(B) Under another MA plan (including a private fee-for-service plan, as defined in § 422.4 of this chapter) unless the drug coverage under the other plan provides qualified prescription drug coverage and unless the requirements of paragraph (f)(3)(i) of this section are met.

(4) *Restrictions on the offering of enhanced alternative coverage by cost plans*.

(i) A cost plan that elects to offer qualified prescription drug coverage may offer enhanced alternative coverage as an optional supplemental benefit under § 417.440(b)(2)(ii) of this chapter only if the cost plan also offers basic prescription drug coverage. An enrollee in the cost plan may, at the individual's option, elect whether to receive qualified prescription drug coverage under the cost plan and, if so, whether to receive basic prescription drug coverage or, if offered by the cost plan, enhanced alternative coverage.

(ii) A cost plan that offers qualified prescription drug coverage as an optional supplemental benefit under § 417.440(b)(2)(ii) of this chapter may not offer prescription drug coverage that is not qualified prescription drug coverage. A cost plan that does not offer qualified prescription drug coverage under § 417.440(b)(2)(ii) of this chapter may offer prescription drug coverage that is not qualified prescription drug coverage under § 417.440(b)(2)(i) of this chapter.

(g) *Negotiated prices*. (1) *Access to negotiated prices*. A Part D sponsor is required to provide its Part D enrollees with access to negotiated prices for covered Part D drugs included in its Part D plan's formulary. Negotiated prices must be provided even if no benefits are payable to the beneficiary for covered Part D drugs because of the application of any deductible or 100 percent coinsurance requirement following satisfaction of any initial coverage limit.

(2) *Interaction with Medicaid best price*. Prices negotiated with a pharmaceutical manufacturer, including discounts, subsidies, rebates, and other price concessions, for covered Part D drugs by the following entities are not taken into account in establishing Medicaid's best price under section 1927(c)(1)(C) of the Act—

(i) A Part D plan, as defined in § 423.4; or

(iii) A qualified retiree prescription drug plan (as defined in § 423.882) for Part D eligible individuals.

(3) *Disclosure*. (i) A Part D sponsor is required to disclose to CMS data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers, as well as data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers that are passed through to beneficiaries, via pharmacies and other dispensers, in the form of lower subsidies paid by CMS on behalf of low-income individuals described in § 423.782, or in the form of lower monthly beneficiary premiums or lower covered Part D drug prices at the point of sale.

(ii) Information on negotiated prices disclosed to CMS under paragraph (g)(3) of this section is protected under the confidentiality provisions applicable under section 1927(b)(3)(D) of the Act.

(4) *Audits*. CMS and the Office of the Inspector General may conduct periodic audits of the financial statements and all records of Part D sponsors pertaining to any qualified prescription drug coverage they may offer under a Part D plan.

§ 423.112 Establishment of prescription drug plan service areas.

(a) *Service area for prescription drug plans*. The service area for a prescription drug plan other than a fallback prescription drug plan consists of one or more PDP regions as established under paragraphs (b) and (c) of this section.

(b) *Establishment of PDP regions*. (1) *General*. CMS establishes PDP regions in a manner consistent with the requirements for the establishment of MA regions as described at § 422.455 of this chapter.

(2) *Relation to MA regions*. To the extent practicable, PDP regions are the same as MA regions. CMS may establish

PDP regions that are not the same as MA regions if CMS determines that the establishment of these regions improves access to prescription drug plan benefits for Part D eligible individuals.

(c) *Authority for territories.* CMS establishes a PDP region or regions for States that are not within the 50 States and the District of Columbia.

(d) *Revision of PDP regions.* CMS may revise the PDP regions established under paragraphs (b) and (c) of this section.

(e) *Regional or national plan.* Nothing in this section prevents a prescription drug plan from being offered in two or more PDP regions in their entirety or in all PDP regions in their entirety.

§ 423.120 Access to covered Part D drugs.

(a) *Assuring pharmacy access.* (1) *Standards for convenient access to network pharmacies.* Except as provided in paragraph (a)(7) of this section, a Part D plan must have a contracted pharmacy network consisting of retail pharmacies sufficient to ensure that for beneficiaries residing in each State in a prescription drug plan's service area(as defined in § 423.112(a)), each State in a regional MA-PD plan's service area (as defined in § 422.2 and § 422.455(a) of this chapter), a local MA-PD plan's service area (as defined in § 422.2 of this chapter), or a cost plan's geographic area (as defined in § 417.401 of this chapter), the following requirements are satisfied:

(i) At least 90 percent of Medicare beneficiaries, on average, in urban areas served by the Part D plan live within 2 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section;

(ii) At least 90 percent of Medicare beneficiaries, on average, in suburban areas served by the Part D plan live within 5 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section; and

(iii) At least 70 percent of Medicare beneficiaries, on average, in rural areas served by the Part D plan live within 15 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.

(2) *Applicability of some non-retail pharmacies to standards for convenient access.* Part D plans may count I/T/U pharmacies and pharmacies operated by Federally Qualified Health Centers and Rural Health Centers toward the standards for convenient access to network pharmacies in paragraph (a)(1) of this section.

(3) *Access to non-retail pharmacies.* A Part D plan's contracted pharmacy network may be supplemented by non-retail pharmacies, including pharmacies offering home delivery via mail-order and institutional pharmacies, provided the requirements of paragraph (a)(1) of this section are met.

(4) *Access to home infusion pharmacies.* A Part D plan's contracted pharmacy network must provide adequate access to home infusion pharmacies consistent with written policy guidelines and other CMS instructions.

(5) *Access to long-term care pharmacies.* A Part D plan must offer standard contracting terms and conditions, including performance and service criteria for long-term care pharmacies that CMS specifies, to all long-term care pharmacies in its service area. The plan must provide convenient access to long-term care pharmacies consistent with written policy guidelines and other CMS instructions.

(6) *Access to I/T/U pharmacies.* A Part D plan must offer standard contracting terms and conditions conforming to the model addendum that CMS develops, to all I/T/U pharmacies in its service area. The plan must provide convenient access to I/T/U pharmacies consistent with written policy guidelines and other CMS instructions.

(7) *Waiver of pharmacy access requirements.* CMS waives the requirements under paragraph (a)(1) of this section in the case of—

(i) An MA-PD plan or cost plan (as described in section 1876(h) of the Act) that provides its enrollees with access to covered Part D drugs through pharmacies owned and operated by the MA organization or cost plan, provided the organization's or plan's pharmacy network meets the access standard set forth under § 422.112 of this chapter for an MA plan, or § 417.416(e) of this chapter for a cost plan.

(ii) An MA private fee-for-service plan described in § 422.4 of this chapter that—

(A) Offers qualified prescription drug coverage; and

(B) Provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies and without charging cost-sharing in excess of that described in § 423.104(d)(2) and (d)(5).

(8) *Pharmacy network contracting requirements.* In establishing its contracted pharmacy network, a Part D sponsor offering qualified prescription drug coverage—

(i) Must contract with any pharmacy that meets the Part D plan's standard terms and conditions; and

(ii) May not require a pharmacy to accept insurance risk as a condition of participation in the Part D plan's contracted pharmacy network.

(9) *Differential cost-sharing for preferred pharmacies.* A Part D sponsor offering a Part D plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs obtained through a preferred pharmacy relative to the copayments or coinsurance applicable for such drugs when obtained through a non-preferred pharmacy. Such differentials are taken into account in determining whether the requirements under § 423.104(d)(2) and (d)(5) and § 423.104(e) are met. Any cost-sharing reduction under this section must not increase CMS payments to the Part D plan under § 423.329.

(10) *Level playing field between mail-order and network pharmacies.* A Part D sponsor must permit its Part D plan enrollees to receive benefits, which may include a 90-day supply of covered Part D drugs, at any of its network pharmacies that are retail pharmacies. A Part D plan may require an enrollee obtaining a covered Part D drug at a network pharmacy that is a retail pharmacy to pay any higher cost-sharing applicable to that covered Part D drug at the network pharmacy that is a retail pharmacy instead of the cost-sharing applicable to that covered Part D drug at the network pharmacy that is a mail-order pharmacy.

(b) *Formulary requirements.* A Part D sponsor that uses a formulary under its qualified prescription drug coverage must meet the following requirements—

(1) *Development and revision by a pharmacy and therapeutic committee.* A Part D sponsor's formulary must be developed and reviewed by a pharmacy and therapeutic committee that—

(i) Includes a majority of members who are practicing physicians and/or practicing pharmacists.

(ii) Includes at least one practicing physician and at least one practicing pharmacist who are independent and free of conflict relative to-

(A) The Part D sponsor and Part D plan; and

(B) Pharmaceutical manufacturers.

(iii) Includes at least one practicing physician and one practicing pharmacist who are experts regarding care of elderly or disabled individuals.

(iv) Bases clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such

information as it determines appropriate.

(v) Considers whether the inclusion of a particular Part D drug in a formulary or formulary tier has any therapeutic advantages in terms of safety and efficacy.

(vi) Reviews policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, generic substitution, and therapeutic interchange.

(vii) Evaluates and analyzes treatment protocols and procedures related to the plan's formulary at least annually consistent with written policy guidelines and other CMS instructions.

(viii) Documents in writing its decisions regarding formulary development and revision and utilization management activities.

(ix) Meets other requirements consistent with written policy guidelines and other CMS instructions.

(2) Provision of an adequate benefit. A Part D plan's formulary must-

(i) Except as provided in paragraph (b)(2)(ii) of this section, include within each therapeutic category and class of Part D drugs at least two Part D drugs that are not therapeutically equivalent and bioequivalent, with different strengths and dosage forms available for each of those drugs, except that only one Part D drug must be included in a particular category or class of covered Part D drugs if the category or class includes only one Part D drug.

(ii) Include at least one Part D drug within a particular category or class of Part D drugs to the extent the Part D plan demonstrates, and CMS approves, the following-

(A) That only two drugs are available in that category or class of Part D drugs; and

(B) That one drug is clinically superior to the other drug in that category or class of Part D drugs.

(iii) Include adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines.

(iv) Be approved by CMS consistent with § 423.272(b)(2).

(3) *Transition Process.* A Part D sponsor must provide for an appropriate transition process for new enrollees prescribed Part D drugs that are not on its Part D plan's formulary. The transition policy must meet requirements consistent with written policy guidelines and other CMS instructions.

(4) *Limitation on changes in therapeutic classification.* Except as CMS may permit to account for new therapeutic uses and newly approved Part D drugs, a Part D sponsor may not change the therapeutic categories and classes in a formulary other than at the beginning of each plan year.

(5) *Provision of notice regarding formulary changes*

(i) Prior to removing a covered Part D drug from its Part D plan's formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug, a Part D sponsor must provide at least 60 days notice to CMS, State Pharmaceutical Assistance Programs (as defined in § 423.454), entities providing other prescription drug coverage (as described in § 423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists prior to the date such change becomes effective, and must either—

(A) Provide direct written notice to affected enrollees at least 60 days prior to the date the change becomes effective; or

(B) At the time an affected enrollee requests a refill of the Part D drug, provide such enrollee with a 60 day supply of the Part D drug under the same terms as previously allowed, and written notice of the formulary change.

(ii) The written notice must contain the following information-

(A) The name of the affected covered Part D drug;

(B) Whether the plan is removing the covered Part D drug from the formulary, or changing its preferred or tiered cost-sharing status;

(C) The reason why the plan is removing such covered Part D drug from the formulary, or changing its preferred or tiered cost-sharing status;

(D) Alternative drugs in the same therapeutic category or class or cost-sharing tier and expected cost-sharing for those drugs; and

(E) The means by which enrollees may obtain a coverage determination under § 423.566 or exception under § 423.578.

(iii) Part D sponsors may immediately remove from their Part D plan formularies covered Part D drugs deemed unsafe by the Food and Drug Administration or removed from the market by their manufacturer without meeting the requirements of paragraphs (b)(5)((i) of this section. Part D sponsors must provide retrospective notice of any such formulary changes to affected enrollees, CMS, State Pharmaceutical Assistance Programs (as defined in § 423.454), entities providing other prescription drug coverage (as described in § 423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists consistent with the requirements of paragraphs (b)(5)(ii)(A), (b)(5)(ii)(B), (b)(5)(ii)(C), and (b)(5)(ii)(D) of this section.

(6) *Limitation on formulary changes prior to the beginning of a contract year.* Except as provided under paragraph (b)(5)(iii) of this section, a Part D sponsor may not remove a covered Part D drug from its Part D plan's formulary, or make any change in the preferred or tiered cost-sharing status of a covered Part D drug on its plan's formulary, between the beginning of the annual coordinated election period described in § 423.38(b) and 60 days after the beginning of the contract year associated with that annual coordinated election period.

(7) *Provider and patient education.* A Part D sponsor must establish policies and procedures to educate and inform health care providers and enrollees concerning its formulary.

(c) *Use of standardized technology.* A Part D sponsor must issue and reissue, as necessary, a card or other type of technology that its enrollees may use to access negotiated prices for covered Part D drugs as provided under § 423.104(g). The card or other technology must comply with standards CMS establishes.

§ 423.124 Special rules for out-of-network access to covered Part D drugs at out-of-network pharmacies.

(a) *Out-of-network access to covered part D drugs.* (1) Out-of-network pharmacy access. A Part D sponsor must ensure that Part D enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when the enrollees—

(i) Cannot reasonably be expected to obtain such drugs at a network pharmacy; and

(ii) Do not access covered Part D drugs at an out-of-network pharmacy on a routine basis.

(2) Physician's office access. A Part D sponsor must ensure that Part D enrollees have adequate access to vaccines and other covered Part D drugs appropriately dispensed and administered by a physician in a physician's office.

(b) *Financial responsibility for out-of-network access to covered Part D drugs.* A Part D sponsor that provides its Part D enrollees with coverage other than defined standard coverage may require its Part D enrollees accessing covered Part D drugs as provided in paragraph (a) of this section to assume financial responsibility for any differential between the out-of-network pharmacy's (or provider's) usual and customary price and the Part D sponsor's plan allowance, consistent with the requirements of § 423.104(d)(2)(i)(B) and § 423.104(e).

(c) *Limits on out-of-network access to covered Part D.* A Part D sponsor must establish reasonable rules to appropriately limit out-of-network access to covered Part D drugs.

§ 423.128 Dissemination of Part D plan information.

(a) *Detailed description.* A Part D sponsor must disclose the information specified in paragraph (b) of this section in the manner specified by CMS.—

(1) To each enrollee of a Part D plan offered by the Part D sponsor under this part;

(2) In a clear, accurate, and standardized form; and

(3) At the time of enrollment and at least annually thereafter.

(b) *Content of Part D plan description.* The Part D plan description must include the following information about the qualified prescription drug coverage offered under the Part D plan—

(1) *Service area.* The plan's service area.

(2) *Benefits.* The benefits offered under the plan, including-

(i) Applicable conditions and limitations.

(ii) Premiums.

(iii) Cost-sharing (such as copayments,

deductibles, and coinsurance), and cost-sharing for subsidy eligible individuals.

(iv) Any other conditions associated with receipt or use of benefits.

(3) *Cost-sharing.* A description of how a Part D eligible individual may obtain more information on cost-sharing requirements, including tiered or other copayment levels applicable to each drug (or class of drugs), in accordance with paragraph (d) of this section.

(4) *Formulary.* Information about the plan's formulary, including-

(i) A list of drugs included on the plan's formulary;

(ii) The manner in which the formulary (including any tiered formulary structure and utilization management procedures used) functions;

(iii) The process for obtaining an exception to a plan's formulary or tiered cost-sharing structure; and

(iv) A description of how a Part D eligible individual may obtain additional information on the formulary, in accordance with paragraph (d) of this section.

(5) *Access.* The number, mix, and distribution (addresses) of network pharmacies from which enrollees may reasonably be expected to obtain covered Part D drugs and how the Part D sponsor meets the requirements of § 423.120(a)(1) for access to covered Part D drugs;

(6) *Out-of-network coverage.* Provisions for access to covered Part D drugs at out-of-network pharmacies, consistent with § 423.124(a).

(7) *Grievance, coverage determinations, and appeals procedures.* All grievance, reconsideration, exceptions, coverage determination, reconsideration, exceptions, and appeal rights and procedures required under § 423.564 et. seq.

(8) *Quality assurance policies and procedures.* A description of the quality assurance policies and procedures required under § 423.153(c), as well as the medication therapy management program required under § 423.153(d).

(9) *Disenrollment rights and responsibilities.*

(10) Potential for contract termination. The fact that a Part D sponsor may terminate or refuse to renew its contract, or reduce the service area included in its contract, and the effect that any of those actions may have on individuals enrolled in a Part D plan;

(c) *Disclosure upon request of general coverage information, utilization, and grievance information.* Upon request of a Part D eligible individual, a Part D sponsor must provide the following information—

(1) *General coverage information.* General coverage information, including—

(i) *Enrollment procedures.* Information and instructions on how to exercise election options under this part;

(ii) *Rights.* A general description of procedural rights (including grievance, coverage determination, reconsideration, exceptions, and appeals procedures) under this part;

(iii) *Benefits.* (A) Covered services under the Part D plan;

(B) Any beneficiary cost-sharing, such as deductibles, coinsurance, and copayment amounts, including cost-sharing for subsidy eligible individuals;

(C) Any maximum limitations on out-of-pocket expenses;

(D) The extent to which an enrollee may obtain benefits from out-of-network providers;

(E) The types of pharmacies that participate in the Part D plan's network and the extent to which an enrollee may select among those pharmacies; and

(F) The Part D plan's out-of-network pharmacy access policy.

(iv) Premiums;

(v) The Part D plan's formulary;

(vi) The Part D plan's service area; and

(vii) Quality and performance indicators for benefits under the Part D plan as determined by CMS.

(2) The procedures the Part D sponsor uses to control utilization of services and expenditures.

(3) The number of disputes, and the disposition in the aggregate, in a manner and form described by CMS. These disputes are categorized as—

(i) Grievances according to § 423.564;

(ii) Appeals according to § 423.580 et. seq.; and

(iii) Exceptions according to § 423.578.

(4) Financial condition of the Part D sponsor, including the most recently audited information regarding, at a minimum, a description of the financial condition of the Part D sponsor offering the Part D plan.

(d) *Provision of specific information.* Each Part D sponsor offering qualified prescription drug coverage under a Part D plan must have mechanisms for providing specific information on a timely basis to current and prospective enrollees upon request. These mechanisms must include—

(1) A toll-free customer call center that—

(i) Is open during usual business hours.

(ii) Provides customer telephone service, including to pharmacists, in accordance with standard business practices.

(2) An Internet website that—

(i) Includes, at a minimum, the information required in paragraph (b) of this section.

(ii) Includes a current formulary for its Part D plan, updated at least monthly.

(iii) Provides current and prospective Part D enrollees with at least 60 days notice regarding the removal or change in the preferred or tiered cost-sharing status of a Part D drug on its Part D plan's formulary.

(3) The provision of information in writing, upon request.

(e) *Claims information.* A Part D sponsor must furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits when prescription drug benefits are provided under qualified prescription drug coverage. The explanation of benefits must—

(1) List the item or service for which payment was made and the amount of the payment for each item or service.

(2) Include a notice of the individual's right to request an itemized statement.

(3) Include the cumulative, year-to-date total amount of benefits provided, in relation to—

(i) The deductible for the current year.

(ii) The initial coverage limit for the current year.

(iii) The annual out-of-pocket threshold for the current year.

(4) Include the cumulative, year-to-date total of incurred costs to the extent practicable.

(5) Include any applicable formulary changes for which Part D plans are required to provide notice as described in § 423.120(b)(5).

(6) Be provided during any month when prescription drug benefits are provided under this part, including for covered Part D spending between the initial coverage limit described in § 423.104(d)(3) and the out-of-pocket threshold described in § 423.104(d)(5)(iii).

§ 423.132 Public disclosure of pharmaceutical prices for equivalent drugs.

(a) *General requirements*. Except as provided under paragraph (c) of this section, a Part D sponsor must require a pharmacy that dispenses a covered Part D drug to inform an enrollee of any differential between the price of that drug and the price of the lowest priced generic version of that covered Part D drug that is therapeutically equivalent and bioequivalent and available at that pharmacy, unless the particular covered Part D drug being purchased is the lowest-priced therapeutically equivalent and bioequivalent version of that drug available at that pharmacy.

(b) *Timing of notice*. Subject to paragraph (d) of this section, the information under paragraph (a) of this section must be provided after the drug is dispensed at the point of sale or, in the case of dispensing by mail order, at the time of delivery of the drug.

(c) *Waiver of public disclosure requirement*. CMS waives the requirement under paragraph (a) of this section in the case of—

(1) An MA private fee-for-service plan described in § 422.4 of this chapter that—

(i) Offers qualified prescription drug coverage and provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies; and

(ii) Does not charge additional cost-sharing for access to covered Part D drugs dispensed at out-of-network pharmacies.

(2) An out-of-network pharmacy;

(3) An I/T/U network pharmacy;

(4) A network pharmacy that is located in any of the U.S. territories; and

(5) Other circumstances where CMS deems compliance with the requirements of paragraph (a) of this section to be impossible or impracticable.

(d) *Modification of timing requirement*. CMS modifies the requirement under paragraph (b) of this section as follows—

(1) For long-term care network pharmacies, which must meet the requirement in paragraph (a) of this section by providing such information to Part D plans for inclusion in the written explanations of benefits required under § 423.128(e); and

(2) Under other circumstances where CMS deems compliance with the requirement under paragraph (b) of this section to be impossible or impracticable.

§ 423.136 Privacy, confidentiality, and accuracy of enrollee records.

For any medical records or other health and enrollment information it maintains with respect to enrollees, a PDP sponsor must establish procedures to do the following—

(a) Abide by all Federal and State laws regarding confidentiality and disclosure of medical records, or other health and enrollment information. The PDP sponsor must safeguard the privacy of any information that identifies a particular enrollee and have procedures that specify—

(1) For what purposes the information is used within the organization; and

(2) To whom and for what purposes it discloses the information outside the organization.

(b) Ensure that medical information is released only in accordance with applicable Federal or State law, or under court orders or subpoenas.

(c) Maintain the records and information in an accurate and timely manner.

(d) Ensure timely access by enrollees to the records and information that pertain to them.

Subpart D—Cost Control and Quality Improvement Requirements for Part D Plans

§ 423.150 Scope.

This subpart sets forth the requirements relating to the following:

(a) Drug utilization management programs, quality assurance measures and systems, and medication therapy management programs (MTMP) for Part D sponsors.

(b) Consumer satisfaction surveys of Part D plans.

(c) Electronic prescription program.

(d) Quality improvement organization (QIO) activities.

(e) Compliance deemed on the basis of accreditation.

(f) Accreditation organizations.

(g) Procedures for the approval of accreditation

organizations as a basis for deeming compliance.

§ 423.153 Drug utilization management, quality assurance, and medication therapy management programs (MTMPs).

(a) *General rule*. Each Part D sponsor must have established, for covered Part D drugs furnished through a Part D plan, a drug utilization management program, quality assurance measures and systems, and an MTMP as described in paragraphs (b), (c), and (d) of this section.

(b) *Drug utilization management*. A Part D sponsor must have established a reasonable and appropriate drug utilization management program that—

(1) Includes incentives to reduce costs when medically appropriate;

(2) Maintains policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications; and

(3) Provides CMS with information concerning the procedures and performance of its drug utilization management program, according to guidelines specified by CMS.

(c) *Quality assurance*. A Part D sponsor must have established quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use that include all of the following—

(1) Representation that network providers are required to comply with minimum standards for pharmacy practice as established by the States.

(2) Concurrent drug utilization review systems, policies, and procedures designed to ensure that a review of the prescribed drug therapy is performed before each prescription is dispensed to an enrollee in a sponsor's Part D plan, typically at the point-of-sale or point of distribution. The review must include, but not be limited to,

(i) Screening for potential drug therapy problems due to therapeutic duplication.

(ii) Age/gender-related contraindications.

(iii) Over-utilization and under-utilization.

(iv) Drug-drug interactions.

(v) Incorrect drug dosage or duration of drug therapy. (vi) Drug-allergy contraindications.

(vii) Clinical abuse/misuse.

(3) Retrospective drug utilization review systems, policies, and procedures designed to ensure ongoing periodic examination of claims data and other records, through computerized drug claims processing and information retrieval systems, in order to identify patterns of inappropriate or medically unnecessary care among enrollees in a sponsor's Part D plan, or associated with specific drugs or groups of drugs.

(4) Internal medication error identification and reduction systems.

(5) Provision of information to CMS regarding its quality assurance measures and systems, according to guidelines specified by CMS.

(d) *Medication therapy management program (MTMP).*

(1) *General rule.* A Part D sponsor must have established a MTMP that—

(i) Is designed to ensure that covered Part D drugs prescribed to targeted beneficiaries described in paragraph (d)(2) of this section are appropriately used to optimize therapeutic outcomes through improved medication use;

(ii) Is designed to reduce the risk of adverse events, including adverse drug interactions, for targeted beneficiaries described in paragraph (d)(2) of this section;

(iii) May be furnished by a pharmacist or other qualified provider; and

(iv) May distinguish between services in ambulatory and institutional settings.

(2) *Targeted beneficiaries.* Targeted beneficiaries for the MTMP described in paragraph (d)(1) of this section are enrollees in the sponsor's Part D plan who —

(i) Have multiple chronic diseases;

(ii) Are taking multiple Part D drugs; and

(iii) Are likely to incur annual costs for covered Part D drugs that exceed a predetermined level as specified by the Secretary.

(3) *Use of experts.* The MTMP must be developed in cooperation with licensed and practicing pharmacists and physicians.

(4) *Coordination with care management plans.* The MTMP must be coordinated with any care management plan established for a targeted individual under a chronic care improvement program (CCIP) under section 1807 of the Act. A Part D sponsor must provide drug claims data to CCIPs for those beneficiaries that are enrolled in CCIPs in a manner specified by CMS.

(5) *Considerations in pharmacy fees.* An applicant to become a Part D sponsor must—

(i) Describe in its application how it takes into account the resources used and time required to implement the MTMP it chooses to adopt in establishing fees for pharmacists or others providing MTMP services for covered Part D drugs under a Part D plan.

(ii) Disclose to CMS upon request the amount of the management and dispensing fees and the portion paid for MTMP services to pharmacists and others upon request. Reports of these amounts are protected under the provisions of section 1927(b)(3)(D) of the Act.

(6) *MTMP reporting.* A Part D sponsor must provide CMS with information regarding the procedures and performance of its MTMP, according to guidelines specified by CMS.

(e) *Exception for private fee-for-service MA plans offering qualified prescription drug coverage.* In the case of an MA plan described in § 422.4(a)(3) of this chapter providing qualified prescription drug coverage, the requirements under paragraphs (b) and (d) of this section do not apply.

§ 423.156 Consumer satisfaction surveys.

CMS conducts consumer satisfaction surveys of Part D plan enrollees similar to the surveys it conducts of MA enrollees under § 422.152 (b) of this chapter.

§ 423.159 Electronic prescription program.

(a) [Reserved]

(b) [Reserved]

(c) *Requirement.* Part D sponsors must support and comply with electronic prescription standards relating to covered Part D drugs for Part D enrollees developed by CMS once final standards are effective.

(d) *Promotion of electronic prescribing by MA-PD plans.* An MA organization offering an MA-PD plan may provide for a separate or differential payment to a participating physician that prescribes covered Part D drugs in accordance with electronic prescription standards, including initial standards and final standards established by CMS once final standards are effective. Any payments must be in compliance with applicable Federal and State laws related to fraud and abuse, including the physician self-referral prohibition (section 1877 of the Act) and the Federal anti kickback statute (section 1128B(b) of the Act).

§ 423.162 Quality improvement organization activities.

(a) *General rule.* Quality improvement organizations (QIOs) are required to offer providers, practitioners, and Part D sponsors quality improvement assistance pertaining to health care services, including those related to prescription drug therapy, in accordance with contracts established with the Secretary.

(b) *Collection of information.* Information collected, acquired, or generated by a QIO in the performance of its responsibilities under this section is subject to the confidentiality provisions of part 480 of this chapter. Part D sponsors are required to provide specified information to CMS for distribution to the QIOs as well as directly to QIOs.

(c) *Applicability of QIO confidentiality provisions.* The provisions of part 480 of this chapter apply to Part D sponsors in the same manner as such provisions apply to institutions under part 480 of this chapter.

§ 423.165 Compliance deemed on the basis of accreditation.

(a) *General rule.* A Part D sponsor is deemed to meet all of the requirements of any of the areas described in paragraph (b) of this section if—

(1) The Part D sponsor is fully accredited (and periodically reaccredited) for the standards related to the applicable area under paragraph (b) of this section by a private, national accreditation organization approved by CMS; and

(2) The accreditation organization uses the standards approved by CMS for the purposes of assessing the Part D sponsor's compliance with Medicare requirements.

(b) Deemable requirements. The requirements relating to the following areas are deemable:

(1) Access to covered drugs, as provided under § 423.120 and § 423.124.

(2) Drug utilization management programs, quality assurance measures and systems, and MTMPs as provided under § 423.153.

(3) Privacy, confidentiality, and accuracy of enrollee records, as provided under § 423.136.

(4) A program to protect against fraud, waste and abuse, as described in § 423.504(b)(4)(vi)(H).

(c) *Effective date of deemed status.* The date the Part D sponsor is deemed to meet the applicable requirements is the later of the following:

(1) The date the accreditation organization is approved by CMS.

(2) The date the Part D sponsor is accredited by the accreditation organization.

(d) *Obligations of deemed Part D sponsors.* A Part D sponsor deemed to meet Medicare requirements must—

(1) Submit to surveys by CMS to validate its accreditation organization's accreditation process; and

(2) Authorize its accreditation organization to release to CMS a copy of its most recent accreditation survey, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

(e) *Removal of deemed status.* CMS removes part or all of a Part D sponsor's deemed status for any of the following reasons—

(1) CMS determines, on the basis of its own investigation, that the Part D sponsor does not meet the Medicare requirements for which deemed status was granted.

(2) CMS withdraws its approval of the accreditation organization that accredited the Part D sponsor.

(3) The Part D sponsor fails to meet the requirements of paragraph (d) of this section.

(f) *Enforcement authority*. CMS retains the authority to initiate enforcement action against any Part D sponsor that it determines, on the basis of its own survey or the results of an accreditation survey, no longer meets the Medicare requirements for which deemed status was granted.

§ 423.168 Accreditation organizations.

(a) *Conditions for approval*. CMS may approve an accreditation organization for a given standard under this part if the organization meets the following conditions:

(1) In accrediting Part D sponsors and Part D plans, it applies and enforces standards that are at least as stringent as Medicare requirements for the standard or standards in question.

(2) It complies with the application and reapplication procedures set forth in § 423.171.

(3) It ensures that—

(i) Any individual associated with it, who is also associated with an entity it accredits, does not influence the accreditation decision concerning that entity;

(ii) The majority of the membership of its governing body is not comprised of managed care organizations, Part D sponsors or their representatives; and

(iii) Its governing body has a broad and balanced representation of interests and acts without bias.

(b) *Notice and comment*. (1) *Proposed notice*. CMS publishes a notice in the **Federal Register** whenever it is considering granting an accreditation organization's application for approval. The notice-

(i) Announces CMS's receipt of the accreditation organization's application for approval;

(ii) Describes the criteria CMS uses in evaluating the application; and

(iii) Provides at least a 30-day comment period.

(2) *Final notice*. (i) After reviewing public comments, CMS publishes a final notice in the **Federal Register** indicating whether it has granted the accreditation organization's request for approval.

(ii) If CMS grants the request, the final notice specifies the effective date and the term of the approval that may not exceed 6 years.

(c) *Ongoing responsibilities of an approved accreditation organization*. An accreditation organization approved by CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS in written form and on a monthly basis all of the following:

(i) Copies of all accreditation surveys, together with any survey-related information that CMS may require including corrective action plans and summaries of unmet CMS requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to deemed Part D sponsors.

(iv) Information about any Part D sponsor against which the accrediting organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the Part D sponsor's accreditation. (The accreditation organization must provide this information within 30 days of taking the remedial or adverse action.)

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without CMS approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 days of a change in CMS requirements, submit the following to CMS—

(i) An acknowledgment of CMS's notification of the change.

(ii) A revised crosswalk reflecting the new requirements.

(iii) An explanation of how the accreditation organization plans to alter its standards to conform to CMS's new requirements, within the timeframes specified in the notification of change it receives from CMS.

(3) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(4) Within 3 days of identifying, in an accredited Part D sponsor, a deficiency that as determined by the accrediting organization poses immediate jeopardy to the plan's enrollees or to the general public, give CMS written notice of the deficiency.

(5) Within 10 days of CMS's notice of withdrawal of approval, give written notice of the withdrawal to all accredited Part D sponsors.

(6) On an annual basis, provide summary data specified by CMS that relate to the past year's accreditation activities and trends.

(d) *Continuing Federal oversight of approved accreditation organizations*. Specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization include the following:

(1) *Equivalency review*. CMS compares the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes when—

(i) CMS imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new standards or changes in its survey process; or

(iii) The term of an accreditation organization's approval expires.

(2) *Validation review*. CMS or its agent may conduct a survey of an accredited organization, examine the results of the accreditation organization's own survey, or attend the accreditation organization's survey to validate the organization's accreditation process. At the conclusion of the review, CMS identifies any accreditation programs for which validation survey results indicate—

(i) A 20 percent rate of disparity between certification by the accreditation organization and certification by CMS or its agent on standards that do not constitute immediate jeopardy to patient health and safety if unmet;

(ii) Any disparity between certification by the accreditation organization and certification by CMS or its agent on standards that constitute immediate jeopardy to patient health and safety if unmet; or

(iii) That, regardless of the rate of disparity, there are widespread or systematic problems in an organization's accreditation process that accreditation no longer provides assurance that the Medicare requirements are met or exceeded.

(3) *Onsite observation*. CMS may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to the following:

(i) Reviewing documents.

(ii) Auditing meetings concerning the accreditation process.

(iii) Evaluating survey results or the accreditation status decision-making process.

(iv) Interviewing the organization's staff.

(4) *Notice of intent to withdraw approval*. If an equivalency review, validation review, onsite observation, or CMS's daily experience with the accreditation organization suggests that

the accreditation organization is not meeting the requirements of this subpart, CMS gives the organization written notice of its intent to withdraw approval.

(5) *Withdrawal of approval.* CMS may withdraw its approval of an accreditation organization at any time if CMS determines that—

(i) Deeming, based on accreditation, no longer guarantees that the Part D sponsor meets the requirements for offering qualified prescription drug coverage, and failure to meet those requirements may jeopardize the health or safety of Medicare enrollees and constitute a significant hazard to the public health; or

(ii) The accreditation organization has failed to meet its obligations under this section or under § 423.165 or § 423.171.

(6) *Reconsideration of withdrawal of approval.* An accreditation organization dissatisfied with a determination to withdraw CMS approval may request a reconsideration of that determination in accordance with subpart D of part 488 of this chapter.

§ 423.171 Procedures for approval of accreditation as a basis for deeming compliance.

(a) *Required information and materials.* A private, national accreditation organization applying for approval must furnish to CMS all of the following information and materials (when reapplying for approval, the organization need furnish only the particular information and materials requested by CMS):

(1) The types of Part D plans and sponsors that it reviews as part of its accreditation process.

(2) A detailed comparison of the organization's accreditation requirements and standards with the Medicare requirements (for example, a crosswalk).

(3) Detailed information about the organization's survey process, including the following:

(i) Frequency of surveys and whether surveys are announced or unannounced.

(ii) Copies of survey forms, and guidelines and instructions to surveyors.

(iii) Descriptions of—

(A) The survey review process and the accreditation status decision making process;

(B) The procedures used to notify accredited Part D sponsors of deficiencies and to monitor the correction of those deficiencies; and

(C) The procedures used to enforce compliance with accreditation requirements.

(4) Detailed information about the individuals who perform surveys for the accreditation organization, including the—

(i) Size and composition of accreditation survey teams for each type of plan reviewed as part of the accreditation process;

(ii) Education and experience requirements surveyors must meet;

(iii) Content and frequency of the in-service training provided to survey personnel;

(iv) Evaluation systems used to monitor the performance of individual surveyors and survey teams; and

(v) Organization's policies and practice for the participation, in surveys or in the accreditation decision process by an individual who is professionally or financially affiliated with the entity being surveyed.

(5) A description of the organization's data management and analysis system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(6) A description of the organization's procedures for responding to and investigating complaints against accredited organizations, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs.

(7) A description of the organization's policies and procedures for the withholding or removal of accreditation for failure to meet the accreditation organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

(8) A description of all types (for example, full or partial) and categories (for example, provisional, conditional, or temporary) of accreditation offered by the organization, the duration of each type and category of accreditation, and a statement identifying the types and categories that serve as a basis for accreditation if CMS approves the accreditation organization.

(9) A list of all currently accredited Part D sponsors and MA organizations and the type, category, and expiration date of the accreditation held by each of them.

(10) A list of all full and partial accreditation surveys scheduled to be performed by the accreditation organization as requested by CMS.

(11) The name and address of each person with an ownership or control interest in the accreditation organization.

(b) *Required supporting documentation.* A private, national accreditation organization applying or reapplying for approval also must submit the following supporting documentation—

(1) A written presentation that demonstrates its ability to furnish CMS with electronic data in CMS compatible format.

(2) A resource analysis that demonstrates that it's staffing, funding, and other resources are adequate to perform the required surveys and related activities.

(3) A statement acknowledging that, as a condition for approval, it agrees to comply with the ongoing responsibility requirements of § 423.168(c).

(c) *Additional information.* If CMS determines that it needs additional information for a determination to grant or deny the accreditation organization's request for approval, it notifies the organization and allows time for the organization to provide the additional information.

(d) *Onsite visit.* CMS may visit the accreditation organization's offices to verify representations made by the organization in its application, including, but not limited to, review of documents and interviews with the organization's staff.

(e) *Notice of determination.* CMS gives the accreditation organization, within 210 days of receipt of its completed application, a formal notice that—

(1) States whether the request for approval is granted or denied;

(2) Gives the rationale for any denial; and

(3) Describes the reconsideration and reapplication procedures.

(f) *Withdrawal.* An accreditation organization may withdraw its application for approval at any time before it receives the formal notice specified in paragraph (e) of this section.

(g) *Reconsideration of adverse determination.* An accreditation organization that has received a notice of denial of its request for approval may request a reconsideration in accordance with subpart D of part 488 of this chapter.

(h) *Request for approval following denial.* (1) Except as provided in paragraph (h)(2) of this section, an accreditation organization that has received notice of denial of its request for approval may submit a new request if it—

(i) Has revised its accreditation program to correct the deficiencies on which the denial was based.

(ii) Can demonstrate that the Part D sponsors that it has accredited meet or exceed applicable Medicare requirements; and

(iii) Resubmits the application in its entirety.

(2) An accreditation organization that has requested reconsideration of CMS' denial of its request for approval may not submit a new request until the reconsideration is administratively final.

Subpart E—[Reserved]

Subpart F—Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

§ 423.251 Scope.

This section sets forth the requirements and limitations on submission, review, negotiation and approval of competitive bids for prescription drug plans and MA-PD plans; the calculation of the national average bid amount; and the determination of enrollee premiums.

§ 423.258 Definitions.

For the purposes of this subpart, the following definitions apply:

Full risk plan means a prescription drug plan that is not a limited risk plan or a fallback prescription drug plan.

Limited risk plan means a prescription drug plan that provides basic prescription drug coverage and for which the PDP sponsor includes a modification of risk level described in § 423.265(d) in its bid submitted for the plan. This term does not include a fallback prescription drug plan.

Standardized bid amount means, for a prescription drug plan that provides basic prescription drug coverage, the PDP approved bid; for a prescription drug plan that provides supplemental prescription drug coverage, the portion of the PDP approved bid that is attributable to basic prescription drug coverage; for a MA-PD plan, the portion of the accepted bid amount that is attributable to basic prescription drug coverage.

§ 423.265 Submission of bids and related information.

(a) *Eligibility for bidding.* An applicant may submit a bid to become a Part D plan sponsor.

(b) *Bid submission.* Not later than the first Monday in June, each potential Part D sponsor must submit bids and supplemental information described in this section for each Part D plan it intends to offer in the subsequent calendar year.

(c) *Basic rule for bid.* Each potential Part D sponsor must submit a bid and supplemental information in a format to be specified by CMS for each Part D plan it offers. Each bid must reflect a uniform benefit package, including premium (except as provided for the late enrollment penalty described in § 423.286(d)(3)) and all applicable cost sharing, for all individuals enrolled in the plan. Each bid must reflect the applicant's estimate of its average monthly revenue requirements to provide qualified prescription drug coverage (including any supplemental coverage) for a Part D eligible individual with a national average risk profile for the factors described in § 423.329(b)(1).

(1) *Included costs.* The bid includes costs (including administrative costs and return on investment/profit) for which the plan is responsible in providing basic and supplemental benefits.

(2) *Excluded costs.* The bid does not include costs associated with payments by the enrollee for deductible, co-payments, coinsurance, and liability above the plan allowance in the case of out-of-network claims, payments projected to be made by CMS for reinsurance, or any other costs for which the sponsor is not responsible.

(3) *Actuarial valuation.* The bid must be prepared in accordance with CMS actuarial guidelines based on generally accepted actuarial principles. A qualified actuary must certify the plan's actuarial valuation (which may be prepared by others under his or her direction or review), and must be a member of the American Academy of Actuaries to be deemed qualified. Applicants may use qualified outside actuaries to prepare their bids.

(d) *Specific requirements for bids.* The bid and supplemental information submission must include the following information:

(1) *Coverage.* A description of the coverage to be provided under the plan, including any supplemental coverage and the deductible and other cost sharing.

(2) *Actuarial value of bid components.* The applicant must provide the following information on bid components, as well as actuarial certification that the values are calculated according to CMS guidelines on actuarial valuation, including adjustment for the effect that providing alternative prescription drug coverage (rather than defined standard prescription drug coverage) has on drug utilization, if applicable.

(i) The actuarial value of the qualified prescription drug coverage to be offered under each plan for a Part D eligible individual with a national average risk profile for the factors described in § 423.329(b)(1) and the basis for the estimate.

(ii) The portion of the bid attributable to basic prescription drug coverage and the portion (if any) attributable to supplemental benefits.

(iii) The assumptions regarding reinsurance amounts payable under § 423.329(c) used in calculating the bid.

(iv) The assumptions regarding low-income cost-sharing payable under § 423.329(d) used in calculating the bid.

(v) The amount of administrative costs and return on investment or profit included in the bid.

(3) *Service area.* A description of the service area of the plan.

(4) *Level of risk assumed.* For a potential Part D sponsor, the level of risk assumed in the bid specified in paragraph (e) of this section.

(5) *Plan Average Risk Score.* An estimate of the plan's average prescription drug risk score (as established under § 423.329(b)) for all projected enrollees for purposes of risk adjusting any supplemental premium.

(6) *Additional information.* Additional information CMS requests to support bid amounts and facilitate negotiation.

(e) *Special rule for PDP sponsors.* Bids for all plans offered by a potential PDP sponsor in a region, but not those of potential MA organizations offering MA-PD plans, PACE organizations offering PACE plans including qualified prescription drug coverage, and cost-based HMOs or CMPs offering section 1876 cost plans including qualified prescription drug coverage, may include a uniform modification of the amount of risk assumed (based on a process to be specified) as described in one or more of the following paragraphs. Any such modification applies to all plans offered by the PDP sponsor in a PDP region.

(1) *Increase in Federal percentage assumed in initial risk corridor.* An equal percentage point increase in the percents applied for costs between the first and second threshold limits under § 423.336(b)(2)(i) and (b)(2)(ii)(A) and § 423.336 (b)(3)(i) and (b)(3)(ii)(A). This provision does not affect the application of a higher percentage for plans in 2006 or 2007 under § 423.336(b)(2)(iii).

(2) *Increase in Federal percentage assumed in second risk corridor.* An equal percentage point increase in the percents applied for costs above the second threshold upper limit or below the second threshold upper limit under paragraphs § 423.336(b)(2)(ii)(B) and (b)(3)(ii)(B).

(3) *Decrease in size of risk corridors.* A decrease in the size of the risk corridors by means of reductions in the threshold risk percentages specified in § 423.336(a)(2)(ii)(A) and/or (a)(2)(ii)(B).

(f) *Special rule for fallback prescription drug plans.* Fallback prescription drug plan bids are not

subject to the rules in this section. They must follow requirements specified in § 423.863.

§ 423.272 Review and negotiation of bid and approval of plans submitted by potential Part D sponsors.

(a) *Review and negotiation regarding information, terms and conditions.* CMS reviews the information filed under § 423.265(c) in order to conduct negotiations regarding the terms and conditions of the proposed bid and benefit plan. In addition to its general negotiating authority under section 1860D–11(d)(2)(A) of the Act, CMS has authority similar to that of the Director of the Office of Personnel Management for health benefit plans under Chapter 89 of title 5, U.S.C..

(b) *Approval of proposed plans.* CMS approves the Part D plan only if the plan and the Part D sponsor offering the plan comply with all applicable CMS Part D requirements, including those related to the provision of qualified prescription drug coverage and actuarial determinations.

(1) *Application of revenue requirements standard.* CMS approves a bid submitted under § 423.265 only if it determines that the portions of the bid attributable to basic and supplemental prescription drug coverage are supported by the actuarial bases provided and reasonably and equitably reflect the revenue requirements (as used for purposes of section 1302(8)(C) of the Public Health Service Act) for benefits provided under that plan, less the sum (determined on a monthly per capita basis) of the actuarial value of the reinsurance payments under section § 423.329(c).

(2) *Plan design.* (i) CMS does not approve a bid if it finds that the design of the plan and its benefits (including any formulary and tiered formulary structure) or its utilization management program are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan.

(ii) If the design of the categories and classes within a formulary is consistent with the model guidelines (if any) established by the United States Pharmacopeia, the formulary categories and classes alone will not be found to discourage enrollment.

(iii) A plan that adopts the categories and classes discussed in paragraph (b)(2)(ii) of this section may nevertheless be found to discourage enrollment because it excludes specific drugs from the formulary.

(c) *Limited risk plans.* (1) Application of limited risk plans. There is no limit on the number of full risk plans that CMS approves under paragraph (b) of this section. CMS approves a limited risk plan in accordance with paragraphs (c)(2) and (c)(3) of this section only if the access requirements under § 423.859 are not otherwise met for a PDP region.

(2) *Maximizing assumption of risk.* CMS gives priority in approval for those limited risk plans bearing the highest level of risk, but may take into account the level of the bids submitted by the plans and is not required to accept the limited risk plan with the highest assumption of risk. In no case does CMS approve a limited risk plan under which the modification of risk level provides for no (or a minimal) level of financial risk.

(3) *Limited exercise of authority.* CMS approves only the minimum number of limited risk plans needed to meet the access requirements.

(d) *Special rules for private fee-for-service (PFFS) plans that offer prescription drug coverage.* PFFS plans (as defined at § 422.4(a)(3)) choosing to offer prescription drug coverage are subject to all MA-PD bid submission and approval requirements applicable to MA-PD plans with the following exceptions:

(1) *Exemption from negotiations.* These plans are exempt from the review and negotiation process in paragraph (a) of this section, and are not held to the revenue requirements standard in paragraph (b)(1) of this section.

(2) *Requirements regarding negotiated prices.* These plans are not required to provide access to negotiated prices. However, if they do, they must meet the applicable requirements of § 423.104(h).

(3) *Modification of pharmacy access standard and disclosure requirement.* If the plan provides coverage for drugs purchased from all pharmacies, without charging additional cost sharing and without regard to whether they are network pharmacies, § 423.120(a) and § 423.132 requiring certain network access standards and the disclosure of the availability of lower cost bioequivalent generic drugs does not apply to the plan.

(e) *Special rule for plans with standardized bids sufficiently below the national average monthly bid to result in a negative premium.* In the event of a negative premium, as described in § 423.286(d)(1), CMS negotiates the incorporation of the negative premium amount into the bid as either a reduction in the supplemental premium if the Part D plan already submitted a bid with an enhanced alternative benefit, or CMS requires the addition of new enhanced alternative benefit of no less value than the amount of the negative premium.

§ 423.279 National average monthly bid amount.

(a) Bids included. For each year (beginning with 2006) CMS computes a national average monthly bid amount from approved bids submitted under § 423.265 in order to calculate the base beneficiary premium, as provided in § 423.286(c). The national average monthly bid amount is equal to a weighted average of the standardized bid amounts for each prescription drug plan (not including fallbacks) and for each MA-PD plan described in section 1851(a)(2)(A)(i) of the Act. The calculation does not include bids submitted by MSA plans, MA private fee-for-service plans, specialized MA plans for special needs individuals, PACE programs under section 1894, and contracts under reasonable cost reimbursement contracts under section 1876(h) of the Act.

(b) Calculation of weighted average. (1) The national average monthly bid amount is a weighted average, with the weight for each plan equal to a percentage with the numerator equal to the number of Part D eligible individuals enrolled in the plan in the reference month (as defined in § 422.258(c)(1) of this chapter) and the denominator equal to the total number of Part D eligible individuals enrolled in a reference month in all Part D plans except MSA plans, fallbacks, MA private fee-for-service plans, specialized MA plans for special needs individuals, PACE programs under section 1894, and contracts under reasonable cost reimbursement contracts under section 1876(h) of the Act.

(2) For purposes of calculating the monthly national average monthly bid amount for 2006, CMS assigns equal weighting to PDP sponsors (other than fallback entities) and assigns MA-PD plans included in the national average bid a weight based on prior enrollment (new MA-PD plans are assigned zero weight).

(c) Geographic adjustment. (1) Upon the development of an appropriate methodology, the national average monthly bid amount for Part D plans will be adjusted to take into account differences in prices for Part D drugs among PDP regions.

(2) CMS does not apply any geographic adjustments if CMS determines that price variations among PDP regions are negligible.

(3) CMS applies any geographic adjustment in a budget neutral manner so as to not result in a change in the aggregate payments that may have been made if CMS had not applied an adjustment.

(4) CMS does not apply any geographic adjustment until an appropriate methodology is developed.

§ 423.286 Rules regarding premiums.

(a) *General rule*. Except as provided in paragraphs (d)(3) and (e) of this section, and with regard to employer group waivers, the monthly beneficiary premium for a Part D plan in a PDP region is the same for all Part D eligible individuals enrolled in the plan. The monthly beneficiary premium for a Part D plan is the base beneficiary premium, as determined in paragraph (c) of this section, adjusted as described in paragraph (d) of this section for the difference between the bid and the national average monthly bid amount, any supplemental benefits and for any late enrollment penalties.

(b) *Beneficiary premium percentage*. The beneficiary premium percentage for any year is a fraction, the—

(1) Numerator of which is 25.5 percent; and

(2) Denominator of which is as follows:

(i) 100 percent minus the percentage established in paragraph (b)(2)(ii) of this section.

(ii) The percentage established in this paragraph equals:

(A) The total reinsurance payments that CMS estimates will be paid under § 423.329(c) for the coverage year; divided by—

(B) The amount estimated under paragraph (b)(2)(ii)(A) of this section for the year plus total payments that CMS estimates will be paid to Part D plans that are attributable to the standardized bid amount during the year, taking into account amounts paid by both CMS and enrollees.

(c) *Base beneficiary premium*. The base beneficiary premium for a Part D plan for a month is equal to the product of the—

(1) Beneficiary premium percentage as specified in paragraph (b) of this section; and

(2) National average monthly bid amount (computed under § 423.279) for the month.

(d) *Adjustments to base beneficiary premium*. The base beneficiary premium may be adjusted to reflect any of the following scenarios, if applicable.

(1) *Adjustment to reflect difference between bid and national average bid*. If the amount of the standardized bid amount exceeds the adjusted national average monthly bid amount, the monthly base beneficiary premium is increased by the amount of the excess. If the amount of the adjusted national average monthly bid amount exceeds the standardized bid amount, the monthly base beneficiary premium is decreased by the amount of the excess. If the amount of the adjusted national average monthly bid amount exceeds the standardized bid amount by an amount greater than the base beneficiary premium and results in a negative premium, then the beneficiary premium is zero, and the excess amount is applied to supplemental Part D benefits as described in § 423.272(e).

(2) *Increase for supplemental prescription drug benefits*. The portion of the Part D plan approved bid that is attributable to supplemental prescription drug benefits increases the beneficiary premium. This supplemental portion of the bid may be adjusted to reflect the average risk of enrollees in the plan as determined based on negotiations between CMS and the Part D sponsor offering the plan.

(3) *Increase for late enrollment penalty*. The base beneficiary premium for a Part D enrollee subject to the late enrollment penalty is increased by the amount of any late enrollment penalty.

(i) *Late enrollment penalty amount*. The penalty amount for a Part D eligible individual for a continuous period of eligibility (as provided in § 423.46(a)) is the greater of—

(A) An amount that CMS determines is actuarially sound for each uncovered month in the same continuous period of eligibility; or

(B) 1 percent of the base beneficiary premium (computed under paragraph (c) of this section) for each uncovered month in the period.

(ii) *Special rule for 2006 and 2007*. In 2006 and 2007 the penalty amount discussed in paragraph (d)(3) of this chapter equals the amount referenced in paragraph (d)(3)(i)(B) of this section unless another amount is specified in a separate issuance based on available analysis or other information as determined by the Secretary.

(e) *Decrease in monthly beneficiary premium for low-income assistance*. The monthly beneficiary premium may be eliminated or decreased in the case of a subsidy-eligible individual under § 423.780.

(f) *Special rules for fallback prescription drug plans*. The monthly beneficiary premium charged under a fallback prescription drug plan is calculated under § 423.867(a) and not under this section, except that enrollees in fallback prescription drug plans are subject to late enrollment penalties under paragraph (d)(3) of this section and fallback prescription drug plan premiums are reduced or eliminated in the case of a subsidy-eligible individual, as described in paragraph (e) of this section.

§ 423.293 Collection of monthly beneficiary premium.

(a) *General rule*. Part D sponsors must charge enrollees a consolidated monthly Part D premium equal to the sum of the Part D monthly premium for basic prescription drug coverage (if any) and the premium for supplemental coverage (if any and if the beneficiary has enrolled in such supplemental coverage). Part D sponsors must also permit each enrollee, at the enrollee's option, to make payment of premiums (if any) under this part to the sponsor using any of the methods listed in § 422.262(f) of this chapter.

(b) *Crediting of late enrollment penalty*. CMS estimates and specifies the portion of the late enrollment penalty imposed under § 423.286(d)(3) attributable to increased actuarial costs assumed by the Part D sponsor and not taken into account through risk adjustment provided under § 423.329(b)(1) or through reinsurance payments under § 423.329(c)) as a result of the late enrollment.

(c) *Collection of late enrollment penalty*. (1) *Collection through withholding*. In the case of a late enrollment penalty that is collected by the government from a Part D eligible individual in the manner described in § 422.262(f)(1) of this chapter, CMS pays only the portion of the late enrollment penalty described in paragraph (b) of this section to the Part D sponsor offering the Part D plan in which the individual is enrolled.

(2) *Collection by plan*. In the case of a late enrollment penalty collected from a Part D eligible individual in a manner other than the manner described in § 422.262(f)(1) of this chapter, CMS reduces payments otherwise made to the Part D plan by an amount equal to the portion of the late enrollment penalty.

(d) *Special rule for fallback plans*. This section does not apply to fallback prescription drug plans. The fallback plans follow the requirements set forth in § 423.867(b).

Subpart G—Payments to Part D Plan Sponsors For Qualified Prescription Drug Coverage

§ 423.301 Scope.

This subpart sets forth rules for the calculation and payment of CMS direct and reinsurance subsidies for Part D plans; the application of risk corridors and risk-sharing adjustments to payments; and retroactive adjustments and reconciliations to actual enrollment and interim payments. This subpart does not apply to fallback entities or fallback prescription drug plans.

§ 423.308 Definitions and terminology.

For the purposes of this subpart, the following definitions apply-

Actually paid means that the costs must be actually incurred by the Part D sponsor and must be net of any direct or indirect remuneration (including discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred by the Part D sponsor for the drug.

Allowable reinsurance costs means the subset of gross covered prescription drug costs actually paid that are attributable to basic prescription drug coverage for covered Part D drugs only and that are actually paid by the Part D sponsor or by (or on behalf of) an enrollee under the Part D plan. The costs for any Part D plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic prescription drug coverage, but also to exclude any costs determined to be attributable to increased utilization over the standard prescription drug coverage as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

Allowable risk corridor costs means the subset of actually paid costs for covered Part D drugs (not including administrative costs, but including dispensing fees) that are attributable to basic prescription drug coverage only and that are incurred and actually paid by the Part D sponsor under the Part D plan. Costs must be based upon imposition of the maximum amount of copayments permitted under § 423.782. The costs for any Part D plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic prescription drug coverage, but also to exclude any prescription drug coverage costs determined to be attributable to increased utilization over standard prescription drug coverage as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

Coverage year means a calendar year in which covered Part D drugs are dispensed if the claim for those drugs (and payment on the claim) is made not later than 3 months after the end of the year

Gross covered prescription drug costs means those actually paid costs incurred under a Part D plan, excluding administrative costs, but including dispensing fees during the coverage year and costs relating to the deductible. They equal-

(1) All reimbursement paid by a Part D sponsor to a pharmacy (or other intermediary) or to indemnify an enrollee when the reimbursement is associated with an enrollee obtaining drugs under the Part D plan; plus

(2) All amounts paid under the Part D plan by or on behalf of an enrollee (such as the deductible, coinsurance, cost-sharing, or amounts between the initial coverage limit and the out-of-pocket threshold) in order to obtain drugs covered under the Part D plan. These costs are determined regardless of whether the coverage under the plan exceeds basic prescription drug coverage.

Target amount for any Part D plan equals the total amount of payments (from both CMS and by or on behalf of enrollees) to that plan for the coverage year for all standardized bid amounts as risk adjusted under § 423.329(b)(1), less the administrative expenses (including return on investment) assumed in the standardized bids.

§ 423.315 General payment provisions.

(a) *Source of payments*. CMS payments under this section are made from the Medicare Prescription Drug Account.

(b) *Monthly payments*. CMS provides a direct subsidy in the form of advance monthly payments equal to the Part D plan's standardized bid, risk adjusted for health status as provided in § 423.329(b), minus the monthly beneficiary premium as determined in § 423.286.

(c) *Reinsurance subsidies*. CMS provides reinsurance subsidy payments described in § 423.329(c) on a monthly basis during a year based on either estimated or incurred allowable reinsurance costs as provided under § 423.329(c)(2)(i), and final reconciliation to actual allowable reinsurance costs as provided in § 423.343(c).

(d) *Low-income subsidies*. CMS makes payments for premium and cost sharing subsidies, including additional coverage above the initial coverage limit, on behalf of certain subsidy-eligible individuals as provided in § 423.780 and § 423.782. CMS provides low-income cost-sharing subsidy payments described in § 423.782 through interim payments of amounts as provided under § 423.329(d)(2)(i) and reconciliation to actual allowable reinsurance costs as provided in § 423.343(d).

(e) *Risk-sharing arrangements*. CMS may issue lump-sum payments or adjust monthly payments in the following payment year based on the relationship of the Part D plan's adjusted allowable risk corridor costs to predetermined risk corridor thresholds in the coverage year as provided in § 423.336.

(f) *Retroactive adjustments and reconciliations*. CMS reconciles payment year disbursements with updated enrollment and health status data, actual low-income cost-sharing costs and actual allowable reinsurance costs as provided in § 423.343.

(g) *Special rules for private fee-for-service plans*.

(1) *Application of reinsurance*. For private fee-for-service plans (as defined by § 422.4(a)(3) of this chapter) offering qualified prescription drug coverage, CMS determines the amount of reinsurance payments as provided under § 423.329(c)(3).

(2) *Exemption from risk corridor provisions*. The provisions of § 423.336 regarding risk sharing do not apply.

§ 423.322 Requirement for disclosure of information.

(a) *Payment conditional upon provision of information*. Payments to a Part D sponsor are conditioned upon provision of information to CMS that is necessary to carry out this subpart, or as required by law.

(b) *Restriction on use of information*. Officers, employees and contractors of the Department of Health and Human Services may use the information disclosed or obtained in accordance with the provisions of this subpart only for the purposes of, and to the extent necessary in, carrying out this subpart including, but not limited to, determination of payments and payment-related oversight and program integrity activities. This restriction does not limit OIG's authority to fulfill the Inspector General's responsibilities in accordance with applicable Federal law.

§ 423.329 Determination of payments.

(a) *Subsidy payments*. (1) *Direct subsidy*. CMS makes a direct subsidy payment for each Part D eligible beneficiary enrolled in a Part D plan for a month equal to the amount of the plan's approved standardized bid, adjusted for health status (as determined under § 423.329(b)(1)), and reduced by the base beneficiary premium for the plan (as determined under § 423.286(c) and adjusted in § 423.286(d)(1)). The direct subsidy payment may be increased by the excess amount of a

negative premium as described in § 423.286(d)(1), if applicable.

(2) *Subsidy through reinsurance*. CMS makes reinsurance subsidy payments as provided under paragraph (c) of this section.

(3) *Low-income cost-sharing subsidy*. CMS makes low-income cost-sharing subsidy payments as provided under paragraph (d) of this section.

(b) *Health status risk adjustment*. (1) *Establishment of risk factors*. CMS establishes an appropriate methodology for adjusting the standardized bid amount to take into account variation in costs for basic prescription drug coverage among Part D plans based on the differences in actuarial risk of different enrollees being served. Any risk adjustment is designed in a manner so as to be budget neutral in the aggregate to the risk of the Part D eligible individuals who enroll in Part D plans.

(2) *Considerations*. In establishing the methodology under paragraph (b)(1) of this section, CMS takes into account the similar methodologies used under § 422.308(c) of this chapter to adjust payments to MA organizations for benefits under the original Medicare fee-for-service program option.

(3) *Data collection*. In order to carry out this paragraph, CMS requires—

(i) PDP sponsors to submit data regarding drug claims that can be linked at the individual level to Part A and Part B data in a form and manner similar to the process provided under § 422.310 of this chapter and other information as CMS determines necessary; and

(ii) MA organizations that offer MA-PD plans to submit data regarding drug claims that can be linked at the individual level to other data that the organizations are required to submit to CMS in a form and manner similar to the process provided under § 422.310 of this chapter and other information as CMS determines necessary.

(4) *Publication*. At the time of publication of risk adjustment factors under § 422.312(a)(1)(ii) of this chapter, CMS publishes the risk adjusters established under this paragraph of this section for the upcoming calendar year.

(c) *Reinsurance payment amount*. (1) *General rule*. The reinsurance payment amount for a Part D eligible individual enrolled in a Part D plan for a coverage year is an amount equal to 80 percent of the allowable reinsurance costs attributable to that portion of gross covered prescription drug costs incurred in the coverage year after the individual has incurred true out-of-pocket costs that exceed the annual out-of-pocket threshold specified in § 423.104(d)(5)(iii).

(2) *Payment method*. Payments under this section are based on a method that CMS determines.

(i) Payments during the coverage year. CMS establishes a payment method by which payments of amounts

under this section are made on a monthly basis during a year based on either estimated or incurred allowable reinsurance costs.

(ii) *Final payments*. CMS reconciles the payments made during the coverage year to final actual allowable reinsurance costs as provided in § 423.343(c).

(3) *Special rules for private fee-for-service Plans offering prescription drug coverage*. CMS determines the amount of reinsurance payments for private fee-for-service plans as defined by § 422.4(a)(3) of this chapter offering qualified prescription drug coverage using a methodology that—

(i) Bases the amount on CMS' estimate of the amount of the payments that are payable if the plan were an MA-PD plan described in section 1851(a)(2)(A)(i) of the Act; and

(ii) Takes into account the average reinsurance payments made under § 423.329(c) for populations of similar risk under MA-PD plans described in section 1851(a)(2)(A)(i) of the Act.

(d) *Low-income cost sharing subsidy payment amount*.

(1) *General rule*. The low-income cost-sharing subsidy payment amount on behalf of a low-income subsidy eligible individual enrolled in a Part D plan for a coverage year is the amount described in § 423.782.

(2) *Payment method*. Payments under this section are based on a method that CMS determines.

(i) *Interim payments*. CMS establishes a payment method by which interim payments of amounts under this section are made during a year based on the low-income cost-sharing assumptions submitted with plan bids under § 423.265(d)(2)(iv) and negotiated and approved under § 423.272.

(ii) *Final payments*. CMS reconciles the interim payments to actual incurred low-income cost-sharing costs as provided in § 423.343(d).

§ 423.336 Risk-sharing arrangements.

(a) *Portion of total payments to a Part D sponsor subject to risk*. (1) *Adjusted allowable risk corridor costs*. For purposes of this paragraph, the term adjusted allowable risk corridor costs means—

(i) The allowable risk corridor costs for the Part D plan for the coverage year, reduced by—

(ii) The sum of—

(A) The total reinsurance payments made under § 423.329(c) to the Part D sponsor of the Part D plan for the year; and

(B) The total non-premium subsidy payments made under § 423.782 to the Part D sponsor of the Part D plan for the coverage year.

(2) *Establishment of risk corridors*. (i) *Risk corridors*. For each year, CMS establishes a risk corridor for each Part D plan. The risk corridor for a plan for a coverage year is equal to a range as follows:

(A) *First threshold lower limit*. The first threshold lower limit of the corridor is equal to—

(*1*) The target amount for the plan; minus

(*2*) An amount equal to the first threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(A) of this section) of the target amount.

(B) *Second threshold lower limit*. The second threshold lower limit of the corridor is equal to—

(*1*) The target amount for the plan; minus

(*2*) An amount equal to the second threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(B) of this section) of the target amount.

(C) *First threshold upper limit*. The first threshold upper limit of the corridor is equal to the sum of—

(*1*) The target amount; and

(*2*) An amount equal to the first threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(A) of this section) of the target amount.

(D) *Second threshold upper limit*. The second threshold upper limit of the corridor is equal to the sum of—

(*1*) The target amount; and

(*2*) An amount equal to the second threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(B) of this section) of the target amount.

(ii) *First and second threshold risk percentage defined*. (A) *First threshold risk percentage*. Subject to paragraph (a)(2)(iii) of this section, the first threshold risk percentage is for—

(*1*) 2006 and 2007, 2.5 percent;

(*2*) 2008 through 2011, 5 percent; and

(*3*) 2012 and subsequent years, a percentage CMS establishes, but in no case less than 5 percent.

(B) *Second threshold risk percentage*. Subject to paragraph (a)(2)(iii) of this section, the second threshold risk percentage is for—

(1) 2006 and 2007, 5.0 percent;

(2) 2008 through 2011, 10 percent

(3) 2012 and subsequent years, a percentage CMS establishes that is greater than the percent established for

the year under paragraph (a)(2)(ii)(A)(3) of this section, but in no case less than 10 percent.

(iii) *Reduction of risk percentage to ensure two Plans in an area.* In accordance with § 423.265(e), a PDP sponsor may submit a bid that requests a decrease in the applicable first or second threshold risk percentages or an increase in the percents applied under paragraph (b) of this section. Only a PDP sponsor may request a reduction of risk under this paragraph. An MA organization offering an MA-PD plan, a PACE program offering qualified prescription drug coverage, and a cost-based HMO or CMP offering qualified prescription drug coverage may not request a reduction of risk under this paragraph.

(3) *Plans at risk for entire amount of supplemental prescription drug coverage.* A Part D sponsor that offers a Part D plan that provides supplemental prescription drug benefits is at full financial risk for the provision of the supplemental benefits.

(b) *Payment adjustments.* (1) *No adjustment if adjusted allowable risk corridor costs within risk corridor.* If the adjusted allowable risk corridor costs for the Part D plan for the coverage year are at least equal to the first threshold lower limit of the risk corridor (specified in paragraph (a)(2)(i)(A) of this section) but not greater than the first threshold upper limit of the risk corridor (specified in paragraph (a)(2)(i)(C) of this section) for the Part D plan for the coverage year, CMS makes no payment adjustment.

(2) *Increase in payment if adjusted allowable risk corridor costs above upper limit of risk corridor.*

(i) *Costs between first and second threshold upper limits.* If the adjusted allowable risk corridor costs for the Part D plan for the year are greater than the first threshold upper limit, but not greater than the second threshold upper limit, of the risk corridor for the Part D plan for the year, CMS increases the total of the payments made to the Part D sponsor offering the Part D plan for the year under this section by an amount equal to 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions described in paragraph (b)(2)(iii) of this section are met for the year) of the difference between the adjusted allowable risk corridor costs and the first threshold upper limit of the risk corridor.

(ii) *Costs above second threshold upper limits.* If the adjusted allowable risk corridor costs for the Part D plan for the year are greater than the second threshold upper limit of the risk corridor for the Part D plan for the year, CMS increases the total of the payments made to the Part D sponsor offering the Part D plan for the year under this section by an amount equal to the sum of—

(A) 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions specified in paragraph (b)(2)(iii) of this section are met for the year) of the difference between the second threshold upper limit and the first threshold upper limit; and

(B) 80 percent of the difference between the adjusted allowable risk corridor costs and the second threshold upper limit of the risk corridor.

(iii) *Conditions for application of higher percentage for 2006 and 2007.* The conditions specified in this paragraph are met for 2006 or 2007 if CMS determines for the year that—

(A) At least 60 percent of Part D plans to which this paragraph applies have adjusted allowable risk corridor costs for the Part D plan for the year that are more than the first threshold upper limit of the risk corridor for the Part D plan for the year; and

(B) Such plans represent at least 60 percent of Part D eligible individuals enrolled in any Part D plan.

(3) *Reduction in payment if adjusted allowable risk corridor costs below lower limit of risk corridor.*

(i) *Costs between first and second threshold lower limits.* If the adjusted allowable risk corridor costs for the Part D plan for the coverage year are less than the first threshold lower limit, but not less than the second threshold lower limit, of the risk corridor for the Part D plan for the coverage year, CMS reduces the total of the payments made to the Part D plan for the coverage year under this section by an amount (or otherwise recovers from the Part D sponsor an amount) equal to 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit of the risk corridor and the adjusted allowable risk corridor costs.

(ii) *Costs below second threshold lower limit.* If the adjusted allowable risk corridor costs for the Part D plan for the coverage year are less the second threshold lower limit of the risk corridor for the Part D plan for the coverage year, CMS reduces the total of the payments made to the Part D sponsor for the coverage year under this section by an amount (or otherwise recovers from the Part D sponsor an amount) equal to the sum of—

(A) 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit and the second threshold lower limit; and

(B) 80 percent of the difference between the second threshold upper limit of the risk corridor and the adjusted allowable risk corridor costs.

(c) *Payment methods.* CMS makes payments after a coverage year after obtaining all of the cost data information in paragraph (c)(1) of this section necessary to determine the amount of payment. CMS will not make payments under this section if the Part D sponsor fails to provide the cost data information in paragraph (c)(1) of this section.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) *Lump sum and adjusted monthly payments.* CMS at its discretion makes either lump-sum payments or adjusts monthly payments in the following payment year based on the relationship of the plan's adjusted allowable risk corridor costs to the predetermined risk corridor thresholds in the coverage year, as determined under this section.

(d) *No effect on monthly premium.* No adjustment in payments made by reason of this section may affect the monthly beneficiary premium for qualified prescription drug coverage.

§ 423.343 Retroactive adjustments and reconciliations.

(a) *Application of enrollee adjustment.* The provisions of § 422.308(f) of this chapter apply to payments to Part D sponsors under this section in the same manner as they apply to payments to MA organizations under section 1853(a) of the Act.

(b) *Health status.* CMS makes adjustments to payments made under § 423.329(a)(1) to account for updated health status risk adjustment data as provided under § 422.310(g)(2) of this chapter. CMS may recover payments associated with health status adjustments if the Part D sponsor fails to provide the information described in § 423.329(b)(3).

(c) *Reinsurance.* CMS makes final payment for reinsurance after a coverage year after obtaining all of the information necessary to determine the amount of payment.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) *Payments.* CMS at its discretion either makes lump-sum payments or adjusts monthly payments throughout the remainder of the payment year following the coverage year based on the difference between monthly reinsurance payments made during the coverage year and the amount payable in § 423.329(c) for the coverage year. CMS may recover payments made through a

lump sum recovery or by adjusting monthly payments throughout the remainder of the coverage year if the monthly reinsurance payments made during the coverage year exceed the amount payable under § 423.329(c) or if the Part D sponsor does not provide the data in paragraph (c)(1) of this section.

(d) *Low-income cost-sharing subsidy*. CMS makes final payment for low-income cost-sharing subsidies after a coverage year after obtaining all of the information necessary to determine the amount of payment.

(1) *Submission of cost data*. Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) *Payments*. CMS at its discretion either makes lump-sum payments or adjusts monthly payments throughout the remainder of the payment year following the coverage year based on the difference between interim low-income cost-sharing subsidy payments and total low-income cost-sharing subsidy costs eligible for subsidy under § 423.782 submitted by the plan for the coverage year. CMS may recover payments made through a lump sum recovery or by adjusting monthly payments throughout the remainder of the coverage year if interim low-income cost-sharing subsidy payments exceed the amount payable under § 423.782 or if the Part D sponsor does not provide the data in paragraph (d)(1) of this section. In the event adequate data is not provided for risk corridor costs, CMS assumes that the Part D plan's adjusted allowable risk corridor costs are 50 percent of the target amount.

§ 423.346 Reopening.

(a) CMS may reopen and revise an initial or reconsidered final payment determination (including a determination on the final amount of direct subsidy described in § 423.329(a)(1), final reinsurance payments described in § 423.329(c), the final amount of the low income subsidy described in § 423.329(d), or final risk corridor payments as described in § 423.336)—

(1) For any reason, within 12 months from the date of the notice of the final determination to the Part D sponsor

(2) After that 12-month period, but within 4 years after the date of the notice of the initial or reconsidered determination to the Part D sponsor, upon establishment of good cause for reopening; or

(3) At any time, in instances of fraud or similar fault of the Part D sponsor or any subcontractor of the Part D sponsor.

(b) For purposes of this section, CMS will find good cause if—

(1) New and material evidence that was not readily available at the time the final determination was made is furnished;

(2) A clerical error in the computation of payments was made; or

(3) The evidence that was considered in making the determination clearly shows on its face that an error was made.

(c) For purposes of this section, CMS will not find good cause if the only reason for reopening is a change of legal interpretation or administrative ruling upon which the final determination was made.

(d) A decision not to reopen under this section is final and is not subject to review.

§ 423.350 Payment appeals.

(a) *Payment determinations*. (1) *Payment methods subject to appeal*. If CMS did not apply its stated payment methodology correctly, a Part D sponsor may appeal the following:

(i) The reconciled health status risk adjustment of the direct subsidy as provided in § 423.343(b).

(ii) The reconciled reinsurance payments under § 423.343(c).

(iii) The reconciled final payments made for low-income cost sharing subsidies provided in § 423.343(d); or

(iv) Final risk-sharing payments made under § 423.336).

(2) *Payment information not subject to appeal*. Payment information submitted to CMS under § 423.322 and reconciled under § 423.343 is final and may not be appealed nor may the appeals process be used to submit new information after the submission of information necessary to determine retroactive adjustments and reconciliations.

(b) *Request for reconsideration*. (1) *Time for filing a request*. The request for reconsideration must be filed within 15 days from the date of the notice of the adverse determination.

(2) *Content of request*. The request for reconsideration must specify the findings or issues with which the Part D sponsor disagrees and the reasons for the disagreements. Excluding new payment information, the request for reconsideration may include additional documentary evidence the sponsor wishes CMS to consider.

(3) *Conduct of informal written reconsideration*.

In conducting the reconsideration, CMS reviews the payment determination, the evidence and findings upon which it was based, and any other written evidence submitted by the Part D sponsor or by CMS before notice of the reconsidered determination is made.

(4) *Decision of the informal written reconsideration*. CMS informs the sponsor of the decision orally or through electronic mail. CMS sends a written decision to the Part D sponsor on the sponsor's request.

(5) *Effect of CMS informal written reconsideration*.

A reconsideration decision, whether delivered orally or in writing, is final and binding unless a request for hearing is filed in accordance with paragraph (c) of this section, or it is revised in accordance with § 423.346.

(c) *Right to informal hearing*. A Part D sponsor dissatisfied with the CMS reconsideration decision is entitled to an informal hearing as provided in this section.

(1) *Manner and timing for request*. A request for a hearing must be made in writing and filed with CMS within 15 days of the date the Part D sponsor receives the CMS reconsideration decision.

(2) *Content of request*. The request for informal hearing must include a copy of the CMS reconsideration decision (if any) and must specify the findings or issues in the decision with which the Part D sponsor disagrees and the reasons for the disagreements.

(3) *Informal hearing procedures*. (i) CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The hearing are conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made both its initial and reconsideration determinations.

(iii) If CMS did not issue a written reconsideration decision, the hearing officer may request, but not require, a written statement from CMS or its contractors explaining CMS' determination, or CMS or its contractors may, on their own, submit the written statement to the hearing officer. Failure of CMS to submit a written statement does not result in any adverse findings against CMS and may not in any way be taken into account by the hearing officer in reaching a decision.

(4) *Decision of the CMS hearing officer*. The CMS hearing officer decides the case and sends a written decision to the Part D sponsor, explaining the basis for the decision.

(5) *Effecting of hearing officer decision*. The hearing officer decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (d) of this section.

(d) *Review by the Administrator*. (1) A Part D sponsor that has received a hearing officer decision upholding a CMS initial or reconsidered determination may request review by the Administrator within 15 days of receipt of the hearing officer's decision.

(2) The Administrator may review the hearing officer's decision, any written documents submitted to CMS or to the hearing officer, as well as any other information included in the record of the hearing officer's decision and determine whether to uphold, reverse or modify the hearing officer's decision.

(3) The Administrator's determination is final and binding.

Subpart H—[Reserved]

Subpart I—Organization Compliance with State Law and Preemption by Federal Law

§ 423.401 General requirements for PDP sponsors.

(a) *General requirements*. Each PDP sponsor of a prescription drug plan must meet the following requirements:

(1) *Licensure*. Except in cases where there is a waiver as specified at § 423.410 or § 423.415, the sponsor is organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan. If not otherwise licensed, the sponsor obtains certification from the State that the organization meets a level of financial solvency and other standards as the State may require for it to operate as a PDP sponsor.

(2) *Assumption of financial risk for unsubsidized coverage*. The PDP sponsor assumes financial risk on a prospective basis for benefits that it offers under a prescription drug plan and that is not covered under section 1860D–15(b) of the Act.

(b) *Reinsurance permitted*. The PDP sponsor may obtain insurance or make other arrangements for the cost of coverage provided to any enrollee to the extent that the sponsor is at risk for providing the coverage.

(c) *Solvency for unlicensed sponsors*. In the case of a PDP sponsor that is not described in § 423.401(a)(1) and for which a waiver is approved under § 423.410 or § 423.415, the sponsor must meet the requirements in § 423.420.

§ 423.410 Waiver of certain requirements to expand choice.

(a) *Authorizing waiver*. In the case of an entity that seeks to offer a prescription drug plan in a State, CMS waives the licensure requirement at § 423.401(a)(1), which requires that the entity be licensed in that State if CMS determines, based on the application and other evidence presented, that any of the grounds for approval of the application described in paragraphs (b), (c), or (d) of this section are met.

(b) *Grounds for approval of waivers*. Subject to the waiver requirements specified in § 423.410(e), waivers may be granted under any of the following conditions:

(1) *Failure to act on licensure application on a timely basis*. The State failed to complete action on the licensing application within 90 days of the date that the State received a substantially complete application.

(2) *Denial of application based on discriminatory treatment*. The State denied the license application on either of the following bases—-

(i) The State imposed material requirements,

procedures, or standards (other than solvency requirements) not generally applied by the State to other entities engaged in a substantially similar business; or

(ii) The State required, as a condition of licensure, that the organization offer any product or plan other than a prescription drug plan.

(3) *Denial of application based on application of solvency requirements*. The State denied the licensure application, in whole or in part, on the basis of the PDP sponsor's failure to meet solvency requirements and

(i) The solvency requirements are different from the solvency standards CMS establishes in accordance with § 423.420; or

(ii) CMS determines that the State imposed, as a condition of licensing, any documentation or information requirements relating to solvency that are different from the standards CMS establishes in accordance with § 423.420.

(4) *Grounds other than those required by Federal Law*. The application by a State of any grounds other than those required under Federal law.

(c) *Waiver when licensing process not in effect*. The grounds for approval specified in paragraph (b)(1) of this section are deemed met if CMS determines that the State does not have a licensing process in effect for PDP sponsors.

(d) *Special waiver for plan years beginning before January 1, 2008*. For plan years beginning before January 1, 2008, if the State has a prescription drug plan or PDP sponsor licensing process in effect, CMS grants a waiver upon a demonstration that an applicant to become a PDP sponsor has submitted a fully completed application for licensure to the State.

(e) *Waiver requirements*. The following rules apply to waiver applications or waivers granted under this section.

(1) *Treatment of waiver*. The waiver applies only to that State, is effective for 36 months, and cannot be renewed.

(2) *Prompt action on application*. CMS grants or denies a waiver application under this section within 60 days after CMS determines that a substantially complete waiver application is received by CMS.

(3) *A State that does not have a PDP sponsor*. In the case of a State that does not have a PDP sponsor licensing process, the 36 month limitation on the waiver discussed in paragraph (e)(1) of this section does not apply, and the waiver may continue in effect for a given State as long as CMS determines that the State does not have a PDP sponsor licensing process in effect, and the PDP sponsor meets the solvency standards of § 423.420(a).

§ 423.415 Temporary waivers for entities seeking to offer a prescription drug plan in more than one State in a region

(a) *General rule*. Subject to paragraphs (b) and (c) of this section, if an applicant seeking to become a PDP sponsor wishes to operate in more than one State in a region, and is licensed as a risk bearing entity in at least one State in the region, then the applicant may receive a temporary regional plan waiver for the States in which it is not licensed.

(b) *Filing of application*. The applicant must demonstrate to the satisfaction of CMS that it filed the necessary licensure applications with each State in the region for which it does not already have State licensure, except that no application is necessary if CMS determines that the State does not have a licensing process for potential PDP sponsors.

(c) *Processing of application for temporary waiver*. The Secretary determines the time period appropriate for the timely processing of the application for temporary waiver.

(d) *Time limit for temporary waiver*. The temporary waiver expires at the end of time period that the Secretary determines is appropriate for timely processing of the application by the State or States, but in no case is a waiver extend beyond the end of the calendar year.

§ 423.420 Solvency standards for non-licensed entities.

(a) *Establishment and publication*. CMS establishes and publishes reasonable financial solvency and

capital adequacy standards for entities specified in paragraph (b) of this section.

(b) *Compliance with standards.* A PDP sponsor that is not licensed by a State and for which a waiver application is approved by CMS under § 423.410 or § 423.415 must maintain reasonable financial solvency and capital adequacy in accordance with the standards established by CMS under paragraph (a) of this section.

§ 423.425 Licensure does not substitute for or constitute certification.

The fact that a Part D sponsor is State licensed or has a waiver application approved under § 423.410 or § 423.415 does not deem the sponsor to meet other requirements imposed under this part for a Part D sponsor.

§ 423.440 Prohibition of State imposition of premium taxes; relation to State laws.

(a) *Federal preemption of State law.* The standards established under this part supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) for Part D plans offered by Part D plan sponsors..

(b) *State premium taxes prohibited.* (1) *Basic rule.* No premium tax, fee, or other similar assessment may be imposed by any State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa, the Mariana Islands or any of their political subdivisions or other governmental authorities for any payment CMS makes on behalf of Part D plan or enrollees under this part (including the direct subsidy, reinsurance payments, and risk corridor payments); or for any payment made to Part D plans by a beneficiary or by a third party on behalf of a beneficiary.

(2) *Construction.* Nothing in this section may be construed to exempt any Part D plan sponsor from taxes, fees, or other monetary assessments related to the net income or profit that accrues to, or is realized by, the organization from business conducted under this part, if that tax, fee, or payment is applicable to a broad range of business activity.

Subpart J—Coordination of Part D Plans With Other Prescription Drug Coverage

§ 423.452 Scope.

This section sets forth the application of Part D rules to Part C plans; establishes waivers for MA-PD plans, employer-sponsored group prescription drug plans, cost plans, and PACE organizations; and establishes requirements for coordination of benefits with State Pharmaceutical Assistance Programs and other providers of prescription drug coverage.

§ 423.454 Definitions.

For purposes of this part, the following definitions apply—

Employer-sponsored group prescription drug plan means prescription drug coverage offered to retirees who are Part D eligible individuals under employment-based retiree health coverage (as defined in § 423.882) approved by CMS as a prescription drug plan.

State Pharmaceutical Assistance Program (SPAP) means a State program that meets the requirements described under § 423.464(e)(1).

§ 423.458 Application of Part D rules to certain Part D plans on and after January 1, 2006.

(a) *Relationship to Part C.* Except as otherwise provided in this Part, the requirements of this Part apply to prescription drug coverage provided by MA-PD plans offered by MA organizations beginning on or after January 1, 2006.

(b) *MA waiver.* CMS waives any provision of this Part otherwise applicable to MA-PD plans or MA organizations under paragraph (a) of this section to the extent CMS determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to the MA organizations or MA-PD plans under Part C of Medicare, or as may be necessary in order to improve coordination of this part with the benefits under Part C.

(1) *Application of waiver.* Any waiver or modification granted by CMS under this section applies to any other similarly situated organization offering or seeking to offer a MA-PD plan that meets the conditions of the waiver.

(2) *Request for waivers.* Organizations offering or

seeking to offer a MA-PD plan may request from CMS in writing—

(i) A waiver of those requirements under this part otherwise applicable to the MA-PD plan or MA organization under paragraph (a) of this section that are duplicative of, or that are in conflict with, provisions otherwise applicable to the MA-PD plan, proposed MA-PD plan, or a MA organization under Part C of Medicare.

(ii) A waiver of a requirement under this part otherwise applicable to the MA-PD plan or MA organization under paragraph (a) of this section, if such waiver improves coordination of benefits provided under Part C of Medicare with benefits under this Part.

(c) *Employer group waiver.* (1) *General rule.* CMS may waive or modify any requirement under this part that hinders the design of, the offering of, or the enrollment in an employer-sponsored group prescription drug plan, including authorizing the establishment of separate premium amounts for enrollees of the employer-sponsored group prescription drug plan and limitations on enrollment in such plan to Part D eligible individuals participating in the sponsor's employment-based retiree health coverage. Any entity seeking to offer, sponsor, or administer an employer-sponsored group prescription drug plan may request, in writing, a waiver or modification of additional requirements under this Part that hinder its design of, the offering of, or the enrollment in, such employer-sponsored group prescription drug plan.

(2) *Use of waiver.* Waivers or modifications approved by CMS under this section apply to any similarly situated entity seeking to offer, sponsor, or administer an employer-sponsored group prescription drug plan, meeting the conditions of the waiver or modification.

(d) *Other waivers.* CMS waives any provision of this Part as applied to a cost plan (as defined in § 417.401 of this chapter) or PACE organization (as defined in § 460.6 of this chapter) that offers qualified prescription drug coverage under Part D to the extent CMS determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to the cost plan under section 1876 of the Act or provisions applicable to PACE organizations under sections 1894 and 1934 of the Act, or as necessary in order to improve coordination of this Part with the benefits offered by cost plans or PACE organizations.

(1) *Application of waiver.* Any waiver or modification granted by CMS under this paragraph applies to any other similarly situated organization offering or seeking to offer qualified prescription drug coverage as a cost plan under section 1876 of the Act or as a PACE organization under sections 1894 and 1934 of the Act.

(2) *Request for waivers.* Cost plans or PACE organizations seeking to offer qualified prescription drug coverage may request from CMS in writing-

(i) A waiver of those requirements under this part otherwise applicable to cost plans or PACE organizations that are duplicative of, or that are in conflict with, provisions otherwise applicable to cost plans or PACE organizations.

(ii) A waiver of a requirement under this part otherwise applicable to cost plans or PACE organizations, if such waiver improves coordination of

benefits provided by the cost plan under section 1876 of the Act, or by the PACE organization under section 1934 of the Act, with the benefits under Part D.

§ 423.462 Medicare secondary payer procedures.

The provisions of § 422.108 of this chapter regarding Medicare secondary payer procedures apply to Part D sponsors and Part D plans (with respect to the offering of qualified prescription drug coverage) in the same way as they apply to MA organizations and MA plans under Part C of title XVIII of the Act, except all references to MA organizations and MA plans are considered references to Part D sponsors and Part D plans.

§ 423.464 Coordination of benefits with other providers of prescription drug coverage.

(a) *General rule.* A Part D plan must permit SPAPs (described in paragraph (e)(1) of this section) and entities providing other prescription drug coverage (described in paragraph (f)(1) of this section) to coordinate benefits with such plan. A Part D plan must comply with all administrative processes and requirements established by CMS to ensure effective exchange of information and coordination between such plan and SPAPs and entities providing other prescription drug coverage for—

(1) Payment of premiums and coverage; and

(2) Payment for supplemental prescription drug benefits as described in § 423.104(f)(1)(ii)(including payment to a Part D plan on a lump sum per capita basis) for Part D eligible individuals enrolled in the Part D plan and the SPAP or entity providing other prescription drug coverage.

(b) *Medicare as primary payer.* The requirements of this subpart do not change or affect the primary or secondary payer status of a Part D plan and a SPAP or other prescription drug coverage. A Part D plan is always the primary payer relative to a State Pharmaceutical Assistance Program.

(c) *User fees.* CMS may impose user fees on Part D plans for the transmittal of information necessary for benefit coordination in accordance with administrative processes and requirements established by CMS to ensure effective exchange of information and coordination between a Part D plan and SPAPs and entities providing other prescription drug coverage in a manner similar to the manner in which user fees are imposed under section 1842(h)(3)(B) of the Act, except that CMS may retain a portion of user fees to defray its costs in carrying out such procedures. CMS will not impose user fees under this subpart on a SPAP or entities providing other prescription drug coverage.

(d) *Cost management tools.* The requirements of this subpart do not prevent a Part D sponsor from using cost management tools (including differential payments) under all methods of operation.

(e) *Coordination with State Pharmaceutical Assistance Programs.* (1) *Requirements to be a State Pharmaceutical Assistance Program (SPAP).* A State program is considered to be a State Pharmaceutical Assistance Program for purposes of this part if it-

(i) Provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals;

(ii) Provides assistance to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls;

(iii) Meets the benefit coordination requirements specified in this subpart;

(iv) Does not follow or adopt rules that change or affect the primary payer status of a Part D plan.

The definition of SPAP excludes State Medicaid programs, section 1115 demonstration programs, and any other program where program funding is from Federal grants, awards, contracts, entitlement programs, or other Federal sources of funding; and

(v) Provides supplemental drug coverage to individuals based on financial need, age, or medical condition, and not based on current or former employment status.

(2) *Use of a single card.* A card that is issued under § 423.120(c) for use under a Part D plan may also be used in connection with coverage of benefits provided under a SPAP and, in such a case, may contain an emblem or symbol indicating such connection.

(3) *Construction.* Nothing in this subpart requires a SPAP to coordinate with, or provide financial assistance to enrollees in, any Part D plan.

(f) *Coordination with other prescription drug coverage.* (1) *Definition of other prescription drug coverage.* Entities that provide other prescription drug coverage include any of the following:

(i) *Medicaid programs.* A State plan under title XIX of the Act, including such a plan operating under a waiver under section 1115 of the Act, if it meets the requirements of paragraph (e)(1)(ii) of this section.

(ii) Group health plans.

(iii) *FEHBP.* The Federal Employee Health Benefits Program under chapter 89 of title 5, United States Code.

(iv) *Military coverage (including TRICARE).* Coverage under chapter 55 of title 10, United States Code.

(v) *Indian Health Service.* Coverage under Chapter 18 of title 28 of the United States Code.

(vi) *Federally qualified health centers.* Federally qualified health centers as defined under section 1861(aa)(4) of the Act.

(vii) *Rural health centers.* Rural health centers as defined under section 1861(aa)(2) of the Act.

(viii) *Other prescription drug coverage.* Other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of Part D drugs on behalf of Part D eligible individuals as CMS may specify.

(2) *Treatment under out-of-pocket rule.* A Part D plan must exclude expenditures for covered Part D drugs made by insurance or otherwise, a group health plan, or other third party payment arrangements, including expenditures by plans offering other prescription drug coverage for purposes of determining whether a Part D plan enrollee has satisfied the out-of-pocket threshold provided under § 423.104(d)(5)(iii). A Part D enrollee must disclose all these expenditures to a Part D plan in accordance with requirements under § 423.32(b)(ii).

(3) *Imposition of fees.* A Part D sponsor may not impose fees on SPAPs and entities offering other prescription drug coverage that are unrelated to the cost of the coordination of benefits.

(4) *Authority to recover expenditures due to incorrect information on true out-of-pocket costs.* In the event that a Part D plan learns that it has made an erroneous payment due to inaccurate or incomplete information on the satisfaction of the out-of-pocket threshold under § 423.104(d)(5)(iii), that plan is authorized to recover such costs directly from the Part D enrollee on whose behalf the costs were incurred. A Part D enrollee must reimburse the Part D plan for payment made for these costs.

Subpart K—Application Procedures and Contracts with Part D plan sponsors

§ 423.500 Scope.

This subpart sets forth application procedures and contracts with Part D plans: application procedures and requirements; contract terms; procedures for termination of contracts; reporting by Part D plans. For purposes

of this subpart, Medicare Advantage (MA) organizations offering Part D plans follow the requirements of part 422 of this chapter for MA organizations, except in cases where the requirements for the qualified prescription drug coverage involve additional requirements.

§ 423.501 Definitions

For purposes of this subpart, the following definitions apply:

Business transaction means any of the following kinds of transactions:

(1) Sale, exchange, or lease of property.

(2) Loan of money or extension of credit.

(3) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(i) Salaries paid to employees for services performed in the normal course of their employment; or

(ii) Health services furnished to the Part D plan sponsor's enrollees by pharmacies and other providers, by Part D plan sponsor staff, medical groups, or independent practice associations, or by any combination of those entities.

Downstream entity means any party that enters into a written arrangement, acceptable to CMS, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

First tier entity means any party that enters into a written arrangement, acceptable to CMS, with a Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.

Party in interest means the following:

(1) Any director, officer, partner, or employee responsible for management or administration of a Part D plan sponsor.

(2) Any person who is directly or indirectly the beneficial owner of more than 5 percent of the organization's equity; or the beneficial owner of a mortgage, deed of trust, note, or other interest secured by and valuing more than 5 percent of the organization.

(3) In the case of a PDP sponsor organized as a nonprofit corporation, an incorporator or member of the corporation under applicable State corporation law.

(4) Any entity in which a person specified in paragraphs (1), (2), or (3) of this definition—

(i) Is an officer, director, or partner; or

(ii) Has the kind of interest described in paragraphs (1), (2), or (3) of this definition.

(5) Any person that directly or indirectly controls, is controlled by, or is under common control with the Part D plan sponsor.

(6) Any spouse, child, or parent of an individual specified in paragraphs (1), (2), or (3) of this definition.

Related entity means any entity that is related to the PDP sponsor by common ownership or control and—

(1) Performs some of the Part D plan sponsor's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the Part D plan sponsor at a cost of more than $2,500 during a contract period.

Significant business transaction means any business transaction or series of transactions of the kind specified in the above definition of business transaction that, during any fiscal year of the Part D plan sponsor, have a total value that exceeds $25,000 or 5 percent of the PDP sponsor's total operating expenses, whichever is less.

§ 423.502 Application requirements.

(a) *Scope*. This section sets forth application requirements for an entity that seeks a determination from CMS that it is qualified to contract as a sponsor of a Part D plan.

(b) *Completion of an application*. (1) In order to obtain a determination on whether it meets the requirements to become a Part D plan sponsor, an entity, or an individual authorized to act for the entity (the applicant), must complete a certified application in the form and manner required by CMS, including the following:

(i) Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards as specified in subpart I of this part; or

(ii) A Federal waiver as specified in subpart I of this part.

(2) The authorized individual must describe thoroughly how the entity is qualified to meet the requirements described in this part.

(c) *Responsibility for making determinations*. (1) CMS is responsible for determining whether an entity is qualified to contract as a Part D plan sponsor and meets the requirements of this part.

(2) A CMS determination that an entity is qualified to act as a Part D plan sponsor is distinct from the bid negotiations that occur under subpart F of part 423 and such negotiations are not subject to the appeals provisions included in subpart N of this part.

(d) *Disclosure of application information under the Freedom of Information Act*. An applicant submitting material that he or she believes is protected from disclosure under 5 USC 552, the Freedom of Information Act, or because of exemptions provided in 45 CFR part 5 (the Department's regulations providing exemptions to disclosure), must label the material ''privileged'' and include an explanation of the applicability of an exemption specified in 45 CFR part 5.

§ 423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.

(a) *Basis for evaluation and determination*. (1) CMS evaluates an entity's application on the basis of information contained in the application itself and any additional information that CMS obtains through on-site visits, publicly available information, and any other appropriate procedures.

(2) After evaluating all relevant information, CMS determines whether the application meets the applicable requirements specified in § 423.504 and § 423.505.

(b) *Use of information from a prior contracting period*. If a Part D plan sponsor fails to comply with the terms of a previous year's contract (or in the case of a fallback entity, the previous 3-year contract) with CMS under title XVIII of the Act, or fails to complete a corrective action plan during the term of the contract, CMS may deny an application based on the applicant's failure to comply with that prior contract with CMS even if the applicant currently meets all of the requirements of this part..

(c) *Notice of determination*. Except for fallback entities, which are governed under subpart Q of this part, CMS notifies each applicant that applies to be determined qualified to contract as a Part D plan sponsor, under this part, of its determination on the application and the basis for the determination. The determination may be one of the following:

(1) *Approval of application*. If CMS approves the application, it gives written notice to the applicant, indicating that it qualifies to contract as Part D plan sponsor.

(2) *Intent to deny*. (i) If CMS finds that the applicant does not appear qualified to contract as a Part D plan sponsor and/or has not provided enough information to evaluate the application, it gives the

applicant notice of intent to deny the application and a summary of the basis for this preliminary finding.

(ii) Within 10 days from the date of the notice, the applicant may respond in writing to the issues or other matters that were the basis for CMS's preliminary finding and may revise its application to remedy any defects CMS identified.

(3) Denial of application. If CMS denies the application, it gives written notice to the applicant indicating—

(i) That the applicant is not qualified to contract as a Part D sponsor under Part D of title XVIII of the Act;

(ii) The reasons why the applicant does is not so qualified; and

(iii) The applicant's right to request reconsideration in accordance with the procedures specified in subpart N.

(d) *Oversight of continuing compliance*. (1) CMS oversees a Part D plan sponsor's continued compliance with the requirements for a Part D plan sponsor.

(2) If a Part D plan sponsor no longer meets those requirements, CMS terminates the contract in accordance with § 423.509.

§ 423.504 General provisions.

(a) *General rule*. Subject to the provisions at § 423.265(a)(1) concerning submission of bids, to enroll beneficiaries in any Part D drug plan it offers and be paid on behalf of Part D eligible individuals enrolled in those plans, a Part D plan sponsor must enter into a contract with CMS. The contract may cover more than one Part D plan.

(b) *Conditions necessary to contract as a Part D plan sponsor*. Any entity seeking to contract as a Part D plan sponsor must—

(1) Complete an application as described in § 423.502 demonstrating that the entity has the capability to meet the requirements of this Part, including those listed in § 423.505.

(2) Be organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a Part D plan, or have secured a Federal waiver, as described in subpart I of this part. (Fallback entity applicants need not be licensed as risk-bearing entities, nor are they required to obtain State licensure demonstrating that the applicant is eligible to offer health insurance or health benefits coverage in each State in which it applies to operate.)

(3) Meet the minimum enrollment requirements of § 423.512(a) unless waived under § 423.512(b).

(4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following:

(i) A policy making body that exercises oversight and control over the Part D plan sponsor's policies and personnel to ensure that management actions are in the best interest of the organization and its enrollees.

(ii) Personnel and systems sufficient for the Part D plan sponsor to organize, implement, control, and evaluate financial and marketing activities, the furnishing of prescription drug services, the quality assurance, medical therapy management, and drug and or utilization management programs, and the administrative and management aspects of the organization.

(iii) At a minimum, an executive manager whose appointment and removal are under the control of the policy making body.

(iv) A fidelity bond or bonds, procured and maintained by the Part D sponsor, in an amount fixed by its policymaking body but not less than $100,000 per individual, covering each officer and employee entrusted with the handling of its funds. The bond may have reasonable deductibles, based upon the financial strength of the Part D plan sponsor.

(v)Insurance policies or other arrangements, secured and maintained by the Part D plan sponsor and approved by CMS to insure the Part D plan sponsor against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks.

(vi) A compliance plan that consists of the following—

(A)Written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State standards.

(B)The designation of a compliance officer and compliance committee accountable to senior management.

(C)Effective training and education between the compliance officer and organization employees, contractors, agents, and directors.

(D)Effective lines of communication between the compliance officer and the organization's employees, contractors, agents, directors, and members of the compliance committee.

(E)Enforcement of standards through well-publicized disciplinary guidelines.

(F) Procedures for effective internal monitoring and auditing.

(G) Procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives relating to the organization's contract as a Part D plan sponsor.

(*1*) If the Part D sponsor discovers evidence of misconduct related to payment or delivery of prescription drug items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct;

(*2*) The Part D sponsor must conduct appropriate corrective actions (for example, repayment of overpayments and disciplinary actions against responsible individuals) in response to the potential violation referenced above.

(H) A comprehensive fraud and abuse plan to detect, correct, and prevent fraud, waste, and abuse. This fraud and abuse plan should include procedures to voluntarily self-report potential fraud or misconduct related to the Part D program to the appropriate government authority.

(5) Not have non-renewed a contract under § 423.507 within the past 2 years unless—

(i) During the 6-month period, beginning on the date the entity notified CMS of the intention to non-renew the most recent previous contract, there was a change in the statute or regulations that had the effect of increasing Part D sponsor payments in the payment area or areas at issue; or

(ii) CMS has otherwise determined that circumstances warrant special consideration.

(6) For a full risk or limited risk PDP applicant, not submitted a bid or offered a fallback prescription drug plan in accordance with the following rules.

(i) CMS does not contract with a potential PDP sponsor for the offering of a full risk or limited risk prescription drug plan in a PDP region for a year if the applicant—

(A) Submitted a bid under § 423.863 for the year (as the first year of a contract period under § 423.863 to offer a fallback prescription drug plan in any PDP region;

(B) Offers a fallback prescription drug plan in any PDP region during the year; or

(C) Offered a fallback prescription drug plan in that PDP region during the previous year.

(ii) *Construction*. For purposes of this paragraph (b)(6), an entity is treated as submitting an application to become qualified to contract as a full risk or limited risk PDP sponsor, if the entity is acting as a subcontractor for an integral part of the drug benefit management activities of a full risk or limited risk PDP sponsor or applicant. The previous sentence does not apply to entities that are subcontractors of an MA organization except insofar as the MA organization is applying to act as a full risk or limited risk PDP sponsor.

(c) *Contracting authority*. CMS may enter into contracts under this part, or in order to carry out this part, without regard to Federal and Departmental acquisition regulations set forth in Title 48 of the CFR and provisions of law or other regulations relating to the making, performance, amendment, or modification of contracts of the United States if CMS determines that those provisions are inconsistent with the efficient and effective administration of the Medicare program.

(d) *Protection against fraud and beneficiary protections*. (1) CMS annually audits the financial records (including, but not limited to, data relating to Medicare utilization and costs, including allowable reinsurance and risk corridor costs as well as low income subsidies and other costs) under this part of at least one-third of the Part D sponsors offering Part D drug plans.

(2) Each contract under this section must provide that CMS, or any person or organization designated by CMS, has the right to—

(i) Inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the Part D plan sponsor's contract;

(ii) Inspect or otherwise evaluate the facilities of the Part D sponsor when there is reasonable evidence of some need for the inspection; and

(iii) Audit and inspect any books, contracts, and records of the Part D plan sponsor that pertain to—

(A) The ability of the organization or its first tier or downstream providers to bear the risk of potential financial losses; or

(B) Services performed or determinations of amounts payable under the contract.

(e) *Severability of contracts*. The contract must provide that, upon CMS' request—

(1) The contract could be amended to exclude any State-licensed entity, or a Part D plan specified by CMS; and

(2) A separate contract for any excluded plan or entity must be deemed to be in place when a request is made.

§ 423.505 Contract provisions.

(a) *General rule*. The contract between the Part D plan sponsor and CMS must contain the provisions specified in paragraph (b) of this section.

(b) *Requirements for contracts*. The Part D plan sponsor agrees to—

(1) All the applicable requirements and conditions set forth in this part and in general instructions.

(2) Accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments, as provided in subpart B of this part.

(3) Comply with the prohibition in § 423.34(a) on discrimination in beneficiary enrollment.

(4) Provide the basic prescription drug coverage as defined under § 423.100 and, to the extent applicable, supplemental benefits as defined in § 423.100. (Fallback entities may offer only standard prescription drug coverage as specified in § 423.855.)

(5) Disclose information to beneficiaries in the manner and the form specified by CMS under § 423.128.

(6) Operate quality assurance, cost and utilization management, medication therapy management, and support e-prescribing as required under subpart D of this part.

(7) Comply with all requirements in subpart M of this part governing coverage determinations, grievances, and appeals, and formulary exceptions.

(8) Comply with the reporting requirements in § 423.514 and the requirements in § 423.329(b) for submitting drug claims and related information to CMS for its use in risk adjustment calculations.

(9) Provide CMS with the information CMS determines is necessary to carry out payment provisions in subpart G of this part (or for fallback entities, the information necessary to carry out the payment provisions in subpart Q of this part).

(10) Allow CMS to inspect and audit any books and records of a Part D plan sponsor that pertain to the information regarding costs provided to CMS under paragraph (b)(9) of this section, or, if a fallback entity, the information submitted under subpart Q.

(11) Be paid under the contract in accordance with the payment rules in subpart G of this part, or, if a fallback entity, in accordance with the payment rules of subpart Q of this part.

(12) Except for fallback entities, submit a future year's bid, including all required information on premiums, benefits, and cost-sharing, by any applicable due date, as provided in subpart F so that CMS and the Part D plan sponsor may conduct negotiations regarding the terms and conditions of the proposed bid and benefit plan renewal.

(13) Permit CMS to determine that it is not qualified to renew its contract or that its contract may be terminated in accordance with this subpart and subpart N of this part. (Subpart N applies to fallback entities only to the extent a fallback contract is terminated.)

(14) Comply with the confidentiality and enrollee record accuracy specified in § 423.136.

(15) Comply with State law and preemption by Federal law requirements described in subpart I of this part.

(16) Comply with the coordination requirements with SPAPs and plans that provide other prescription drug coverage as described in subpart J of this part.

(17) Provide benefits by means of point of service systems to adjudicate in a drug claims in a timely and efficient manner in compliance with CMS standards, except when necessary to provide access in underserved areas, I/T/U pharmacies (as defined in § 423.100), and long-term care pharmacies (as defined in § 423.100).

(18) To agree to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy.

(c) *Communication with CMS*. The Part D plan sponsor must have the capacity to communicate with CMS electronically in accordance with CMS requirements.

(d) *Maintenance of records*. The Part D plan sponsor agrees to maintain, for 10 years, books, records, documents, and other evidence of accounting procedures and practices that-

(1) Are sufficient to do the following:

(i) Accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, and computation of the bid of part D plan sponsors).

(ii) Enable CMS to inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the contract and the facilities of the organization.

(iii) Enable CMS to audit and inspect any books and records of the Part D plan sponsor that pertain to the ability of the organization to bear the risk of potential financial losses, or to services performed or determinations of amounts payable under the contract.

(iv) Except for fallback entities, properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of the Part D plan sponsor's bid and necessary for the calculation of gross covered prescription drug costs, allowable reinsurance costs, and allowable risk corridor costs (as defined in § 423.308).

(v) Except for fallback entities, establish the basis for the components, assumptions, and analysis used by the Part D plan in determining the actuarial valuation of standard, basic alternative, or enhanced alternative coverage offered in accordance with the CMS guidelines specified in § 423.265(c)(3).

(2) Include records of the following:

(i) Ownership and operation of the Part D sponsor's financial, medical, and other record keeping systems.

(ii) Financial statements for the current contract period and 10 prior periods.

(iii) Federal income tax or informational returns for the current contract period and 10 prior periods.

(iv) Asset acquisition, lease, sale, or other actions.

(v) Agreements, contracts, and subcontracts.

(vi) Franchise, marketing, and management agreements.

(vii) Matters pertaining to costs of operations.

(viii) Amounts of income received by source and payment.

(ix) Cash flow statements.

(x) Any financial reports filed with other Federal programs or State authorities.

(xi) All prescription drug claims for the current contract period and 10 prior periods.

(xii) All price concessions (including concessions offered by manufacturers) for the current contract period and 10 prior periods accounted for separately from other administrative fees.

(e) *Access to facilities and records*. The Part D plan sponsor agrees to the following:

(1) HHS, the Comptroller General, or their designee may evaluate, through inspection or other means—

(i) The quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract;

(ii) The facilities of the Part D plan sponsor; and

(iii) The enrollment and disenrollment records for the current contract period and 10 prior periods.

(2) HHS, the Comptroller General, or their designees may audit, evaluate, or inspect any books, contracts, medical record s, patient care documentation, and other records of the Part D plan sponsor, related entity(s), contractor(s), subcontractor(s), or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or as the Secretary may deem necessary to enforce the contract.

(3) The Part D plan sponsor agrees to make available, for the purposes specified in paragraph (d) of this section, its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that CMS may require.

(4) HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 10 years from the end of the final contract period or completion of audit, whichever is later unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the Part D plan sponsor at least 30 days before the normal disposition date;

(ii) There is a termination, dispute, or allegation of fraud or similar fault by the Part D plan sponsor, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, or fraud or similar fault; or

(iii) CMS determines that there is a reasonable possibility of fraud or similar fault, in which case CMS may inspect, evaluate, and audit the Part D plan sponsor at any time.

(f) *Disclosure of information*. The Part D plan sponsor agrees to submit to CMS—

(1) Certified financial information that must include the following:

(i) Information as CMS may require demonstrating that the organization has a fiscally sound operation.

(ii) Information as CMS may require pertaining to the disclosure of ownership and control of the Part D plan sponsor.

(2) All information to CMS that is necessary for CMS to administer and evaluate the program and to simultaneously establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining prescription drug coverage. This information includes, but is not limited to:

(i) The benefits covered under a Part D plan.

(ii) The Part D plan monthly basic beneficiary premium and Part D plan monthly supplemental beneficiary premium, if any, for the plan. Fallback entities submit the monthly beneficiary premium for standard prescription drug coverage.

(iii) The service area of each plan.

(iv) Plan quality and performance indicators for the benefits under the plan including—

(A) Disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous 2 years;

(B) Information on Medicare enrollee satisfaction;

(C) The recent records regarding compliance of the plan with requirements of this part, as determined by CMS; and

(D) Other information determined by CMS to be necessary to assist beneficiaries in making an informed choice regarding Part D plans.

(v) Information about beneficiary appeals and their disposition, and formulary exceptions.

(vi) Information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization.

(vii) Information on other matters that CMS may require, including, but not limited to, program monitoring and oversight, performance measures, quality assessment, research and evaluation, CMS outreach activities, payment-related oversight*, and fraud, abuse, and waste*, as specified in CMS guidelines.

(viii) Any other information deemed necessary to CMS for the administration or evaluation of the Medicare program.

(3)To its enrollees, all informational requirements under § 423.128 and, upon an enrollee's request, the financial disclosure information required under § 423.128(c)(4).

(g) *Beneficiary financial protections*. The Part D plan sponsor agrees to comply with the following requirements:

(1) Each Part D plan sponsor must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability for payment of any fees that are the legal obligation of the Part D sponsor. To meet this requirement, the Part D plan sponsor must—

(i) Ensure that all contractual or other written arrangements prohibit the sponsor's contracting agents from holding any beneficiary enrollee liable for payment of any such fees; and

(ii) Indemnify the beneficiary enrollee for payment of any fees that are the legal obligation of the Part D plan sponsor for covered prescription drugs furnished by non-contracting pharmacists, or that have not otherwise entered into an agreement with the Part D plan sponsor, to provide services to the organization's beneficiary enrollees.

(2) In meeting the requirements of this paragraph, other than the provider contract requirements specified in paragraph (g)(1)(i) of this section, the Part D plan sponsor may use—

(i) Contractual arrangements;

(ii) Insurance acceptable to CMS;

(iii) Financial reserves acceptable to CMS; or

(iv) Any other arrangement acceptable to CMS.

(h) *Requirements of other laws and regulations*.

The Part D plan sponsor agrees to comply with-

(1) Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to

applicable provisions of Federal criminal law, the False Claims Act (32 U.S.C. §§ 3729 *et seq.*), and the anti-kickback statute (section 1128B(b) of the Act).

(2) HIPAA Administrative Simplification rules at 45 CFR parts 160, 162, and 164.

(i) *Relationship with related entities, contractors, and subcontractors.* (1) Notwithstanding any relationship(s) that the Part D plan sponsor may have with related entities, contractors, or subcontractors, the Part D sponsor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS.

(2) The Part D plan sponsor agrees to require all related entities, contractors, or subcontractors to agree that—

(i) HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any pertinent contracts, books, documents, papers, and records of the related entity(s), contractor(s), or subcontractor(s) involving transactions related to CMS' contract with the Part D plan sponsor; and

(ii) HHS', the Comptroller General's, or their designee's right to inspect, evaluate, and audit any pertinent information for any particular contract period exists through 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

(3) All contracts or written arrangements between Part D plan sponsors and pharmacies or other providers, related entities, contractors, subcontractors, first tier and downstream entities must contain the following:

(i) Enrollee protection provisions that provide, consistent with paragraph (g)(1) of this section, arrangements that prohibit pharmacies or other providers from holding an enrollee liable for payment of any fees that are the obligation of the Part D plan sponsor.

(ii) Accountability provisions that indicate that the Part D sponsor may delegate activities or functions to a pharmacy, related entity, contractor, or subcontractor only in a manner consistent with requirements set forth at paragraph (i)(4) of this section.

(iii) A provision requiring that any services or other activity performed by a related entity, contractor, subcontractor, or first-tier or downstream entity in accordance with a contract or written agreement are consistent and comply with the Part D plan sponsor's contractual obligations.

(4) If any of the Part D plan sponsors' activities or responsibilities under its contract with CMS is delegated to other parties, the following requirements apply to any related entity, contractor, subcontractor, or pharmacy:

(i) Written arrangements must specify delegated activities and reporting responsibilities.

(ii) Written arrangements must either provide for revocation of the delegation activities and reporting responsibilities described in paragraph (i)(4)(i) of this section or specify other remedies in instances when CMS or the Part D plan sponsor determine that the parties have not performed satisfactorily.

(iii) Written arrangements must specify that the Part D plan sponsor on an ongoing basis monitors the performance of the parties.

(iv) All contracts or written arrangements must specify that the related entity, contractor, or subcontractor must comply with all applicable Federal laws, regulations, and CMS instructions.

(5) If the Part D plan sponsor delegates selection of its prescription drug providers to another organization, the Part D sponsor's written arrangements with that organization must state that the CMS-contracting Part D plan sponsor retains the right to approve, suspend, or terminate any such arrangement.

(j) *Additional contract terms.* The Part D plan sponsor agrees to include in the contract other terms and conditions as CMS may find necessary and appropriate in order to implement requirements in this part.

(k) *Certification of data that determine payment.*

(1) *General rule.* As a condition for receiving a monthly payment under subpart G of this part (or for fallback entities, payment under subpart Q of this part),, the Part D plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.

(2) *Certification of enrollment and payment information.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that each enrollee for whom the organization is requesting payment is validly enrolled in a program offered by the organization and the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

(3) *Certification of claims data.* The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under § 423.329(b)(3) (or for fallback entities, under § 423.871(f)) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement. If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement.

(4) *Certification of bid submission information.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information in its bid submission and assumptions related to projected reinsurance and low income cost sharing subsidies is accurate, complete, and truthful and fully conforms to the requirements in § 423.265.

(5) *Certification of allowable costs for risk corridor and reinsurance information.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of supporting allowable costs, as defined in § 423.308, is accurate, complete, and truthful and fully conforms to the requirements in § 423.336 and § 423.343 and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

(6) *Certification of Accuracy of Data for Price Comparison.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of

price comparison is accurate, complete, and truthful.

§ 423.506 Effective date and term of contract.

(a) *Effective date*. The contract is effective on the date specified in the contract between the Part D plan sponsor and CMS.

(b) *Term of contract*. Each contract is for a period of 12 months.

(c) *Qualification to renew a contract*. In accordance with § 423.507 of this subpart, an entity is determined qualified to renew its contract annually only if—

(1) CMS informs the Part D plan sponsor that it is qualified to renew its contract; and

(2) The Part D plan sponsor has not provided CMS with a notice of intention not to renew.

(d) *Renewal of contract contingent on reaching agreement on the bid*. Although a Part D plan sponsor may be determined qualified to renew its contract under this section, if the sponsor and CMS cannot reach agreement on the bid under subpart F, no renewal takes place, and the failure to reach agreement is not subject to the appeals provisions in subpart N of this part.

(e) The provisions of this section do not apply to fallback entities.

§ 423.507 Nonrenewal of contract.

(a) *Nonrenewal by a Part D plan sponsor*. (1) Except for fallback entities, a Part D plan sponsor may elect not to renew its contract with CMS, effective at the end of the term of the contract for any reason provided it meets the timeframes for doing so set forth in paragraphs (a)(2) and (a)(3) of this section.

(2) If a Part D plan sponsor does not intend to renew its contract, it must notify—

(i) CMS in writing by the first Monday of June in the year in which the contract ends;

(ii) Each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective. This notice must include a written description of alternatives available for obtaining qualified prescription drug coverage within the PDP region, including MA-PD plans , and other PDPs, and must receive CMS approval prior to issuance; and

(iii) The general public, at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

(3) If a Part D plan sponsor does not renew a contract under this paragraph (a), CMS cannot enter into a contract with the organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS.

(4) If a Part D plan sponsor does not renew a contract under this paragraph (a), it must ensure the timely transfer of any data or files.

(b) *CMS decision that a Part D plan sponsor is not qualified to renew*. (1) Except for fallback entities, CMS may determine that a Part D plan sponsor is not qualified to renew its contract for any of the following reasons:

(i) The reasons listed in § 423.509(a) that also permit CMS to terminate the contract.

(ii) The Part D plan sponsor has committed any of the acts in § 423.752 that support the imposition of intermediate sanctions or civil money penalties under § 423.750.

(2) *Notice of decision*. CMS provides notice of its decision of whether a Part D plan sponsor is qualified to renew its contract as follows:

(i) To the Part D plan sponsor by May 1 of the current contract year.

(ii) If CMS decides that a Part D plan sponsor is not qualified to renew its contract, to the Part D plan sponsor's Medicare enrollees by mail at least 90 days before the end of the current calendar year.

(iii) If CMS determines that the Part D plan sponsor is not qualified to renew its contract, to the general public at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

(iv) The notice provisions in paragraphs (b)(2)(ii) and (iii) of this section also apply in cases where a non-renewal results because CMS and the Part D plan sponsor are unable to reach agreement on the bid under subpart F.

(3) *Notice of appeal rights*. CMS gives the Part D plan sponsor written notice of its right to appeal the decision that the sponsor is not qualified renew its contract in accordance with § 423.642(b).

§ 423.508 Modification or termination of contract by mutual consent.

(a) *General rule*. A contract may be modified or terminated at any time by written mutual consent.

(b) *Notification of termination*. If the contract is terminated by mutual consent, the Part D plan sponsor must provide notice to its Medicare enrollees and the general public as provided in paragraph (c) of this section.

(c) *Notification of modification*. If the contract is modified by mutual consent, the Part D plan sponsor must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification within timeframes specified by CMS.

(d) *Timely transfer of data and files*. If a contract is terminated under paragraph (a) of this section, the Part D plan sponsor must ensure the timely transfer of any data or files.

§ 423.509 Termination of contract by CMS.

(a) *Termination by CMS*. CMS may terminate a contract for any of the following reasons if the Part D sponsor—

(1) Failed substantially to carry out the terms of its contract with CMS;

(2) Is carrying out its contract with CMS in a manner that is inconsistent with the effective and efficient implementation of this part;

(3) No longer meets the requirements of this part for being a contracting organization;

(4) There is credible evidence that the Part D sponsor committed or participated in false, fraudulent, or abusive activities affecting the Medicare program, including submission of false or fraudulent data;

(5) Experiences financial difficulties so severe that its ability to provide necessary prescription drug coverage is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that a risk to health exists;

(6) Substantially fails to comply with the requirements in subpart M of this part relating to grievances and appeals;

(7) Fails to provide CMS with valid risk adjustment, reinsurance and risk corridor related data as required under § 423.322 and § 423.329 (or, for fallback entities, fails to provide the information in § 423.871(f)).

(8) Substantially fails to comply with the service access requirements in § 423.120;

(9) Substantially fails to comply with the marketing requirements in § 423.128;

(10) Substantially fails to comply with the coordination with plans and programs that provide prescription drug coverage as described in subpart J of this part; or

(11) Substantially fails to comply with the cost and utilization management, quality improvement, medication therapy management and fraud, abuse and waste program requirements as specified in subparts D and K of this part.

(b) *Notice of termination*. If CMS decides to terminate a contract for

reasons other than the grounds specified in paragraph (a)(4) or (a)(5) of this section, it gives notice of the termination as follows:

(1) *Termination of contract by CMS.* (i) CMS notifies the Part D plan in writing 90 days before the intended date of the termination.

(ii) The Part D plan sponsor notifies its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination.

(iii) The Part D plan sponsor notifies the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

(iv) If a Part D plan sponsor's contract is terminated under paragraph (a) of this section, it must ensure the timely transfer of any data or files.

(2) *Immediate termination of contract by CMS.* (i) For terminations based on violations specified in paragraph (a)(4) or paragraph (a)(5) of this section, CMS notifies the Part D plan sponsor in writing that its contract is terminated effective the date of the termination decision by CMS. If termination is effective in the middle of a month, CMS has the right to recover the prorated share of the prospective monthly payments made to the Part D sponsor covering the period of the month following the contract termination.

(ii) CMS notifies the Part D plan sponsor's Medicare enrollees in writing of CMS's decision to terminate the Part D plan sponsor's contract. This notice occurs no later than 30 days after CMS notifies the plan of its decision to terminate the Part D plan sponsor's contract. CMS simultaneously informs the Medicare enrollees of alternative options for obtaining qualified prescription drug coverage, including alternative PDP sponsors and MA-PDs in a similar geographic area.

(iii) CMS notifies the general public of the termination no later than 30 days after notifying the plan of CMS's decision to terminate the Part D plan sponsor's contract. This notice is published in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

(c) *Corrective action plan.* (1) *General rule.* Before terminating a contract for reasons other than the grounds specified in paragraph (a)(4) or (a)(5) of this section, CMS provides the Part D plan sponsor with reasonable opportunity to develop and receive CMS approval of a corrective action plan to correct the deficiencies that are the basis of the proposed termination.

(2) *Exception.* If a contract is terminated under paragraph (a)(4) or (a)(5) of this section, the Part D plan sponsor does not have the opportunity to submit a corrective action plan.

(d) *Appeal rights.* If CMS decides to terminate a contract, it sends written notice to the Part D plan sponsor informing it of its termination appeal rights in accordance with § 423.642.

§ 423.510 Termination of contract by the Part D sponsor.

(a) *Cause for termination.* The Part D plan sponsor may terminate its contract if CMS fails to substantially carry out the terms of the contract.

(b) *Notice of termination.* The Part D plan sponsor must give advance notice as follows:

(1) To CMS, at least 90 days before the intended date of termination. This notice must specify the reasons why the Part D sponsor is requesting contract termination.

(2) To its Medicare enrollees, at least 60 days before the termination effective date. This notice must include a written description of alternatives available for obtaining qualified prescription drug coverage within the services area, including alternative PDPs, MA-PDPs, and original Medicare and must receive CMS approval.

(3) To the general public, at least 60 days before the termination effective date by publishing a CMS-approved notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's geographic area.

(c) *Effective date of termination.* The effective date of the termination is determined by CMS and is at least 90 days after the date CMS receives the Part D plan sponsor's notice of intent to terminate.

(d) *CMS's liability.* CMS's liability for payment to the Part D plan sponsor ends as of the first day of the month after the last month for which the contract is in effect.

(e) *Effect of termination by the organization.* CMS does not enter into an agreement with an organization that has terminated its contract within the preceding 2 years unless there are circumstances that warrant special consideration, as determined by CMS.

(f) *Timely transfer of data and files.* If a contract is terminated under paragraph (a) of this section, the Part D plan sponsor must ensure the timely transfer of any data or files.

§ 423.512 Minimum enrollment requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, CMS does not enter into a contract under this subpart unless the organization meets the following minimum enrollment requirement:

(1) At least 5,000 individuals are enrolled for the purpose of receiving prescription drug benefits from the organization; or

(2) At least 1,500 individuals are enrolled for purposes of receiving prescription drug benefits from the organization and the organization primarily serves individuals residing outside of urbanized areas as defined in § 412.62(f) of this chapter;

(3) Except as provided for in paragraph (b) of this section, a Part D plan sponsor must maintain a minimum enrollment as defined in paragraphs (a)(1) and (a)(2) of this section for the duration of its contract.

(b) *Minimum enrollment waiver.* CMS waives the requirement of paragraphs (a)(1) and (a)(2) of this section during the first contract year for a sponsor in a region.

§ 423.514 Reporting requirements.

(a) *Required information.* Each Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, statistics indicating the following—

(1) The cost of its operations.

(2) The patterns of utilization of its services.

(3) The availability, accessibility, and acceptability of its services.

(4) Information demonstrating that the Part D plan sponsor has a fiscally sound operation.

(5) Other matters that CMS may require.

(b) *Significant business transactions.* Each Part D plan sponsor must report to CMS annually, within 120 days of the end of its fiscal year (unless, for good cause shown, CMS authorizes an extension of time), the following:

(1) A description of significant business transactions, as defined in § 423.501, between the Part D plan sponsor and a party in interest, including the following:

(i) Indication that the costs of the transactions listed in paragraph (c) of this section do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or

(ii) If they do exceed, a justification that the higher costs are consistent with

prudent management and fiscal soundness requirements.

(2) A combined financial statement for the Part D plan sponsor and a party in interest if either of the following conditions is met:

(i) Thirty five percent or more of the costs of operation of the Part D sponsor go to a party in interest.

(ii) Thirty five percent or more of the revenue of a party in interest is from the Part D plan sponsor.

(c) *Requirements for combined financial statements.* (1) The combined financial statements required by paragraph (b)(2) of this section must display in separate columns the financial information for the Part D plan sponsor and each of the parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) The statements must be examined by an independent auditor in accordance with generally accepted accounting principles and must include appropriate opinions and notes.

(4) Upon written request from a Part D plan sponsor showing good cause, CMS may waive the requirement that the organization's combined financial statement include the financial information required in this paragraph (c) of this section for a particular entity.

(d) *Reporting and disclosure under Employee Retirement Income Security Act of 1974 (ERISA).* (1) For any employees' health benefits plan that includes a Part D plan sponsor in its offerings, the PDP sponsor must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (for the particular PDP sponsor) under the Employee Retirement Income Security Act of 1974 (ERISA).

(2) The PDP sponsor must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term ''administrator'' is defined in ERISA.

(e) *Loan information.* Each Part D plan sponsor must notify CMS of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities.

(f) *Enrollee access to information.* Each Part D plan sponsor must make the information reported to CMS under this section available to its enrollees upon reasonable request.

§ 423.516 Prohibition of midyear implementation of significant new regulatory requirements.

CMS may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a PDP sponsor or a prescription drug plan.

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

§ 423.551 General provisions.

(a) *Change of ownership.* The following constitute a change of ownership:

(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law, constitutes a change of ownership.

(2) *Asset transfer.* Transfer of substantially all the assets of the sponsor to another party constitutes a change of ownership.

(3) *Corporation.* The merger of the PDP sponsor's corporation into another corporation or the consolidation of the PDP sponsor's organization with one or more other corporations, resulting in a new corporate body.

(b) *Change of ownership, exception.* Transfer of corporate stock or the merger of another corporation into the PDP sponsor's corporation, with the PDP sponsor surviving, does not ordinarily constitute change of ownership.

(c) *Advance notice requirement.* (1) A PDP sponsor that has a Medicare contract in effect under § 423.502 and is considering or is negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change. The PDP sponsor must also provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) If the PDP sponsor fails to give CMS the required notice in a timely manner, it continues to be liable for payments that CMS makes to it on behalf of Medicare enrollees after the date of change of ownership.

(d) *Novation agreement defined.* A novation agreement is an agreement among the current owner of the PDP sponsor, the prospective new owner, and CMS that—

(1) Is embodied in a document executed and signed by all 3 parties;

(2) Meets the requirements of § 423.552; and

(3) Recognizes the new owner as the successor in interest to the current owner's Medicare contract.

(e) *Effect of change of ownership without novation agreement.* Except to the extent provided in paragraph (c)(2) of this section, the effect of a change of ownership without a novation agreement is that—

(1) The existing contract becomes invalid; and

(2) If the new owner wishes to participate in the Medicare program, it must apply for, and enter into, a contract in accordance with subpart K of this part.

(f) *Effect of change of ownership with novation agreement.* If the PDP sponsor submits a novation agreement that meets the requirements of § 423.552 and CMS signs it, the new owner becomes the successor in interest to the current owner's Medicare contract under § 423.502.

§ 423.552 Novation agreement requirements.

(a) *Conditions for CMS approval of a novation agreement.* CMS approves a novation agreement if the following conditions are met:

(1) *Advance notification.* The PDP sponsor notifies CMS at least 60 days before the date of the proposed change of ownership. The PDP sponsor also provides CMS with updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) *Advance submittal of agreement.* The PDP sponsor submits to CMS, at least 30 days before the proposed change of ownership date, three signed copies of the novation agreement containing the provisions specified in paragraph (b) of this section, and one copy of other relevant documents required by CMS.

(3) *CMS's determination.* When reviewing a novation agreement, CMS makes a determination concerning the following:

(i) The proposed new owner is in fact a successor in interest to the contract.

(ii) Recognition of the new owner as a successor in interest to the contract is in the best interest of the Medicare program.

(iii) The successor organization meets the requirements to qualify as a PDP sponsor under subpart K of this part.

(b) *Provisions of a novation agreement.* A valid novation agreement requires the following:

(1) *Assumption of contract obligations.* The new owner must assume all obligations under the contract.

(2) *Waiver of right to reimbursement.* The previous owner must waive its rights to reimbursement for covered services furnished during the rest of the current contract period.

(3) *Guarantee of performance.* The previous owner must—

(i) Guarantee performance of the contract by the new owner during the contract period; or

(ii) Post a performance bond that is satisfactory to CMS.

(4) *Records access.* The previous owner must agree to make its books and records and other necessary information available to the new owner and to CMS to permit an accurate determination of costs for the final settlement of the contract period.

§ 423.553 Effect of leasing of a PDP sponsor's facilities.

(a) *General effect of leasing.* If a PDP sponsor leases all or part of its facilities to another entity, the other entity does not acquire PDP sponsor status under section 1860D–12(b) of the Act.

(b) *Effect of lease of all facilities.* (1) If a PDP sponsor leases all of its facilities to another entity, the contract terminates.

(2) If the other entity wishes to participate in Medicare as a PDP sponsor, it must apply for and enter into a contract in accordance with § 423.502.

(c) *Effect of partial lease of facilities.* If the PDP sponsor leases part of its facilities to another entity, its contract with CMS remains in effect while CMS surveys the PDP sponsor to determine whether it continues to be in compliance with the applicable requirements and qualifying conditions specified in subpart K of this part.

Subpart M—Grievances, Coverage Determinations, and Appeals

§ 423.560 Definitions.

As used in this subpart, unless the context indicates otherwise—

Appeal means any of the procedures that deal with the review of adverse coverage determinations made by the Part D plan sponsor on the benefits under a Part D plan the enrollee believes he or she is entitled to receive, including delay in providing or approving the drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage, as defined in § 423.566(b). These procedures include redeterminations by the Part D plan sponsor, reconsiderations by the independent review entity, ALJ hearings, reviews by the Medicare Appeals Council (MAC), and judicial reviews.

Appointed representative means an individual either appointed by an enrollee or authorized under State or other applicable law to act on behalf of the enrollee in obtaining a coverage determination or in dealing with any of the levels of the appeals process. Unless otherwise stated in this subpart, the appointed representative has all of the rights and responsibilities of an enrollee in obtaining a coverage determination or in dealing with any of the levels of the appeals process, subject to the rules described in part 422, subpart M of this chapter.

Drug Use means an enrollee is receiving the drug in the course of treatment, including time off if it is part of the treatment.

Enrollee means a Part D eligible individual who has elected or has been enrolled in a Part D plan.

Grievance means any complaint or dispute, other than one that involves a coverage determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D plan sponsor, regardless of whether remedial action is requested.

Physician has the meaning given the term in section 1861(r) of the Act.

Projected value means the charges incurred by the enrollee and future charges that are incurred within 12 months from the date the request for coverage determination or exception is received by the plan. Projected value includes enrollee co-payments, all expenditures incurred after an enrollee's expenditures exceed the initial coverage limit, and expenditures paid by other entities.

Reconsideration means a review of an adverse coverage determination by an independent review entity (IRE), the evidence and findings upon which it was based, and any other evidence the enrollee submits or the IRE obtains.

Redetermination means a review of an adverse coverage determination by a Part D plan sponsor, the evidence and findings upon which it is based, and any other evidence the enrollee submits or the Part D plan sponsor obtains.

§ 423.562 General provisions.

(a) *Responsibilities of the Part D plan sponsor.* A Part D plan sponsor must meet all of the following requirements.

(1) A Part D plan sponsor, for each Part D plan that it offers, must establish and maintain—

(i) A grievance procedure as described in § 423.564 for addressing issues that do not involve coverage determinations;

(ii) A procedure for making timely coverage determinations, including determinations on requests for exceptions to a tiered cost-sharing structure or to a formulary; and

(iii) Appeal procedures that meet the requirements of this subpart for issues that involve coverage determinations.

(2) A Part D plan sponsor must ensure that all enrollees receive written information about the—

(i) Grievance and appeal procedures that are available to them through the Part D plan sponsor; and

(ii) Complaint process available to the enrollee under the QIO process as set forth under section 1154(a)(14) of the Act.

(3) A Part D plan sponsor must arrange with its network pharmacies to post or distribute notices instructing enrollees to contact their plans to obtain a coverage determination or request an exception if they disagree with the information provided by the pharmacist.

(4) In accordance with subpart K of this part, if the Part D plan sponsor delegates any of its responsibilities under this subpart to another entity or individual through which the Part D plan sponsor provides covered benefits, the Part D plan sponsor is ultimately responsible for ensuring that the entity or individual satisfies the relevant requirements of this subpart.

(b) *Rights of enrollees.* In accordance with the provisions of this subpart, enrollees have all of the following rights under Part D plans:

(1) The right to have grievances between the enrollee and the Part D plan sponsor heard and resolved by the plan sponsor, as described in § 423.564.

(2) The right to a timely coverage determination by the Part D plan sponsor, as specified in § 423.566 and § 423.568, including the right to request from the Part D plan sponsor an exception to its tiered cost-sharing structure or formulary, as specified in § 423.578.

(3) The right to request from the Part D plan sponsor an expedited coverage determination, as specified in § 423.570.

(4) If dissatisfied with any part of a coverage determination, all of the following appeal rights:

(i) The right to a redetermination of the adverse coverage determination by the Part D plan sponsor, as specified in § 423.580.

(ii) The right to request an expedited redetermination, as provided under § 423.584.

(iii) If, as a result of a redetermination, a Part D plan sponsor affirms, in whole or in part, its adverse coverage determination, the right to a reconsideration or expedited reconsideration by an independent review entity (IRE) contracted by CMS, as specified in § 423.600.

(iv) If the IRE affirms the plan's adverse coverage determination, in whole or in part, the right to an ALJ hearing if the amount in controversy meets the requirements in § 423.610.

(v) If the ALJ affirms the IRE's adverse coverage determination, in whole or in part, the right to request MAC review of the ALJ hearing decision, as specified in § 423.620.

(vi) If the MAC affirms the ALJ's adverse coverage determination, in whole or in part, the right to judicial review of the hearing decision if the amount in controversy meets the requirements in § 423.630.

(c) *When other regulations apply.* Unless this subpart provides otherwise, the regulations in part 422, subpart M of this chapter (concerning the administrative review and hearing processes under titles II and XVIII, and representation of parties under title XVIII of the Act) and any interpretive rules or CMS rulings issued under these regulations, apply under this subpart to the extent they are appropriate.

(d) *Relation to ERISA Requirements.* Consistent with section 1860D–22(b) of the Act, provisions of this subpart may, to the extent applicable under the regulations adopted by the Secretary of Labor, apply to claims for benefits under group health plans subject to the Employee Retirement Income Security Act.

§ 423.564 Grievance procedures.

(a) *General rule.* Each Part D plan sponsor must provide meaningful procedures for timely hearing and resolving grievances between enrollees and the Part D plan sponsor or any other entity or individual through whom the Part D plan sponsor provides covered benefits under any Part D plan it offers.

(b) *Distinguished from appeals.* Grievance procedures are separate and distinct from appeal procedures, which address coverage determinations as defined in § 423.566(b). Upon receiving a complaint, a Part D plan sponsor must promptly determine and inform the enrollee whether the complaint is subject to its grievance procedures or its appeal procedures.

(c) *Distinguished from the quality improvement organization complaint process.* Under section 1154(a)(14) of the Act, the quality improvement organization (QIO) must review enrollees' written complaints about the quality of services they have received under the Medicare program. This process is separate and distinct from the grievance procedures of the Part D plan sponsor. For quality of care issues, an enrollee may file a grievance with the Part D plan sponsor, file a written complaint with the QIO, or both. For any complaint submitted to a QIO, the Part D plan sponsor must cooperate with the QIO in resolving the complaint.

(d) *Method for filing a grievance.* (1) An enrollee may file a grievance with the Part D plan sponsor either orally or in writing.

(2) An enrollee must file a grievance no later than 60 days after the event or incident that precipitates the grievance.

(e) *Grievance disposition and notification.* (1) The Part D plan sponsor must notify the enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 days after the date the Part D plan sponsor receives the oral or written grievance.

(2) The Part D plan sponsor may extend the 30-day timeframe by up to 14 days if the enrollee requests the extension or if the Part D plan sponsor justifies a need for additional information and documents how the delay is in the interest of the enrollee. When the Part D plan sponsor extends the deadline, it must immediately notify the enrollee in writing of the reason(s) for the delay.

(3) The Part D plan sponsor must inform the enrollee of the disposition of the grievance in accordance with the following procedures:

(i) All grievances submitted in writing must be responded to in writing.

(ii) Grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.

(iii) All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO. For any complaint submitted to a QIO, the Part D plan sponsor must cooperate with the QIO in resolving the complaint.

(f) *Expedited grievances.* A Part D plan sponsor must respond to an enrollee's grievance within 24 hours if the complaint involves a refusal by the Part D plan sponsor to grant an enrollee's request for an expedited coverage determination under § 423.570 or an expedited redetermination under § 423.584, and the enrollee has not yet purchased or received the drug that is in dispute.

(g) *Record keeping.* The Part D plan sponsor must have an established process to track and maintain records on all grievances received both orally and in writing, including, at a minimum, the date of receipt, final disposition of the grievance, and the date that the enrollee was notified of the disposition.

§ 423.566 Coverage determinations.

(a) Responsibilities of the Part D plan sponsor. Each Part D plan sponsor must have a procedure for making timely coverage determinations in accordance with the requirements of this subpart regarding the prescription drug benefits an enrollee is entitled to receive under the plan, including basic prescription drug coverage as specified in § 423.100 and supplemental benefits as specified in § 423.104(f)(1)(ii), and the amount, including cost sharing, if any, that the enrollee is required to pay for a drug. The Part D plan sponsor must have a standard procedure for making determinations, in accordance with § 423.568, and an expedited procedure for situations in which applying the standard procedure may seriously jeopardize the enrollee's life, health, or ability to regain maximum function, in accordance with § 423.570.

(b) Actions that are coverage determinations. The following actions by a Part D plan sponsor are coverage determinations:

(1) A decision not to provide or pay for a Part D drug (including a decision not to pay because the drug is not on the plan's formulary, because the drug is determined not to be medically necessary, because the drug is furnished by an out-of-network pharmacy, or because the Part D plan sponsor determines that the drug is otherwise excludable under section 1862(a) of the Act if applied to Medicare Part D) that the enrollee believes may be covered by the plan;

(2) Failure to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee;

(3) A decision concerning an exceptions request under § 423.578(a);

(4) A decision concerning an exceptions request under § 423.578(b); or

(5) A decision on the amount of cost sharing for a drug.

(c) Who can request a coverage determination. Individuals who can request a standard or expedited coverage determination are—

(1) The enrollee;

(2) The enrollee's appointed representative, on behalf of the enrollee; or

(3) The prescribing physician, on behalf of the enrollee.

§ 423.568 Standard timeframe and notice requirements for coverage determinations.

(a) *Timeframe for requests for drug benefits.* When a party makes a request for a drug benefit, the Part D plan sponsor must notify the enrollee (and the prescribing physician involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request, or, for an exceptions request, the physician's supporting statement.

(b) *Timeframe for requests for payment.* When a party makes a request

for payment, the Part D plan sponsor must notify the enrollee of its determination no later than 72 hours after receipt of the request.

(c) *Written notice for denials by a Part D plan sponsor.* If a Part D plan sponsor decides to deny a drug benefit, in whole or in part, it must give the enrollee written notice of the determination.

(d) *Form and content of the denial notice.* The notice of any denial under paragraph (c) of this section must—

Use approved notice language in a readable and understandable form;

State the specific reasons for the denial;

Inform the enrollee of his or her right to a redetermination;

(i) For drug coverage denials, describe both the standard and expedited redetermination processes, including the enrollee's right to, and conditions for, obtaining an expedited redetermination and the rest of the appeals process;

(ii) For payment denials, describe the standard redetermination process and the rest of the appeals process; and

Comply with any other notice requirements specified by CMS.

(e) *Effect of failure to meet the adjudicatory timeframes.* If the Part D plan sponsor fails to notify the enrollee of its determination in the appropriate timeframe under paragraphs (a) or (b) of this section, the failure constitutes an adverse coverage determination, and the plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

§ 423.570 Expediting certain coverage determinations.

(a) *Request for expedited determination.* An enrollee or an enrollee's prescribing physician may request that a Part D plan sponsor expedite a coverage determination involving issues described in § 423.566(b). This does not include requests for payment of Part D drugs already furnished.

(b) *How to make a request.* (1) To ask for an expedited determination, an enrollee or an enrollee's prescribing physician on behalf of the enrollee must submit an oral or written request directly to the Part D plan sponsor, or if applicable, to the entity responsible for making the determination, as directed by the Part D plan sponsor.

(2) A prescribing physician may provide oral or written support for an enrollee's request for an expedited determination.

(c) *How the Part D plan sponsor must process requests.* The Part D plan sponsor must establish and maintain the following procedures for processing requests for expedited determinations:

(1) An efficient and convenient means for accepting oral or written requests submitted by enrollees or prescribing physicians.

(2) A method for documenting all oral requests and maintaining the documentation in the case file; and

(3) A means for issuing prompt decisions on expediting a determination, based on the following requirements:

(i) For a request made by an enrollee, provide an expedited determination if it determines that applying the standard timeframe for making a determination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by an enrollee's prescribing physician, provide an expedited determination if the physician indicates that applying the standard timeframe for making a determination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If a Part D plan sponsor denies a request for expedited determination, it must take the following actions:

(1) Make the determination within the 72 hour timeframe established in § 423.568(a) for a standard determination. The 72 hour period begins on the day the Part D plan sponsor receives the request for expedited determination, or, for an exceptions request, the physician's supporting statement.

(2) Give the enrollee and prescribing physician prompt oral notice of the denial that—

(i) Explains that the Part D plan sponsor must process the request using the 72 hour timeframe for standard determinations;

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the decision by the Part D plan sponsor not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited determination with the prescribing physician's support; and

(iv) Provides instructions about the plan's grievance process and its timeframes.

(3) Subsequently deliver, within 3 calendar days, equivalent written notice.

(e) *Actions on accepted requests for expedited determination.* If a Part D plan sponsor grants a request for expedited determination, it must make the determination and give notice in accordance with § 423.572.

§ 423.572 Timeframes and notice requirements for expedited coverage determinations.

(a) *Timeframe for determinations and notification.* Except as provided in paragraph (b) of this section, a Part D plan sponsor that approves a request for expedited determination must make its determination and notify the enrollee (and the prescribing physician involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request, or, for an exceptions request, the physician's supporting statement.

(b) *Confirmation of oral notice.* If the Part D plan sponsor first notifies an enrollee of an adverse expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

(c) Content of the notice of expedited determination.

(1) The notice of any expedited determination must state the specific reasons for the determination in understandable language.

(2) If the determination is not completely favorable to the enrollee, the notice must—

(i) Inform the enrollee of his or her right to a redetermination;

(ii) Describe both the standard and expedited redetermination processes, including the enrollee's right to request, and conditions for obtaining, an expedited redetermination, and the rest of the appeal process; and

(iii) Comply with any other requirements specified by CMS.

(d) *Effect of failure to meet the adjudicatory timeframes.* If the Part D plan sponsor fails to notify the enrollee of its determination in the timeframe specified in paragraph (a) of this section, the failure constitutes an adverse coverage determination, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

§ 423.576 Effect of a coverage determination.

The coverage determination is binding on the Part D plan sponsor and the enrollee unless it is reviewed and revised under § 423.580 through § 423.630 or is reopened and revised under § 423.634.

§ 423.578 Exceptions process.

(a) *Requests for exceptions to a plan's tiered cost-sharing structure.* Each Part D plan sponsor that provides prescription drug benefits for Part D

drugs and manages this benefit through the use of a tiered formulary must establish and maintain reasonable and complete exceptions procedures subject to CMS' approval for this type of coverage determination. The Part D plan sponsor grants an exception whenever it determines that the non-preferred drug for treatment of the enrollee's condition is medically necessary, consistent with the physician's statement under paragraph (a)(4) of this section.

(1) The exceptions procedures must address situations where a formulary's tiering structure changes during the year and an enrollee is using a drug affected by the change.

(2) The exceptions criteria of a Part D plan sponsor must include, but are not limited to—

(i) A description of the criteria a Part D plan sponsor uses to evaluate a determination made by the enrollee's prescribing physician under paragraph (a)(4) of this section.

(ii) Consideration of whether the requested Part D drug that is the subject of the exceptions request is the therapeutic equivalent, as defined in § 423.100, of any other drug on the plan's formulary.

(iii) Consideration of the number of drugs on the plan's formulary that are in the same class and category as the requested prescription drug that is the subject of the exceptions request.

(3) An enrollee or the enrollee's prescribing physician may file a request for an exception.

(4) A prescribing physician must provide an oral or written supporting statement that the preferred drug for the treatment of the enrollee's condition—

(i) Would not be as effective for the enrollee as the requested drug;

(ii) Would have adverse effects for the enrollee; or

(iii) Both paragraphs (a)(4)(i) and (a)(4)(ii) of this section apply.

(5) If the physician provides an oral supporting statement, the Part D plan sponsor may require the physician to subsequently provide a written supporting statement to demonstrate the medical necessity of the drug. The Part D plan sponsor may require the prescribing physician to provide additional supporting medical documentation as part of the written follow-up.

(6) In no case is a Part D plan sponsor required to cover a non-preferred drug at the generic drug cost-sharing level if the plan maintains a separate tier dedicated to generic drugs.

(7) If a Part D plan sponsor maintains a formulary tier in which it places very high cost and unique items, such as genomic and biotech products, the sponsor may design its exception process so that very high cost or unique drugs are not eligible for a tiering exception.

(b) *Request for exceptions involving a non-formulary Part D drug.* Each Part D plan sponsor that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a formulary must establish and maintain exceptions procedures subject to CMS' approval for receipt of an off-formulary drug. The Part D plan sponsor must grant an exception whenever it determines that the drug is medically necessary, consistent with the physician's statement under paragraph (b)(5) of this section, and that the drug would be covered but for the fact that it is an off-formulary drug. Formulary use includes the application of cost utilization tools, such as a dose restriction, including the dosage form, that causes a particular Part D drug not to be covered for the number of doses prescribed or a step therapy requirement that causes a particular Part D drug not to be covered until the requirements of the plan's coverage policy are met, or a therapeutic substitution requirement.

(1) The plan's formulary exceptions process must address each of the following circumstances:

(i) Situations where a formulary changes during the year, and situations where an enrollee is already using a given drug.

(ii) Continued coverage of a particular Part D prescription drug that the Part D plan sponsor is discontinuing coverage on the formulary for reasons other than safety or because the Part D prescription drug cannot be supplied by or was withdrawn from the market by the drug's manufacturer.

(iii) An exception to a plan's coverage policy that causes a Part D prescription drug not to be covered because of cost utilization tools, such as a requirement for step therapy, dosage limitations, or therapeutic substitution.

(2) The exception criteria of a Part D plan sponsor must include, but are not limited to—

(i) A description of the criteria a Part D plan sponsor uses to evaluate a prescribing physician's determination made under paragraph (b)(5) of this section;

(ii) A process for gathering and comparing applicable medical and scientific evidence on the safety and effectiveness of the requested non-formulary drug with the formulary drug for the enrollee, including safety information generated by an authoritative government body; and

(iii) A description of the cost-sharing scheme that will be applied when coverage is provided for a non-formulary drug.

(3) If the Part D plan sponsor covers a non-formulary drug, the cost(s) incurred by the enrollee for that drug are treated as being included for purposes of calculating and meeting the annual out-of-pocket threshold.

(4) An enrollee, the enrollee's appointed representative, or the prescribing physician (on behalf of the enrollee) may file a request for an exception.

(5) A prescribing physician must provide an oral or written supporting statement that the requested prescription drug is medically necessary to treat the enrollee's disease or medical condition because—

(i) All of the covered Part D drugs on any tier of a plan's formulary for treatment for the same condition would not be as effective for the enrollee as the non-formulary drug, would have adverse effects for the enrollee, or both;

(ii) The prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements—

(A) Has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the enrollee and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

(B) Has caused or based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the enrollee; or

(iii) The number of doses that is available under a dose restriction for the prescription drug has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the enrollee and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.

(6) If the physician provides an oral supporting statement, the Part D plan sponsor may require the physician to subsequently provide a written supporting statement. The Part D plan sponsor may require the prescribing physician to provide additional supporting medical documentation as part of the written follow-up.

(c) *Requirements for exceptions.* (1) *General rule.* A decision by a Part D

plan sponsor concerning an exceptions request under this section constitutes a coverage determination as specified at § 423.566.

(2) When a Part D plan sponsor does not make a timely decision. If the Part D plan sponsor fails to make a decision on an exceptions request and provide notice of the decision within the timeframe required under § 423.568(a) or § 423.572(a), as applicable, the failure constitutes an adverse coverage determination, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(3) *When a tiering exceptions request is approved.* Whenever an exceptions request made under § 423.578(a) is approved, the Part D plan sponsor must provide coverage for the approved prescription drug at the cost-sharing level that applies for preferred drugs, and may not require the enrollee to request approval for a refill, or a new prescription to continue using the Part D prescription drug after the refills for the initial prescription are exhausted, as long as—

(i) The enrollee's prescribing physician continues to prescribe the drug;

(ii) The drug continues to be considered safe for treating the enrollee's disease or medical condition; and

(iii) The enrollment period has not expired. If an enrollee renews his or her membership after the plan year, the plan may choose to continue coverage into the subsequent plan year.

(4) *When a non-formulary exceptions request is approved.* Whenever an exceptions request made under § 423.578(b) is approved—

(i) The Part D plan sponsor may not require the enrollee to request approval for a refill, or a new prescription to continue using the Part D prescription drug after the refills for the initial prescription are exhausted, as long as—

(A) The enrollee's prescribing physician continues to prescribe the drug;

(B) The drug continues to be considered safe for treating the enrollee's disease or medical condition; and

(C) The enrollment period has not expired. If an enrollee renews his or her membership after the plan year, the plan may choose to continue coverage into the subsequent plan year.

(ii) The Part D plan sponsor must not establish a special formulary tier or co-payment or other cost-sharing requirement that is applicable only to prescription drugs approved for coverage under this section.

(iii) An enrollee may not request a tiering exception for a non-formulary prescription drug approved under § 423.578(b).

(d) *Notice regarding formulary changes.* Whenever a Part D plan sponsor removes a covered part D drug from its formulary or makes any changes in the preferred or tiered cost-sharing status of such a drug, the Part D plan sponsor must provide notice in accordance with § 423.120(b)(5).

(e) *Limitation of the exceptions procedures to Part D drugs.* Nothing in this section may be construed to allow an enrollee to use the exceptions processes set out in this section to request or be granted coverage for a prescription drug that does not meet the definition of a Part D drug.

(f) *Implication of the physician's supporting statement.* Nothing in this section should be construed to mean that the physician's supporting statement required for an exceptions request will result in an automatic favorable determination.

§ 423.580 Right to a redetermination.

An enrollee who has received a coverage determination (including one that is reopened and revised as described in § 423.634) may request that it be redetermined under the procedures described in § 423.582, which address requests for a standard redetermination. An enrollee or an enrollee's prescribing physician (acting on behalf of an enrollee) may request an expedited redetermination specified in § 423.584.

§ 423.582 Request for a standard redetermination.

(a) *Method and place for filing a request.* An enrollee must ask for a redetermination by making a written request with the Part D plan sponsor that made the coverage determination. The Part D plan sponsor may adopt a policy for accepting oral requests.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, an enrollee must file a request for a redetermination within 60 calendar days from the date of the notice of the coverage determination.

(c) *Extending the time for filing a request.* (1) *General rule.* If an enrollee shows good cause, the Part D plan sponsor may extend the timeframe for filing a request for redetermination.

(2) *How to request an extension of timeframe.* If the 60-day period in which to file a request for a redetermination has expired, an enrollee may file a request for redetermination and extension of time frame with the Part D plan sponsor. The request for redetermination and to extend the timeframe must—

(i) Be in writing; and

(ii) State why the request for redetermination was not filed on time.

(d) *Withdrawing a request.* The person who files a request for redetermination may withdraw it by filing a written request with the Part D sponsor.

§ 423.584 Expediting certain redeterminations.

(a) *Who may request an expedited redetermination.* An enrollee or an enrollee's prescribing physician may request that a Part D plan sponsor expedite a redetermination that involves the issues specified in § 423.566(b). (This does not include requests for payment of drugs already furnished.)

(b) *How to make a request.* (1) To ask for an expedited redetermination, an enrollee or a prescribing physician acting on behalf of an enrollee must submit an oral or written request directly to the Part D plan sponsor or, if applicable, to the entity responsible for making the redetermination, as directed by the Part D plan sponsor.

(2) A prescribing physician may provide oral or written support for an enrollee's request for an expedited redetermination.

(c) *How the Part D plan sponsor must process requests.* The Part D plan sponsor must establish and maintain the following procedures for processing requests for expedited redetermination:

(1) *Handling of requests.* The Part D plan sponsor must establish an efficient and convenient means for individuals to submit oral or written requests, document all oral requests in writing, and maintain the documentation in the case file.

(2) *Prompt decision making.* The Part D plan sponsor must promptly decide whether to expedite the redetermination or follow the timeframe for standard redetermination based on the following requirements:

(i) For a request made by an enrollee, the Part D plan sponsor must provide an expedited redetermination if it determines that applying the standard timeframe for making a redetermination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a prescribing physician, the Part D plan sponsor must provide an expedited redetermination if the physician indicates that applying the standard timeframe for conducting a redetermination may seriously jeopardize the life or health of the

enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial of a request.* If a Part D plan sponsor denies a request for expedited redetermination, it must take the following actions:

(1) Make the determination within the 7-day timeframe established in § 423.590(a). The 7-day period begins the day the Part D plan sponsor receives the request for expedited redetermination.

(2) Give the enrollee prompt oral notice of the denial that—

(i) Explains that the Part D plan sponsor processes the enrollee's request using the 7-day timeframe for standard redetermination;

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the decision by the Part D plan sponsor not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited redetermination with the prescribing physician's support; and

(iv) Provides instructions about the expedited grievance process and its timeframes.

(3) Subsequently deliver, within three calendar days, equivalent written notice.

(e) *Action following acceptance of a request.* If a Part D plan sponsor grants a request for expedited redetermination, it must conduct the redetermination and give notice in accordance with § 423.590(d).

§ 423.586 Opportunity to submit evidence.

The Part D plan sponsor must provide the enrollee or the prescribing physician, as appropriate, with a reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing. In the case of an expedited redetermination, the opportunity to present evidence is limited by the short timeframe for making a decision. Therefore, the Part D plan sponsor must inform the enrollee or the prescribing physician of the conditions for submitting the evidence.

§ 423.590 Timeframes and responsibility for making redeterminations.

(a) *Standard redetermination—request for covered drug benefits.* (1) If the Part D plan sponsor makes a redetermination that is completely favorable to the enrollee, the Part D plan sponsor must notify the enrollee in writing of its redetermination (and effectuate it in accordance with § 423.636(a)(1)) as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for a standard redetermination.

(2) If the Part D plan sponsor makes a redetermination that affirms, in whole or in part, its adverse coverage determination, it must notify the enrollee in writing of its redetermination as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for a standard redetermination.

(b) *Standard redetermination—request for payment.* (1) If the Part D plan sponsor makes a redetermination that is completely favorable to the enrollee, the Part D plan sponsor must issue its redetermination (and effectuate it in accordance with § 423.636(a)(2)) no later than 7 calendar days from the date it receives the request for redetermination.

(2) If the Part D plan sponsor affirms, in whole or in part, its adverse coverage determination, it must notify the enrollee in writing of its redetermination no later than 7 calendar days from the date it receives the request for redetermination.

(c) *Effect of failure to meet timeframe for standard redeterminations.* If the Part D plan sponsor fails to provide the enrollee with a redetermination within the timeframes specified in paragraphs (a) or (b) of this section, the failure constitutes an adverse redetermination decision, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(d) *Expedited redetermination.* (1) *Timeframe.* A Part D plan sponsor that approves a request for expedited redetermination must complete its redetermination and give the enrollee (and the prescribing physician involved, as appropriate), notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request.

(2) How the Part D plan sponsor must request additional information. If the Part D plan sponsor must receive medical information, the Part D plan sponsor must request the necessary information within 24 hours of the initial request for an expedited redetermination. Regardless of whether the Part D plan sponsor requests additional information, the Part D plan sponsor is responsible for meeting the timeframe and notice requirements.

(e) *Failure to meet timeframe for expedited redetermination.* If the Part D plan sponsor fails to provide the enrollee or the prescribing physician, as appropriate, with the results of its expedited redetermination within the timeframe described in paragraph (d) of this section, the failure constitutes an adverse redetermination decision, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(f) *Who must conduct the review of an adverse coverage determination.* (1) A person or persons who were not involved in making the coverage determination must conduct the redetermination.

(2) When the issue is the denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the redetermination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the redetermination need not, in all cases, be of the same specialty or subspecialty as the prescribing physician.

(g) *Form and content of an adverse redetermination notice.* The notice of any adverse determination under paragraphs (a)(2) or (b)(2) of this section must—

(1) Use approved notice language in a readable and understandable form;

(2) State the specific reasons for the denial;

(3) Inform the enrollee of his or her right to a reconsideration;

(i) For adverse drug coverage redeterminations, describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeals process;

(ii) For adverse payment redeterminations, describe the standard reconsideration process and the rest of the appeals process; and

(4) Comply with any other notice requirements specified by CMS.

§ 423.600 Reconsideration by an independent review entity (IRE).

(a) An enrollee who is dissatisfied with the redetermination of a Part D plan sponsor has a right to a reconsideration by an independent review entity that contracts with CMS. An enrollee must file a written request for reconsideration with the IRE within 60 days of the date of the redetermination by the Part D plan sponsor.

(b) When an enrollee files an appeal, the IRE is required to solicit the views of the prescribing physician. The IRE may solicit the views of the prescribing physician orally or in writing. A written account of the prescribing physician's views (prepared by either the prescribing physician or IRE, as

appropriate) must be contained in the IRE's record.

(c) In order for an enrollee to request an IRE reconsideration of a determination by a Part D plan sponsor not to provide for a Part D drug that is not on the formulary, the prescribing physician must determine that all covered Part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the non-formulary drug, would have adverse effects for the individual, or both.

(d) The independent review entity must conduct the reconsideration as expeditiously as the enrollee's health condition requires but must not exceed the deadlines applicable in § 423.590, including those deadlines that are applicable when a request for an expedited reconsideration is received and granted.

(e) When the issue is the denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the reconsideration must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the reconsideration need not, in all cases, be of the same specialty or subspecialty as the prescribing physician.

§ 423.602 Notice of reconsideration determination by the independent review entity.

(a) *Responsibility for the notice.* When the IRE makes its reconsideration determination, it is responsible for mailing a notice of its determination to the enrollee and the Part D plan sponsor, and for sending a copy to CMS.

(b) *Content of the notice.* The notice must—

(1) State the specific reasons for the IRE's decision in understandable language;

(2) If the reconsideration determination is adverse (that is, does not completely reverse the adverse coverage determination by the Part D plan sponsor), inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the threshold requirement under § 423.610;

(3) Describe the procedures that must be followed to obtain an ALJ hearing; and

(4) Comply with any other requirements specified by CMS.

§ 423.604 Effect of a reconsideration determination.

A reconsideration determination is final and binding on the enrollee and the Part D plan sponsor, unless the enrollee files a request for a hearing under the provisions of § 423.612.

§ 423.610 Right to an ALJ hearing.

(a) If the amount remaining in controversy after the IRE reconsideration meets the threshold requirement established annually by the Secretary, an enrollee who is dissatisfied with the IRE reconsideration determination has a right to a hearing before an ALJ.

(b) If the basis for the appeal is the refusal by the Part D plan sponsor to provide drug benefits, CMS uses the projected value of those benefits to compute the amount remaining in controversy. The projected value of a Part D drug or drugs shall include any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year.

(c) *Aggregating appeals to meet the amount in controversy.* (1) *Enrollee.* Two or more appeals may be aggregated by an enrollee to meet the amount in controversy for an ALJ hearing if—

(i) The appeals have previously been reconsidered by an IRE;

(ii) The request for ALJ hearing lists all of the appeals to be aggregated and each aggregated appeal meets the filing requirement specified in § 423.612(b); and

(iii) The ALJ determines that the appeals the enrollee seeks to aggregate involve the delivery of prescription drugs to a single enrollee.

(2) *Multiple enrollees.* Two or more appeals may be aggregated by multiple enrollees to meet the amount in controversy for an ALJ hearing if—

The appeals have previously been reconsidered by an IRE;

The request for ALJ hearing lists all of the appeals to be aggregated and each aggregated appeal meets the filing requirement specified in § 423.612(b); and

The ALJ determines that the appeals the enrollees seek to aggregate involve the same prescription drug.

§ 423.612 Request for an ALJ hearing.

(a) *How and where to file a request.* The enrollee must file a written request for a hearing with the entity specified in the IRE's reconsideration notice.

(b) *When to file a request.* Except when an ALJ extends the timeframe as provided in part 422, subpart M of this chapter, the enrollee must file a request for a hearing within 60 days of the date of the notice of an IRE reconsideration determination. The time and place for a hearing before an ALJ will be set in accordance with § 405.1020 of this chapter.

(c) *Insufficient amount in controversy.* (1) If a request for a hearing clearly shows that the amount in controversy is less than that required under § 423.610, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than the amount required under § 423.610, the ALJ discontinues the hearing and does not rule on the substantive issues raised in the appeal.

§ 423.620 Medicare Appeals Council (MAC) review.

An enrollee who is dissatisfied with an ALJ hearing decision may request that the MAC review the ALJ's decision or dismissal. The regulations under part 422, subpart M of this chapter regarding MAC review apply to matters addressed by this subpart, to the extent applicable.

§ 423.630 Judicial review.

(a) *Review of ALJ's decision.* The enrollee may request judicial review of an ALJ's decision if—

(1) The MAC denied the enrollee's request for review; and

(2) The amount in controversy meets the threshold requirement established annually by the Secretary.

(b) *Review of MAC decision.* The enrollee may request judicial review of the MAC decision if it is the final decision of CMS and the amount in controversy meets the threshold established in paragraph (a)(2) of this section.

(c) How to request judicial review. In order to request judicial review, an enrollee must file a civil action in a district court of the United States in accordance with section 205(g) of the Act. (See part 422, subpart M of this chapter, for a description of the procedures to follow in requesting judicial review.)

§ 423.634 Reopening and revising determinations and decisions.

(a) A coverage determination or redetermination made by a Part D plan sponsor, a reconsideration made by the independent review entity specified in § 423.600, or the decision of an ALJ or the MAC that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, under the rules in part 422, subpart M of this chapter.

(b) The filing of a request for reopening does not relieve the Part D plan sponsor of its obligation to make payment or provide benefits as specified in § 423.636 or § 423.638.

(c) Once an entity issues a revised determination or decision, the revisions made by the decision may be appealed.

(d) A decision not to reopen by the Part D plan sponsor or any other entity is not subject to review.

§ 423.636 How a Part D plan sponsor must effectuate standard redeterminations, reconsiderations, or decisions.

(a) *Reversals by the Part D plan sponsor.* (1) *Requests for benefits.* If, on redetermination of a request for benefit, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for redetermination.

(2) *Requests for payment.* If, on redetermination of a request for payment, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize payment for the benefit within 7 calendar days from the date it receives the request for redetermination, and make payment no later than 30 calendar days after the date the plan sponsor receives the request for redetermination.

(b) *Reversals other than by the Part D plan sponsor.* (1) *Requests for benefits.* If, on appeal of a request for benefit, the determination by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize or provide the benefit under dispute within 72 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

(2) *Requests for payment.* If, on appeal of a request for payment, the determination by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize payment for the benefit within 72 hours, but make payment no later than 30 calendar days from the date it receives notice reversing the coverage determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

§ 423.638 How a Part D plan sponsor must effectuate expedited redeterminations or reconsiderations.

(a) *Reversals by the Part D plan sponsor.* If, on an expedited redetermination of a request for benefits, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the Part D plan sponsor receives the request for redetermination.

(b) *Reversals other than by the Part D plan sponsor.* If the expedited determination or expedited redetermination for benefits by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires but no later than 24 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

Subpart N—Medicare Contract Determinations and Appeals

§ 423.641 Contract determinations.

This subpart establishes the procedures for reviewing the following contract determinations:

(a) A determination that an entity is not qualified to enter into a contract with CMS under Part D of title XVIII of the Act.

(b) A determination not to authorize a renewal of a contract with a PDP sponsor in accordance with § 423.507(b).

(c) A determination to terminate a contract with a PDP sponsor in accordance with § 423.509.

(d) Fallback entities are governed under subpart Q of this part, and are not subject to this subpart, except to the extent a fallback prescription drug plan contract is terminated by CMS.

§ 423.642 Notice of contract determination.

(a) When CMS makes a contract determination under § 423.641, it gives the PDP sponsor written notice.

(b) The notice specifies the—

(1) Reasons for the determination; and

(2) PDP sponsor's right to request reconsideration.

(c) For CMS-initiated terminations, CMS mails notice 90 days before the anticipated effective date of the termination. For terminations based on initial determinations described at § 423.509(a)(4) or (a)(5), CMS immediately notifies the PDP sponsor of its decision to terminate the organization's PDP contract.

(d) When CMS determines that it is not going to authorize a contract renewal, CMS mails the notice to the PDP sponsor by May 1 of the current contract year.

§ 423.643 Effect of contract determination.

The contract determination is final and binding unless—

(a) The determination is reconsidered in accordance with § 423.644 through § 423.649;

(b) A timely request for a hearing is filed under § 423.651; or

(c) The reconsideration decision is revised as a result of a reopening under § 423.668.

§ 423.644 Reconsideration: Applicability.

(a) Reconsideration is the first step for appealing a contract determination specified in § 423.641.

(b) CMS reconsiders the specified determinations if the contract applicant or the PDP sponsor files a written request in accordance with § 423.645.

§ 423.645 Request for reconsideration.

(a) *Method and place for filing a request.* A request for reconsideration must be made in writing and filed with any CMS office.

(b) *Time for filing a request.* The request for reconsideration must be filed within 15 days from the date of the notice of the initial determination.

(c) *Proper party to file a request.* Only an authorized official of the contract applicant or PDP sponsor that was the subject of a contract determination may file the request for reconsideration.

(d) *Withdrawal of a request.* The PDP sponsor or contract applicant who filed the request for a reconsideration may withdraw it at any time before the notice of the reconsidered determination is mailed. The request for withdrawal must be in writing and filed with CMS.

§ 423.646 Opportunity to submit evidence.

CMS provides the PDP sponsor or contract applicant and the CMS official or officials who made the contract determination reasonable opportunity, not to exceed the timeframe in which a PDP sponsor chooses to request a hearing as described at § 423.651, to present as evidence any documents or written statements that are relevant and material to the matters at issue.

§ 423.647 Reconsidered determination.

A reconsidered determination is a new determination that—

(a) Is based on a review of the contract determination, the evidence and findings upon which that was based, and any other written evidence submitted before notice of the reconsidered determination is mailed, including facts relating to the status of the PDP sponsor subsequent to the contract determination; and

(b) Affirms, reverses, or modifies the initial determination.

(c) Any favorable redetermination, including those resulting from a hearing or Administrator review, must be made by July 15 for the contract in question to be effective on January of the following year.

§ 423.648 Notice of reconsidered determination.

(a) CMS gives the PDP sponsor or contract applicant written notice of the reconsidered determination.

(b) The notice—

(1) Contains findings for the contract applicant's qualifications to enter into, or the PDP sponsor's qualifications to remain under, a contract with CMS under Part D of the Act;

(2) States the specific reasons for the reconsidered determination; and

(3) Informs the PDP sponsor or contract applicant of its right to a hearing if it is dissatisfied with the determination.

§ 423.649 Effect of reconsidered determination.

A reconsidered determination is final and binding unless a request for a hearing is filed in accordance with § 423.651 or it is revised in accordance with § 423.668.

§ 423.650 Right to a hearing.

The following parties are entitled to a hearing:

(a) A contract applicant that is determined in a reconsidered determination to be unqualified to enter into a contract with CMS under Part D of title XVIII of the Act.

(b) A PDP sponsor whose contract with CMS is terminated or is not renewed as a result of a contract determination as provided in § 423.641.

§ 423.651 Request for hearing.

(a) *Method and place for filing a request.* A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or PDP sponsor that was the party to the determination under appeal. The request for a hearing must be filed with any CMS office.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 days after the date of the reconsidered determination.

(c) *Parties to a hearing.* The parties to a hearing must be—

(1) The parties described in § 423.650;

(2) At the discretion of the hearing officer, any interested parties who make a showing that their rights may be prejudiced by the decision to be rendered at the hearing; and

(3) CMS.

§ 423.652 Postponement of effective date of a contract determination when a request for a hearing for a contract determination is filed timely.

(a) CMS postpones the proposed effective date of the contract determination to terminate a contract with a PDP sponsor until a hearing decision is reached and affirmed by the Administrator following review under § 423.666 in instances where a PDP sponsor requests review by the Administrator; and

(b) CMS extends the current contract at the end of the contract period (in the case of a determination not to renew) only—

(1) If CMS finds that an extension of the contract is consistent with the purpose of this part; and

(2) For the period as CMS and the PDP sponsor agree.

(c) Exception: A contract terminated in accordance with § 423.509(a)(4) or (a)(5) is immediately terminated and is not postponed if a hearing is requested.

§ 423.653 Designation of hearing officer.

CMS designates a hearing officer to conduct the hearing. The hearing officer need not be an ALJ.

§ 423.654 Disqualification of hearing officer.

(a) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(c) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(1) If the hearing officer withdraws, CMS designates another hearing officer to conduct the hearing.

(2) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to CMS.

§ 423.655 Time and place of hearing.

(a) The hearing officer fixes a time and place for the hearing, which is not to exceed 30 days from the receipt of the request for the hearing, and sends written notice to the parties. The notice also informs the parties of the general and specific issues to be resolved and information about the hearing procedure.

(b) The hearing officer may, on his or her own motion, or at the request of a party, change the time and place for the hearing. The hearing officer may adjourn or postpone the hearing.

(c) The hearing officer gives the parties reasonable notice of any change in time or place of hearing, or of adjournment or postponement.

§ 423.656 Appointment of representatives.

A party may appoint as its representative at the hearing anyone not disqualified or suspended from acting as a representative before the Secretary or otherwise prohibited by law.

§ 423.657 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 423.656, on behalf of the represented party—

(1) Gives or accepts any notice or request pertinent to the proceedings set forth in this subpart;

(2) Presents evidence and allegations as to facts and law in any proceedings affecting that party; and

(3) Obtains information to the same extent as the party.

(b) A notice or request sent to the representative has the same force and effect as if it is sent to the party.

§ 423.658 Conduct of hearing.

(a) The hearing is open to the parties and to the public.

(b) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(c) The hearing officer provides the parties an opportunity to enter any objection to the inclusion of any document.

(d) The hearing officer decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

§ 423.659 Evidence.

The hearing officer rules on the admissibility of evidence and may admit evidence that is inadmissible under rules applicable to court procedures.

§ 423.660 Witnesses.

(a) The hearing officer may examine the witnesses.

(b) The parties or their representatives are permitted to examine their witnesses and cross-examine witnesses of other parties.

§ 423.661 Discovery.

(a) Prehearing discovery is permitted upon timely request of a party.

(b) A request is timely if it is made before the beginning of the hearing.

(c) A reasonable time for inspection and reproduction of documents is provided by order of the hearing officer.

(d) The hearing officer's order on all discovery matters is final.

§ 423.662 Prehearing.

The hearing officer may schedule a prehearing conference if he or she believes that a conference may more clearly define the issues.

§ 423.663 Record of hearing.

(a) A complete record of the proceedings at the hearing is made and transcribed and made available to all parties upon request.

(b) The record may not be closed until a hearing decision is issued.

§ 423.664 Authority of hearing officer.

In exercising his or her authority, the hearing officer must comply with the provisions of title XVIII and related provisions of the Act, the regulations issued by the Secretary, and general instructions issued by CMS in implementing the Act.

§ 423.665 Notice and effect of hearing decision.

(a) As soon as practical after the close of the hearing, the hearing officer issues a written decision that—

(1) Is based upon the evidence of record; and

(2) Contains separately numbered findings of fact and conclusions of law.

(b) The hearing officer provides a copy of the hearing decision to each party.

(c) The hearing decision is final and binding unless it is reversed or modified by the Administrator following review under § 423.666, or reopened and revised in accordance with § 423.668.

§ 423.666 Review by the Administrator.

(a) *Request for review by the Administrator.* A PDP sponsor that receives a hearing decision upholding a contract termination determination may request review by the Administrator within 15 days of receiving the hearing decision as provided under § 423.665(b).

(b) *Review by the Administrator.* The Administrator must review the hearing officer's decision, and determine, based upon this decision, the hearing record, and any written arguments submitted by the PDP sponsor, whether the termination decision must be upheld, reversed, or modified.

(c) *Decision by the Administrator.* The Administrator issues a written decision, and furnishes the decision to the PDP sponsor requesting review.

§ 423.667 Effect of Administrator's decision.

A decision by the Administrator under section § 423.666(c) is final and binding unless it is reopened and revised in accordance with § 423.668.

§ 423.668 Reopening of contract or reconsidered determination or decision of a hearing officer or the Administrator.

(a) *Initial or reconsidered determination.* CMS may reopen and revise an initial or reconsidered determination upon its own motion within 1 year of the date of the notice of determination.

(b) *Decision of hearing officer.* A decision of a hearing officer that is unfavorable to any party and is otherwise final may be reopened and revised by the hearing officer upon the officer's own motion within 1 year of the notice of the hearing decision. Another hearing officer designated by CMS may reopen and revise the decision if the hearing officer who issued the decision is unavailable.

(c) *Decision of Administrator.* A decision by the Administrator that is otherwise final may be reopened and revised by the Administrator upon the Administrator's own motion within 1 year of the notice of the Administrator's decision.

(d) *Notices.* (1) The notice of reopening and of any revisions following the reopening is mailed to the parties.

(2) The notice of revision specifies the reasons for revisions.

§ 423.669 Effect of revised determination.

The revision of a contract or reconsidered determination is binding unless a party files a written request for hearing of the revised determination in accordance with § 423.651.

Subpart O—Intermediate Sanctions

§ 423.750 Kinds of sanctions.

(a) The following intermediate sanctions and civil money penalties may be imposed:

(1) Civil money penalties ranging from $10,000 to $100,000 depending upon the violation.

(2) Suspension of enrollment of Medicare beneficiaries.

(3) Suspension of payment to the Part D sponsor for Medicare beneficiaries who enroll.

(4) Suspension of all Part D plan marketing activities to Medicare beneficiaries for the Part D plan subject to the intermediate sanctions.

(b) The enrollment, payment, and marketing sanctions continue in effect until CMS is satisfied that the deficiency on which the determination was based is corrected and is not likely to recur.

§ 423.752 Basis for imposing sanctions.

(a) *All intermediate sanctions.* For the violations listed below, we may impose one, or more, of the sanctions specified in § 423.750(a)(2), (a)(3) or (a)(4) on any Part D sponsor that has a contract in effect. The Part D sponsor may also be subject to other applicable remedies available under law.

(1) Fails substantially to provide, to a Part D plan enrollee, medically necessary services that the organization is required to provide (under law or under the contract) to a Part D plan enrollee, and that failure adversely affects (or is substantially likely to adversely affect) the enrollee.

(2) Imposes on Part D plan enrollees premiums in excess of the monthly basic and supplemental beneficiary premiums permitted under section 1860D–1 *et seq.* of the Act and subpart F of this part.

(3) Acts to expel or refuses to reenroll a beneficiary in violation of the provisions of this part.

(4) Engages in any practice that may reasonably be expected to have the effect of denying or discouraging enrollment of individuals whose medical condition or history indicates a need for substantial future medical services.

(5) Misrepresents or falsifies information that it furnishes—

(i) To CMS; or

(ii) To an individual or to any other entity under the Part D drug benefit program.

(6) Employs or contracts with an individual or entity who is excluded from participation in Medicare under section 1128 or 1128A of the Act (or with an entity that employs or contracts with an excluded individual or entity) for the provision of any of the following:

(i) Health care.

(ii) Utilization review.

(iii) Medical social work.

(iv) Administrative services.

(b) *Suspension of enrollment and marketing.* If CMS makes a determination that could lead to a contract termination under § 423.509(a), CMS may instead impose the intermediate sanctions in § 423.750(a)(2) and (a)(4).

§ 423.756 Procedures for imposing sanctions.

(a) *Notice of sanction and opportunity to respond.*

(1) Notice of sanction. Before imposing the intermediate sanctions specified in paragraph (c) of this section, CMS—

(i) Sends a written notice to the Part D sponsor stating the nature and basis of the proposed sanction; and

(ii)Sends the Office of the Inspector General a copy of the notice.

(2) *Opportunity to respond.* CMS allows the Part D sponsor 15 days from

receipt of the notice to provide evidence that it has not committed an act or failed to comply with the requirements described in § 423.752, as applicable. CMS may allow a 15-day addition to the original 15 days upon receipt of a written request from the Part D sponsor. To be approved, the request must provide a credible explanation of why additional time is necessary and be received by CMS before the end of the 15-day period following the date of receipt of the sanction notice. CMS does not grant an extension if it determines that the Part D sponsor's conduct poses a threat to an enrollee's health and safety.

(b) *Informal reconsideration*. If, consistent with paragraph (a)(2) of this section, the Part D sponsor submits a timely response to CMS' notice of sanction, CMS conducts an informal reconsideration that—

(1) Consists of a review of the evidence by an CMS official who did not participate in the initial decision to impose a sanction; and

(2) Gives the Part D sponsor a concise written decision setting forth the factual and legal basis for the decision that affirms or rescinds the original determination.

(c) *Specific sanctions*. If CMS determines that a Part D sponsor has acted or failed to act as specified in § 423.752 and affirms this determination in accordance with paragraph (b) of this section, CMS may—

(1) Require the Part D sponsor to suspend acceptance of applications made by Medicare beneficiaries for enrollment in the sanctioned plan during the sanction period;

(2) In the case of a violation under § 423.752(a), suspend payments to the Part D sponsor for Medicare beneficiaries enrolled in the sanctioned plan during the sanction period; and

(3) Require the Part D sponsor to suspend all marketing activities for the sanctioned plan to Medicare enrollees.

(d) *Effective date and duration of sanctions*. (1) *Effective date*. Except as provided in paragraph (d)(2) of this section, a sanction is effective 15 days after the date that the organization is notified of the decision to impose the sanction or, if the Part D sponsor seeks reconsideration in a timely manner under paragraph (b) of this section, on the date specified in the notice of CMS' reconsidered determination.

(2) *Exception*. If CMS determines that the Part D sponsor's conduct poses a serious threat to an enrollee's health and safety, CMS may make the sanction effective on a date before issuance of CMS' reconsidered determination.

(3) *Duration of sanction*. The sanction remains in effect until CMS notifies the Part D sponsor that CMS is satisfied that the basis for imposing the sanction is corrected and is not likely to recur.

(e) *Termination by CMS*. In addition to or as an alternative to the sanctions described in paragraph (c) of this section, CMS may decline to authorize the renewal of an organization's contract in accordance with § 423.507(b)(2) and (b)(3), or terminate the contract in accordance with § 423.509.

(f) *Civil money penalties*. (1) If CMS determines that a Part D sponsor has committed an act or failed to comply with a requirement described in § 423.752, CMS notifies the OIG of this determination, and also notifies OIG when CMS reverses or terminates a sanction imposed under this part.

(2) In the case of a violation described in § 423.752(a), or a determination under § 423.752(b) based upon a violation under § 423.509(a)(4) (involving fraudulent or abusive activities), in accordance with the provisions of part 1003 of this chapter, the OIG may impose civil money penalties on the Part D sponsor in accordance with part 1003 of this chapter in addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

(3) In the case of a determination under § 423.752(b) other than a determination based upon a violation under § 423.509(a)(4), CMS may impose civil money penalties on the Part D sponsor in the amounts specified in § 423.758 in addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

§ 423.758 Maximum amount of civil money penalties imposed by CMS.

If CMS makes a determination under § 423.509(a), as described in § 423.752(b), excepting those determinations under § 423.509(a)(4), CMS may impose civil money penalties, in addition to, or in place of, the sanctions that CMS may impose under § 423.756(c), in the following amounts:

(a) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more Part D plan enrollees—up to $25,000 for each determination.

(b)For each week that a deficiency remains uncorrected after the week in which the Part D sponsor receives CMS' notice of the determination—up to $10,000 per week.

(c)If CMS makes a determination that a Part D sponsor has terminated its contract with CMS other than in a manner described in § 423.510 and that the sponsor has therefore failed to substantially carry of the terms of the contract, $250 per Medicare enrollee from the terminated Part D plan or plans at the time the Part D sponsor terminated its contract, or $100,000, whichever is greater.

§ 423.760 Other applicable provisions.

The provisions of section 1128A of the Act (except paragraphs (a) and (b)) apply to civil money penalties under this subpart to the same extent that they apply to a civil money penalty or procedure under section 1128A of the Act.

Subpart P—Premiums and Cost-Sharing Subsidies for Low-Income Individuals

§ 423.771 Basis and scope.

(a) *Basis*. This subpart is based on section 1860D–14 of the Act.

(b) *Scope*. This subpart sets forth the requirements and limitations for payments by and on behalf of low-income Medicare beneficiaries who enroll in a Part D plan.

§ 423.772 Definitions.

For purposes of this subpart, the following definitions apply:

Applicant means the Part D eligible individual applying for the subsidies available to subsidy eligible individuals under this subpart.

Family size means the applicant, the spouse who is living in the same household, if any and the number of individuals who are related to the applicant or applicants, who are living in the same household and who are dependent on the applicant or the applicant's spouse for at least one-half of their financial support.

Federal poverty line (FPL) has the meaning given that term in section 673(2) of the Community Services Block Grant Act (42 USC 9902(2)), including any revision required by that section.

Full-benefit dual eligible individual means an individual who, for any month—

(1) Has coverage for the month under a prescription drug plan under Part D of title XVIII, or under an MA-PD plan under Part C of title XVIII; and

(2) Is determined eligible by the State for medical assistance for full benefits under title XIX for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. (This does not include individuals under Pharmacy Plus program demonstrations or under a section 1115 demonstration that provides pharmacy-only benefits to

these individuals.). It also includes any individual who is determined by the State to be eligible for medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) of the Act for any month if the individual was eligible for medical assistance in any part of the month.

Full subsidy means the subsidies available to full subsidy eligible individuals under § 423.780(a) and § 423.782(a).

Full subsidy eligible individuals means individuals meeting the eligibility requirements under § 423.773(b).

Income means income as described under section 1905(p)(1) of the Act without use of any more liberal disregards under section 1902(r)(2) of the Act (that is, as defined by section 1612 of the Act). This definition includes the income of the applicant and spouse who is living in the same household, if any, regardless of whether the spouse is also an applicant.

Institutionalized individual means a full-benefit dual eligible individual who is an inpatient in a medical institution or nursing facility for which payment is made under Medicaid throughout a month, as defined under section 1902(q)(1)(B) of the Act.

Other subsidy eligible individuals means those individuals meeting the eligibility requirements under § 423.773(d).

Personal representative for purposes of this subpart means —

(1) An individual who is authorized to act on behalf of the applicant;

(2) If the applicant is incapacitated; or incompetent, someone acting responsibly on their behalf, or

(3)An individual of the applicant's choice who is requested by the applicant to act as his or her representative in the application process.

Resources means liquid resources of the applicant (and, if married, his or her spouse who is living in the same household), such as checking and savings accounts, stocks, bonds, and other resources that can be readily converted to cash within 20 days, that are not excluded from resources in section 1613 of the Act, and real estate that is not the applicant's primary residence or the land on which the primary residence is located.

State means for purposes of this subpart each of the 50 States and the District of Columbia.

§ 423.773 Requirements for eligibility

(a) *Subsidy eligible individual.* A subsidy eligible individual is a Part D eligible individual residing in a State who is enrolled in, or seeking to enroll in a Part D plan and meets the following requirements:

(1) Has income below 150 percent of the FPL applicable to the individual's family size.

(2) Has resources at or below the resource thresholds set forth in § 423.773(b)(2) or (d)(2).

(b) *Full subsidy eligible individual.* A full subsidy eligible individual is a subsidy eligible individual who—

(1) Has income below 135 percent of the FPL applicable to the individual's family size; and

(2)Has resources that do not exceed—

(i) For 2006, 3 times the amount of resources an individual may have and still be eligible for benefits under the Supplemental Security Income (SSI) program under title XVI of the Act (including the assets or resources of the individual's spouse).

(ii) For subsequent years, the amount of resources allowable for the previous year under this paragraph (b)(2) increased by the annual percentage increase in the consumer price index (all items, U.S. city average) as of September of that previous year, rounded to the nearest multiple of $10. The nearest multiple are rounded up if it is equal to or greater than $5 and down if it is less than $5.

(c)(1) *Individuals treated as full subsidy eligible.* An individual must be treated as meeting the eligibility requirements for full subsidy eligible individuals under paragraph (b) of this section if the individual is a—

(i) Full-benefit dual eligible individual;

(ii) Recipient of SSI benefits under title XVI of the Act; or

(iii) Eligible for Medicaid as a Qualified Medicare Beneficiary (QMB), Specified Low Income Medicare Beneficiary (SLMB), or a Qualifying Individual (QI) under a State's plan.

(2) CMS notifies an individual treated as a full subsidy eligible under this paragraph (c) of this section that he or she does not need to apply for the subsidies available under this subpart, and is deemed eligible for a full subsidy for a period up to one year.

(d) *Other low-income subsidy individuals.* Other low-income subsidy individuals are subsidy eligible individuals who—

(1) Have income less than 150 percent of the FPL applicable to the individual's family size; and

(2) Have resources that do not exceed—

(i) For 2006, $10,000 if single or $20,000 if married (including the assets or resources of the individual's spouse).

(ii) For subsequent years, the resource amount

allowable for the previous year under this paragraph (d)(2), increased by the annual percentage increase in the consumer price index (all items, U.S. city average) as of September of the previous year, rounded to the nearest multiple of $10. The nearest multiple will be rounded up if it is equal to or greater than $5 and down if it is less than $5.

§ 423.774 Eligibility determinations, redeterminations, and applications.

(a) *Determinations of whether an individual is a subsidy eligible individual.* Determinations of eligibility for subsidies under this subpart are made by the State under its State plan under title XIX of the Act if the individual applies with the Medicaid agency, or if the individual applies with the Social Security Administration (SSA), the Commissioner of Social Security in accordance with the requirements of section 1860D–14(a)(3) of the Act.

(b) *Effective date of initial eligibility determinations.* Initial eligibility determinations are effective beginning with the first day of the month in which the individual applies, but no earlier than January 1, 2006 and remain in effect for a period not to exceed 1 year.

(c) *Redeterminations and appeals of low-income subsidy eligibility.*

(1) *Redeterminations and appeals of low-income subsidy eligibility determinations—eligibility determinations made by States.* Redeterminations and appeals of low-income subsidy eligibility determinations by States must be made in the same manner and frequency as the redeterminations and appeals are made under the State's plan.

(2) *Redeterminations and appeals of low-income subsidy eligibility—eligibility determinations made by Commissioner of Social Security.* Redeterminations and appeals of eligibility determinations made by the Commissioner will be made in the manner specified by the Commissioner of Social Security.

(d) *Application requirements.* (1) In order for applications for the subsidies under this subpart to be considered complete, applicants or personal representatives applying on the individual's behalf, must—

(i) Complete all required elements of the application; (ii) Provide any statements from financial institutions,

as requested, to support information in the application; and

(iii) Certify, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the application form.

(2) Multiple applications. If the individual or his or her personal representative has previously filed an application with the State or SSA which seeks subsidy eligibility for any portion of the eligibility period covered by a subsequent application, the later application is void if the individual has received a positive subsidy determination on that earlier application from the State or SSA.

§ 423.780 Premium subsidy.

(a) *Full subsidy eligible individuals.* Full subsidy eligible individuals are entitled to a premium subsidy equal to 100 percent of the premium subsidy amount.

(b) *Premium subsidy amount.*

(1) The premium subsidy amount is equal to an amount which is the lesser of:

(i) Under the Part D plan selected by the beneficiary, the monthly beneficiary premium for a Part D plan other than a MA-PD plan that is basic prescription drug coverage, the portion of the monthly beneficiary premium attributable to basic prescription drug coverage for a Part D plan other than a MA-PD plan that is enhanced alternative coverage, or the MA monthly prescription drug beneficiary premium as defined under section 1854(b)(2)(B) of the Act, or

(ii) The greater of the low-income benchmark premium amount for a PDP region as determined under paragraph (b)(2) of this section or the lowest monthly beneficiary premium for a prescription drug plan that offers basic prescription drug coverage in the PDP region.

(2) *Calculation of the low-income benchmark premium amount.* (i) The low-income benchmark premium amount for a PDP region is a weighted average of the premium amounts described in this paragraph (b)(2)(ii) of this section , with the weight for each PDP and MA-PD plan equal to a percentage, the numerator being equal to the number of Part D eligible individuals enrolled in the plan in the reference month (as defined in § 422.258(c)(1) of this chapter) and the denominator equal to the total number of Part D eligible individuals enrolled in all PDP and MA-PD plans (but not including PACE, private fee-for-service plans or 1876 cost plans)in a PDP region in the reference month.

(ii) Premium amounts: The premium amounts used to calculate the low-income benchmark premium amount are as follows:

(A) The monthly beneficiary premium for a PDP that is basic prescription drug coverage;

(B) The portion of the monthly beneficiary premium attributable to basic prescription drug coverage for a PDP that is enhanced alternative coverage; or,

(C)The MA monthly prescription drug beneficiary premium (as defined under section 1854(b)(2)(B) of the Act) for a MA-PD plan.

(c) *Special rule for 2006 to weight the low-income benchmark premium.* For purposes of calculating the low-income benchmark premium amount for 2006, CMS assigns equal weighting to PDP sponsors (including fallback entities) and assigns MA-PD plans a weight based on prior enrollment. New MA-PD plans are assigned a zero weight. PACE, private fee-for-service plans and 1876 cost plans are not included.

(d) *Other low-income subsidy eligible individuals—sliding scale premium.* Other low-income subsidy eligible individuals are entitled to a premium subsidy based on a linear sliding scale ranging from 100 percent of the premium subsidy amount described in paragraph (b) of this section as follows:

(1) For individuals with income at or below 135 percent of the FPL applicable to their family size, the full premium subsidy amount.

(2) For individuals with income greater than 135 percent but at or below 140 percent of the FPL applicable to the family size, a premium subsidy equal to 75 percent of the premium subsidy amount.

(3) For individual with income greater than 140 percent but at or below 145 percent of the FPL applicable to the family size a premium subsidy equal to 50 percent of the premium subsidy amount.

(4) For individuals with income greater than 145 percent but below 150 percent of FPL applicable to the family size a premium subsidy equal to 25 percent of the premium subsidy amount.

(e) *Premium subsidy for late enrollment penalty.* Full subsidy eligible individuals who are subject to late enrollment penalties under § 423.46 are entitled to an additional premium subsidy equal to 80 percent of the late enrollment penalty for the first 60 months during which the penalty is imposed and 100 percent of their late enrollment penalty thereafter.

§ 423.782 Cost-sharing subsidy.

(a) *Full subsidy eligible individuals.* Full subsidy eligible individuals are entitled to the following:

(1) Elimination of the annual deductible under § 423.104(d)(1).

(2) Reduction in cost-sharing for all covered Part D drugs covered under the PDP or MA-PD plan below the out-of-pocket limit (under § 423.104), including Part D drugs covered under the PDP or MA-PD plan obtained after the initial coverage limit (under § 423.104(d)(4)), as follows:

(i) Except as provided under paragraphs (a)(2)(ii) and (a)(2)(iii) of this section, copayment amounts not to exceed the copayment amounts specified in § 423.104(d)(5)(A). This applies to both:

(A) those full-benefit dual eligible individuals who are not institutionalized and who have income above 100 percent of the Federal poverty line applicable to the individual's family size and

(B) those individuals who have income under 135 percent of the Federal poverty line applicable to the individual's family size who meet the resources test described at § 423.773(b)(2).

(ii) Full-benefit dual eligible individuals who are institutionalized have no cost-sharing for covered Part D drugs covered under their PDP or MA-PD plans.

(iii) Full-benefit dual eligible individuals with incomes that do not exceed 100 percent of the Federal poverty line applicable to the individual's family size are subject to cost-sharing for covered Part D drugs equal to the lesser of:

(A) A copayment amount of not more than $1 for a generic drug or preferred drugs that are multiple source (as defined under section 1927(k)(7)(A)(i) of the Act) or $3 for any other drug in 2006, or for years after 2006 the amounts specified in this paragraph (a)(2)(iii)(A) for the percentage increase in the Consumer Price Index, rounded to the nearest multiple of 5 cents or 10 cents, respectively; or

(B) The copayment amount charged to other individuals under this paragraph (a)(2)(i) of this section.

(3) Elimination of all cost-sharing for covered Part D drugs covered under the PDP or MA-PD plan above the out-of-pocket limit (under § 423.104(d)(5)).

(b) *Other low-income subsidy eligible individuals.* Other low-income subsidy eligible individuals are entitled to the following:

(1) In 2006, reduction in the annual deductible to $50. This amount is increased each year beginning in 2007

by the annual percentage increase in average per capita aggregate expenditures for Part D drugs, rounded to the nearest multiple of $1.

(2) Fifteen percent coinsurance for all covered Part D drugs obtained after the annual deductible under the plan up to the out-of-pocket limit (under § 423.104(d)(5)(iii)).

(3) For covered Part D drugs above the out-of-pocket limit (under § 423.104(d)(5)(iii)), in 2006, copayments not to exceed $2 for a generic drug or preferred drugs that are multiple source drugs (as defined under section 1927(k)(7)(A)(i) of the Act) and $5 for any other drug. For years beginning in 2007, the amounts specified in section paragraph (b)(3) for the previous year increased by the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of 5 cents.

§ 423.800 Administration of subsidy program.

(a) *Notification of eligibility for low-income subsidy.* CMS notifies the Part D sponsor offering the Part D plan, in which a subsidy eligible individual is enrolled, of the individual's eligibility for a subsidy under this section and the amount of the subsidy.

(b) *Reduction of premium or cost-sharing by PDP sponsor or organization.* The Part D sponsor offering the Part D plan, in which a subsidy eligible individual is enrolled must reduce the individual's premiums and cost-sharing as applicable, and provide information to CMS on the amount of those reductions, in a manner determined by CMS. The Part D sponsor must track the application of the subsidies under this subpart to be applied to the out-of-pocket threshold.

(c) *Reimbursement for cost-sharing paid before notification of eligibility for low-income subsidy.* The Part D sponsor offering the Part D plan must reimburse subsidy eligible individuals, and organizations paying cost-sharing on behalf of such individuals, any excess premiums and cost-sharing paid by such individual or organization after the effective date of the individual's eligibility for a subsidy under this subpart.

Subpart Q—Guaranteeing Access to a Choice of Coverage (Fallback Prescription Drug Plans)

§ 423.851 Scope.

This subpart sets forth—the rights of beneficiaries to a choice of at least two sources of qualified prescription drug coverage; requirements and limitations on the bid submission, review and approval of fallback prescription drug plans, and the determination of enrollee premium and plan payments for these plans.

§ 423.855 Definitions.

As used in this subpart, unless specified otherwise-

Actual costs means the subset of prescription drug costs (not including administrative costs or return on investment, but including costs directly related to the dispensing of covered Part D drugs during the year) that are attributable to standard benefits only and that are incurred and actually paid by the sponsor or organization under the plan.

Actually paid has the same meaning described in § 423.308.

Eligible fallback entity or *fallback entity* means an entity that, for a particular contract period-

(1) Is a PDP sponsor that does not have to be a risk-bearing entity (or, if applying to become a fallback entity, an entity that meets all the requirements to become a Part D plan sponsor except that it does not have to be a risk-bearing entity); and

(2) Does not submit a risk bid under § 423.265 for offering a prescription drug plan for any PDP region for the first year of that contract period. An entity is treated as submitting a risk bid if the entity is acting as a subcontractor for an integral part of the drug benefit management activities of an entity that is or applies to become a non-fallback PDP sponsor. An entity is not treated as submitting a bid if it is a subcontractor of an MA organization, unless that organization is acting as or applies to become a non-fallback PDP sponsor for a prescription drug plan.

Fallback prescription drug plan means a prescription drug plan (PDP) offered by a fallback entity that--

(1) Offers only defined standard or actuarially equivalent standard prescription drug coverage as defined in § 423.100;

(2) Provides access to negotiated prices, including discounts from manufacturers; and

(3) Meets all other requirements established for prescription drug plans, except as otherwise specified by CMS in this subpart or in separate guidance.

Qualifying plan means a full-risk or limited-risk prescription drug plan, as defined in § 423.258, or an MA-PD plan described in section 1851(a)(2)(A)(i) of the Act, that provides required prescription drug coverage, as defined in § 423.100 An MA-PD plan must be open for enrollment and not operating under a capacity waiver to be counted as a qualifying plan. A PDP must not be operating under a restricted enrollment waiver, such as those that may be granted to special needs plans or employer group plans, in order to be counted as a qualifying plan in an area.

§ 423.859 Assuring access to a choice of coverage.

(a) *Choice of at least 2 qualifying plans in each area.* Each Part D eligible individual must have available a choice of enrollment in at least 2 qualifying plans (as defined in § 423.855) in the area in which the individual resides. This requirement is not satisfied if only one entity offers all the qualifying plans in the area. At least 1 of the 2 qualifying plans must be a prescription drug plan.

(b) *Fallback service area.* (1) *For coverage year.* Before the start of each coverage year CMS determines if Part D eligible individuals residing in a PDP region have access to a choice of enrollment in a minimum of 2 qualifying plans, as described in paragraph (a) of this section. If CMS determines that Part D eligible individuals in a PDP region, or some portion of the region, do not have available a choice of enrollment in a minimum of two qualified plans, CMS designates the region or portion of a region as a fallback service area. Each Part D eligible individual in a fallback service area is given the opportunity to enroll in a fallback prescription drug plan.

(2) *For mid-year changes.* If a contract with a qualifying plan is terminated in the middle of a contract year (as provided for in § 423.508, § 423.509, or § 423.510), CMS determines if Part D eligible individuals residing in the affected PDP region still have access to a choice of enrollment in a minimum of 2 qualifying plans, as described in paragraph (a) of this section. If CMS determines that Part D eligible individuals in a PDP region, or some portion of the region, no longer have available a choice of enrollment in a minimum of two qualifying plans, CMS designates the region or portion of a region as a fallback service area.

(c) *Access to coverage in the territories.* CMS may waive or modify the requirements of this part if--

(1) CMS determines that waiver or modification is necessary to secure access to qualified prescription drug coverage for Part D eligible individuals residing in a State other than the 50 States or the District of Columbia; or

(2) An entity seeking to become a prescription drug plan in an area such as a territory, other than the 50 States or the District of Columbia requests waiver or modification of any Part D

requirement in order to provide qualified prescription drug coverage.

§ 423.863 Submission and approval of bids.

(a) *Submission of Bids.* (1) *Solicitation of bids.* Separate from the risk bidding process under § 423.265, CMS solicits bids from eligible fallback entities for the offering in all fallback service areas in one or more PDP regions of a fallback prescription drug plan during the contract period specified in § 423.871(b).

(2) *Timing of bids.* CMS determines when to solicit bids for 2006 so that potential fallback prescription drug plans have enough time to prepare a bid. After that, bids are solicited on 3 year cycles, or annually thereafter as needed to replace contractors between contracting cycles.

(3) *Format of bid.* CMS specifies the form and manner in which fallback bids are submitted in separate guidance to bidders.

(b) *Negotiation and acceptance of bids.*

(1) *General rule.* Except as provided in this section, the provisions of § 423.272 apply for the approval or disapproval of fallback prescription drug plans. CMS enters into contracts under this paragraph with eligible fallback entities for the offering of approved fallback prescription drug plans in potential fallback service areas.

(2) *Flexibility in risk assumed and application of fallback prescription drug plan.* In order to ensure access in an area in accordance with § 423.859(a), CMS may approve limited risk plans under § 423.272(c) for that area. If the access requirement is still not met after applying § 423.272(c), CMS provides for the offering of a fallback prescription drug plan in that area.

(3) *Limitation of 1 Plan for all fallback service areas in a PDP region.* All fallback service areas in any PDP region for a contract period must be served by the same fallback prescription drug plan.

(4) *Competitive procedures.* CMS uses competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5)) to enter into a contract under this paragraph. The provisions of section 1874A(d) of the Act apply to a contract under this section in the same manner as they apply to a contract under that section.

(5) *Timing of contracts.* CMS approves a fallback prescription drug plan for a PDP region in a manner so that, if there are any fallback service areas in the region for a year, the fallback prescription drug plan is offered at the same time as prescription drug plans are otherwise offered. In the event of mid-year changes and as required by § 423.859(b)(2), CMS approves a fallback prescription drug plan for a PDP region in a manner so that the fallback prescription drug plan is offered within 90 days of notice.

(6) *No national fallback prescription drug plan.* CMS may not enter into a contract with a single fallback entity for the offering of fallback prescription drug plans throughout the United States.

§ 423.867 Rules regarding premiums.

(a) *Monthly beneficiary premium.* Except as provided in § 423.286(d)(3) (relating to late enrollment penalty) and subject to subpart P (relating to low-income assistance), the monthly beneficiary premium under a fallback prescription drug plan must be uniform for all fallback service areas in a PDP region. It must equal 25.5 percent of CMS's estimate of the average monthly per capita actuarial cost, including administrative expenses, of providing coverage in the PDP region based on similar expenses of prescription drug plans that are not fallback prescription drug plans.

(b) *Special rule for collection of premiums in fallback prescription drug plans.* In the case of a fallback prescription drug plan, the provisions of § 423.293 (b) concerning payments of the late enrollment penalty to the PDP sponsor do not apply and the monthly beneficiary premium is collected in the manner specified in § 422.262(f)(1) of this chapter, or paid directly to the fallback entity by the beneficiary if there are either no benefits, or insufficient benefits available to be collected in the manner specified under § 422.262(f)(1) of this chapter. The amount of any premiums collected by the fallback entity is deducted from management fees due from CMS.

§ 423.871 Contract terms and conditions.

(a) *General.* Except as may be appropriate to carry out the requirements of this section, the terms and conditions of contracts with eligible fallback entities offering fallback prescription drug plans are the same as the terms and conditions of contracts at § 423.504 and § 423.505 for Part D plans.

(b) *Period of contract.* A contract with a fallback entity for fallback service areas for a PDP region is in effect for a period of 3 years. However, a fallback prescription drug plan may be offered for any year within the contract period for a particular area only if the area is a fallback service area for that year.

(c) *Entity not permitted to market or brand fallback prescription drug plans.* Notwithstanding any other provisions of this part, an eligible fallback entity with a contract under this part may not engage in any marketing or branding of a fallback prescription drug plan.

(d) *Performance measures.* CMS issues guidance establishing performance measures for fallback prescription drug plans based on the following:

(1) *Types of performance measures.* Performance measures include at least measures for each of the following:

(i) *Costs.* The entity contains costs to the Medicare Prescription Drug Account and to Part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity through mechanisms such as generic substitution and price discounts.

(ii) *Quality programs.* The entity provides the enrollees in its fallback prescription drug plan with quality programs that avoid adverse drug reactions, monitor for appropriate utilization, and reduce medical errors.

(iii) *Customer service.* The entity provides timely and accurate delivery of services and pharmacy and beneficiary support services.

(iv) *Benefit administration and claims adjudication.* The entity provides efficient and effective benefit administration and claims adjudication.

(2) *Development of performance measures.* CMS establishes detailed performance measures for use in evaluating fallback entity performance and determination of certain management fees based on criteria from historical performance, application of acceptable statistical measures of variation to fallback entity and PDP sponsor (other than fallback entities) experience nationwide during a base period, or changing program emphases or requirements.

(e) *Payment terms.* A contract approved with a fallback entity includes terms for payment for--

(1) The actual costs of covered Part D drugs provided to Part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity; and

(2) Management fees that consist of administrative costs and return on investment and are tied to the performance measures established by CMS for the management, administration, and delivery of the benefits under the contract as provided under paragraph (d) of this section.

(f) *Requirement for the submission of information.* Each contract for a fallback prescription drug plan requires an eligible fallback entity offering a fallback prescription drug plan to provide CMS with the information CMS

determines is necessary to carry out the payment provisions under subpart G or under this subpart, or as required by law. Information disclosed to determine Medicare payment or reimbursement to the fallback entity may be used by the officers, employees and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, determining such payment or reimbursement. This restriction does not limit CMS or OIG authority to conduct audits and evaluations necessary to ensure accurate and correct payment and to otherwise oversee Medicare reimbursement

(g) *Amendment to reflect changes in service area*. The contract may be amended by CMS at any time as needed to reflect the exact regions or counties where the fallback plan are required to operate within the contracted service area(s).

§ 423.875 Payment to fallback plans.

The amount payable for a fallback prescription drug plan is the amount determined under the contract for the plan in accordance with § 423.871(e).

Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans

§ 423.880 Basis and scope.

(a) Basis. This subpart is based on section 1860D–22 of the Act, as amended by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

(b) Scope. This section implements the statutory requirement that a subsidy payment be made to sponsors of qualified retiree prescription drug plans.

§ 423.882 Definitions.

For the purposes of this subpart, the following definitions apply:

Allowable retiree costs, in accordance with section 1860D–22(a)(3)(C)(i) of the Act, means gross covered retiree plan-related prescription drug costs that are actually paid (net any manufacturer or pharmacy discounts, chargebacks, rebates, and similar price concessions) by either the qualified retiree prescription drug plan or the qualifying covered retiree (or on the qualifying covered retiree's behalf).

Benefit option means a particular benefit design, category of benefits, or cost-sharing arrangement offered within a group health plan.

Employment-based retiree health coverage means coverage of health care costs under a group health plan based on an individual's status as a retired participant in the plan, or as the spouse or dependent of a retired participant. The term includes coverage provided by voluntary insurance coverage, or coverage as a result of a statutory or contractual obligation.

Gross covered retiree plan-related prescription drug costs, or *gross retiree costs means*, for a qualifying covered retiree who is enrolled in a qualified retiree prescription drug plan during a plan year, non-administrative costs incurred under the plan for Part D drugs during the year, whether paid for by the plan or the retiree, including costs directly related to the dispensing of Part D drugs.

Group health plans include plans as defined in section 607(1) of ERISA, 29 U.S.C. § 1167(1). They also include the following plans:

(1) A Federal or State governmental plan, which is a plan providing medical care that is established or maintained for its employees by the Government of the United States, by the government of any State or political subdivision of a State (including a county or local government), or by any agency or instrumentality or any of the foregoing, including a health benefits plan offered under chapter 89 of Title 5, United States Code (the Federal Employee Health Benefit Plan (FEHBP)).

(2) A collectively bargained plan, which is a plan providing medical care that is established or maintained under or by one or more collective bargaining agreements.

(3) A church plan, which is a plan providing medical care that is established and maintained for its employees or their beneficiaries by a church or by a convention or association of churches that is exempt from tax under section 501 of the Internal Revenue Code of 1986 (26 U.S.C. 501).

(4) An account-based medical plan such as a Health Reimbursement Arrangement (HRA) as defined in Internal Revenue Service Notice 2002–45, 2002–28 I.R.B. 93, a health Flexible Spending Arrangement (FSA) as defined in Internal Revenue Code (Code) section 106(c)(2), a health savings account (HSA) as defined in Code section 223, or an Archer MSA as defined in Code section 220, to the extent they are subject to ERISA as employee welfare benefit plans providing medical care (or would be subject to ERISA but for the exclusion in ERISA section 4(b), 29 U.S.C.§ . § 1003(b), for governmental plans or church plans).

Part D drug is defined in § 423.100 of this part.

Part D eligible individual is defined in § 423.4 of this part.

Qualified retiree prescription drug plan means employment-based retiree health coverage that meets the requirements set forth in § 423.884 of this chapter for a Part D eligible individual who is a retired participant or the spouse or dependent of a retired participant under the coverage.

Qualifying covered retiree means a Part D eligible individual who is: a participant or the spouse or dependent of a participant; covered under employment-based retiree health coverage that qualifies as a qualified retiree prescription drug plan; and not enrolled in a Part D plan. For this purpose, the determination of whether an individual is covered under employment-based retiree health coverage is made by the sponsor in accordance with the rules of its plan. For purposes of this subpart, however, an individual is presumed not to be covered under employment-based retiree health coverage if, under the Medicare Secondary Payer rules in § 411.104 of this chapter and related CMS guidance, the person is considered to be receiving coverage by reason of current employment status. The presumption applies whether or not the Medicare Secondary Payer rules actually apply to the sponsor. For this purpose, a sponsor also may treat a person receiving coverage under its qualified retiree prescription drug plan as the dependent of a qualifying covered retiree in accordance with the rules of its plan, regardless of whether that person constitutes the qualifying covered retiree's dependent for Federal or State tax purposes.

Retiree drug subsidy amount, or subsidy payment, means the subsidy amount paid to sponsors of qualified retiree prescription drug coverage under § 423.886(a).

Standard prescription drug coverage is defined in § 423.100 of this part.

Sponsor is a plan sponsor as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1002(16)(B), except that, in the case of a plan maintained jointly by one employer and an employee organization and for which the employer is the primary source of financing, the term means the employer.

Sponsor agreement means an agreement by the sponsor to comply with the provisions of this subpart.

§ 423.884 Requirements for qualified retiree prescription drug plans.

(a) *General*. Employment-based retiree health coverage is considered to be a qualified retiree prescription drug plan if all of the following requirements are satisfied:

(1) An actuarial attestation is submitted in accordance with paragraph (d) of this section. The rules for submitting attestations as part of

subsidy applications are described in paragraph (c) of this section.

(2) Part D eligible individuals covered under the plan are provided with creditable coverage notices in accordance with § 423.56.

(3) Records are maintained and made available for audit in accordance with paragraph (f) of this section and § 423.888(d).

(b) *Disclosure of information*. The sponsor must have a written agreement with its health insurance issuer (as defined in 45 CFR 160.103), or group health plan (as applicable) regarding disclosure of information to CMS, and the issuer or plan must disclose to CMS, on behalf of the sponsor, the information necessary for the sponsor to comply with this subpart.

(c) *Application*. (1) *Submitting an application*. The sponsor (or its designee) must submit an application for the subsidy to CMS that is signed by an authorized representative of the sponsor. The application must be provided in a form and manner specified by CMS.

(2) *Required information*. In connection with each application the sponsor (either directly or through its designee) must submit the following:

(i) Employer Tax ID Number (if applicable).

(ii) Sponsor name and address.

(iii) Contact name and email address.

(iv) Actuarial attestation that satisfies the standards specified in paragraph (d) of this section and any other supporting documentation required by CMS for each qualified retiree prescription drug plan for which the sponsor seeks subsidy payments.

(v) A list of all individuals the sponsor believes (using information reasonably available to the sponsor when it submits the application) are qualifying covered retirees enrolled in each prescription drug plan (including spouses and dependents, if Medicare-eligible), along with the information about each person listed below in this paragraph:

(A) Full name.

(B) Health Insurance Claim (HIC) number or Social Security number.

(C) Date of birth.

(D) Gender.

(E) Relationship to the retired employee.

(vi) A sponsor may satisfy paragraph (c)(2)(v) of this section by entering into a voluntary data sharing agreement (VDSA) with CMS (or any other arrangement CMS may make available).

(vii) A signed sponsor agreement.

(viii) Any other information specified by CMS.

(3) *Terms and conditions*. To receive a subsidy payment, the sponsor (through the signed sponsor agreement or as otherwise specified by CMS) must specifically accept and agree to:

(i) Comply with the terms and conditions of eligibility for a subsidy payment set forth in this regulation and in any related CMS guidance;

(ii) Acknowledge that the information in the application is being provided to obtain Federal funds; and

(iii) Require that all subcontractors, including plan administrators, acknowledge that information provided in connection with the subcontract is used for purposes of obtaining Federal funds.

(4) *Signature by sponsor*. An authorized representative of the requesting sponsor must sign the completed application and certify that the information contained in the application is true and accurate to the best of the sponsor's knowledge and belief.

(5) *Timing*. (i) *General rule*. An application for a given plan year must be submitted by no later than 90 days prior to the beginning of the plan year, unless a request for an extension has been filed and approved under procedures established by CMS.

(ii) *Transition rule*. For plan years that end in 2006, an application must be submitted by September 30, 2005 unless a request for an extension has been filed and approved under procedures established by CMS.

(6) *Updates*. The sponsor (or the designee) must provide updates to CMS in a manner specified by CMS of the information required in paragraph (c)(2) of this section on a monthly basis or at a frequency specified by CMS.

(7) *Data match*. Once the full application for the subsidy payment is submitted, CMS—

(i) Matches the names and identifying information of the individuals submitted as qualifying covered retirees with the Medicare Beneficiary Database (MBD) to determine which retirees are Part D eligible individuals who are not enrolled in a Part D plan.

(ii) Provides information concerning the results of the search in paragraph (c)(7)(i) of this paragraph (such as names and other identifying information, if necessary) to the sponsor (or to a designee).

(d) *Actuarial attestation-general*. The sponsor of the plan must provide to CMS an attestation in a form and manner specified by CMS that the actuarial value of the retiree prescription drug coverage under the plan is at least equal to the actuarial value of the defined standard prescription drug coverage (as defined at § 423.100). The attestation must meet all of the following standards.

(1) Contents of the attestation include the following assurances:

(i) The actuarial gross value of the retiree prescription drug coverage under the plan for the plan year is at least equal to the actuarial gross value of the defined standard prescription drug coverage under Part D for the plan year in question.

(ii) The actuarial net value of the retiree prescription drug coverage under the plan for that plan year is at least equal to the actuarial net value of the defined standard prescription drug coverage under Part D for the plan year in question.

(iii) The actuarial values must be determined using the methodology in paragraph (d)(5) of this section.

(2) The attestation must be made by a qualified actuary who is a member of the American Academy of Actuaries. Applicants may use qualified outside actuaries, including (but not limited to) actuaries employed by the plan administrator or an insurer providing benefits under the plan. If an applicant uses an outside actuary, the attestation can be submitted directly by the outside actuary or by the plan sponsor.

(3)The attestation must be signed by a qualified actuary and must state that the attestation is true and accurate to the best of the attester's knowledge and belief.

(4) The attestation must contain an acknowledgement that the information being provided in the attestation is being used to obtain Federal funds.

(5) Methodology. (i) *Basis of the attestation*. The attestation must be based on generally accepted actuarial principles and any actuarial guidelines established by CMS in this section or in future guidance. To the extent CMS has not provided guidance on a specific aspect of the actuarial equivalence standard under this section, an actuary providing the attestation may rely on any reasonable interpretation of this section and section 1860D–22(a) of the Act consistent with generally accepted actuarial principles in determining actuarial values.

(ii) *Specific rules for determining the actuarial value of the sponsor's retiree prescription drug coverage*.

(A) The gross value of coverage under the sponsor's retiree prescription drug plan must be determined using the actual claims experience and demographic data for Part D eligible individuals who are participants and beneficiaries in the sponsor's plan, provided that sponsors without creditable data due to their size or other factors, may use normative databases as

specified by CMS. Sponsors may use other actuarial approaches specified by CMS as an alternative to the actuarial valuation specified by this paragraph (d)(5)(ii)(A).

(B) The net value of coverage provided under the sponsor's retiree prescription drug plan must be determined by reducing the gross value of such coverage as determined under paragraph (d)(5)(ii)(A) of this section by the expected premiums paid by Part D eligible individuals who are plan participants or their spouses and dependents. For sponsors of plans that charge a single, integrated premium or contribution to their retirees for both prescription drug coverage and other types of medical coverage, the attestation must allocate a portion of the premium/contribution to prescription drug coverage under the sponsor's plan, under any method determined by the sponsor or its actuary.

(iii) *Specific rules for calculating the actuarial value of defined standard prescription drug coverage under Part D.*

(A) The gross value of defined standard prescription drug coverage under Part D must be determined using the actual claims experience and demographic data for Part D eligible individuals in the sponsor's plan, provided that sponsors without credible data due to their size or other factors may use normative databases as specified by CMS. Sponsors may use other actuarial approaches specified by CMS as an alternative to the actuarial valuation specified by this paragraph (d)(5)(iii)(A).

(B) To calculate the net value of defined standard prescription drug coverage under Part D, the gross value of defined standard prescription drug coverage under Part D as determined by paragraph (d)(5)(iii)(A) of this section is reduced by the following amounts:

(1) The monthly beneficiary premiums (as defined in § 423.286) expected to be paid for standard prescription drug coverage; and

(2) An amount calculated to reflect the impact on the value of defined standard prescription drug coverage of supplemental coverage provided by the sponsor. Sponsors may use other actuarial approaches specified by CMS as an alternative to the actuarial valuation specified in this paragraph (d)(5)(iii)(B)(2).

(C) The valuation of defined standard prescription drug coverage for a given plan year is based on the initial coverage limit cost-sharing and out-of-pocket threshold for defined standard prescription drug coverage under Part D in effect at the start of such plan year. The attestation, however, must be submitted to CMS no later than 60 days after the publication of the Part D coverage limits for the upcoming calendar year otherwise, such valuation is based on the initial coverage limit, cost-sharing amounts, and out-of-pocket threshold for defined standard prescription drug coverage under Part D for the upcoming calendar year.

(D) Example. If a sponsor's retiree prescription drug plan operates under a plan year that ends March 30, the attestation for the year April 1, 2007–March 30, 2008 is based on the coverage limit, cost-sharing and out-of-pocket threshold that apply to defined standard prescription drug coverage under Part D in 2007 provided the attestation is submitted within 60 days after the publication of the Part D coverage limits for 2008. If the attestation is submitted more than 60 days after the 2008 coverage limits have been published, the 2008 coverage limits would apply.

(iv) Employment-based retiree health coverage with two or more benefit options. For the assurance required under paragraph (d)(1)(i) of this section, the assurance must be provided separately for each benefit option for which the sponsor requests a subsidy under this subpart. For the assurance required under paragraph (d)(1)(ii) of this section, the assurance may be provided either separately for each benefit option for which the sponsor provided assurances under paragraph (d)(1)(i) of this section, or in the aggregate for all benefit options for which the sponsor provided assurances under paragraph (d)(1)(i) of this section.

(6) Timing. (i) *Annual submission.* The attestation must be provided annually at the time the sponsor's subsidy application is submitted, or at such other times as specified by CMS in further guidance.

(ii) *Submission following material change.* The attestation must be provided no later than 90 days before the implementation of a material change to the drug coverage of the sponsor's plan that impacts the actuarial value of the coverage.

(e) *Disclosure of creditable prescription drug coverage status.* The sponsor must disclose to all of its retirees and their spouses and dependents eligible to participate in its plan who are Part D eligible individuals whether the coverage is creditable prescription drug coverage under § 423.56 in accordance with the notification requirements under that section.

(f) *Access to records for audit.* The sponsor (and where applicable, its designee) must meet the requirements of § 423.888(d). Failure to comply with § 423.888(d) may result in nonpayment or recoupment of all or part of a subsidy payment.

§ 423.886 Retiree drug subsidy amounts.

(a) *Amount of subsidy payment.* (1) For each qualifying covered retiree enrolled with the sponsor of a qualified retiree prescription drug plan in a plan year, the sponsor receives a subsidy payment in the amount of 28 percent of the allowable retiree costs (as defined in § 423.882) in the plan year for such retiree attributable to gross retiree costs between the cost threshold and the cost limit as defined in paragraph (b) of this section. The subsidy payment is calculated by first determining gross retiree costs between the cost threshold and cost limit, and then determining allowable retiree costs attributable to the gross retiree costs. For this purpose and where otherwise relevant in this subpart, plan year is the calendar, policy, or fiscal year on which the records of a plan are kept.

(2) *Transition provision.* For a qualified retiree prescription drug plan that has a plan year which begins in calendar year 2005 and ends in calendar year 2006, the subsidy for the plan year must be determined in the following manner. Claims incurred in all months of the plan year (including claims incurred in 2005) are taken into account in determining which claims fall within the cost threshold and cost limit for the plan year. The subsidy amount is determined based only on costs incurred on and after January 1, 2006.

(b) *Cost threshold and cost limit.* The following cost threshold and cost limits apply—

(1) Subject to paragraph (b)(3) of this section, the cost threshold under this section is equal to $250 for plan years that end in 2006.

(2) Subject to paragraph (b)(3) of this section, the cost limit under this section is equal to $5,000 for plan years that end in 2006.

(3) The cost threshold and cost limit specified in paragraphs (b)(1) and (b)(2) of this section, for plan years that end in years after 2006, are adjusted in the same manner as the annual Part D deductible and the annual Part D out-of-pocket threshold are adjusted annually under § 423.104(d)(1)(ii) and (d)(5)(iii)(B), respectively.

§ 423.888 Payment methods, including provision of necessary information.

(a) *Basis.* The provisions of § 423.301 through § 423.343, including requirements to provide information necessary to ensure accurate subsidy payments, govern payment under

§ 423.886 except to the extent the provisions in this section specify otherwise.

(b) *General payment rules.* Payment under § 423.886 is conditioned on provision of accurate information. The information must be submitted, in a form and manner and at the times provided in this paragraph and under other guidance specified by CMS, by the sponsor or its designee.

(1) *Timing.* Payment can be made on a monthly, quarterly or annual basis, as elected by the plansponsor under guidance specified by CMS, unless CMS determines that the options must be restricted because of operational limitations.

(i) *Monthly or quarterly payments.* If the plan sponsor elects for payment on a monthly or quarterly basis, it must provide information described in paragraph (b)(2)(i) of this section on the same monthly or quarterly basis, or at such time as CMS specifies.

(ii) *Annual payments.* If the sponsor elects an annual payment, it must submit to CMS actual rebate and other price concession data within 15 months after the end of the plan year.

(2) *Submission of cost data.* (i) *Monthly or quarterly payments.* If the plan sponsor elects to receive payment on a monthly or quarterly basis, it must submit to CMS, in a manner specified by CMS, the gross covered retiree plan-related prescription drug costs (as defined in § 423.882) incurred for its qualifying covered retirees during the payment period for which it is claiming a subsidy payment and any other data CMS may require. Except as otherwise provided by CMS in future guidance, the sponsor must also submit, using historical data and generally accepted actuarial principles, an estimate of the extent to which its expected allowable retiree costs differs from the gross covered retiree plan-related prescription drug costs, based on expected rebates and other price concessions for the upcoming plan year. The estimate must be used to reduce the periodic payments for the plan year. Final allocation of price concession data must occur after the end of the year under the reconciliation provisions of paragraph (b)(4) of this section

(ii) *Annual payments.* If the plan sponsor elects a one-time final annual payment, it must submit, in a manner specified by CMS, within 15 months, or within any other longer time limit specified by CMS, after the end of the plan year, the total gross covered retiree plan-related prescription drug costs (as defined in § 423.882) for the plan year for which it is claiming a subsidy payment, actual rebate and other price concession data described in paragraph (b)(1)(ii) of this section, and any other data CMS may require. The alternative is that the sponsor can elect an interim annual payment, in which case it must submit the following to CMS, at a time and in a manner specified by CMS: the gross covered retiree plan-related prescription drug costs (as defined in § 423.882) incurred for all of its qualifying covered retirees during the payment period for which it is claiming a subsidy payment; an estimate (using historical data and generally accepted actuarial principles) of the difference between such gross costs and allowable costs (based on expected rebates and other price concessions for the upcoming plan year); and any other data CMS may require.

(3) *Payment by CMS.* CMS makes payment after the sponsor's submission of the cost data at a time and in a manner to be specified by CMS.

(4) *Reconciliation.* (i) Sponsors who elect either monthly, quarterly or an interim annual payment must submit to CMS, within 15 months, or within any other longer time limit specified by CMS, after the end of its plan year, the total gross covered retiree plan-related prescription drug costs (as defined in § 423.882), in a manner specified by CMS; actual rebate and other price concession data for the plan year in question; and any other data CMS may require.

(ii) Upon receiving this data, CMS adjusts the payments made for the plan year in question in a manner to be specified by CMS.

(5) *Special rule for insured plans.* (i) *Interim payments.* Sponsors of group health plans that provide benefits through health insurance coverage (as defined in 45 CFR 144.103) and that choose either monthly payments, quarterly payments or an interim annual payment in paragraphs (b)(1) and (b)(2) of this section , may elect to determine gross covered plan-related retiree prescription drug costs for purposes of the monthly, quarterly or interim annual payments based on a portion of the premium costs paid by the sponsor (or by the qualifying covered retirees) for coverage of the covered retirees under the group health plan. Premium costs that are determined, using generally accepted actuarial principles, may be attributable to the gross prescription drug costs incurred by the health insurance issuer (as defined in 45 CFR § 144.103) for the sponsor's qualifying covered retirees, except that administrative costs and risk charges must be subtracted from the premium.

(ii) *Final payments.* At the end of the plan year, actual gross retiree plan-related prescription drug costs incurred by the insurer (or the retiree), and the allowable costs attributable to the gross costs, are determined for each of the sponsor's qualifying covered retirees and submitted for reconciliation after the end of the plan year as specified in paragraph (b)(4)of this section. The data for the reconciliation can be submitted directly to CMS by the insurer in a manner to be specified by CMS. Upon receiving this data, CMS adjusts the payments made for the relevant plan year in a manner to be specified by CMS.

(c) *Use of information provided.* Officers, employees and contractors of the Department of Health and Human Services, including the Office of Inspector General (OIG), may use information collected under this section only for the purposes of, and to the extent necessary in, carrying out this subpart including, but not limited to, determination of payments and payment-related oversight and program integrity activities, or as otherwise required by law. This restriction does not limit OIG authority to conduct audits and evaluations necessary for carrying out these regulations.

(d) *Maintenance of records.* (1) The sponsor of the qualified retiree prescription drug plan (or a designee), as applicable, must maintain, and furnish to CMS or the OIG upon request, the records enumerated in paragraph (d)(3) of this section. The records must be maintained for 6 years after the expiration of the plan year in which the costs were incurred for the purposes of audits and other oversight activities conducted by CMS to assure the accuracy of the actuarial attestation and the accuracy of payments.

(2) CMS or the OIG may extend the 6-year retention requirement for the records enumerated in paragraph (d)(3) of this section in the event of an ongoing investigation, litigation, or negotiation involving civil, administrative or criminal liability. In addition, the sponsor of the qualified retiree prescription drug plan (or a designee), as applicable, must maintain the records enumerated in paragraph (d)(3) of this section longer than 6 years if it knows or should know that the records are the subject of an ongoing investigation, litigation or negotiation involving civil, administrative or criminal liability.

(3) The records that must be retained are:

(i) Reports and working documents of the actuaries who wrote the attestation submitted in accordance with § 423.884(a).

(ii)All documentation of costs incurred and other relevant information

utilized for calculating the amount of the subsidy payment made in accordance with § 423.886, including the underlying claims data.

(iii) Any other records specified by CMS.

(4) CMS may issue additional guidance addressing recordkeeping requirements, including (but not limited to) the use of electronic media.

§ 423.890 Appeals.

(a) *Informal written reconsideration.* (1) *Initial determinations.* A sponsor is entitled to an informal written reconsideration of an adverse initial determination. An initial determination is a determination regarding the following:

(i) The amount of the subsidy payment.

(ii) The actuarial equivalence of the sponsor's retiree prescription drug plan.

(iii) If an enrollee in a retiree prescription drug plan is a qualifying covered retiree; or

(iv) Any other similar determination (as determined by CMS) that affects eligibility for, or the amount of, a subsidy payment.

(2) *Effect of an initial determination regarding the retiree drug subsidy.* An initial determination is final and binding unless reconsidered in accordance with this paragraph (a) of this section.

(3) *Manner and timing for request.* A request for reconsideration must be made in writing and filed with CMS within 15 days of the date on the notice of adverse determination.

(4) *Content of request.* The request for reconsideration must specify the findings or issues with which the sponsor disagrees and the reasons for the disagreements. The request for reconsideration may include additional documentary evidence the sponsor wishes CMS to consider.

(5) *Conduct of informal written reconsideration.* In conducting the reconsideration, CMS reviews the subsidy determination, the evidence and findings upon which it was based, and any other written evidence submitted by the sponsor or by CMS before notice of the reconsidered determination is made.

(6) *Decision of the informal written reconsideration.* CMS informs the sponsor of the decision orally or through electronic mail. CMS sends a written decision to the sponsor on the sponsor's request.

(7) *Effect of CMS informal written reconsideration.* A reconsideration decision, whether delivered orally or in writing, is final and binding unless a request for hearing is filed in accordance with paragraph (b) of this section, or it is revised in accordance paragraph (d) of this section.

(b) *Right to informal hearing.* A sponsor dissatisfied with the CMS reconsideration decision is entitled to an informal hearing as provided in this section.

(1) *Manner and timing for request.* A request for a hearing must be made in writing and filed with CMS within 15 days of the date the sponsor receives the CMS reconsideration decision.

(2) *Content of request.* The request for informal hearing must include a copy of the CMS reconsideration decision (if any) and must specify the findings or issues in the decision with which the sponsor disagrees and the reasons for the disagreements.

(3) *Informal hearing procedures.* (i)CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The hearing is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made both its initial and reconsideration determinations.

(iii) If CMS did not issue a written reconsideration decision, the hearing officer may request, but not require, a written statement from CMS or its contractors explaining CMS' determination, or CMS or its contractors may, on their own, submit the written statement to the hearing officer. Failure of CMS to submit a written statement does not result in any adverse findings against CMS and may not in any way be taken into account by the hearing officer in reaching a decision.

(4) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the sponsor, explaining the basis for the decision.

(5) *Effect of hearing officer decision.* The hearing officer decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (c) of this section.

(c) *Review by the Administrator.* (1) A sponsor that has received a hearing officer decision upholding a CMS initial or reconsidered determination may request review by the Administrator within 15 days of receipt of the hearing officer's decision.

(2) The Administrator may review the hearing officer's decision, any written documents submitted to CMS or to the hearing officer, as well as any other information included in the record of the hearing officer's decision and determine whether to uphold, reverse or modify the hearing officer's decision.

(3) The Administrator's determination is final and binding.

(d) *Reopening.* (1) *Ability to reopen.* CMS may reopen and revise an initial or reconsidered determination upon its own motion or upon the request of a sponsor:

(i) Within 1 year of the date of the notice of determination for any reason.

(ii) Within 4 years for good cause.

(iii) At any time when the underlying decision was obtained through fraud or similar fault.

(2) *Notice of reopening.* (i) Notice of reopening and any revisions following the reopening are mailed to the sponsor.

(ii) Notice of reopening specifies the reasons for revision.

(3) *Effect of reopening.* The revision of an initial or reconsidered determination is final and binding unless-

(i) The sponsor requests reconsideration in accordance with paragraph (a) of this section;

(ii) A timely request for a hearing is filed under paragraph (b) of this section;

(iii) The determination is reviewed by the Administrator in accordance with paragraph (c) of this section; or

(iv) The determination is reopened and revised in accordance with paragraph (d) of this section.

(4) *Good cause.* For purposes of this section, CMS finds good cause if —

(i) New and material evidence exists that was not readily available at the time the initial determination was made;

(ii) A clerical error in the computation of payments was made; or

(iii) The evidence that was considered in making the determination clearly shows on its face that an error was made.

(5) For purposes of this section, CMS does not find good cause if the only reason for reopening is a change of legal interpretation or administrative ruling upon which the initial determination was made.

(6) A decision by CMS not to reopen an initial or reconsidered determination is final and binding and cannot be appealed.

§ 423.892 Change of ownership.

(a) *Change of ownership.* Any of the following constitutes a change of ownership:

(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law.

(2) *Asset sale.* Transfer of all or substantially all of the assets of the sponsor to another party.

(3) *Corporation*. The merger of the sponsor's corporation into another corporation or the consolidation of the sponsor's organization with one or more other corporations, resulting in a new corporate body.

(b) *Change of ownership, exception*. Transfer of corporate stock or the merger of another corporation into the sponsor's corporation, with the sponsor surviving, does not ordinarily constitute change of ownership.

(c) *Advance notice requirement*. A sponsor that has a sponsor agreement in effect under this part and is considering or negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change.

(d) *Assignment of agreement*. When there is a change of ownership as specified in paragraph (a) of this section, and this results in a transfer of the liability for prescription drug costs, the existing sponsor agreement is automatically assigned to the new owner.

(e) *Conditions that apply to assigned agreements*. The new owner to whom a sponsor agreement is assigned is subject to all applicable statutes and regulations and to the terms and conditions of the sponsor agreement.

§ 423.894 Construction.

Nothing in this part must be interpreted as prohibiting or restricting:

(a) A Part D eligible individual who is covered under employment-based retiree health coverage, including a qualified retiree prescription drug plan, from enrolling in a Part D plan;

(b) A sponsor or other person from paying all or any part of the monthly beneficiary premium (as defined in § 423.286) for a Part D plan on behalf of a retiree (or his or her spouse or dependents);

(c) A sponsor from providing coverage to Part D eligible individuals under employment-based retiree health coverage that is—

(1) Supplemental to the benefits provided under a Part D plan; or

(2) Of higher actuarial value than the actuarial value of standard prescription drug coverage (as defined in § 423.104(d)); or

(d) Sponsors from providing for flexibility in the benefit design and pharmacy network for their qualified retiree prescription drug coverage, without regard to the requirements applicable to Part D plans under § 423.104, as long as the requirements under § 423.884 are met.

Subpart S—Special Rules for States-Eligibility Determinations for Subsidies and General Payment Provisions.

§ 423.900 Basis and scope.

(a) *Basis*. This subpart is based on sections 1935(a) through (d) of the Act as amended by section 103 of the MMA.

(b) *Scope*. This subpart specifies State agency obligations for the Part D prescription drug benefit.

§ 423.902 Definitions.

The following definitions apply to this subpart:

Actuarial value of capitated prescription drug benefits is the estimated actuarial value of prescription drug benefits provided under a comprehensive Medicaid managed care plan per full-benefit dual eligible individual for 2003, as determined using data as the Secretary determines appropriate. This value will be established using data determined by the Secretary to be the best available among the following options:

(1) State rate setting documentation for drug costs to the full dual eligible population;

(2) State encounter and enrollment record databases including cost data; and

(3) State managed care plan-specific financial cost data; and

(4) Other appropriate data.

Applicable growth factor for each of 2004, 2005, and 2006, is the average annual percent change (to that year from the previous year) of the per capita amount of prescription drug expenditures (as determined based on the most recent National Total Drug National Health Expenditure projections for the years involved). The growth factor for 2007 and succeeding years will equal the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals for the 12-month period ending in July of the previous year, as described in § 423.104(d)(5)(iv). CMS provides further detail regarding the sources of data to be used and how the annual percentage increase will be determined via operational guidance to States.

Base year Medicaid per capita expenditures are equal to the weighted average of:

(1) The gross base year (calendar year 2003) per capita Medicaid expenditures for prescription drugs, reduced by the rebate adjustment factor; and

(2) The estimated actuarial value of prescription drug benefits provided under a comprehensive capitated Medicaid managed care plan per full-benefit dual eligible for 2003. The per capita payments for full-benefit dual eligibles with comprehensive managed care and non-managed care are weighted by the respective average monthly full dual eligible enrollment populations reported through the Medicaid Statistical Information System (MSIS).

Full-benefit dual eligible individual means an individual who, for any month-

(1) Has coverage for the month under a prescription drug plan under Part D of title XVIII, or under an MA-PD plan under Part C of title XVIII; and

(2) Is determined eligible by the State for medical assistance for full benefits under title XIX for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. (This does not include individuals under Pharmacy Plus demonstrations or under a section 1115 of the Act demonstration that provides pharmacy only benefits to these individuals.) It also includes any individual who is determined by the State to be eligible for medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) of the Act for any month if the individual was eligible for medical assistance in any part of the month. For the 2003 baseline calculations, the full-benefit dual eligibles are those individuals reported in MSIS as having Medicaid drug benefit coverage and Medicare Part A or Part B coverage. Dual eligibility status will be established by CMS using an algorithm that incorporates the quarterly MSIS dual eligibility code for the prescription fill date and the dual eligibility code for the prior quarter.

Gross base year Medicaid per capita expenditures are equal to the expenditures, including dispensing fees, made by the State and reported in MSIS during calendar year 2003 for covered outpatient drugs, excluding drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1860D–2 of the Act, other than smoking cessation agents determined per full-benefit dual eligible individual for the individuals not receiving medical assistance for the drugs through a comprehensive Medicaid managed care plan. This amount is determined based on MSIS drug claims paid during the four quarters of calendar year 2003 and the corresponding dual eligibility enrollment status of the beneficiary. MSIS drug claims having National Drug

Codes determined by CMS to be in the Part D excluded drug class, and claims having a program type code indicating Indian Health Service or Family Planning will be excluded from the calculation.

Phased-down State contribution factor for a month in 2006 is 90 percent; in 2007 is 88 1/3 percent; in 2008 is 86 2/3 percent; in 2009 is 85 percent; in 2010 is 83 1/3 percent; in 2011 is 81 2/3 percent; in 2012 is 80 percent; in 2013 is 78 1/3 percent; in 2014 is 76 2/3 percent; or after December 2014, is 75 percent.

Phased-down State contribution payment refers to the States' monthly payment made to the Federal government beginning in 2006 to defray a portion of the Medicare drug expenditures for full-benefit dual eligible individuals whose Medicaid drug coverage is assumed by Medicare Part D. The contribution is calculated as 1/12th of the base year (2003) Medicaid per capita expenditures for prescription drugs (that is, covered Part D drugs) for full-benefit dual eligible individuals,

(1) Multiplied by the State medical assistance percentage;

(2) Increased for each year (beginning with 2004 up to and including the year involved) by the applicable growth factor;

(3) Multiplied by the number of the State's full-benefit dual eligible individuals for the given month; and

(4) Multiplied by the phased-down State contribution factor.

Rebate adjustment factor takes into account drug rebates and, for a State, is equal to the ratio of the four quarters of calendar year 2003 of aggregate rebate payments received by the State under section 1927 of the Act to the gross expenditures for covered outpatient drugs.

State medical assistance percentage means the proportion equal to 100 percent minus the State's Federal medical assistance percentage, applicable to the State for the fiscal year in which the month occurs.

§ 423.904 Eligibility determinations for low-income subsidies.

(a) *General rule*. The State agency must make eligibility determinations and redeterminations for low-income premium and cost-sharing subsidies in accordance with subpart P of part 423.

(b) *Notification to CMS*. The State agency must inform CMS of cases where eligibility is established or redetermined, in a manner determined by CMS.

(c) *Screening for eligibility for Medicare cost-sharing and enrollment under the State plan*. States must—

(1) Screen individuals who apply for subsidies under this part for eligibility for Medicaid programs that provide assistance with Medicare cost-sharing specified in section 1905(p)(3) of the Act.

(2) Offer enrollment for the programs under the State plan (or under a waiver of the plan) for those meeting the eligibility requirements.

(d) *Application form and process*. (1) *Assistance with application*. No later than July 1, 2005, States must make available—

(i) Low-income subsidy application forms;

(ii) Information on the nature of, and eligibility requirements for, the subsidies under this section; and

(iii) Assistance with completion of low-income subsidy application forms.

(2) *Completion of application*. The State must require an individual or personal representative applying for the low-income subsidy to—

(i) Complete all required elements of the application and provide documents, as necessary, consistent with paragraph (d)(3) of this section; and

(ii) Certify, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the application form.

(3) *The application process and States*. (i) States may require submission of statements from financial institutions for an application for low-income subsidies to be considered complete; and

(ii) May require that information submitted on the application be subject to verification in a manner the State determines to be most cost-effective and efficient.

(4) *Other information*. States must provide CMS with other information as specified by CMS that may be needed to carry out the requirements of the Part D prescription drug benefit.

§ 423.906. General payment provisions.

(a) *Regular Federal matching*. Regular Federal matching applies to the eligibility determination and notification activities specified in § 423.904(a) and (b).

(b) *Medicare as primary payer*. Medicare is the primary payer for covered drugs for Part D eligible individuals. Medical assistance is not available to full-benefit dual eligible individuals, including those not enrolled in a Part D plan, for—

(1) Covered Part D drugs; or

(2) Any cost-sharing obligations under Part D relating to covered Part D drugs.

(3) The effective date of paragraphs (b)(1) and (b)(2) of this section is January 1, 2006.

(c) *Non-covered drugs*. States may elect to provide coverage for outpatient drugs other than covered Part D drugs in the same manner as provided for non-full benefit dual eligible individuals or through an arrangement with a prescription drug plan or a MA-PD plan.

§ 423.907 Treatment of territories.

(a) *General rules*. (1) Low-income Part D eligible individuals who reside in the territories are not eligible to receive premium and cost-sharing subsidies under subpart P of this part.

(2) A territory may submit a plan to the Secretary under which medical assistance is to be provided to low-income individuals for the provision of covered Part D drugs.

(3) Territories with plans approved by the Secretary will receive increased grants under section 1935(e)(3) of the Act as described in paragraph (c) of this section.

(b) *Plan requirements*. Plans submitted to the Secretary must include the following:

(1) A description of the medical assistance to be provided.

(2) The low-income population (income less than 150 percent of the Federal poverty level) to receive medical assistance.

(3) An assurance that no more than 10 percent of the amount of the increased grant will be used for administrative expenses.

(c) *Increased grant amounts*. The amount of the grant provided under section 1108 (f) of the Act as increased by section 1108 (g) of the Act for each territory with an approved plan for a year is the amount in paragraph (d) of this section multiplied by the ratio of—

(1) The number of individuals who are entitled to benefits under Part A or enrolled under Part B and who reside in the territory (as determined by the Secretary based on the most recent available data for the beginning of the year); and

(2) The sum of the number of individuals in all territories in paragraph (c)(1) of this section with approved plans.

(d) *Total grant amount*. The total grant amount is—

(1) For the last three quarters of fiscal year 2006, $28,125,000;

(2) For fiscal year 2007, $37,500,000; and

(3) For each subsequent year, the amount for the prior fiscal year increased by the annual percentage increase described in § 423.104(d)(5)(iv).

§ 423.908. Phased-down State contribution to drug benefit costs assumed by Medicare.

This subpart sets forth the requirements for State contributions for Part D drug benefits based on full-benefit dual eligible individual drug expenditures.

§ 423.910 Requirements.

(a) *General rule*. Each of the 50 States and the District of Columbia is required to provide for payment to CMS a phased-down contribution to defray a portion of the Medicare drug expenditures for individuals whose projected Medicaid drug coverage is assumed by Medicare Part D.

(b) *State contribution payment*. (1) *Calculation of payment*. The State contribution payment is calculated by CMS on a monthly basis, as indicated in the following chart. For States that do not meet the quarterly reporting requirement for the monthly enrollment reporting, the State contribution payment is calculated using a methodology determined by CMS.

ILLUSTRATIVE CALCULATION OF STATE PHASED-DOWN MONTHLY CONTRIBUTION FOR 2006

	Item	Illustrative Value	Source
(i)	Gross per capita Medicaid expenditures for prescription drugs for 2003 for full-benefit dual eligibles not receiving drug coverage through a comprehensive Medicaid managed care plan, excluding drugs not covered by Part D	$2,000	CY MSIS data
(ii)	Aggregate State rebate receipts in calendar year 2003	$100,000,000	CMS–64
(iii)	Gross State Medicaid expenditures for prescription drugs in calendar year 2003	$500,000,000	CMS–64
(iv)	Rebate adjustment factor	0.2000	(2) ÷ (3)
(v)	Adjusted 2003 gross per capita Medicaid expenditures for prescription drugs for full-benefit dual eligibles not in comprehensive managed care plans	$1,600	(1) x [1- (4)]
(vi)	Estimated actuarial value of prescription drug benefits under comprehensive capitated managed care plans for full-benefit dual eligibles for 2003	$1,500	To be Determined
(vii)	Average number of full-benefit dual eligibles in 2003 who did not receive covered outpatient drugs through comprehensive Medicaid managed care plans	90,000	CY MSIS data
(viii)	Average number of full-benefit dual eligibles in 2003 who received covered outpatient drugs through comprehensive Medicaid managed care plans	10,000	CY MSIS data
(ix)	Base year State Medicaid per capita expenditures for covered Part D drugs for full-benefit dual eligible individuals (weighted average of (5) and (6))	$1,590	[(7)x(5) + (8)x(6)]÷[(7) + (8)]
(x)	100 minus Federal Medical Assistance Percentage (FMAP) applicable to month of State contribution (as a proportion)	0.4000	**Federal Register**
(xi)	Applicable growth factor (cumulative increase from 2003 through 2006)	50.0%	NHE projections
(xii)	Number of full-benefit dual eligibles for the month	120,000	State submitted data
(xiii)	Phased-down State reduction factor for the month	0.9000	specified in statute
(xiv)	Phased-down State contribution for the month	$8,586,000	1/12 x (9) x (10) x [1+(11)] x (12) x (13)

(2) *Method of payment*. Payments for the phased down State contribution begins in January 2006, and are made on a monthly basis for each subsequent month. State payment must be made in a manner specified by CMS that is

similar to the manner in which State payments are made under the State Buy-in Program except that all payments must be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund. The policy on collection of the Phased-down State contribution payment is the same as the policy that governs collection of Part A and Part B Medicare premiums for State Buy-in.

(c) *State Medicaid Statistical Information System (MSIS) Reporting.* Effective with calendar year (CY) 2003 and all subsequent MSIS data submittals, States are required to provide accurate and complete coding to identify the numbers and types of Medicaid and Medicare dual eligibles. Calendar year 2003 submittals must be complete and must be accepted, based on CMS' data quality review, by December 31, 2004.

(d) *State monthly enrollment reporting.* Effective June 2005, and each subsequent month, States must submit an electronic file, in a manner specified by CMS, identifying each full-benefit dual eligible individual enrolled in the State for each month. This file must include specified information including identifying information, a dual eligible type code, available income data and institutional status. The file includes data on enrollment for the current month, plus retroactive changes in enrollment characteristics for prior months. This file will be used by CMS to establish the monthly enrollment for those individuals with Part D drug coverage who are also determined by the State to be eligible for full Medicaid benefits subject to the phased down State contribution payment. This file is due to CMS no later than the last day of the reporting month. For States that do not submit an acceptable file by the end of the month, the phased down State contribution for that month is based on data deemed appropriate by CMS.

(e) *Data match.* CMS performs those periodic data matches as may be necessary to identify and compute the number of full-benefit dual eligible individuals needed to establish the State contribution payment.

(f) *Rebate adjustment factor.* CMS establishes the rebate adjustment factor using total drug expenditures made and drug rebates received during calendar year 2003 as reported on CMS 64 Medicaid expenditure reports for the four quarters of calendar year 2003 that were received by CMS on or before March 31, 2004. Rebates include rebates received under the national rebate agreement and under a State supplemental rebate program, as reported on CMS–64 expenditure reports for the four quarters of calendar year 2003.

(g) *Annual per capita drug expenditures.* CMS notifies each State no later than October 15 before each calendar year, beginning October 15, 2005, of their annual per capita drug payment expenditure amount for the next year.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare Supplementary Medical Insurance Program)

Dated: January 10, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Dated: January 14, 2005.

Tommy G. Thompson,

Secretary of Health and Human Services.

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 417 and 422

Medicare Program; Establishment of the Medicare Advantage Program; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417 and 422

CMS–4069–F

RIN 0938–AN06

Medicare Program; Establishment of the Medicare Advantage Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule implements provisions of the Social Security Act (the Act) establishing and regulating the Medicare Advantage (MA) program. The MA program was enacted in Title II of The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) on December 8, 2003. The MA program replaces the Medicare+Choice (M+C) program established under Part C of title XVIII of the Act, while retaining most key features of the M+C program.

The MA program attempts to broadly reform and expand the availability of private health plan options to Medicare beneficiaries.

This final rule responds to public comments on a proposed rule published on August 3, 2004 (FR 69 46866).

EFFECTIVE DATE: These regulations are effective March 22, 2005 except for the following changes which will become effective on January 1, 2006: amendment of § 417.600(b); removal of § 417.602 through § 417.638; and amendments to § 417.832(d); and § 417.840.

FOR FURTHER INFORMATION CONTACT: Eligibility, Election, and Enrollment—Lynn Orlosky, 410–786–9064 or Randy Brauer, (410) 786–1618.

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Submission of Bids, Premiums, and Plan Approval—Anne Hornsby, 410–786–1181.

Payments to MA Organizations—Anne Hornsby, 410–786–1181.

Special Rules for MA Regional Plans—Marty Abeln, 410–786–1032.

Contracts with MA Organizations—Mark Smith, 410–786 8015.

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General Information—410–786–1296.

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Table of Contents

I. Background
- A. Medicare Prescription Drug, Improvement, and Modernization Act of 2003
- B. Relevant Legislation
- 1. Balanced Budget Act of 1997
- 2. Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000
- 3. Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)
- C. Codification of Regulations
- D. Organizational Overview of Part 422

II. Analysis of and Responses to Public Comments
- A. Overview
- 1. Comments on the August 3, 2004 Proposed Rule
- 2. Organization of the Final Rule
- B. General Comments
- 1. Administrative Procedure Act (APA) Issues
- 2. Other General Comments

III. Provisions of the Proposed Rule, Analysis of and Responses to Comments on the Proposed Rule, and Final Decisions

IV. Provisions of the Final Rule

V. Collection of Information Requirements

VI. Regulatory Impact Analysis

Regulations Text

Acronyms

Because of the many terms to which we refer by acronym in this final rule, we are listing the acronyms used and their corresponding terms in alphabetical order below:

ABN	Advance beneficiary notice
ACR	Adjusted Community Rate
ACRP	Adjusted Community Rate Proposal
ADL	Activities of Daily Living
AHRQ	Agency for Healthcare Research and Quality
AI/AN	American Indian and Alaska Native
ALJ	Administrative law judge
APA	Administrative Procedure Act
BBA	Balanced Budget Act of 1997
BBRA	Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, (Pub. L. 106–113)
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub L. 105–33)
CAH	Critical Access Hospitals
CCPs	Coordinated Care Plans
CMPs	Competitive Medical Plans
CORF	Comprehensive outpatient rehabilitation facility
DSH	Disproportionate Share Hospital
EGPH	Employer and Union Group Health Plans
EOC	Evidence of coverage
ESRD	End-Sage Renal Disease
FEHB	Federal Employees Health Benefits
FFS	Fee-for-Service plans
FI	Fiscal Intermediaries
HCPP	Health care prepayment plan
HHA	Home health agency
HMO	Health Maintenance Organizations
HOS	Health Outcomes Survey
ICF/MR	Intermediate Care Facilities for Mentally Retarded
IHS	Indian Health Service
IPA	Independent Physician Association
ISAR	Intra-Service Area Rate
I/T/U	Indian Health Service, Tribal and Urban Health Program
LEP	Limited English Proficiency
LMRP	Local Medical Review Policy
M+C	Medicare+Choice
MA	Medicare Advantage
MA-PD	Medicare Advantage Prescription Drug
MAC	Medicare Appeals Council
MCOs	Managed Care Organizations
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MSA	Medical Savings Account
MYBE	Mid-year Benefit Enhancement
OACT	Office of the Actuary
OPM	Office of Personnel Management
PACE	Program All-Inclusive Care for the Elderly
P4P	Pay for Performance
PCP	Primary Care Physician
PDP	Prescription Drug Plan
PFFS	Private Fee-For-Service
POS	Point of Service
PPOs	Preferred Provider Organizations
PSOs	Provider Sponsored Organizations
QI	Quality Improvement
QIO	Quality Improvement Organization
RFB	Religious Fraternal Benefit
SAE	Service Area Expansion
SEP	Special Election Period
SHIP	State Health Insurance Programs

SNF	Skilled Nursing Facility
SNPs	Special Needs Plans

I. Background

A. Medicare Prescription Drug, Improvement, and Modernization Act of 2003

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) was enacted on December 8, 2003. Title II of the MMA makes important changes to the current Medicare+Choice (M+C) program by replacing it with a new Medicare Advantage (MA) program under Part C of Medicare. On August 3, 2004, we published a proposed rule in the **Federal Register** (69 FR 46866) that set forth the provisions that would implement Title II of the MMA. Beginning in 2006, the MA program is designed to:

- Provide for regional plans that may make private plan options available to many more beneficiaries, especially those in rural areas.
- Expand the number and type of plans provided for, so that beneficiaries can choose from Health Maintenance Organizations (HMOs), Preferred Provider Organization (PPO) plans (the most popular type of employer-sponsored plan), Fee-for-Service (FFS) plans, and Medical Savings Account (MSA) plans, if available where the beneficiary lives.
- Enrich the range of benefit choices available to enrollees including improved prescription drug benefits, other benefits not covered by original Medicare, and the opportunity to share in savings where MA plans can deliver benefits at lower costs.
- Provide incentives to plans, and add specialized plans to coordinate and manage care in ways that comprehensively serve those with complex and disabling diseases and conditions.
- Use open season competition among MA plans to improve service, improve benefits, invest in preventive care, and hold costs down in ways that attract enrollees.
- Enhance and stabilize payments to organizations, improve program design, introduce new flexibility for plans, and reduce impediments to plan participation.
- Advance the goal of improving quality and increasing efficiency in the overall health care system. Medicare is the largest payer of health care in the world. Medicare can drive changes in the entire health care system.

With these new and improved choices, Medicare beneficiaries, like Federal employees and retirees in the Federal Employees Health Benefits (FEHB) Program, will have the opportunity to obtain improved benefits, improved services, and reduced costs. However, beneficiaries will still be able to remain in traditional Medicare (referred to throughout as ''original'' Medicare), enhanced by the new Part D drug benefit. All will have the opportunity to switch among plans, or to or from original Medicare, during the annual election period (or ''open season'') in November and December.

Over time, participating plans will be under continued competitive pressure to improve their benefits, reduce their premiums and cost sharing, and improve their networks and services, in order to gain or retain enrollees. In addition, we expect plans to use integrated health plan approaches such as disease prevention, disease management, and other care coordination techniques. In doing so, integrated plans that combine the original Parts A and B of Medicare and the new Part D drug benefit and apply these innovative techniques must pass on savings that may result from these care coordination techniques to the enrollee through reduced premiums or additional benefits.

Beginning in 2006, payments for local and regional MA plans will be based on competitive bids rather than administered pricing. MA organizations will submit an annual aggregate bid amount for each MA plan. An aggregate plan bid is based upon the MA organization's determination of expected costs in the plan's service area for the national average beneficiary for providing non-drug benefits (that is, original Medicare (Part A and Part B) benefits), Part D basic prescription drugs, and supplemental benefits if any (including reductions in cost sharing). Our payment to an MA organization for an MA plan's coverage of original Medicare benefits depends on the relationship of the plan's basic A/B bid to the plan benchmark. For a plan with a basic A/B bid below its benchmark, we will pay the MA organization the basic A/B bid amount, adjusted by the individual enrollee's risk factor, plus the rebate amount. (The rebate is 75 percent of the difference between the plan bid and benchmark, and is used to provide mandatory supplemental benefits or reductions in Part B or Part D premiums. The government retains the other 25 percent.) For a plan with a bid equal to or above its benchmark, we will pay the MA organization the plan benchmark, adjusted by the individual enrollee's risk factor. In addition, we would pay the bid amount, if any, for Part D basic coverage. The MMA also requires other adjustments to payments. See the subpart G preamble for a discussion of the geographic Intra-Service Area Rate (ISAR) adjustment and the government premium adjustment (referred to in the MMA as the ''adjustment relating to risk adjustment'').

We will be able to negotiate bid amounts with plans in a manner similar to negotiations conducted by the Office of Personnel Management(OPM) with FEHB plans. We will work with plans to ensure benefit packages meet the needs of our population and that information is made available to beneficiaries so that they can make decisions about which plans best meet their needs.

Finally, in conjunction with the new drug benefit required under Title I of MMA, which is addressed in separate rulemaking found in part 423, changes made in the MMA to the M+C program (now called the MA program) are intended to bring about broad-based improvements to the Medicare program's benefit structure, including improved prescription drug coverage under the MA program. Organizations offering local and regional coordinated care MA plans must offer at least one plan with the Medicare prescription drug benefit or an actuarially equivalent drug benefit.

In addition to the changes because of the MMA, we identified many areas in the proposed rule where we believed we could prevent or reduce unnecessary burden, duplication, or complexity either in interpreting the new MMA provisions or in modifying existing rules to accommodate MA reforms.

B. Relevant Legislation

1. Balanced Budget Act of 1997

Section 4001 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) added sections 1851 through 1859 to the Social Security Act (the Act) establishing a new Part C of the Medicare program, known as the Medicare+Choice (M+C) program. Under section 1851(a)(1) of the Act, every individual entitled to Medicare Part A and enrolled under Medicare Part B, except for individuals with end-stage renal disease (ESRD), could elect to receive benefits either through the original Medicare program or an M+C plan, if one was offered where he or she lived.

The primary goal of the M+C program was to provide Medicare beneficiaries with a wider range of health plan choices through which to obtain their Medicare benefits. The BBA authorized

us to contract with private organizations offering a variety of private health plan options for beneficiaries, including both traditional managed care plans (such as those offered by HMOs that had been offered under section 1876 of the Act), and new options that were not previously authorized. Four types of M+C plans were authorized under the new Part C, as follows:

- M+C coordinated care plans, including HMOs (with or without point-of-service options (POS)), provider sponsored organizations (PSOs), and PPOs.
- M+C MSA plans (combinations of a high deductible M+C health insurance plan and a contribution to an M+C MSA).
- M+C private fee-for-service (PFFS) plans.
- M+C religious and fraternal benefit (RFBs)plans.

The BBA changed the payment methodology to Medicare health plans and initially afforded beneficiaries more choice of plans nationally. However, payment rates grew modestly in relation to the costs health plans incurred, resulting in fewer health plans participating in the M+C program, decreased choice of plans available to beneficiaries, and fewer extra benefits available to enrollees. Although there were large payment increases in rural areas as a result of the BBA provisions, access to Medicare coordinated care plans declined significantly in rural areas after 1997.

To implement these changes, we published an interim final rule in the **Federal Register** on June 26, 1998 (63 FR 34968); a final rule on February 17, 1999 (64 FR 7968); and a final rule with comment on June 29, 2000 (65 FR 40170).

2. Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. 106–113 (BBRA) amended the M+C provisions of the BBA. Many of these amendments were reflected in the June 29, 2000 final rule with comment period. In addition, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. 106–554 (BIPA), enacted December 21, 2000, further amended the M+C provisions of the BBA and BBRA. A final rule containing BIPA provisions was published in the **Federal Register** on March 22, 2002 (67 FR 13278), as well as on August 22, 2003 (68 FR 50855).

These laws enacted subsequent to the BBA made incremental changes to M+C payments and provided financial incentives to plans to participate in the M+C program. While these efforts helped stabilize the M+C program, they did not generally improve plan participation in the M+C program nor did they increase overall beneficiary enrollment or access to plans in rural areas.

3. Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)

The specific sections of Part C of the Social Security Act that were impacted by the MMA are as follows:

Section 1851—Eligibility, election and enrollment.

Section 1852—Benefits and beneficiary protections.

Section 1853—Payments to MA organizations.

Section 1854—Premiums.

Section 1855—Organizational and financial requirements for MA organizations.

Section 1856—Establishment of standards.

Section 1857—Application procedures and contracts with MA organizations.

Section 1858—Special rules for MA regional plans [added by the MMA].

Section 1859—Definitions; Miscellaneous provisions.

This final rule addresses the new MA provisions in Title II of MMA. The requirement in 1858(a)(2)(D) of the Act to conduct a market survey and analysis before establishing MA regions took place concurrent with the publication of the MA proposed rules. The announcement of the establishment of the MA and Prescription Drug Plan (PDP) regions occurred on December 6, 2004. The regions may be found at *http://cms.hhs.gov/medicarereform/mmaregions*.

Provisions of the MMA addressed in this final rule outside of Title II of the MMA include Section 722—Medicare Advantage Quality Improvement Program, of Title VII. Quality improvement provisions in this final rule may be found under Subpart D—Quality Assurance.

C. Codification of Regulations

The final provisions set forth here are codified in 42 CFR Part 422, The Medicare Advantage Program.

The regulations for managed care organizations (MCOs) that contract with CMS under cost contracts will continue to be located in 42 CFR part 417, Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans.

D. Organizational Overview of Part 422

The MMA amended the existing provisions of the Medicare statute found in Part C of Title XVIII, sections 1851 through 1859 of the Act, and added a new section 1858 to the Act. This final rule covers a wide range of topics included in the existing part 422, including eligibility and enrollment, benefits and beneficiary protections, payment, contracting requirements, and grievances and appeals. We have generally retained the organization of the sections from part 422, except for reordering subparts F and G to place the bidding and payment provisions in sequential order.

Where the MMA did not amend existing statute, this final rule does not set forth unchanged regulations text from the previous part 422. Thus, this final rule contains only the necessary revisions to existing part 422. In some subparts of part 422, the only changes are in nomenclature, that is, the replacement of M+C references with MA references. The regulations in that subpart H are not set forth in this final rule. The subparts with substantive changes are as follows:

Subpart A—General provisions, establishment of the Medicare Advantage Program, definitions, types of MA plans, and cost-sharing in enrollment-related costs (user fees).

Subpart B—Requirements concerning beneficiary eligibility, election, and enrollment and disenrollment procedures.

Subpart C—Requirements concerning benefits, access to services, coverage determinations, and application of special benefit rules to PPOs and regional plans.

Subpart D—Quality improvement program, chronic care improvement program requirements, and quality improvement projects.

Subpart E—Relationships with providers.

Subpart F—Submission of bids, premiums, and related information and plan approval.

Subpart G—Payments for MA organizations.

Subpart I—Organization compliance with State law and preemption by Federal law.

Subpart J—Special rules for MA regional plans, including the establishment of MA regions, stabilization fund, and risk sharing.

Subpart K—Application and contract requirements for MA organizations.

Subpart L—Effect of change of ownership or leasing of facilities during term of contract.

Subpart M—Beneficiary grievances, organization determinations, and appeals.

Subpart N—Medicare contract determinations and appeals.

Subpart O—Intermediate sanctions. Each of these subparts is discussed below in section II of this preamble.

II. Analysis of and Responses to Public Comments

A. Overview

1. Comments on the August 3, 2004 Proposed Rule

We received 186 items of correspondence containing more than a thousand specific comments on the August 3, 2004 proposed rule. Commenters included MCOs and other industry representatives, representatives of physicians and other health care professionals, beneficiary advocacy groups, representatives of hospital and other providers, insurance companies, employers, States, accrediting and peer review organizations, members of the Congress, Indian Health Service (HIS), Indian Health Service, Tribal and Urban Health Programs (I/T/U), American Indians and Alaska Natives (AI/AN), and others. Consistent with the scope of the August 3, 2004 proposed rule, most of the comments addressed multiple issues, often in great detail. We received many comments expressing concerns unrelated to the proposed rule. Some commenters expressed concerns about Medicare unrelated to the MA program, while others addressed concerns about health care and health insurance coverage unrelated to Medicare. Because of the volume of comments we received in response to the August 3, 2004 proposed rule we will be unable to address comments and concerns that are unrelated to the proposed rule. Listed below are the six areas of the proposed regulation that generated the most concern:

- Bidding and Payment.
- Access issues, including network adequacy and access providers, including rural providers.
- Specialized Medicare Advantage Plans.
- Establishment of MA Regions.
- Eligibility and enrollment issues, including disenrollment for failure to pay cost sharing and lock in.

In addition, we received many comments on the proposed rule relating to Part 417 for Health Maintenance Organizations; Competitive Medical Plans, and Health Care Prepayment Plans that contract with CMS under cost contracts. A discussion of those comments may be found separately at that Part.

2. Organization of the Final Rule

In this final rule, we address all comments received on the proposed rule. We are addressing issues according to the numerical order of the relative regulation sections.

B. General Comments

1. Administrative Procedure Act (APA) Issues

We received several comments on various aspects of the rulemaking process, as discussed below:

Comment: One commenter suggested that we waive the APA provision that requires at least 30 days notice prior to a final regulation becoming effective in order to allow applicants applying to become specialized MA plans for special needs individuals, or ''SNPs,'' to have the new requirements apply as soon as possible. The commenter made this recommendation in the event that this final regulation was not issued prior to the MMA statutory deadline for issuing a final regulation for SNPs that was 1 year following the date of enactment, or December 8, 2004.

Response: The first two categories of special needs individuals, institutionalized persons and dual eligibles, were specified in the statute, and we have already begun working with plans wishing to become specialized MA plans for these categories of special needs individuals. We discuss in subpart A below our approach to allowing for the additional category of special needs individuals—those with severe or disabling chronic conditions. This final rule will take effect March 22, 2005, *except where otherwise noted*. We do not believe it is necessary to waive the 30-day notice period because it likely will take longer than the 30-day period for a plan's application and approval process to occur. However, we intend to work with applicants who wish to offer specialized MA plans to ensure that the approval process is as efficient and timely as possible.

Comment: We received a number of comments on the timing of the regulation and the short timeframe between issuance of the final regulation and preparation of applications and bids early in 2005 for contract year 2006. One commenter stated that the time required to re-contract with its commercial provider networks to ensure that the PPO contracts contain the Medicare required language and rate structure that are reflective of CMS reimbursements, is substantial. The commenter indicated that it needed more time to build the system infrastructure to support a new systems platform than would be required for commercial enrollees. The commenters suggested that plans may have to limit the number of regions in which they participate because of the short timeframes between issuance of the regulation and the application filing deadline.

Response: We agree that working within the statutory constraints of the MMA, including the relatively short period of about 13 months between enactment of the legislation and issuance of final regulations, there is little time between issuance of the regulation and the preparation of applications and bids in 2005 for contract year 2006. With respect to the short time frame in applications and submission of bids, please refer to the comments and responses related to bidding at § 422.254 and § 422.502 related to application requirements. Our goal beginning on the date of enactment of the MMA was to issue final regulations as soon as possible so that prospective MA plans would have the necessary information to be able to make business decisions before bids are due mid 2005.

Comment: Several commenters recommended that CMS issue a final rule with comment period prior to implementation of the final rules. The commenters expressed concern that certain aspects of the proposed rule that would impact rural providers have not been specified in sufficient detail. One commenter recommended that CMS conduct a second notice of proposed rulemaking incorporating changes from the first round of comments and allowing for public comment on the additional details that are currently under development, or issue the regulations on an interim basis with a second comment period on the additional, important details that are currently under development or that reflect decisions made following this round of comments.

Response: Under the APA, we are required to provide the public with the opportunity to review and comment upon proposed regulations. We have done this through the publication of the August 3, 2004 proposed rule and its corresponding comment period. We believe that allowing for a second round of comments or publishing interim regulations would make it difficult for MA organizations wishing to offer MA plans in 2006 to prepare to meet the new requirements imposed by the MMA and implemented by this final rule.

2. Other General Comments

Comment: A number of commenters stated that the final regulation must

address the unique state of AI/AN people and the Indian health program. In particular, these comments raise concerns about the implications of the proposed rules on the Indian health care delivery system. For example, there is concern that the proposed rules will jeopardize significant revenues the Indian health system now collects from Medicaid for ''dual eligibles,'' that is, those individuals who are eligible for both Medicare and Medicaid. They ask for substantial modifications to the proposed rules to enable voluntary enrollment by AI/AN populations in MA plans. Some of the suggested modifications include: (1) encouraging MA enrollment by AI/AN by removing financial barriers, such as waiving AI/AN cost sharing for all plans; (2) ensuring that I/T/U Health Programs are held harmless financially, and are fully reimbursed for covered services provided to AI/AN who enroll in a MA plan.

Response: We appreciate the numerous comments that provided information on unique health needs for the AI/AN populations. As noted elsewhere, we are implementing the MMA statute through this rulemaking. We do not have the flexibility to include language that would carve out a subset of Medicare beneficiaries, such as AI/AN populations, if it is not provided for in statutory language. Specific comments raised by the AI/AN and I/T/U organizations will be addressed in the respective subparts under which the comments were submitted. In general, however, we believe that the newly created regional plans will create new choices for the AI/AN populations, and that access to MA plans will be improved. Similarly, because MA regional plans must reimburse for all covered benefits in and out of network, IHS facilities may receive reimbursement for out of network care provided to a regional MA plan AI/AN beneficiary by that MA regional plan. Under provisions designed to protect the Medicare program from fraud and abuse, a broad waiver of beneficiary cost sharing of the type the commenter requests would not be permitted. However, we make no statement regarding the applicability of existing statutory and regulatory provisions that may allow for the waiver of cost sharing in certain cases.

Comment: One commenter recommended that CMS develop and conduct educational and informational activities on the differences in the various MA options, particularly in areas where there are choices of original Medicare, managed care plans, PPOs, MSAs and PPFs plans. The commenter believes that there is a potential for confusion and error for beneficiaries with so many choices.

Response: We agree that strong outreach to beneficiaries about their new choices of MA plans, as well as the drug benefit, is critical to the success of these new programs. We will be devoting more resources to providing new information and education on the new plan choices and drug benefit.

Comment: We received a number of general comments on specialized MA plans for special needs individuals, sometimes referred to as ''SNPs'' or ''special needs plans''. Comments relating to definitions of SNPs may be found in subpart A and comments on enrollment may be found in subpart B below. Among the general comments was a suggestion to disseminate a set of guiding principles for SNPs and further refine them as experience increases. We also received a comment that network adequacy for SNPs should be evaluated to ensure timely, accessible, and appropriate care and that all necessary specialists are represented. Further, it was suggested that the provider network should be broad enough to ensure that vulnerable populations served have timely access to all necessary specialists required to address special needs.

Additionally, several commenters stated that CMS should incorporate into regulation the authority to waive or modify MA requirements that conflict with the intent of the SNP provision. Finally, some commenters requested that CMS provide guidance with regard to the States' role in developing and approving SNPs for dual eligibles. It was recommended that CMS give states maximum flexibility in using waiver authority to integrate Medicare and Medicaid benefits for dual eligibles under SNP programs. A commenter suggested that CMS consult with State Medicaid agencies where Home and Community-based waivers are operating before allowing these populations to be enrolled in SNPs because this could add to the cost and complexity of providing services.

Response: We provided Interim Guidance for SNPs in the 2005 Call Letter in June 2004 and will provide additional operational guidance for SNPs after publication of the final rule. Interim guidance may be obtained at *www.cms.hhs.gov/healthplans/specialneedsplans/qaspecneeds06-23.pdf*. Consistent with current policy for network adequacy for MA plans as found at § 422.112, we will require that MA organizations submit information about their provider network and will review this information as part of the application and approval process to ensure that timely, accessible, and appropriate care is provided. We will be particularly interested in the availability of care designed to address the needs of the enrolled special needs population. While the MMA allows SNPs to limit enrollment to a defined population, as described in § 422.52, the law does not provide for waiver of other MA requirements for SNPs. We encourage States and MA plans to work cooperatively in developing programs to serve dual eligibles and will help to coordinate these efforts where appropriate. We believe that SNPs can be appropriate for care and services to those in the community and lead to the coordination of the complex services they need.

Finally, we note that program oversight is an essential government function that is an integral component of implementing the MA program. Throughout this rulemaking, we refer to government activity necessary to implement this section, which includes program oversight authority.

III. Provisions of the Proposed Rule, Analysis of and Responses to Comments on the Proposed Rule, and Final Decisions

Part 417—Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans

Subpart J–Qualifying Conditions for Medicare Contracts Extension of Reasonable Cost Contracts (§ 417.402)

Authority for cost HMOs/CMPs (cost plans) was due to expire on December 31, 2004. Section 234 of the MMA provides an initial extension of cost plans through December 31, 2007. It also provides for a continued extension of cost plans beyond December 31, 2007, under specific conditions.

Effective for contract years beginning on or after January 1, 2008, cost plans may be extended where there are fewer than two coordinated care plan-model MA plans of the same type available to Medicare beneficiaries in the same service area. Both of the ''competing'' MA plans of the same type must meet minimum enrollment requirements for the entire previous year in order to trigger mandatory cost plan non-renewal or service area reduction. We interpreted the statute to require cost plan service area reduction where there are two or more MA plans of the same type meeting minimum enrollment requirements competing for Medicare members in a portion of the cost plan's service area. We asked for comment on our interpretation in the proposed rule related to mandatory service area reductions, saying that an alternative

reading of section 234 of the MMA might permit renewal of a cost plan in all parts of its service area until there was competition from two (or more) MA coordinated care plans throughout the cost plan's service area. After reviewing comments and responding (below), we are adopting the proposed policy as final.

At § 417.402, we proposed to permit existing cost plans to expand their service areas through September 1, 2006. Thereafter, service area expansion applications by cost HMOs/CMPs will be initially evaluated and accepted only when there are not two or more MA plans of the same type meeting minimum enrollment requirements in the area in which the cost plan proposes to expand. After reviewing comments and responding (below), we are adopting the proposed policy as final.

We received the following comments on the proposed provisions for subpart J of part 417 and have provided our responses:

Comment: Many commenters supported the non-renewal of cost HMOs/CMPs as proposed in the proposed rule. These commenters made reference to the statutory and Conference Committee Report language that indicated the Congressional intent that cost plans are to be required to operate under the same provisions as other private plans to the extent other private plans are willing to enter the cost plan's service area. Many other commenters objected to the partial non-renewal proposal made in the proposed rule. Many stated that competition from MA coordinated care plans was more likely in urban areas, where most cost plan enrollment is concentrated. These commenters stated that even where there is no MA coordinated care plan competition in rural areas, the viability of a cost plan without an urban ''core'' would likely be threatened. To the extent CMS non-renewed cost plans in urban areas, the financial viability of the organization offering the cost plan would be undermined in rural areas as well because of the loss of economies of scale. Such a result would be contrary, these commenters said, to an underlying concept of the MMA, which is to increase choices for Medicare beneficiaries in rural areas. Finally, many of these commenters stated that continuity of care would be needlessly lost for members in urban areas enrolled in cost plans that were partly non-renewed, because the members would be forced to change Medicare plans and providers.

Response: We generally support the notion of continuity of care. However, we believe that when competing MA coordinated care plans are available in an area that will be non-renewed for a cost plan, non-renewed cost members are able to continue to receive services from current providers through either enrollment in one of the competing MA coordinated care plans or by returning to FFS Medicare. We recognize that when a cost plan is non-renewed in an urban area with MA coordinated care plan competition, the financial viability of the cost plan in rural areas without MA coordinated care plan competition may be undermined. However, we believe that allowing a cost plan to continue to compete for members in areas of MA competition would unfairly undermine the financial viability of the competing MA coordinated care plans. Therefore, we have not modified our regulation. We believe that this interpretation is consistent with the statutory intent that cost plans will not be permitted to compete for new members under different provisions from those applicable to other private plans that have entered the cost plan's service area.

Comment: Some commenters stated that the proposed regulation text at § 417.402(c)(1) and (2) did not specify what kind of ''year'' was meant—calendar year, 12 month period, or something else. All of these commenters also recommended that CMS specify in regulation text that the ''year'' referred to is a calendar year.

Response: We agree with this comment and have modified the regulation text to specify that the ''year'' in question is a calendar year. This is consistent with the statute, in that MA and cost plan offerings are for calendar years. To the extent that competition has been present for the entire previous calendar year, it should mean the calendar year immediately prior to the year in which the cost plan will be required to non-renew in a portion of its service area or have its contract non-renewed.

Comment: Many commenters recommended that CMS distinguish between the meaning of ''plan'' within the section 1876 cost program and the meaning of ''plan'' within the MA program. Under the section 1876 cost program, each CMS-contracting HMO/CMP is allowed to offer a single Medicare cost ''plan''—see section 1876(c)(2)(A)(I) of the Act. On the other hand, under the MA program, each CMS-contracting MA organization is permitted to offer many MA ''plans''—see § 422.4(b).

Response: We disagree with the commenters. Section 234 of the MMA expressly provides that a cost contract may not be extended or renewed for a service area if such service area during the previous year was within the service area of two or more coordinated care plans of the same type (that is, regional or local) that meet the relevant enrollment requirements. Because a single MA organization may offer two different MA coordinated care plans within a cost plan's service area, a single MA organization can trigger the non-renewal of the cost contract, if the other requirements of Section 1876(h)(5)(C)(ii) of the Act are met.

Comment: Several commenters submitted comments stating that specialized MA plans for special needs individuals (special needs plans or SNPs) (defined at § 422.2) should not count in the MA coordinated care plan competition tests in § 417.402(c)(1) through (3), because they are not available to the general public and therefore not a true test of the availability of MA coordinated care plans in the service area of a cost plan.

Response: We agree with the commenter that the Congress intended to permit cost plans to remain in place in an area until the enrollees in that cost plan have at least two local or two regional MA plan options to choose from in the area. Because in many cases cost enrollees would not be eligible to enroll in a SNP, we do not believe that the existence of a SNP in a service area should automatically count as an option available in that service area. We note that the statute refers to a cost plan's service area being within the ''service area'' of two local or regional MA plans. The MA regulations at § 422.2 define a plan's service area as an area within which an MA-eligible individual may enroll in a particular MA plan offered by an MA organization. Although a SNP's service area is open to all individuals in the service area who are in the special needs category served by the plan, it may not be open generally to MA-eligible individuals (for example, if it is a SNP that exclusively, rather than disproportionately, enrolls special needs individuals). For this reason, we believe that a cost plan may not be ''within the service area'' of a SNP, as this term is used in the competition test, in some cases. We will therefore apply the competition test on a case-by-case basis with respect to SNPs. If the SNP is an option available to the cost plan's enrollees, and the SNP meets the requirements of section 1876(h)(5)(C)(ii) of the Act and § 417.402(c), it will be taken into account in determining whether the cost plan may be renewed. Similar considerations apply to MA plans that exclusively enroll employer/labor group members under authority provided in section 1857(i) of the Act

and § 422.106(c) and (d). To the extent the employer/labor group MA plan is available to the cost plan's enrollees, and the MA plan meets the requirements of section 1876(h)(C)(ii) of the Act and § 417.402(c), it will be taken into account in determining whether the cost plan may be renewed. Thus, we will also apply the competition test on a case-by-case basis with respect to employer/labor group MA plans.

Comment: One commenter suggested that implicit in the ''competition'' tests was the fact that the MA coordinated care plans that caused the non-renewal in a portion of the service area, or that caused the non-renewal of the cost plan in its entire service area, would be available in the coming year. The commenter was concerned that CMS might enforce this section of the cost regulations, even if one of the MA plans used in establishing the ''competition'' threshold were non-renewing or withdrawing from the service area in the year in which enforcement would occur.

Response: Because such a result would be contrary to statutory intent, CMS will not proceed with enforcement when fewer than two MA coordinated care plans will be offered to Medicare beneficiaries in the affected area at the time of enforcement.

Comment: One commenter asked CMS to state its clear intent in regulatory text that we will allow cost plans to expand service areas after September 1, 2006.

Response: As we said in the preamble of the proposed rule and repeated in this preamble: ''We will permit existing cost plans to expand their service areas through September 1, 2006. Thereafter, service area expansion applications by cost HMOs/CMPs will be initially evaluated and accepted only when there are not two or more MA plans of the same type meeting minimum enrollment requirements in the area in which the cost plan proposes to expand.'' We specifically included the first sentence in regulation text at § 417.402(b). However, service area expansions are not guaranteed after that date. Please note that the regulation text at § 417.402(b) specifically authorizing service area expansions through September 1, 2006, does not preclude them thereafter. Additionally, the new language replaces identical language in this section of the regulation (and which language first appeared in section 634 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA)) which provided service area expansion authority for cost plans through September 1, 2003. The commenter should note that we have previously interpreted the language in BIPA and in our regulations to be permissive in this area, rather than proscriptive. We will continue to apply it permissively in this area to the extent that the conditions for non-renewal under Section 1876(h)(5)(C) and § 417.402(c) are not present.

Subpart Q—Beneficiary Appeals

Changes to subpart Q are addressed in the preamble discussion for subpart M, which deals with appeals policy for MA plans, cost plans and HCPPs.

A. Subpart A—General Provisions (§ 422.1)

1. Conforming Changes

Subpart A of the August 3, 2004 proposed rule set forth several general and conforming changes dictated by MMA. Below is a summary of the provisions in subpart A. (For a broader discussion of the provisions, please refer to our proposed rule.) The provisions are as follows:

- Section § 422.1 lists the statutory authority that is implemented in part 422. In § 422.1, we have added the new section 1858 of the Act that pertains to ''Special rule for MA Regional Plans.''
- We removed provisions relating to application requirements and evaluation and determination procedures in § 422.6 and § 422.8 and added them to § 422.501 and § 422.502 of subpart K, so that all application and contracting information is in one place.
- We redesignated and amended § 422.10 as § 422.6 and amended newly redesignated § 422.6. Section 422.6 (formerly § 422.10) described the user fees associated with the Medicare Beneficiary Education and Information Campaign, required under section 1857(e)(2) of the Act.

2. Definitions (§ 422.2)

The majority of the proposed changes in subpart A concerned new, revised, and obsolete definitions for the new MA Program in § 422.2. The MMA required several new and broad definitions; ''MA regional plans,'' ''specialized MA plans,'' ''ACR,'' ''Additional benefits,'' ''Adjusted community rate,'' and ''M+C'' obsolete after 2006.

In proposed § 422.2, we also revised several existing definitions to make them consistent with the MMA statute. For example, Mandatory supplemental benefits are redefined to incorporate language reflecting that these benefits may be paid for through premiums and cost sharing or through the application of a rebate, or both. Therefore, mandatory supplemental benefits are defined as health care services not covered by Medicare that an MA enrollee must purchase as part of an MA plan. Benefits may include reductions in cost sharing for benefits under the original Medicare FFS program, and are paid for in the form of premiums and cost sharing, or by an application of the beneficiary rebate rule in section 1854(b)(1)(C)(ii)(I) of the Act, or both.

However, optional supplemental benefits retained the same definition as under the M+C program as health services not covered by Medicare that are purchased at the option of the MA enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost-sharing. (Throughout the regulation, the phrase ''supplemental benefits'' refers to both mandatory and optional supplemental benefits.) The terms ''mandatory supplemental'' and ''optional supplemental'' are used when referring specifically to one of the types of supplemental benefits.

We removed ''additional benefits'' from the definition of ''basic benefits'' because MA plans will no longer offer additional benefits. In addition, we replaced the word ''ACR'' process with the words ''annual bidding'' process in the definition of ''benefits'' to reflect the new bidding process for submission and approval of benefits. Finally, we revised the definition of ''service area'' to incorporate the concept of the new MA regional plan's service area that consists of an entire region.

Under section 1851(a)(2)(A) of the Act, two new types of coordinated care plans were established; MA Regional plans, which are regional PPO plans, and specialized MA plans for special needs individuals, or SNPs. We defined an ''MA local area'' as a county or other area specified by us because it is important to distinguish an MA local area from an MA region. We defined an ''MA regional plan'' because it is a new type of coordinated care plan choice for beneficiaries. While PPOs first became a choice for beneficiaries under the BBA, they operated as ''local'' plans on a county (including multi-county) or partial county basis. The MA regional plan functions like a local PPO but must serve an entire region.

A regional MA plan's service area is one or more entire MA regions; thus, we defined an ''MA regional plan'' as a private health plan that operates as a PPO, but serves an entire CMS-designated region. Local PPOs that may offer MA plans under the MA program, the regional PPOs must have a network of contracting providers that have agreed to a specific reimbursement for covered benefits that are offered by the MA regional plan, and must also provide for reimbursement for all

covered benefits regardless of whether the covered benefits are provided through the network providers or outside of the network.

We defined an ''MA local plan'' as one that is not an MA regional plan. Also defined under part 422 are the ''Prescription Drug Sponsor,'' ''PDP,'' and a ''MA Prescription Drug (MA-PD) plan.'' A sponsor must be a private entity that meets our requirements and standards. PDP sponsors may offer multiple plans throughout the country or in a region, but sponsors must submit an individual bid for each plan.

An MA-PD plan is an MA plan that also provides qualified prescription drug coverage as found in Part D of the Act. An organization offering a coordinated care MA plan must have an MA-PD plan in each of the service areas in which it operates, as required under section 1860D 21(a)(1) and (2) of Part D of the Act.

In section 1859(b)(6)(A) of the Act, specialized MA plans for special needs individuals or SNPs are defined to be MA plans that exclusively serve special needs individuals defined in section 1859(b)(6)(B) of the Act. The establishment of specialized MA plans allows MA plans to exclusively enroll special needs individuals in MA plans that have targeted clinical programs for these individuals.

Section 1859(b)(6)(B) of the Act identifies three types of special needs individual as: (1) institutionalized individuals; (2) individuals entitled to medical assistance under a State plan under Title XIX; and (3) other individuals with severe or disabling chronic conditions as the Secretary determines would benefit from enrollment in a SNP plan.

Comment: One commenter supported a broad definition that tracks section 1859(b)(6) of the Act in order to provide CMS with the flexibility needed to approve a wide range of proposals to meet the unique needs of special populations and expand their choices.

Response: We agree with the commenter. We are providing general guidelines in our regulations in order to maintain the flexibility to approve a wide range of proposals, while also protecting the interests of special needs beneficiaries.

The Secretary may also designate an MA plan as a specialized MA plan for special needs individuals, ''SNP,'' if the plan ''disproportionately'' serves special needs individuals.

Comment: Several commenters responded to the question in the proposed rule as to whether CMS should allow specialized MA plans that disproportionately enroll special needs individuals, or ''disproportionate percentage'' plans and how they should be defined. Most commenters supported including ''disproportionate percentage'' plans in the definition of SNPs. One of the reasons given was to allow married beneficiaries, or children of special needs individuals, to enroll in the same plan as the spouse or parent, even if only one individual meets the definition of a special needs individual.

Many commenters suggested that CMS not establish detailed criteria to define disproportionate percentage, particularly at the outset. It was felt that enrollment thresholds might act as a barrier to plan participation and limit choices available to Medicare beneficiaries. Some commenters suggested that CMS identify ''exclusive'' and ''disproportionate'' plans at the time of each application. Some commenters recommended that the criteria be national, not regional or local.

Several commenters agreed that the criteria should be quantitative, for example, an MA plan risk score in the upper quintile of all MA plans, or a frailty score in the upper quintile of all MA plans as measured by Activities of Daily Living (ADL) scores on the Health Outcomes Survey (HOS).

Some commenters recommended that a ''disproportionate percentage'' SNP enroll fifty (50) percent or more special needs individuals. Another commenter suggested that SNPs remain exclusive, but if plans were able to enroll those without special needs, at least eighty-five (85) percent of the plan's enrollees should be individuals with special needs. Another commenter stated that requiring an upper limit of more than seventy-five (75) percent of special needs individuals would be problematic. One commenter believes that ''redesignated'' SNPs, that is, regular MA plans that become SNPs, be allowed to continue enrolling non-special needs individuals as long as overall enrollment contains a higher proportion of special needs individuals than exist in the plan's service area. One commenter suggested that—(1) an annual certification and compliance process; (2) that new plans have a 3-year startup period to attain the threshold, and (3) that CMS annually publish risk score distributions. Another commenter recommended that non-exclusive plans be defined as having a higher than average enrollment of one or more of the special needs individuals groups as estimated for MA plans and/or the FFS population.

Response: We agree that a special needs individual's family members may want to join the same plan. We acknowledge that MA plans do not have to be exclusive to provide quality specialized programs for special needs individuals. We received a wide range of recommendations for defining a ''disproportionate percentage'' SNP. We acknowledge that there are numerous ways to define and identify disproportionate percentage SNPs and agree with those commenters who felt the parameters should not be overly restrictive, particularly at the outset. SNPs are a new type of coordinated care plan and we believe that plans and CMS might not anticipate all factors that should be considered in determining an acceptable percentage. We also want to encourage plans to develop programs to more effectively care for special needs individuals. In order to ensure flexibility, and take into consideration the experience gained by plans and CMS as SNPs mature, we will define a ''disproportionate percentage'' SNP as one that enrolls a greater proportion of the target group (dually eligible, institutionalized, or those with a specified chronic illness or disability) of special needs individuals than occur nationally in the Medicare population based on data acceptable to CMS. We will provide further guidance as to what data sources may be used to determine a national percentage for a special needs group being targeted by the disproportionate percentage plan. Under our authority as provided in section 231(d) of the MMA, we are revising the definition of specialized MA plan to include ''disproportionate percentage'' plans.

Comment: Several comments were received regarding how CMS should identify those with severe or disabling chronic conditions that would make them eligible for enrollment in a SNP. Several commenters suggested using broad flexibility, reflecting the language in section 1858(b)(6) of the Act. Other commenters recommended that SNPs should serve as laboratories for developing population-based management protocols, not single-disease State management protocols for diagnoses that could be well-served by a standard MA plan. Another commenter recommended limiting enrollment to those with late-stage chronic conditions, those with co-morbidities, adult disabled, and frail elderly. Some commenters suggested basing the definition on conditions for which alternate care delivery models, such as disease management and evidence-based medicine, exist, and also take into consideration conditions that are expensive and prevalent for

there to be savings and risk-management potential.

Commenters also recommended that conditions should be those associated with recognized quality measures, so that CMS may carefully monitor specialized MA plans. None of the commenters objected to including those individuals who are not institutionalized but require an equivalent level of care. ESRD, diabetes, congestive heart failure, Alzheimer's and other dementias along with one or more other serious conditions, HIV/AIDs, and frail elderly and adult disabled with multiple chronic conditions requiring complex medical management were among the specific conditions suggested for specialized MA plans.

Another commenter suggested that on an interim basis CMS restrict the definition to those who are nursing home certifiable, as defined by each State; ESRD patients; and those diagnosed with AIDs, and, in the meantime, collect ADL data through the Health Outcomes Survey (HOS) and use this measure in conjunction with Activities of Daily Living (ADL) measures to identify high-risk groups. Other commenters suggested additional detailed formulas for identifying groups eligible for specialized MA plans.

Response: Because this is a new ''untested'' type of MA plan, we are not setting forth in regulation a detailed definition of severe and disabling chronic condition that might limit plan flexibility. We will review and evaluate proposals for specialized MA plans that serve severe or disabling chronic disease categories, including HIV/AIDs, on a case-by-case basis. Among the criteria to be considered will be the appropriateness of the target population, the existence of clinical programs or special expertise to serve the target population, and whether the proposal discriminates against ''sicker'' members of the target population.

Other Comments on § 422.2

We requested comments on § 422.2 on the development of an HIV/AIDS special needs plan that would address the special health needs, including prescription drugs, of the Medicare-eligible population living with HIV/AIDS.

We received several comments supportive of the development of an HIV/AIDS special needs plan. Therefore, we will consider this type of plan application to become a special needs plan for Medicare-eligible individuals living with HIV/AIDs.

For purposes of specialized MA plans, we proposed to define ''institutionalized'' in the proposed rule as residing in a long-term care facility for more than 90 days as determined by the presence of a 90-day assessment in the Minimum Data Set (MDS).

Comment: Several commenters suggested that the 90-day residence requirement (as determined by a 90-day assessment in the minimum data set) be modified. One commenter suggested determining institutional status based on the discharge potential at admission. Another commenter suggested changing the requirement to 30 days. One commenter did not object to 90 days, but recommended changing the language to allow CMS to approve exceptions in case the institution failed to perform the assessment. In addition, one commenter suggested that ''institutionalized'' also include those residing in Intermediate Care Facilities for the Mentally Retarded (ICF/MR). Several commenters recommended that those living in the community while requiring an institutional level of care be considered institutionalized.

Response: In response to comments, we are clarifying and broadening the definition of institutionalized for purposes of defining a special needs individual to take into consideration those with chronic mental conditions and other chronic conditions. For purposes of defining a special needs individual, ''institutionalized'' means residing in or expected to reside in a long-term care facility which is a skilled nursing facility (SNF) as defined in section 1819(a) of the Act; a nursing facility (NF) as defined in section 1919(a) of the Act; a SNF/NF; an intermediate care facility for the mentally retarded (ICF/MR) as defined in section 1905(d) of the Act; or an inpatient psychiatric facility as defined in section 1861(f) of the Act for 90 days or longer.

A SNP may enroll special needs individuals prior to a 90-day stay based on an assessment of the potential for a stay of that length as long as the assessment is of a type approved by CMS.. For example, a SNP for individuals with serious mental conditions may show us that the State requires a plan of care or similar assessment prepared by a health professional upon admission. We recognize that this definition is not the same as the definition of ''institutionalized individual'' in 42 CFR § 423.772. That provision is an income and resource-based definition for the purpose of determining Part D premiums and cost-sharing subsidies for low-income individuals. The term ''institutionalized'' as used for purposes of defining a special needs individual under this Part is for the purpose of identifying a vulnerable population that might benefit from enrollment into a SNP. We also wish to clarify that our definition of institutionalized for purposes of defining a special *needs individual does not relate to the MA payment methodology*.

For purposes of SNPs, we may also consider as institutionalized those individuals living in the community but requiring a level-of-care equivalent to that of those individuals in the aforementioned long term care facilities. We believe that 90 days is the most appropriate and accurate timeframe for determining long-term residence in an institution. We base this on information we collected showing that, once a beneficiary is institutionalized for 90 or more days, it is less likely that that individual will return to a community setting. However, SNPs may enroll institutionalized beneficiaries based on a CMS-approved assessment (as described in further operational guidance following publication of this rule) showing the beneficiary is expected to reside in the institution for 90 days or more. Given the latitude provided under the disproportionate percentage criteria, we do not think that the 90-day definition for institutionalized will adversely affect specialized MA plans' ability to enroll eligible beneficiaries.

Comment: Several commenters supported the proposed approach to require all specialized MA plans to provide Part D coverage.

Response: We agree with the commenters, especially in light of the fact that special needs individuals in particular need access to prescription drugs to manage and control their severe or disabling chronic conditions. Therefore, we are including the Part D coverage requirement for all specialized MA plans at § 422.2 in the definition of a specialized MA Plan.

Comment: One commenter recommended that CMS change the definition of PDP as it is incorrect and not consistent with the Medicare Prescription Drug Benefit Program proposed rule.

Response: We agree with the recommended change to the definitions of PDP and PDP sponsor found at § 422.2. To avoid any confusion, we are revising the definitions in Title II to cross-reference the definitions of PDP and PDP sponsor found in part 423, the Medicare Prescription Drug Benefit.

Comment: Several commenters recommended that CMS make a revision to the basic benefits definition found at § 422.2 to add ''including covered services received through an IHS

program.'' Other commenters recommended that CMS add to the special needs individual definition ''AI/IN are exempt from mandatory enrollment in Title XIX plans but would qualify for optional enrollment in an AI/AN specialized need plan.''

Response: We do not believe there is a statutory basis in the MMA to include non-covered Medicare services received through an IHS program in the definition of basic benefits. We also do not believe it is necessary to include a specific reference to Medicare covered services provided through an IHS program in the definition of basic benefits. If a service is a covered service, it is already included in the definition. Therefore, we are not making the requested change. Similarly, the MMA does not authorize us to revise the definition of special needs individual as suggested. The statute defines special needs individuals who are defined as those who are Medicaid, institutionalized or those with severe or disabling chronic conditions. Clearly, AI/AN individuals who fit any of those definitions could choose to enroll in a specialized MA plan if one were offered in their area. The suggested change to the definition of special needs individuals to add optional enrollment in an AI/AN specialized MA plan suggests that some AI/AN organizations may be interested in offering a specialized MA plan. Under the statute, a specialized MA plan must be open to all eligible Medicare beneficiaries who are within the class of special needs individuals the plan serves. We see no statutory basis for allowing a plan to limit enrollment only to AI/AN Medicare beneficiaries. Conceptually, supplemental benefits could be offered in the specialized MA plan to assist chronically ill enrollees to prevent or treat illnesses that affect AI/AN populations and others enrolled in the plan. As described at § 422.501, a prospective SNP would need to submit an application to CMS detailing its plan for treating those with severe or disabling chronic conditions. Finally, we would note that we are not adding language exempting AI/AN from mandatory enrollment in Title XIX plans as it is not within the scope of this rulemaking. We note however, that under sections 1115 and 1915(b) of the Act, mandatory enrollment under Medicaid for such populations is permitted.

Comment: Several commenters suggested that CMS add a new definition to § 422.2 to afford specialized MA plans the status of regional MA plans for most purposes (including special rules and incentives applicable to regional MA plans), without having to cover multiple States. The commenters suggested that plans may be reluctant to take on multiple State regions with enrollment limited to Medicaid eligibles in the region.

Response: As described in section 1858(a)(1) of the Act and as reflected in § 422.455(a), a MA plan must cover an entire region, including offering enrollment to all eligible Medicare beneficiaries within that region whether the region is a single State or multiple State area. Therefore, a special needs plan may receive the stabilization fund payments and other incentives for its participation as a regional plan only if the plan would comply with all requirements in section 1858 of the Act applicable to Regional MA plans. This means, that it would have to be open to enrollment for every member of the special needs category in the entire region in question, meet access standards for the individuals in all areas of the region, market to all areas of the region, and offer uniform benefits and cost-sharing in all areas of the region.

Comment: A commenter recommended that CMS revise the definition of service area as found in § 422.2. The commenter indicated that as proposed, the language of § 422.2 appears to have established a lower standard for approval of regional PPO service areas. The commenter recommended that CMS separately define service area requirements for HMOs and PPOs and that the requirements for approval of a PPO apply to both local and regional PPO plans alike.

The commenter also recommended that CMS consider the more flexible design of a PPO and in turn allow for more flexibility with respect to service area approval. The commenter understands that local PPOs are not required to cover an entire region, but also indicated that it is difficult even in small States to meet the availability and accessibility requirements by the time the service area application is due.

Response: We appreciated the comment to clarify this definition as we found it had been improperly numbered and created some confusion. Therefore, we have renumbered the sub-definitions and included language that makes clear that we may consider whether the contracting provider network meets the access and availability standards set forth in § 422.112, for all MA coordinated care plans and network MA MSA plans. We also have made technical corrections because the distinction between non-network and network MSA plans is no longer applicable, as discussed in further detail below. We believe this change will further reduce confusion.

3. Types of MA Plans (§ 422.4)

The MA program is intended to provide beneficiaries access to a wider array of private health plan choices than under the M+C program and to increase the number of areas in which private health care options are available to Medicare beneficiaries. Entities can contract with us to provide five general categories or types of plans: (1) local MA coordinated care plans; (2) MA MSA plans; (3) MA PFFS plans; (4) regional PPO coordinated care plans; and (5) specialized MA coordinated care plans.

In the August 3, 2004 proposed rule, we proposed to clarify that the PPO definition that was in existence before (defined by the BBRA) was solely for purposes of the application of the more limited quality assurance requirements. For PPO-type plans that are offered by MA organizations that are licensed or organized under State law as HMOs, the quality assurance requirements that apply to all other coordinated care plans in section 1852(e) of the Act also apply to those PPO-type plans.

Effective January 1, 2006, MA organizations that offer MA local plans that are PPOs will need to provide only for the collection, analysis, and reporting of data that permit the measurement of health outcomes and other indices of quality insofar as services are furnished by providers that have contracted with the MA organization under those PPO plans. However, a local PPO offered by an MA organization that is licensed or organized under State law as an HMO will be required to meet the normal data collection, analysis, and reporting requirements. We proposed to modify the definition of PPOs in § 422.4 to account for this more limited interpretation of State licensure requirements and modified headings in § 422.152(b) and (e).

Under section 233 of the MMA, MA organizations are authorized to offer MSA plans as a permanent option. MMA also eliminated the limits imposed on MSA plans by the BBA, including a time limit on enrollment and a limit on the number of beneficiaries who could enroll in the plans, and exempted MSA plans from certain quality assurance requirements that the BBA applied to ''network'' MSA plans.

To conform with MMA's changes to MSAs, we proposed to delete the descriptions of the M+C network MSA plan and M+C non-network MSA plan as different types of plans at

§ 422.4(a)(2)(ii), since the distinction between network and non-network MSAs for the purpose of quality assurance requirements was no longer applicable. As noted above, we are making similar changes to the definition of service area at § 422.2.

We are making a technical correction to the final MA regulation. Our current regulations at § 422.2 read ''Religious and Fraternal Benefit (RFB) Society.'' We are amending the definition of ''Religious and Fraternal Benefit (RFB) Society'' by removing the words ''Religious and fraternal'' and adding the words ''Religious fraternal'' in their place. We are making this change to the definition as it is potentially confusing and is not consistent with the statutory definition of ''Religious Fraternal Benefit Society'' at section 1859(e)(3) of the Social Security Act. We are also making a technical change to § 422.4(a) to clarify that RFB Society plans may be any type of MA plan, and are not restricted to being a type of coordinated care plan only, as implied by the inclusion of ''RFBs'' exclusively in § 422.4(a)(1)(iii). Thus, we are removing the reference to RFBs from that section. We also are deleting the word ''network'' from the parenthetical at the end of § 422.4(a)(1)(iii) because the distinction between network and non-network MSAs no longer applies.

Comment: Many commenters suggested that CMS more clearly coordinate between the Medicare Prescription Drug Benefit Rule at part 423 and the MA Program Rule at part 422.

Response: In response to this comment, we are making several changes to clarify the interaction between Part C and Part D. Specifically, we are clarifying the language at § 422.4 on types of MA plans and Part D prescription drug coverage. We are adding a new paragraph (c), Rule for MA Plans' Part D Coverage. This paragraph clarifies the requirements for MA coordinated care plans, MA MSAs, and MA PFFS plans by stating that a coordinated care plan must offer qualified Part D coverage meeting the requirements in § 423.104 in that plan or in another MA plan in that area. We also added language that MSAs cannot offer drug coverage, other than that required under Parts A and B of Title XVIII of the Act. Finally, we added language that MA organizations offering PFFS plans can choose to offer qualified Part D coverage meeting the requirement in § 423.104 in that plan.

Comment: One commenter recommended that CMS clarify the language at § 422.4(a)(1)(v). The commenter wants to ensure that an organization that wants to apply as a local HMO, but does not have an HMO license in its State, but is otherwise licensed as a risk-bearing entity in its State, will not be considered a PPO and thus subject to the 2-year moratorium on local PPOs as found at section 221(a)(2) of the MMA and proposed at § 422.451.

Response: We do not believe that a clarification of § 422.4(a)(1)(v) is required as § 422.400 already provides that an MA organization must be licensed under State law, or otherwise authorized to operate under State law, as a risk-bearing entity (as defined in § 422.2) eligible to offer health insurance or health benefits coverage in each State in which it offers one or more MA plans. Therefore, an organization that wishes to apply as a local MA plan HMO and has a State-risk bearing license would be considered an HMO and not be considered as a local MA plan PPO nor subject to the PPO moratorium described at § 422.451. However, a plan would have to market itself as an HMO or an HMO with a POS option. A plan could not market itself as a PPO because of the potential for confusion.

Comment: Several commenters recommended that CMS include new language in the final regulation that ensures that the type of denial of covered services as described in the Government Accountability Office (GAO) report entitled ''Medicare Demonstration PPOs: Financial and Other Advantages for Plans, Few Advantages for Beneficiaries (GAO–04–960)'' never happens again. One commenter, also referring to the GAO report, expressed concern that the Agency is not effectively enforcing current law, based on the recent GAO findings.

Response: In response to the GAO evaluation, we agreed to implement the GAO recommendation for us to instruct Medicare PPO Demonstration plan participants to remove impermissible restrictions on an enrollee's access to providers for all covered plan benefits. We are committed to assuring that local and regional PPOs provide reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers as found in § 422.4(a)(1)(v).

Comment: Several commenters recommended that CMS require non-contracted providers to accept Medicare fees as payment in full with no balance billing to the beneficiary. The commenters believe that this approach will protect beneficiaries from excessive payment liability for out of network services.

Response: As discussed in further detail in subpart C of the preamble to this final rule, there are several existing limitations on balance billing that apply to protect Medicare beneficiaries regardless of whether they are enrolled in an MA plan. Further, under existing rules, beneficiaries may not be held liable for more than the amount of out-of-network cost sharing for the service specified in the plan. For these reasons, we do not believe the changes requested by the commenter are necessary.

Comment: Several commenters supported the amendment found in the proposed rule that clarifies that a plan licensed as an HMO may still become a PPO under its HMO license as long as the State allows the HMO to offer a PPO under its HMO license. However, the commenters suggested that CMS revise § 422.4(a)(1)(v) in the following two ways: (1) clarify that PPOs may establish before authorization requirements for services obtained out-of-network that would allow for a review based on medical appropriateness; and (2) modify the provision to indicate that PPOs are not obligated to make available out of network certain types of programs, like health and wellness programs, for which no non-network counterpart is available.

The commenters also recommended that CMS clarify that only original Medicare benefits must be covered both in and out of network and that covered benefits that are not part of original Medicare need not be covered out of network. The commenters opposed CMS' requirement that for 2005, PPO plans must offer all benefits both in and out of network. The commenters stated that many plans in the private sector and in the FEHB program limit out-of-network coverage for some services. The commenters believe that requiring coverage of all non-original Medicare benefits in and out of network implies that there is a standard allowance or price reference upon which to base payments for these services. The commenters also suggest that there are no balance billing protections for the beneficiary who seeks care out of network. The commenter expressed similar concerns around the Medicare drug benefit and the lack of specificity regarding coverage of non-original Medicare benefits. The commenter also believe that covering certain benefits out of network (for example, disease management, 24-hour advice nurse lines, and wellness programs) will pose a significant challenge.

Response: To respond to the first recommended change to § 422.4(a)(1)(v)requesting that MA plans be allowed to impose pre-authorization

requirements on out-of-network care by PPOs, section 1852(e)(3)(A)(iv)(II) of the Act states that a PPO plan must provide for reimbursement for all covered benefits, regardless of whether the benefits are provided within the plan's network of providers. Similarly, section 1859(b)(4)(B) of the Act, which defines MA regional PPOs, includes the same requirement to provide for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers. These provisions indicate the Congress's clear intent to ensure that PPOs provide coverage for all plan-covered benefits both in and out of network. Further, although other coordinated care plans may include mechanisms to control utilization, such as referrals from gatekeepers for an enrollee to receive services within the plan, the definition of PPO contained in sections 1852(e)(3)(A)(iv) and 1859(b)(4)(b) of the Act indicates that local and regional PPOs may not use similar mechanisms, such as pre-authorization, to restrict enrollee access to out-of-network services. However, there are several ways PPOs can appropriately seek to promote the use of in-network services. For example, PPOs may encourage beneficiaries to notify them before seeking care out of network, so that care is coordinated in and out of network. PPO plans may offer incentives to beneficiaries to provide notice of their intent to seek out-of-network services by discounting out-of-network cost sharing when beneficiaries provide notice before receiving services. Further, MA organizations are required to have procedures for making determinations of whether an enrollee is entitled to receive a health service and the amount that the enrollee will be required to pay for the service. Thus, a PPO plan enrollee and provider may seek an advance determination of coverage before receiving the service, and we encourage PPO enrollees to avail themselves of this option.

On the commenters' request to clarify in § 422.4(a)(1)(v) that only original Medicare benefits must be covered in and out of network, we believe that the clear language in the statute at section 1859(b)(4)(B) of the Act relating to regional MA plans and section 1852(e)(3)(A)(iv)(II) of the Act relating to local PPOs, does not permit us to limit the requirement that PPOs provide for reimbursement for all plan-covered benefits both in and out of network. Therefore, we are not modifying the definition of PPOs at § 422.4(a)(1)(v). However, to respond to some of the concerns raised in the comment, we again note that plans can reduce the regular cost sharing for out-of-network benefits for beneficiaries who voluntarily seek pre-authorization for those benefits. As described by another response to comment above, we disagree with the commenter that there are no balance billing protections for beneficiaries. There are limitations on balance billing to protect beneficiaries regardless of whether they are involved in an MA plan or not. Finally, on the issue of benefits, such as nurse advice lines, which plans believe should not be made available out of network, we believe that as a practical matter, most of these types of benefits will be unattainable out of network because they are designed to be provided exclusively to plan members. Additional discussion of these types of out-of-network benefits can be found in the subpart C preamble.

Comment: Comments were received on § 422.4(a)(1)(v). Several commenters suggested that CMS address perceived inconsistencies in licensing requirements for PPOs as compared to HMOs by confirming the scope of State licensure requirements that apply to entities offering MA PPO plans, as State licensing laws may restrict an HMO's ability to offer a PPO plan.

Response: We do not believe there are inconsistencies. All MA plans must be licensed by the State as a risk-bearing entity. State law controls whether the MA organization is licensed or authorized to offer the type of MA plan it proposes to offer. As we explained in the preamble discussion in subpart A of the proposed rule, the fact that MA organizations offering local PPOs that are (or are not) licensed as HMOs is pertinent to the MA program solely for purposes of the application of quality improvement standards in section 1852(e) of the Act, and has no specific bearing on whether an MA organization has State authority under applicable State law to offer an HMO or PPO under the MA program. Whether an MA organization (licensed either as an HMO or otherwise) can offer a specific type of MA plan continues to rest upon whether the organization has State licensure or authority to offer such a type of MA plan.

Comment: One commenter requested that CMS consider enabling the PFFS model as an option under the regional preferred provider organization structure. The PFFS model in the MA program enables broader geographic coverage without the specific provider contracting requirements. This option could expand participation in the regional program by enhancing participation and access in rural areas without specific provider contracting access requirements as is currently available under the existing MA PFFS plans.

Response: Since a PFFS plan is not defined as a type of coordinated care plan under section 1851(a)(2)(A)(i) of the Act, it would not be possible to allow an MA organization to offer a PFFS plan as an MA regional plan. Additionally, MA PFFS plans are defined at section 1859(b)(2) of the Act, while MA regional plans are defined at section 1859(b)(4) of the Act. The definitions are mutually exclusive.

Comment: A few commenters asked whether SNPs could be any type of coordinated care plan.

Response: We believe that section 1851(a)(2)(A)(ii) of the Act clearly states that SNPs can be any type of coordinated care plan.

4. Expansion of the Beneficiary Education and Information Campaign ''User Fees'' (§ 422.6, formerly § 422.10)

The last section of subpart A contained regulations implementing the user fees provided for in section 1857(e)(2) of the Act. MMA expanded the user fee to include PDP sponsors as well as MA plans as contributors. The expansion of the user fee recognizes the increased Medicare beneficiary education activities that we would require around the new prescription drug benefit.

As before, the user fee would pay for the ongoing costs of the national beneficiary education campaign that includes developing and disseminating print materials, the 1–800 telephone line, community based outreach to support SHIPs, and other enrollment and information activities required under section 1851 of the Act and counseling assistance under section 4360 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 103–66).

As indicated in the proposed rule and in this final rule (§ 422.6), in fiscal year 2006 and thereafter, the MMA authorizes up to $200,000,000, reduced by the fees collected from MA organizations and PDP sponsors in that fiscal year. (The total amount is not indexed in any way.) In each year, the total amount of collected user fees may not exceed the estimated costs in the fiscal year for carrying out the enrollment and dissemination of information activities in the MA and Part D prescription drug programs or the applicable portions of $200,000,000, whichever is less.

These user fee provisions establish the applicable aggregate contribution portions for MA organizations and PDP

sponsors. The applicable portion of the user fee for MA organizations will be based on the total proportion of expenditures for Medicare Part C as well as for payments under Part D that are made to MA organizations as a percent of Title XVIII expenditures. The PDP sponsor's applicable portion is the estimate of the total proportion of expenditures under Title XVIII that are attributable to expenditures made to PDP sponsors for prescription drugs under Part D. The fees charged to individual MA plans and PDP sponsors would continue to be determined by CMS. These fees are calculated by a percent of plan's revenue to avoid over-burdening smaller plans.

Comment: One commenter supported CMS' efforts to increase user fees to support beneficiary education. The commenter recommended that CMS collect the entire amount authorized under the statute and work with the Congress to either index it or otherwise lift the cap if needed to adequately inform beneficiaries about the new complexities with private plans.

Response: The changes the commenter requested are beyond the scope of this rulemaking. We do not intend for the user fee to be exclusively for education on MA plans. We anticipate that the user fee will also be used on the new Part D drug benefit, which we believe will consume a large portion of the user fees, due to the newness of the benefit.

Comment: Two commenters believe that there is insufficient funding of the SHIP program and recommended that CMS use a portion of the MA and PDP user fees to support SHIPs.

Response: Early in the implementation of the M+C program, SHIPs received some funding from the user fee. However, for the last several years, SHIP funding has been a specific line item appropriation by the Congress. We have some discretion regarding how the user fees are spent in terms of beneficiary education, so it is possible for SHIPs to get some of their funding from the user fee. However, decisions on how to spend user fees are internal management decisions relating to resource allocation, and therefore will not be included in this regulation.

Comment: One commenter recommended that beneficiary educational materials be shared with Congressional committees of jurisdiction prior to releasing them.

Response: The timelines for providing education materials are limited. Although we do not intend to seek Congressional authorization before the release of the education materials, the materials will comply with the provisions of the statute and regulations, and we will make every effort to ensure that they are useful to beneficiaries in making their choices. CMS' Office of Legislation works closely with the Congressional offices to ensure that they are aware of and have open access to copies of various educational materials either before or in the same timeframe as their constituents to help with education and outreach activities.

Comment: One commenter expressed concern that the funds used to educate beneficiaries may be more focused on explaining the array of choices and not focused enough on encouraging beneficiaries to actually make a choice. The commenter encouraged CMS to work directly with experienced plans to conduct information campaigns that result in significant Part D uptake rates for PDPs and MA-PDs. The commenter was concerned that beneficiaries may be confused by the changes beginning in 2006.

Response: We appreciate the commenter's suggestion for us to work with experienced plans to conduct information campaigns that could expand enrollment in MA-PDs and PDPs beginning in 2006 (especially in light of the new options that will be available at that time). We expect to engage a strong network of experienced plans, providers, and other stakeholders and partners to provide input and feedback on beneficiary education plans and to provide specific suggestions on ways to communicate the changes that will occur in the MA program in 2006.

Comment: One commenter believes that CMS will require the resources, both financial and human, to help beneficiaries make choices about benefit and plan options that appropriately reflect their needs and preferences. The commenter recommended that CMS bolster programs such as one-on-one counseling, which beneficiaries prefer, and to design beneficiary materials in formats that make information easy to interpret and understand. The commenter also recommended that CMS create information resources, such as the 1–800 number, but also help beneficiaries understand the information that is being presented.

Response: We agree that we will have to continue to educate beneficiaries on MA program changes in a way that helps the beneficiary to understand the program and understand what type of Medicare plan would best suit his or her individual health and financial needs. We routinely test education and outreach products with beneficiaries during development to ensure that they are broadly accessible and understandable to the appropriate target audiences.

Comment: A commenter indicated that there are high costs to I/T/U for MMA implementation costs related to outreach, education and enrollment of an AI/AN individual. The commenter encouraged CMS to acknowledge the need for funding that is specifically directed to local I/T/U to support these activities where the work is done and where bearing the costs is the most difficult. The commenter believes that unlike other Medicare populations, AI/AN beneficiaries are unlikely to enroll in MA plans without specific information from their I/T/U.

Response: We agree that education and outreach efforts should be tailored to the needs of specific populations interested in enrolling in MA plans, to the greatest extent possible. We will continue our collaboration with the IHS and other partners to identify the most effective ways to reach beneficiaries in the AI/AN population.

Subpart B—Eligibility, Election and Enrollment

We proposed generally to retain the same eligibility, election and enrollment rules that currently apply to the Medicare Advantage program. We received numerous comments on this subpart in response to the August 2004 proposed rule. These comments and our responses are presented below.

1. Eligibility to Elect an MA Plan (§ 422.50)

In this section, we specified the following:

- Reference to an ''MA plan'' includes both MA local and MA regional plans, unless specifically noted otherwise in the text.
- We reserve the authority to allow additional optional mechanisms for elections (for example, website enrollment) to provide a more efficient and simplified election process for beneficiaries and partner organizations.

Comment: Several commenters supported the proposal to retain the authority to allow additional optional MA election mechanisms, stating that this change will promote the development of more efficient and simplified processes for beneficiaries. One commenter requested clarification that any such alternate election mechanism would be optional for individual MA organizations to use. Another commenter supported the change, but stated that CMS should not mandate that MA organizations accept electronic elections.

Response: The revision made to this section is intended only to permit us to

approve alternate optional election mechanisms (in addition to paper election forms) in the future. We anticipate that such mechanisms will be available at the option of each MA organization. Furthermore, we believe it is important to clarify that, as other election mechanisms are approved and implemented, we do not intend to permit MA organizations to require beneficiaries to use any such election mechanism. We will require all MA organizations to establish a minimum standard process, which, at this time, will be a paper process, and will be made available to prospective enrollees and plan members in conjunction with any optional election mechanism. In the future, as technology evolves, another process may be a more appropriate minimum standard. To ensure that these points are clear, we are amending § 422.50(a)(5) to provide that beneficiaries may make elections by completing an enrollment form or by completing another CMS-approved election mechanism offered by the MA organization.

Comment: One commenter requested that CMS clarify the use of alternate election mechanisms with respect to employer or union group MA plans.

Response: Section 422.50 applies equally to all beneficiaries making MA elections and therefore applies to those individuals making an election to or from an MA plan sponsored by an employer or union as well. Current processes already established in our manual guidance for MA plans offered by employer or union groups are not changed by this revision.

Subpart B—Eligibility, Election and Enrollment

2. Eligibility to Elect a Special Needs MA Plan (§ 422.52)

Section 231 of the MMA authorized the creation of a new type of MA coordinated care plan, called a ''Specialized MA Plan for Special Needs Individuals.'' These plans will be referred to throughout as SNPs.

We believe the new requirements regarding SNPs are primarily intended to encourage more choices for certain populations by allowing organizations that specialize in the treatment of beneficiaries with particular needs to have MA contracts. These organizations could provide and coordinate services for these individuals and would be permitted to limit plan enrollment to such individuals, or to a certain proportion of such individuals. This provision could encourage organizations to develop new products in the marketplace by giving them the opportunity to develop expertise in efficiently serving special needs populations. Our overall policy goal will be to allow MA organizations as much flexibility as possible (within defined parameters), while maintaining beneficiary protections.

SNPs may restrict enrollment solely to those who are entitled to Medicaid (dually eligible), institutionalized individuals who meet the definition in § 422.2, and/or beneficiaries who have a severe or disabling condition, as defined by the Secretary in regulations. Section 231 of the MMA also gives the Secretary the authority by regulation to designate certain MA plans as SNPs if they ''disproportionately serve(s) special needs individuals.'' Special needs individuals are defined in § 422.2.

In the proposed rule, we asked for comment as to whether SNPs should be allowed to exclusively enroll certain subgroups of those categories of special needs individuals described in § 422.52(b)(1) and § 422.52(b)(2) (dual eligible or institutionalized beneficiaries) and, if so, what categories would be appropriate.

The MMA gave us the authority to waive section 1851(a)(3)(B) of the Act, which precludes beneficiaries with ESRD from enrolling in MA plans. In the proposed rule, we solicited comments as to whether we should waive this section of the Act and whether beneficiaries with ESRD should be considered to meet the requirement for special needs status.

We also have the authority to apply to SNPs a provision under section 1894(c)(4) of the Act that applies to enrollees in the Program of All-Inclusive Care for the Elderly (PACE). This section provides for deemed continued eligibility in certain situations. Specifically, it allows an beneficiary enrolled in a PACE plan who no longer meets the eligibility criteria, but who can reasonably be expected to, in the absence of continued coverage under the PACE plan, meet the criteria of the plan within a period of time not to exceed 6 months. In the proposed rule, we proposed applying this provision to individuals enrolled in SNPs who longer meet a plan's unique eligibility criteria, who can reasonably expected to meet the plans criteria within a period of time not to exceed 6 months.

In the proposed rule, we provided in § 422.52(e) that individuals who are enrolled in MA plans that are subsequently designated as SNPs would be ''grandfathered,'' that is, allowed to continue to be enrolled or choose to elect another MA plan during appropriate election periods provided to all MA eligible individuals. We proposed this based on the belief that the Congress did not intend for individuals already enrolled in an MA plan to be involuntarily disenrolled. However, we also invited comment on an alternative approach wherein any non-special needs individuals in an MA plan that is subsequently designated as an SNP would have to be involuntarily disenrolled. In this situation, we proposed to establish, through further operational guidance, an SEP for these individuals. Statutory language also provided that a newly designated MA plan may restrict future enrollment of individuals to those specialized individuals it intends to serve.

We also indicated in the proposed rule that, if we did allow ''grandfathered'' members to remain in the SNP, we would distinguish them from those individuals who join a new SNP and then lose their special needs status on other than a temporary basis. Those special needs individuals would be involuntarily disenrolled after losing their special needs status (and after any period of deemed continued eligibility, if appropriate) and receiving proper notice. SNPs that exclusively enroll special needs individuals would be required to inform individuals before their initial enrollment that they could only remain enrolled in the plan for as long as they were considered special needs individuals as defined by CMS.

Comment: One commenter felt that CMS should not allow SNPs to exclusively enroll certain subgroups of dual eligible or institutionalized beneficiaries. The commenter's rationale was that requiring MA organizations to accept all dual eligibles into its specialized MA plan would maintain the integrity of the dual-eligible risk pool and prevent the offering of an SNP plan to those who are the least poor (and presumably, most healthy) segment of duals. On the other hand, several commenters suggested that CMS allow SNPs that would enroll subgroups of dual eligibles if supported by a State Medicaid agency. The vast majority of commenters supported allowing SNPs to serve subsets of both the dual eligible and institutionalized populations.

The most prevalent rationale for allowing subsets of dual eligibles was to allow States to develop specialized Medicaid programs to compliment Medicare coverage by SNPs. Most commenters described the difficulties and complexities of serving all dual eligibles as impediments and disincentives to developing a program to coordinate Medicaid managed care programs with Medicare. If required to serve all dual eligible beneficiaries, MA organizations would have to offer

Medicaid-covered benefits, such as long-term care, to individuals who are not eligible for full Medicaid benefits. One commenter stated that allowing subsets of dual eligibles would also facilitate transitioning full dual eligibles from Medicaid prescription coverage to Medicare Part D coverage in 2006. Another commenter suggested that CMS clarify that plans must uniformly offer the same set of benefits to all classes of dual eligibles as provided under the State's Medicaid program. Several commenters recommended that CMS let the MA organization propose eligibility criteria and then evaluate its plan, delivery systems, and related programs, possibly modifying them as part of the review and approval process. Some commenters noted the significant investment of time and resources required to develop targeted clinical programs for different subgroups with different, complex conditions.

Commenters also suggested allowing specific subsets, including full benefit dual eligibles, the frail elderly, those who are nursing home certifiable, children or adults with physical disabilities, developmental disabilities or mental impairments, and community-based or institutional individuals.

Two commenters recommended that CMS not include subsets of duals in the third category of specialized MA plan eligibles, those with severe or disabling conditions. The rationale given was that the identifying characteristics of subsets of duals are not appropriately described within the third category and these individuals should remain in the second category.

Once commenter recommended allowing organizations to serve other subgroups of Medicaid eligible and institutionalized if there is a pervasive justification based on common characteristics of the subgroup, that is, institutionalized beneficiaries in a specified network of nursing homes.

Several commenters stated that adverse selection would be mitigated by phase-in of risk adjustment because payment would take into consideration the individual's disease category.

Response: Consistent with the majority of these comments, we do not intend to adopt a regulation that would preclude MA organizations from offering SNPs to appropriate subsets of the population in a plan service area, including subsets within the SNP populations identified in the statute. Thus, in the interest of facilitating the coordinated delivery of Medicare and Medicaid services, we will consider requests for SNPs that serve certain subsets of dual eligibles and institutionalized individuals on a case-by-case basis. Subsets of those two categories will be included in category one and category two respectively, rather than in the third category of special needs individuals, those with chronic or disabling conditions. In addition, because of the unique nature of some plans serving the institutionalized and dual eligibles, we will also consider subsets based on common characteristics, such as a specific network of facilities and Medicaid eligibility. We will provide further operational guidance following publication of this rule.

Comment: The MMA allows for the enrollment of ESRD beneficiaries in SNPs designed for this population. One commenter said that CMS should delay enrollment of ESRD beneficiaries in MA plans until results of CMS' capitated ESRD Disease Management demonstration are available. The commenter also objected to allowing ESRD patients to enroll in managed care because, in the commenter's view, managed care plans disrupt existing relationships between patients and health care providers. The commenter expressed concerns that an ESRD patient who drops or declines Medigap insurance to join a managed care plan would permanently be locked into the managed care plan and could not switch to Original Medicare, since ESRD would make him/her ineligible for Medigap coverage. The remainder of those commenting on permitting ESRD SNPs supported the proposal.

Response: Individuals with ESRD may choose to receive care under an MA plan for a variety of reasons, including coordination of care and lower out-of-pocket costs. Anecdotal experience with the MA program has shown that MA enrollees with ESRD generally remain enrolled in their plan, or join another existing plan if the one in which they are enrolled terminates. We believe that these beneficiaries should have the option of enrolling in an MA plan, if they so desire. Therefore, we will amend § 422.50(a)(2) by adding language to allow SNPs to serve ESRD individuals.

In order to mitigate the commenter's concerns, we would require that, prior to enrollment in an MA SNP, the organization notify potential enrollees that enrollment is fully optional and of the potential impact that their enrollment could have on their Medigap rights. In addition, MA Organizations will be required to provide clear and accurate provider information for potential enrollees so they may determine whether their current providers are part of the specialized MA plan's network.

Comment: Many commenters supported the proposed approach at § 422.52(e) to allow individuals already enrolled in an MA plan that we subsequently designate as an SNP to remain enrolled or be allowed to elect another other MA plan. Most of these commenters also recommended that CMS allow for a Special Election Period (SEP) to facilitate selecting a new MA plan or Original Medicare. Several commenters remarked on the need to maintain adequate enrollment levels once an SNP gains a new designation. None of the commenters supported the alternative proposal under which non-special needs individuals would have to be involuntarily disenrolled if their MA plan became an SNP.

Response: We will allow members of MA plans that are subsequently ''redesignated'' as SNPs to be ''grandfathered,'' that is, remain enrolled in that plan indefinitely. These individuals may not be involuntarily disenrolled on the basis of not meeting the definition of special needs individual. However, once a grandfathered individual voluntarily disenrolls from the SNP, he or she would not be eligible to reenroll in that SNP unless he or she meets the definition of special need individual. We will establish an SEP for these individuals for exceptional circumstances in further operational guidance. An SNP that chooses to exclusively enroll special needs individuals will not be considered a ''disproportionate share'' SNP, as defined in § 422.2, on the basis of serving ''grandfathered'' members.

Comment: Many commenters supported not requiring plans to involuntarily disenroll beneficiaries who lose their special needs plan eligibility if it is reasonable to assume that they would again meet the special needs eligibility criteria within a certain period as determined by CMS. Some commenters stated that it is not uncommon for beneficiaries to have temporary lapses in eligibility, particularly in situations where a dual eligible loses Medicaid eligibility due to a temporary change in financial circumstances or failure to provide information for recertification. The commenters generally believed that continued eligibility leads to continuity of care and improved clinical outcomes. Two commenters requested an additional 6-month ''grace period'' (commenter's terminology) for individuals who lose their eligibility as well as retroactive payments for their care in the event that eligibility is established retroactively.

One commenter recommended that CMS continue funding Part D and other benefits for the entire ''30-day notice period'' (commenter's terminology) regardless of an individual's eligibility to enroll in a SNP.

One commenter requested continued eligibility for ''exclusive'' as well as ''non-exclusive'' plans (commenter's terminology), including MA plans that may temporarily fall below the required threshold for the special needs designation.

Response: We believe that the Congress' goal was to encourage continuity of care for these at-risk individuals and that a period of deemed continued eligibility for a minimum of 30 days but no longer than 6 months is reasonable for beneficiaries who are likely to regain eligibility. The 6-month period is consistent with the PACE language at § 460.160, which provides that a participant may be deemed to continue to be eligible if, in the absence of continued coverage, the participant reasonably would be expected to meet the requirement within the next 6 months. However, we will not include ''in the absence of continued coverage'' in § 422.52(d).

Our rationale is that this appears to reference ineligibility due to a health condition that could deteriorate without plan membership. In the case of an SNP for dual eligibles, a lapse in SNP eligibility could be due to a lapse of Medicaid eligibility, and such eligibility may be based on the beneficiary's financial circumstances, not his or her health condition.

The MA organization may choose any length of time from 30 days through 6 months for deemed continued eligibility as long as it applies this period consistently among all members in its plan and fully informs its members of this time period. Further guidance on applying deemed eligibility will be provided in operational instructions following publication of this regulation.

We believe that the ''30-day notice period'' referred to by one commenter is from our interim guidance for SNPs, issued as part of its 2005 Call Letter. This guidance established a 30-day minimum timeframe for continued eligibility for an SNP enrollee who loses his or her special needs status. This individual is a member during the period of deemed continued eligibility and until his or her disenrollment becomes effective. Payments will continue on the enrollee's behalf until the period of deemed continued eligibility ends and the enrollee is involuntarily disenrolled. Retroactive payment will not be necessary in these instances.

All SNPs, including ''disproportionate percentage'' SNPs, as defined in § 422.2, may apply the deemed eligibility provision. Deemed eligibles would be counted toward the number of special needs individuals enrolled in the SNP rather than toward the number of non-special needs individuals.

Comment: Several commenters supported allowing SNPs to disenroll enrollees who no longer meet the special needs eligibility criteria. Two commenters wanted SNPs to have the choice of whether to continue to provide Medicare services to individuals who lose special needs status. Another commenter supported involuntary disenrollment for exclusive MA SNPs only, stating that this requirement would hinder disproportionate SNPs' ability to maintain enrollment at or above the regulatory threshold.

Response: In our interim guidance and our proposed rule, we interpreted the statutory phrase ''exclusively serves special needs individuals'' to mean that the plan is exclusively marketed to special needs individuals and exclusively enrolls special needs individuals. This interpretation allowed us to permit existing non-special needs enrollees to remain enrolled in an MA plan that changed its status to an SNP.

Thus, under this definition, existing enrollees who did not enroll when the plan was an SNP would not be affected by the plan definition, and we do not believe they should be disenrolled. Moreover, the existence of such enrollees does not preclude the plan from remaining a plan that ''exclusively serves≥(that is, markets to and enrolls) special needs individuals. As noted above, however, an individual who enrolls in an SNP as a special needs enrollee is different, since he or she would have no expectation of being enrolled in that plan if he or she were not in the special needs category. The case of an SNP that has never had non-SNP enrollees is also different, as any enrollee that it markets to or enrolls would have to be a special needs enrollee, if it is an ''exclusive'' plan.

In order to address these latter situations, we will add a new part (iv) to § 422.74(b)(2) to show that in these cases loss of special needs status (and of deemed continued eligibility, if applicable) is a basis for required disenrollment from an SNP that enrolls only special needs individuals.

We have the authority to waive minimum enrollment requirements as necessary. Therefore, we do not envision the minimum enrollment requirements adversely affecting disproportionate share SNPs.

Comment: One commenter recommended that CMS allow MA SNPs to charge an enrollee for benefits no longer covered by the State or Federal cost-sharing arrangements and to terminate coverage for nonpayment of premiums or cost sharing.

Response: An SNP is the same as any other MA plan with respect to rules governing the charges that may be imposed on enrollees. Enrollees may be charged for benefits that would not otherwise be covered by Medicare. Under § 422.74(d)(1), coverage may be terminated for a failure to pay premiums. As discussed below in connection with disenrollment for disruptive behavior, a failure to pay cost sharing is not in itself a basis for disenrollment.

Comment: Two commenters asked for clarification of whether the regulation refers to Special Needs Health Plans or the Special Needs Health Options.

Response: The regulation refers to a ''Specialized MA plan for special needs individuals'' (SNPs), as created by Section 231 of the MMA.

3. Continuation of Enrollment for MA Local Plans (§ 422.54)

The MMA limits the offering of MA plan continuation areas to MA local plans only and we made this conforming change at § 422.54. We received no comments on this section and adopted the conforming changes as proposed.

4. Enrollment in an MA MSA Plan (§ 422.56)

Section 233 amended the Act to eliminate the cap on the number of individuals that may enroll in MA MSA plans removed the existing deadline for enrolling in such a plan. Because this deadline had already passed without anyone enrolling in an MSA plan, the original MSA plan provisions had become a nullity. The effect of section 233 was to make the authority to offer MSA plans permanent and unlimited. This change is reflected at § 422.56, along with new language allowing the Secretary to permit enrollment in MSAs by enrollees of other Federal. We included this language to reflect the fact that, under the statute, such enrollment could be authorized contingent on the adoption of new policies by the OPM.

Comment: Two commenters suggested deleting the language authorizing the Secretary to permit enrollment in MSAs by enrollees of the Federal programs specified. Both commenters contended that it was unlikely that OPM would ever be able to certify that MSA enrollment would not raise costs in the FEHB, Veterans' Administration, or

TRICARE programs and that, accordingly, the inclusion of this language is unnecessary.

Response: The statute at section 1851(b)(2) provides for the potential for such individuals to become eligible to enroll in an MSA plan. Therefore, our clarification of § 422.56(b) supporting this provision is appropriate.

5. Election Process (§ 422.60)

In proposed § 422.60, we set forth changes that would allow other election and notice mechanisms other than paper forms or written documents. We also clarified that MA organizations may submit requests to restrict enrollment for capacity reasons to CMS at any time during the year.

Comment: Two commenters supported the conforming revisions to § 422.60 permitting us to approve alternate election mechanisms, as discussed in the comments on proposed § 422.50(a)(5). The commenters also approved of the clarification to § 422.60(b) regarding requests for enrollment limits due to capacity reasons.

Response: We adopt these revisions as proposed.

Comment: One commenter suggested that CMS make further amendments to the regulatory text to ensure that the current options we have established for individuals to elect MA plans sponsored by employer or union groups are retained, including the policy that documentation may be retained by an employer or union group rather than the MA plan.

Response: As discussed above, we are confident that the proposed revisions provide us with sufficient flexibility to foster innovative election processes that use modern technology for all individuals, not just employer or union groups. Therefore, it is not necessary to reiterate that these alternative enrollment mechanisms are also available to employers or union groups. We will continue to retain current policy for employer or union group elections in our operational guidance and as an option for MA organizations.

Comment: One commenter suggested that CMS require MA and MA-PD plans to accept AI/AN enrollees even if a plan has received CMS approval to close enrollment for capacity reasons.

Response: The ability to request a capacity limit is an important element of the MA program that helps ensure that plan enrollees will have sufficient access to needed providers and services. CMS' approval of a capacity limit request indicates that we agree with the requesting MA organization that its defined network of providers is sufficient to deliver health care only to a limited number of plan members. Thus, we do not permit the MA organization to enroll any individual beyond the capacity limit of a given plan, and we do not believe it would be appropriate to undermine this protection by waiving capacity limits for the AI/AN population or any other group.

Comment: Two commenters requested that CMS modify the regulations to more clearly allow for what the commenter referred to as ''passive elections.''

Response: The elections to which the commenters are referring are those in which an individual is informed that the process for making an election of a particular plan is taking no action, while other options are exercised by declaring an affirmative intent to elect that option. CMS have limited such a process to situations when it can be reasonably concluded that an individual will clearly want to enroll in the MA plan offered by the same organization.

We do not believe that a regulatory change is needed to continue to allow such elections. The revisions made to § 422.50(a)(5) and the conforming revisions to § 422.60 provide us with appropriate flexibility to define and approve MA election mechanisms, including allowing such ''passive elections'' as described above in specific limited circumstances.

6. Election of Coverage Under an MA Plan (§ 422.62)

Similar to the election periods in place in past years, the MA *Annual Coordinated Election Period* will run from November 15 through December 31 of each year. For 2006, the annual coordinated election period is extended through May 15, 2006.

Based on our interpretation of the MMA, we proposed revising § 422.62 to ensure that an individual who is newly eligible for MA has the full opportunity to elect an MA plan as part of their *Initial Coverage Election Period*. In developing the proposed rule, we determined that the intent of the Congress was to provide for an initial coverage election period for MA that ends on the later of the day it would end under pre-MMA rules or the last day of the Medicare Part B initial enrollment period. This approach extends an individual's MA initial election period in some instances, and never reduces or eliminates it.

Through 2005, the *Open Enrollment Period* extends throughout the year, providing unlimited opportunities for MA eligible beneficiaries to enroll in, disenroll from, and or change enrollment in an MA plan. This change was reflected in § 422.62(a)(3) of our proposed regulations.

Section 1851(e)(2)(B)(1) of the Act was revised to establish that the open enrollment period in 2006 will be the first 6 months of the year. In addition, individuals who are newly eligible for MA in 2006 are provided an open enrollment period that consists of the first 6 months the individual is MA eligible, but cannot extend past December 31, 2006.

Under revised section 1851(e)(2)(C)(i) of the Act, the open enrollment period for 2007 and subsequent years will be the first 3 months of each year. In addition, individuals who first become MA eligible during 2007 and subsequent years will be provided an open enrollment period that consists of the first 3 months the individual is MA eligible, not to extend past December 31, 2006. Although this specific period does not extend past December 31, 2006, it is important to remember that all individuals will be provided a 3-month open enrollment period from January through March 2007, as discussed in this section.

Section 1851(e)(2)(C) of the Act limits a change of election made during an open enrollment period in 2006 and later years to the same type of plan in which the individual making the election is already enrolled. Specifically, an individual in an MA plan that does not provide drug coverage may change only to another similar MA plan, or to original Medicare, but may not enroll in an MA plan that provides Part D coverage, or enroll in a Part D plan. Similarly, an individual enrolled in an MA plan that includes Part D coverage may enroll only in another MA plan with Part D coverage, or change to original Medicare coverage with an election of a Part D plan. As noted in the proposed rule, we clarified a conflict between clause I and II of section 1851(e)(2)(C)(iii) of the Act. Clause (I) of section 1851(e)(2)(C)(iii) states that an individual who is ''enrolled in an MA plan that does provide qualified prescription drug coverage,'' may only elect a plan that does not provide that coverage. A literal reading of this language would be in direct conflict with clause (II) of that same section, which says that an individual who is enrolled in an MA plan that provides qualified prescription drug coverage may not enroll in an MA plan that provides no Part D coverage.

This contradiction, plus (1) the fact that section 1851(e)(2)(C)(iii)(I) of the Act refers to a ''another'' MA plan that ''does not'' provide Part D coverage, (2) the fact that clause (I) is contrasted with

clause (II) with the word ''or'', and (3) committee report language, make it clear that the word ''not'' was inadvertently omitted from the first clause of section 1851(e)(2)(C)(iii) of the Act.

Comment: Numerous commenters opposed the ''lock-in'', that is, the statutory provisions that limit beneficiaries from choosing a different type of coverage to certain times of the year. Several commenters stated that these provisions severely limit the choice of beneficiaries. Others commented that implementing lock-in under the MA program at the initiation of the new Part D program would be confusing to beneficiaries. Commenters also noted that such a provision would have a negative impact on the MA organizations, by making it difficult to maintain a dedicated sales staff and increasing the administrative costs and burden of educating beneficiaries about both Part D and MA changes.

Response: The provisions that limit the times in which an individual may change his or her election were originally created by the BBA, and were to become effective during 2002. However, because of subsequent statutory changes, these provisions have never taken full effect (except for a temporary period during 2002). These provisions were modified by the MMA to incorporate the Part D prescription drug benefit and the statute is clear on their applicability. Thus, we have no authority to modify these requirements.

Comment: One commenter suggested that CMS develop appropriate procedures to administer these election restrictions and inform organizations as to what type of plan an individual is eligible to elect (for example, an MA only or an MA-PD plan). Another commenter recommended that the organization have access to information about whether an individual is eligible to elect a certain plan, both in advance of an enrollment application and upon receipt of an enrollment application.

Response: We understand that we will need to maintain data history of the number of times an individual has made an election during a specific election period, as well as the type of plan an individual is eligible to elect. Such information will be necessary in order to determine whether an individual is eligible to elect an MA plan at a given time. We will work with plans to establish a reliable process to determine the eligibility of an individual based on these requirements.

Comment: Several commenters responded to the request for comments on the provision that an enrollee may only change to the same type of plan (either with drug coverage or without) during the open enrollment period. Some commenters opposed the interpretation that restricts a beneficiary from switching plans, even when life circumstances had changed. Others supported the interpretation and indicated that such a provision reinforced the overall integrity of the program. Others believe that we need to maintain flexibility with employer-sponsored plans.

Response: After review of the statutory provisions and the comments, we believe that the Congress clearly intended that a beneficiary may obtain or discontinue Part D coverage *ONLY* during the annual coordinated election period that begins in November each year. Notwithstanding SEPs established by the statute and in our regulations and subsequent guidance, it is only during the Annual Coordinated Election Period that all Medicare beneficiaries are free to elect among all available options, whether original Medicare, MA plans, MA-PD plans or PDPs. The statutory provisions governing Part D in 1860D–1 do not provide for an open enrollment period that would allow beneficiaries to elect the prescription drug benefit outside of the AEP. Permitting beneficiaries to discontinue Part D coverage at any time during the year, without a corresponding election period to enroll in such coverage, could result in a gap in coverage that may result in a late enrollment penalty. Therefore, we believe that it is appropriate to interpret the statute to require that individuals may not make an election that would result in adding or dropping prescription drug coverage except during the annual election period.

Comment: One commenter recommended that CMS clarify how the annual coordinated election period and the open enrollment period will be administered in 2006, since these periods overlap from January 2006 through May 15, 2006.

Response: In 2006, we envision that the annual coordinated election period will provide each individual with the ability to choose either an MA plan or original Medicare, with or without drug coverage. The open enrollment period will provide individuals the opportunity to change their election from the MA program to original Medicare (or vice versa), but not to obtain or discontinue drug coverage. We will provide information about these election periods in beneficiary materials, such as the Medicare & You Handbook.

Comment: A few commenters submitted comments regarding the special election periods (SEPs), as described at § 422.62(b). One commenter asked if CMS expected to apply the SEPs established under the M+C program to the MA program. Another commenter requested confirmation that the current SEP for PACE enrollees (described in manual guidance) would be applied to the MA program. One commenter suggested that CMS consider an exception to the Open Enrollment Period for SNPs and for individuals eligible for both Medicare and Medicaid.

In addition, a commenter asked CMS to consider the creation of an SEP for beneficiaries in markets with MA market penetration rates below 20 percent; such an SEP would allow time for educating beneficiaries on MA plans and how they operate. Many commenters submitted comments on establishing SEPs for special needs plans. The commenters generally approved of a permissive special election period policy to allow special needs individuals to change plans at any time. Others believe that the enrollment periods established in § 422.62 do not provide sufficient opportunity for beneficiaries to enroll in a special needs plan.

Response: We have historically included in our regulations those SEPs that have been specifically named in the statute, and established SEPs for exceptional circumstances in our operational guidance. We will review the SEPs in current MA guidance and consider their applicability for the MA program in 2006, as well as consider new SEPs that may be necessary to coordinate the new Part D program. We appreciate the suggestions provided by the commenters and will consider these in developing guidance following publication of the rule.

Comment: Several commenters addressed the AI/AN population and the need to modify the regulations to allow AI/AN individuals to switch between MA or MA-PD at various times rather than be limited to changing only at certain times during the year.

Response: We recognize the need to coordinate between the IHS, Tribe, or Tribal organization, or Urban Indian (I/T/U) programs. We have the authority to recognize certain circumstances as exceptional and provide special election periods. Providing such exceptions, however, would not always benefit an individual, as we discussed in our response to a previous comment under § 422.50 regarding capacity limits. Such limits are necessary to ensure that health plans have the appropriate number of providers and are able to provide access to all beneficiaries enrolled in their plan. As discussed in the previous comment regarding

establishment of SEPs in operational guidance, we are not establishing any non-statutory SEPs in the regulation, but retain the authority to establish an SEP in the future under exceptional conditions. This same policy applies to the AI/AN population.

7. Coordination of Enrollment and Disenrollment through MA Organizations (§ 422.66)

In keeping with our proposed clarification at § 422.50(a)(5) regarding election mechanisms other than, and in addition to, paper forms, we proposed conforming changes at § 422.66. We also proposed similar changes in § 422.66(b) to provide for a more efficient notice process, including eliminating the requirement for MA plans to send a copy of the individual's disenrollment request back to the individual.

Section 1860D–21(b) provides the Secretary with the authority to implement default enrollment rules at 1851(c)(3)(A)(ii) for the MA-PD program, which begins in 2006. This provision permits the establishment of procedures whereby an individual currently enrolled in a health plan offered by an MA organization at the time of his or her Initial Coverage Election Period is deemed to have elected an MA-PD plan offered by the organization if he or she does not elect to receive coverage other than through that organization. In our proposed rule, we discussed the requirement for individuals to make affirmative elections upon becoming entitled to Medicare as provided under § 422.66. Affirmative elections may ensure that individuals have the ability to remain with the organization that offers their health plan and protects beneficiary choice by requiring an individual to make an affirmative election. However, based upon comments received, we will revise the regulatory language to retain the ability to allow for default enrollment, as discussed in our responses below.

At § 422.66(e) we also proposed to add language that implemented new rules for continuing MA coverage for individuals enrolled in MA plans as of December 31, 2005. Under section 1860D–21(b)(2), individuals enrolled in an MA plan that, as of December 31, 2005, provides any prescription drug coverage would be deemed to be enrolled in an MA-PD plan offered by that same organization as of January 1, 2006. If an individual is enrolled with an MA organization that offers more than one MA plan that includes drug coverage, and is enrolled in one of those plans as of December 31, 2005, the individual would be deemed to have elected to remain enrolled in that plan on January 1, 2006 if it becomes an MA-PD plan on that date. An individual enrolled in an MA-PD plan on December 31 of a year would be deemed to elect to remain enrolled in that plan on January 1 of the following year (that is, the next day).

Comment: Several comments were received regarding the revisions to the disenrollment process described above. Several commenters supported the change in language allowing optional mechanisms for disenrollment elections. Several commenters also supported the elimination of the requirement that organizations return a copy of the disenrollment request to the individual.

Response: We received no opposing comments to these provisions and adopt these provisions as proposed.

Comment: One commenter recommended that CMS clarify that MA plan members who have selected prescription drug coverage as an optional supplemental benefit, and are receiving such benefits as of December 31, 2005, will be deemed to have enrolled in an MA-PD plan.

Response: Individuals who are enrolled in an MA that offers any prescription drug coverage, including coverage offered as an optional supplemental benefit, as of December 31, 2005, will be deemed to have enrolled into an MA-PD plan offered by that organization.

Comment: Several commenters stated that additional information is needed to implement the deemed enrollment provision for MA enrollees who do not make an affirmative election into an MA-PD plan. If the MA organization offers more than one MA-PD plan, it is unclear into which plan the individual will be deemed enrolled.

Response: We will provide further guidance to MA organizations on this issue, as we do at the end of each contract year through our plan ''cross-walk'' guidance. Under this guidance, the existing policy, under which the MA organization may designate the plan that is ''continuing'' into the next year, would apply to this situation.

Comment: Several commenters supported and opposed the implementation of default enrollment rules as discussed at section 1851(c)(3)(A)(ii) of the Act for the MA-PD program.

Several commenters support implementing the default enrollment provision and believe that it would simplify the enrollment process for beneficiaries. They believe that such a process could be coupled with advanced notice that would also give the member the opportunity to ''opt-out'' of the ''default'' enrollment. Other commenters stated that the MA organization should have the option of applying ''default'' enrollment in certain situations, for example, with its employer group members. Commenters stated that if the MA organization chose to implement the option, each beneficiary would also be provided the option to decline prior to enrollment.

Several commenters opposed default enrollment and supported requiring an affirmative election by the beneficiary. These commenters believe that a default enrollment process would be difficult and confusing for beneficiaries. They do not believe that beneficiaries should be ''defaulted'' into the same health plan that provided pre-Medicare coverage. Many commenters recommended that MA plans obtain accurate information from prospective enrollees through the affirmative election process, and, without such a process, MA plans may not have up-to-date information about the beneficiary. Finally, there are those who neither support nor oppose the default enrollment process, but instead suggest that we modify the regulatory language to allow us to implement such a provision in the future.

Response: The commenters raise several good points regarding the implications of default enrollment. The intent of default enrollment is not to reduce beneficiary choice, but rather to ensure continuity of care. At this time, we will retain the flexibility to implement this provision through future instructions and guidance to MA organizations. We do not envision mandating that organizations use default procedures, but instead would give organizations the option of implementing such a process for its enrollees. Any such process would require that advance notice be provided to an individual, and that affected individuals have the ability to ''opt out'' of such an enrollment. We believe that we can achieve the same flexibility provided with respect to default enrollment that exists at § 422.60(b)(3)(c), which allows for elections using alternative mechanisms. Thus, we have revised proposed § 422.66(d)(5) to allow us to offer default enrollment as an option in the future, in a form and manner specified by CMS.

Comment: One commenter suggested that, rather than prohibit default enrollment, CMS should develop a method to allow enrollees in an MA plan with or without prescription drug coverage, who do not make an election by December 31, 2005 to remain with their current MA organization in an MA-PD plan. Another commenter assumed that CMS intends that

individuals enrolled in an MA plan without drugs who do not make a plan election into an MA-PD plan for January 1, 2006 will be defaulted into original Medicare.

Response: The statute provides for an individual in an MA plan with drug coverage on December 31, 2005, to be deemed enrolled in an MA-PD plan as of January 1, 2006. However, the statute does not allow an individual who is in an MA-only plan that continues in January 2006 to be deemed to make an MA-PD election. The statute is clear that those individuals will remain in an MA-only plan unless those individuals take an action to elect an MA-PD plan. Pursuant to section 1861(b)(3) of the Act, individuals may be deemed to have elected Original Medicare only if the MA-only plan in which they are enrolled is terminated. Thus, in general, we would not be defaulting MA plan members into original Medicare.

Comment: Several commenters recommended that CMS coordinate the enrollment of full benefit dual eligible individuals. A few commenters suggested that CMS apply the default enrollment provisions for dual eligible individuals who have not otherwise elected an MA-PD or PDP into an MA-PD that is administered by an MA organization that operates the Medicaid managed care organization in which the individual is enrolled. Another commenter supports the inclusion of sufficient flexibility in our regulations to enable us to develop solutions that best meet the needs of beneficiaries and are coordinated with the MA organizations.

Response: As discussed above, we will consider requests to adopt such default enrollment processes only with respect to a newly-Medicare eligible individual who is enrolled with an organization as a Medicaid enrollee at the time he or she becomes eligible for Medicare. In such a case, the individual could be considered by default to have elected that organization for purposes of Medicare benefits upon the individual's becoming eligible for Medicare. The default authority in 1851(c)(3)(A)(ii) of the Act would not, however, permit an individual to be considered by default to have elected an MA-PD plan if he or she was already a Medicare beneficiary and had elected not to receive Medicare benefits through an MA organization. Therefore, we decline to enroll by default existing full-benefit dual eligible individuals into an MA-PD if they are currently in Original Medicare and only receive Medicaid benefits through that organization. We will continue to evaluate alternatives to facilitate enrollment in Part D for this population.

Comment: Several commenters suggest that each MA plan that becomes an MA-PD plan send a notice to their enrollees that the enrollees will be automatically enrolled in the MA-PD plan unless they choose to change plans. Further, it is suggested that CMS create a model letter for this purpose.

Response: MA plans are required to send out notices in October of every year to their members, also known as the annual notice of change (ANOC). We will revise the language in the ANOC for MA plans to provide to members in October 2005 in order to reflect this policy.

Comment: Several commenters recommend that CMS establish a default enrollment process for AI/AN if a certain plan meets AI/AN needs.

Response: CMS recognizes the need to coordinate between the I/T/U programs. Given the new regulatory language at § 422.66(d)(5), which allows us to offer default enrollment as an option to MA organizations, we could consider requests by MA organizations to offer default enrollment to the AI/AN population in the case of newly-Medicare eligible individuals who are enrolled in a non-Medicare product of an MA organization at the time they become Medicare eligible.

8. Effective Dates of Coverage and Change of Coverage (§ 422.68)

To coordinate the effective date of elections with the 2006 special annual coordinated election period (to be held November 15, 2005 through May 15, 2006), section 1851(f)(3) of the Act was amended by the MMA to provide that the effective date of elections for the annual coordinated election period does not apply during the 2006 special annual election period, when enrollment will be effective on the first day of the month following the month in which an election is made. We proposed to revise § 422.68(b) to provide for this coordination and to make the effective date of elections in the annual coordinated election period for 2006 that are made in 2006 (that is, from January 1 through May 15, 2006) the first day of the calendar month following the month in which the election is made. We received no comments on this section and adopted the proposed language as final.

9. Disenrollment by the MA Organization (§ 422.74)

Under the current regulations at § 422.74(d)(1), MA plans are required to provide, at a minimum, a 90-day grace period before disenrolling individuals for failure to pay plan premiums. Thus, MA plans must maintain enrollment for individuals who do not pay their premiums for more than 90 days.

We proposed to provide greater flexibility to MA organizations by replacing the 90-day grace period in § 422.74(d)(1) with the long-standing approach under § 417.460(c)(1), which governs disenrollment from HMOs with cost contracts under section 1876. Under this proposal, we would instead specify that a disenrollment could be effectuated no sooner than 1 month from the date the premium was due.

We have also proposed revisions to the regulations at § 422.74(d)(2) regarding disenrollment of an individual for disruptive behavior. Our goal was to create a more objective definition that is based upon an individual's behavior, rather than upon the application of such subjective terms as ''unruly,'' ''abusive,'' and ''uncooperative.'' We also recognized that, in revising this definition, we needed to strike a balance that would ensure all individuals are afforded protection from unwarranted disenrollment actions while protecting the health and safety of all those concerned including the individual. The best solution is to create a definition of disruptive behavior based on objective criteria, ensure that MA organizations make serious efforts to resolve problems with beneficiaries who are disruptive, and to require MA organizations to make ''reasonable accommodations'' for vulnerable beneficiaries, including those with serious mental illness. Furthermore, we will ensure that CMS staff with appropriate clinical or medical expertise will be involved in the review of the MA organization's request before we make a final decision. We will work with organizations that ask to disenroll these individuals on a case-by-case basis to ensure that they are not left without Part D coverage. We will also remove the provision for an expedited disenrollment we had proposed and ensure that MA organizations provide due process before disenrolling an individual.

Comment: Several commenters supported the proposed revisions to § 422.74(d)(1) regarding procedures for involuntary disenrollment for failure to pay plan premiums. Other commenters opposed these revisions as ''overly broad'' and felt the lack of a specific time frame could be a disadvantage for plan enrollees.

Response: Our proposed changes to this section were intended to provide flexibility for MA organizations in addressing the issue of plan members who fail to pay required plan premiums. Under the existing rule, MA organizations were obligated to provide

all plan benefits to an individual who has failed to pay required plan premiums for a full 90-day period. This period often exceeded 90 days because the notice requirements we imposed fell after the end of the 90-day period, but must still be met by the organization before the individual could be disenrolled. Our experience and feedback from MA organizations indicated that these requirements, while intended to protect beneficiaries enrolled in MA plans, may instead artificially inflate plan premiums because MA organizations are required to continue to provide services to these beneficiaries for up to 4 months, even though they have not paid the required plan premiums.

After reviewing the comments and feedback we received on the proposed rule, we determined that it would be prudent to include a minimum grace period in the revisions we are making to address this issue. Therefore, we have revised this section to include a 1-month grace period during which an enrollee who has failed to pay required premiums must be notified of the impending disenrollment action and afforded the opportunity to pay past due premiums in full or under payment terms agreed upon by the beneficiary and the MA organization, as the organization allows. This period will begin on the first day of the month for which the premium was unpaid. For example, the grace period for a March premium will begin March 1st and, if the organization does not receive payment by March 31st, the individual will be disenrolled effective April 1st. We will provide specific time frames for required notices in additional guidance to ensure beneficiaries have adequate time to respond before disenrollment takes effect. Since we are establishing this 1-month grace period as a minimum requirement, MA organizations still have the option of lengthening this period.

Comment: Three commenters suggested that CMS allow MA organizations to ''move'' or ''default'' plan members who have failed to pay premiums in one MA plan to another MA plan in the same organization that is offered at a lower or no premium, so that beneficiaries do not suffer an interruption in MA benefits.

Response: This suggestion is inconsistent with the statute. Section 1851(g)(3)(C)(i) of the Act clearly provides that individuals who are disenrolled from an MA plan for failing to pay premiums are deemed to have elected original Medicare.

Comment: Several commenters submitted comments on the proposed revisions to § 422.74(d)(2) concerning the disenrollment of individuals who exhibit disruptive behavior. Some commenters supported the proposed approach, noting that the inability to effectuate such disenrollment has been an ongoing issue for MA plans. Other commenters recommended that CMS further clarify the meaning of the term ''decision-making capacity,'' and one commenter in particular suggested that CMS adopt a definition based on legal conservatorship.

Several commenters, on the other hand, expressed concern that the expanded definition of disruptive behavior does not adequately protect individuals whose behavior is induced by a mental illness, a medical condition, or certain prescribed drugs. These commenters were concerned about the loss of protection for individuals with diminished mental capacity. Several commenters expressed concern that the definition of disruptive behavior was overly subjective, particularly the use of terms such as ''unruly'', ''abusive'' and ''uncooperative.''

Response: In the final rule, we aim to strike a balance between allowing MA organizations to disenroll individuals who exhibit disruptive behavior and creating adequate protections for individuals who face involuntary disenrollment from a plan. Since the statute (at section 1851(g)(3)(B)(ii) of the Act) permits an MA organization to disenroll an individual who engages in disruptive behavior, we must establish a process for allowing these types of disenrollments. At the same time, we recognize that such a process must include adequate safeguards for individuals whose disruptive behavior is due to mental illness or a medical condition, especially in light of the crucial importance of prescription drug therapy for these individuals. It is also important to recognize that some prescription drug therapies may well induce such behavior.

Therefore, we are revising our proposed definition of disruptive behavior in § 422.74(d)(2)(i) of the final rule to focus on the behavior that substantially impairs the plan's ability to arrange or provide care for the individual or other plan members. We recognized that terms such as ''unruly'', ''abusive'', ''uncooperative'', as well as an assessment of the enrollee's ''decision-making capacity'' are subjective terms that make reviewing and approving such requests difficult.

In addition, we agree with commenters that arranging or providing care for individuals with mental illness, cognitive impairments such as Alzheimer's disease or other dementias, and medical conditions and treatments that may cause disruptive behavior warrants special consideration. Therefore, we are revising § 422.74(d)(2)(v) to also require MA organizations to provide a ''reasonable accommodation'' to individuals in such exceptional circumstances that we deem necessary. Such accommodations could include providing the individual with a SEP to choose another plan, or requiring the plan to maintain the individual's enrollment until the end of the year, when the individual could choose another plan. We will determine the type of accommodation necessary after a case-by-case review of the needs of all parties involved. This review will be conducted as part of CMS' existing review and approval process required under § 422.74(d)(2)(v). The regulations (at § 422.74(d)(2)(iii)), will continue to require that that before an organization can request to disenroll a member for disruptive behavior, it first must make a serious effort to resolve the problems presented by the individual's behavior, including the use of the organization's grievance procedures. The MA organization must then document the individual's behavior, its own efforts to resolve the problem, and the use or attempted use of its internal grievance procedures.

We believe that these policies will achieve the twin goals of permitting involuntary disenrollment when appropriate due to an individual's disruptive behavior, while also establishing necessary protections for beneficiaries in certain circumstances.

Comment: One commenter stated that the proposed rule denies protection to individuals who comply with medical advice by trying an on-formulary drug instead of the drug originally prescribed or by seeing their primary care physician rather than a specialist and subsequently experience an adverse reaction that triggered the disruptive behavior. Another commenter believed that, in cases where an individual is unstable, disruptive behavior could be related to unsuccessful attempts to find the proper medication or due to a plan's step therapy requirement.

Response: We agree with the commenter, and clarify in the final rule at § 422.74(d)(2)(i) that an individual's behavior cannot be considered disruptive if such behavior is related to the use of medical services or compliance (or non-compliance) with medical advice or treatment. For example, an individual who chooses to disregard medical advice, such as not heeding the advice to stop using tobacco products, is not exhibiting disruptive behavior.

Comment: Several commenters supported the flexibility afforded by allowing MA organizations to limit re-enrollment for individuals who are disenrolled for disruptive behavior. One commenter however, opposed the provision on the grounds that prohibiting an individual from re-enrolling in a plan for a specified period could cause undue harm.

Response: In the proposed rule, we specified that, under § 422.74(d)(2)(vi), an MA organization had the option to decline future enrollment by an individual who had been disenrolled for disruptive behavior. Although a prohibition on re-enrollment would still be possible under this final rule, we are not leaving this matter to the discretion of the MA organization. Instead, we are providing that an organization must request any future conditions on re-enrollment with their disenrollment request. We will then review each request on a case-by-case basis, consistent with § 422.75(d)(2)(v).

Comment: Several commenters submitted mix comments on the proposed expedited disenrollment process. Some commenters felt that the expedited process undermines the standards and requirements that are in place to protect beneficiaries, while other commenters supported the greater flexibility in cases where such behavior poses an immediate threat of health or safety to others.

Response: We believe that all individuals facing involuntary disenrollment for disruptive behavior must have sufficient opportunity, as provided by the notice requirements, to change their behavior and/or grieve the MA organization's decision to request involuntary disenrollment from CMS. Although we recognize that threatening behavior is a real, if rare, problem, we do not believe that expedited disenrollment is the appropriate remedy. Rather, we would recommend either a medical approach or, if warranted, a law enforcement solution for truly threatening situations. Therefore we are removing this provision from the final regulation.

Comment: One commenter recommended that the process for disenrolling AI/AN from MA organizations that contract with the HIs, an Indian Tribe or Tribal organization, or an I/T/U include direct communication with the I/T/U entity with adequate documentation of and steps taken to resolve the problem as well as adequate timelines.

Response: MA organizations have the statutory authority at Section 1851(g)(3)(B)(ii) of the Act to disenroll an individual from a plan if the individual has engaged in disruptive behavior and are required to provide sufficient notice to the individual in accordance with the timeframes specified in manual instructions. Because an individual is an enrollee of MA plan, the individual's relationship with the plan is primary. The MA organization, not the health care provider, is obligated to communicate with the individual or the individual's authorized representative as defined under State law. We believe that a provision requiring consultation with I/T/U entities would not be within the scope of the authority in section 1851(g)(3)(B)(ii) of the Act.

Comment: Several commenters submitted comments on whether nonpayment of cost-sharing should constitute disruptive behavior. Many commenters supported this interpretation, noting the negative impact that non-payment of cost sharing has on an MA organization's ability to provide or arrange for services for the individual. These commenters generally recommended that CMS establish a clear and uniform process for plans to follow. Another commenter suggested that such disenrollments be permitted only for certain types of services that represent significant portions of a member's overall cost-sharing responsibility. One commenter suggested that CMS establish a threshold of $2,000 of outstanding cost sharing, including two or more failures to pay cost sharing.

Other commenters, however, opposed including nonpayment of cost sharing as a basis for disenrollment. Some commenters stated that this policy would be discriminatory, placing very ill patients with high medical costs at a severe disadvantage and leading plans to cherry pick healthier patients. Another commented that CMS needed to take into account an individual who experiences a change in circumstances that may affect his or her ability to pay cost sharing.

Several commenters raised questions about how CMS would treat low-income individuals. Some commenters were supportive of a low-income exception for such disenrollments, while other commenters noted the administrative difficulty in applying the exception, since plans do not have mechanisms in place to determine beneficiary income levels or intervene on behalf on the enrollee with the provider.

Response: We appreciate the feedback provided on whether the nonpayment of cost-sharing should constitute disruptive behavior. We continue to believe that disenrollment for failure to pay cost-sharing may be disruptive under certain circumstances. At the same time, we believe that all the protections, such as notice requirements and case-by-case CMS review, should apply in these situations. Thus, we are not ruling out such disenrollment in certain cases, and we will consider these comments in developing guidance for the disruptive behavior provisions.

Comment: Other commenters recommended that CMS institute specific protections for individuals facing involuntary disenrollment, including an appeals process.

Response: Although we agree with the commenter that CMS should establish a procedure for beneficiaries to dispute enrollment denials, we do not believe that a formal appeals process is necessary. Instead, we intend to address beneficiary complaints regarding enrollment in a similar manner as we have done under the MA program. Under the MA program, individuals are advised through their notice of denial of enrollment that if they disagree with the decision, they may contact the MA organization. We provide assistance to MA organizations to handle beneficiary inquiries and complaints regarding enrollment through staff assigned to each MA organization. We envision a similar process being established under the PDP program.

10. Approval of Marketing Materials and Election Forms (§ 422.80)

We proposed to codify at § 422.80(a)(3) the ''file-and- use'' program already in place. This provision recognizes an MA organization's consistent compliance with marketing guidelines by providing for streamlined approval of marketing materials submitted by that organization. Organizations that have demonstrated to us that they continually meet a specified standard of performance are allowed to have certain types of marketing materials deemed to be approved by us if they are not disapproved within 5 days of submission to us for prior approval. In addition, the time frames under § 422.80(e)(5) were made consistent with those provided under § 422.80(a)(1). Lastly, we proposed clarifying changes to the discussion of prohibited marketing activities for MA plans.

Comment: Several commenters submitted comments regarding the ''file-and-use'' provisions. Many commenters supported incorporating this provision into the regulation and suggested that CMS consider even further flexibility as plans transition to the new Part D benefit in 2006. One commenter in support of the provision did note,

however, that small plans are more affected by the process since these plans submit fewer materials and a smaller number of errors impact their ability to participate. This commenter recommended that CMS consider this issue with regard to smaller organizations.

Many commenters opposed this provision and believe that the provision weakens the marketing rules and that MA organizations have not demonstrated that they deserve such a process. Given the new upcoming options and diversity of plan benefits, many believe stronger marketing requirements are needed. They were concerned that this process would perpetuate the perceived inconsistency in the marketing material approval process within CMS. Others were concerned that the short timeframe for CMS to review and approve would result in essentially CMS ''rubber stamping'' materials. One commenter suggested that plans present all marketing materials at least 30 days before proposed distribution.

Response: The ''file-and-use'' program streamlines the marketing review process while assuring that beneficiaries marketing materials are of a high quality and clarity. While we understand the concerns raised by smaller organizations, this program was developed to be available to those MA organizations that demonstrate they can consistently achieve a high level of performance with respect to producing accurate and clear marketing materials over a sustained period of time, regardless of the size of the organization.

It is also important to note that there are marketing materials that are not ''eligible'' to be considered under this program. Any marketing materials that describe benefits, cost sharing or plan rules are not eligible for the file-and-use status.

We retain the right to rescind file-and-use status from an MA organization if the organization fails to meet the rigid standards of compliance laid out in the file-and-use guidelines. We do not believe that the beneficiary is at greater risk as a result of the file-and-use program, but may actually benefit from being able to receive certain educational and outreach materials in a timely manner.

In response to the commenters seeking greater marketing flexibility, we also are providing in § 422.80(a)(2) of this final rule for organizations that are not currently eligible for the file-and-use method to use this method with respect to materials that pose the lowest risk of confusing or misleading beneficiaries. With respect to these materials, any MA organization may follow the file-and-use procedures if it certifies that it followed all applicable marketing guidelines, or that it used, without modification, model language specified by CMS.

Comment: One commenter expressed disappointment that CMS retained the prohibition on door-to-door solicitation. The commenter did not believe that retaining this ban was justified and the ban is outdated, since it was added 20 years ago when this activity was more difficult to monitor.

Response: We understand the need by MA plans to have additional flexibility in developing their marketing strategies. The purpose of this prohibition was to provide beneficiaries with appropriate beneficiary protections. Some individuals may not welcome unsolicited visits or may not be prepared to discuss their options, yet may feel pressured to do so. Given the complexity of the new programs and the upcoming limitations when individuals are able to make choices in their coverage, as well as increased competition, we believe that prohibition of door-to-door solicitation remains to be in the best interest of the beneficiary.

Comment: One commenter did not believe the regulatory language addressed the CMS timeline for review when materials are submitted after CMS' initial 45-day review period. Current guidance allows for an additional 45-day review period for CMS to review a document after it has been resubmitted. The commenter recommends instituting a 10-day review period for resubmitted materials.

Response: We appreciates this feedback and will take this under further consideration.

Comment: One commenter supported the extension of file and use to SNPs.

Response: Since SNPs are MA plans, all MA rules will apply to SNPs unless otherwise provided by us. Therefore, SNPs will qualify to participate in the file-and-use program provided the necessary requirements are met.

Comment: Several comments requested clarification from CMS that outreach workers employed by tribal and IHS facilities will continue to be encouraged to provide information about Medicare alternatives to the AI/AN elderly and this outreach would not fall under the prohibition against door-to-door marketing.

Response: We appreciate these concerns and will work with Tribal and IHS organizations to find solutions that both meet the needs of the AI/AN population and satisfy the requirements of the MA program.

Subpart C—Benefits and Beneficiary Protections

In the areas of benefits and beneficiary protections, we proposed regulatory reforms based on our program experience, as well as provisions implementing new requirements in the MMA. We tried to integrate new requirements in the MMA with existing regulations, while at the same time removing impediments in the existing rules that have tended to stifle innovation by M+C organizations. We believe our proposals addressed the paramount task of ensuring that beneficiaries continue to be fully informed and protected in their receipt of essential health care services under the Medicare program.

The regulatory reforms we proposed included: (1) New beneficiary protections related to receipt of covered health care services from contracted providers; (2) revisions to the rules limiting beneficiary cost sharing related to emergency episodes; (3) new rules affording additional protections to MA regional plans enrollees; (4) incentives for MA organizations to offer MA regional plans that would serve all beneficiaries in all areas; (5) the elimination of administratively burdensome requirements on MA organizations that are duplicative of other activities already conducted by us; and (6) the elimination of a number of unnecessary, duplicative, or overly burdensome access to care provisions.

We received hundreds of comments on subpart C from approximately 150 commenters in response to our August 3, 2004 proposed rule. Below we provide a brief summary of the proposed provisions and respond to public comments. (For a broader discussion of the proposed provisions, please refer to our proposed rule.)

1. General Requirements (§ 422.100)

MA MSAs are ''high deductible'' MA plans and are defined at section 1859(b)(3) of the Act. Until the deductible is met, the MA MSA enrollee is generally responsible for payment for all covered services. Once the MA MSA deductible is met, the MA organization offering the MSA plan is responsible for payment of 100 percent of the expenses related to covered services. In both cases, whether it is the enrollee or the MA organization offering the MSA that assumes responsibility for payment, providers and other entities are required to accept the amount that FFS would have paid (including permitted beneficiary cost sharing) as payment in full.

Section 233(c) of the MMA amended the Act to include enrollees in MSA plans offered by an MA organization with MA coordinated care plans as having protection from balance billing by noncontracting providers. In our proposed rule, we stated that for covered services provided to an MA MSA plan enrollee, a physician or other entity that does not have a contract with an MA MSA plan must now accept as payment in full the amount they could have collected had the individual not been enrolled in the MA MSA plan.

In the proposed rule, we specified that:

- The proposed provision applied to physicians and other entities. (Note that ''providers of services,'' as defined in section 1861(u) of the Act, are similarly restricted from balance billing MA MSA enrollees under section 1866(a)(1)(O) of the Act.)
- In cases in which Medicare participating physicians do not have an agreement with an MA organization in place governing the amount of payment, they must accept the amount they would have received under FFS Medicare as payment in full (including permitted beneficiary cost sharing).
- In cases in which Medicare non-participating physicians do not have an agreement with an MA organization in place governing the amount of payment, they also must accept the amount they would have received under FFS Medicare as payment in full (including permitted beneficiary cost sharing). (Medicare non-participating physicians are permitted to accept assignment on a case by case basis. For non-assigned claims, Medicare non-participating physicians are subject to the ''limiting charge.'')

These FFS charge limits have always applied to the charges that providers and other entities could impose when providing covered services to enrollees in MA coordinated care plans and private FFS plans, when there is no agreement with an MA organization in place governing the payment amount. The MMA added the same protections for MA MSA plan enrollees and we proposed conforming changes in subpart C and at § 422.214.

In addition to the new MA MSA ''charge'' protections, we proposed amending § 422.100 to provide for other changes for purposes of administrative simplification and clarification:

- We deleted the parenthetical ''(other than an M+C MSA plan)'' from the first sentence of § 422.100(b)(2) and replaced it with ''(and an MA MSA plan, after the annual deductible in § 422.103(d) has been met).''
- We modified the reference to ''additional benefits'' in § 422.100(c), as those benefits are no longer applicable to MA plans offered on or after January 1, 2006.
- We removed § 422.100(e) because it was duplicative, and we made the necessary redesignation changes.
- We removed the reference to operational policy letters in § 422.100(f).
- We added ''or encourage disenrollment'' to § 422.100(f)(2), after ''discourage enrollment,'' as one of the prohibitions on the design of benefit packages.

Comment: One commenter recommended that CMS clarify whether the proposed provider rules will now require providers accepting Medicare assignment to limit their charges to 100 percent of Medicare allowable costs for members of an MA MSA plan.

Response: The protections from physician balance billing that are described in section 1848(g) of the Act apply to all Medicare beneficiaries, including those enrolled in any type of MA plan. This includes enrollees of MA MSA plans. This means that for a Medicare participating physician, for instance, the billed charges cannot exceed the Medicare participating fee schedule amount for a Medicare-covered service. For Medicare non-participating physicians that do not accept Medicare assignment in a specific case, the charges cannot exceed 115 percent of the Medicare non-participating fee schedule amount for a Medicare-covered service.

Similarly, for providers of services, as defined at section 1861(u) of the Act, the participation agreement with Medicare requires the provider to accept the FFS payment amount as payment in full for services provided to Medicare beneficiaries, including those enrolled in any type of MA plan (see section 1866(a)(1)(O) of the Act).

Comment: A few commenters stated that CMS should clarify regulatory language to require MA plans to include statutory add-on payments under FFS Medicare to the noncontracting provider payments they are required to make under § 422.100(b)(2). Some commenters specifically mentioned such add-on payments (for example, DSH, outliers, GME, and IME payments) as part of the total payment amount that the provider would have received under original Medicare, and also including the balance billing permitted under Part A and Part B. Some commenters specifically mentioned the ''special'' hospital category payments for sole community hospitals, Medicare dependent hospitals, and critical access hospitals. Another commenter recommended that CMS clarify this ''new'' provision and asked why CMS made a distinction between providers of services, physicians, and other entities.

Response: This section of the regulation has been in place since the original M+C interim final regulation was published on June 26, 1998. In our August3, 2004 proposed rule, we simply added the billing protections for MA MSAs based on the amendment to section 1852(k)(1) of the Act provided in section 233(c) of the MMA. Otherwise, the distinction between providers of services, physicians, and other entities is statutory and based on the fact that noncontracting providers of services are required to accept Medicare payment rates from MA organizations based on section 1866(a)(1)(O) of the Act, while noncontracting physicians and other entities are required to accept Medicare payment rates from MA organizations based on section 1852(k) of the Act.

Additionally, we believe our regulation already requires FFS ''add-on'' payments (including those to both providers of services, physicians, and other entities), because they are generally considered part of the FFS payment that an MA organization must make to noncontracting providers, physicians, and other entities for covered services. However, an MA organization is not required to include IME and GME payments to noncontracting hospital providers to the extent the hospital providers receive IME and GME payments for MA plan enrollees directly from the fiscal intermediary (see § 422.214(b)). The fiscal intermediary's direct payments to hospitals of IME and GME amounts for MA enrollees are based on sections 1886(d)(11) and 1886(h)(3)(D) of the Act, respectively. Finally, § 422.100(b)(2) references the balance billing permitted under Part A and Part B of Medicare, which represents the maximum required payment due from the MA organization, less applicable MA enrollee cost sharing.

Comment: Several commenters recommended that CMS adopt blanket policies that would require MA and MA-PD plans to pay I/T/U facilities that serve AI/AN in a special manner. Among other proposals, these commenters suggested that CMS require MA organizations to waive cost sharing for AI/AN and that CMS require MA organizations to pay the ''full IHS Medicaid'' rate to I/T/U facilities, or that we establish other special payment methodologies related to MA reimbursement to I/T/U facilities.

Response: We are implementing the MMA statute through this rulemaking. The MMA did not provide for special

treatment under the MA program for AI/AN beneficiaries. For this reason, we do not see a statutory basis to apply different rules to a subset of Medicare beneficiaries, such as AI/AN populations. In general, however, we believe that MA regional plans will create new choices for beneficiaries, including AI/AN populations, and that access to MA plans will be improved. Similarly, because MA regional plans must reimburse for all covered benefits in and out of network, IHS facilities may receive reimbursement for out-of-network care provided to an MA regional plan AI/AN enrollee that they may otherwise not have been entitled to under the M+C program. However, the rate of reimbursement actually paid to an I/T/U facility for an AI/AN enrollee will vary based on the type of plan, type of service, and the plan-required level of enrollee cost sharing. For instance, for emergency department services, an MA plan enrollee's cost sharing would be limited to $50 and the MA organization (regardless of plan type) would be responsible for payment of the rest of the billed amount, up to the full Medicare rate. Similarly, an I/T/U, for an AI/AN MA PPO enrollee, could expect MA organization reimbursement for routine covered services provided to such an enrollee, although the amount of reimbursement directly provided by the MA organization would be limited to the full Medicare rate, less applicable enrollee cost sharing.

Finally, a broad waiver of beneficiary cost sharing of the type the commenters requested would not be permitted under provisions designed to protect the Medicare program from fraud and abuse. However, existing statutory and regulatory provisions may allow for the waiver of cost sharing in certain cases.

Comment: One commenter suggested that CMS require pre-approval before permitting an MA organization to adopt a local coverage determination for an MA regional plan under § 422.101(b)(4). This commenter also suggested that CMS require public comment on the choice of local coverage determination by an MA organization for either a local MA plan under § 422.101(b)(3) or an MA regional plan under § 422.101(b)(4).

Response: We do not interpret the statute at section 1858(g) to require CMS pre-approval of the local coverage determination an MA organization sponsoring an MA regional plan selects to apply to all enrollees of the MA regional plan. The statutory provision also does not include a requirement for public notice, but rather allows the MA organization to elect to have a local coverage determination apply to all enrollees of the MA regional plan. The MA organization must comply with applicable statutory and regulatory requirements in making such election, including the requirement, discussed below, that all local coverage determinations of the contractor selected by the MA organization be applied to the MA regional plan's enrollees.

Comment: One commenter recommended that CMS clarify whether or not MA organizations are required to provide all Medicare covered benefits in the MA plans they offer to Medicare beneficiaries. This commenter had specific concerns related to outpatient occupational therapy and whether a home visit by an occupational therapist to evaluate for safety and function post stroke, for instance, is a Medicare benefit that MA organizations have to offer enrollees of MA plans.

Response: Occupational therapy is a Medicare-covered outpatient benefit under section 1861(s)(2)(D) of the Act. Under section 1852(a) of the Act, an MA organization must provide all benefits under the original Medicare FFS program option. Therefore, MA plans must cover all services covered under Medicare Parts A and B.

Comment: One commenter stated that CMS is directed to ''replace'' Medicare carriers and fiscal intermediaries with Medicare Administrative Contractors (MACs) by section 911 of the MMA. The commenter asked what impact such a ''replacement'' would have on MA plans, which will likely cover larger areas than current FFS contractors.

Response: Transition from Medicare carrier and fiscal intermediary contractors to MACs is to occur between 2005 and 2011. We have modified the regulatory language in § 422.101(b)(3) to account for the transition to MACs by removing specific reference to Medicare carriers and fiscal intermediaries. We expect the impact this ''replacement'' will have on MA plans related to this section of the regulation will be insignificant. To the extent MACs will cover larger geographic areas than current FFS contractors, and to the extent MACs will apply local coverage determinations across those larger geographic areas, the opportunity for MA organizations to elect to apply uniform coverage rules in § 422.101(b)(3) or (b)(4) will also be likely to decline.

2. Requirements Relating to Basic Benefits (§ 422.101)

Section 221 of the MMA added a new section 1858(g) to the Act that provided for a special rule related to the way local coverage determinations (for example, ''local medical review policies,'' or ''LMRPs'') will be applied by MA regional plans. MA regional plans are permitted to elect any one of the local coverage determinations that applies to original Medicare FFS beneficiaries in any part of an MA region to apply to its enrollees in all parts of the MA region. Based on our interpretation of the statute, we proposed at § 422.101(b)(4) that an MA regional plan, if it chooses this option, must elect a single FFS contractor's local coverage determination that it will apply to all members of an MA regional plan. The MA organization would not be permitted to select local coverage policies from more than one FFS contractor that it would apply to all members of an MA regional plan.

Comment: A number of commenters recommended that CMS clarify the proposed language in § 422.101(b)(4). Some commenters recommended that CMS ensure that the understanding comported with ''the common understanding'' that regional plans can select coverage determinations issued by different intermediaries and carriers within the region. Some commenters also suggested that CMS extend the same flexibility to local MA plans. Others suggested that CMS allow MA organizations that sponsored multiple local MA plans to apply one FFS contractor's coverage determinations to its entire MA population.

Response: We disagree with the commenters who have requested the ability to select coverage determinations of multiple intermediaries or carriers within a region. As we stated in the proposed rule, our interpretation of section 1858(g) of the Act is that an MA regional plan exercising this option must elect a single FFS contractor group of local coverage determinations or policies that it will apply to all members of an MA regional plan and that an MA regional plan may not select local coverage policies from more than one FFS contractor. We are adopting this interpretation in the final rule.

The reason for this interpretation is two-fold. First, to the extent that local carrier and intermediary medical directors apply uniform experience to a broad range of coverage policies, it would be inappropriate to allow selection of a specific coverage policy from one carrier medical director and a different coverage policy on a different medical item or service from another carrier medical director. Second, to the extent that local carrier and intermediary coverage policies are generally statements of non-coverage, restricted coverage, or conditions for receipt of a specific health care item or service, it would be inappropriate to

allow an MA regional plan to adopt coverage policies issued by more than one carrier or intermediary. This interpretation would permit MA regional plans to deny coverage for what would otherwise be Medicare-covered services at a frequency and under conditions that no individual FFS beneficiary would ever face. For example, carrier ''X'' might have decided that Medicare coverage was not available for ''A'' in a local coverage area. Carrier ''Y'' might have decided that Medicare coverage was not available for ''B'' in a local area. In such a situation, were we to permit an MA regional plan to adopt the coverage policies of both carrier X and carrier Y, an MA plan enrollee of that regional plan would not have coverage for either A or B, while original FFS enrollees residing in carrier X's service area would have coverage for B, and those residing in carrier Y's service area would have coverage for A. Therefore, to emphasize these points and to correct the apparently common misunderstanding mentioned in the comment, we are modifying the language in § 422.101(b)(4). Further, the statutory language will not permit an extension to local MA plans of the requirement we are codifying in regulation at § 422.101(b)(4). Local MA plans whose service areas encompass more than one local coverage policy area will continue to be required to follow rules previously established for them in § 422.101(b)(3) based on statutory authority at section 1852(a)(2)(C) of the Act.

Finally, we respond to the commenters that asked whether an MA organization could apply a single FFS contractor's coverage determinations to its entire MA population and across local MA plans. Such a policy would not be in accord with the statute, which is specific as to both local and MA regional plans. The selection of a uniform coverage determination policy for both MA local and regional plans is available only at the plan level.

Comment: A commenter recommended that CMS revise the regulation at § 422.101(b)(4) in order to permit MA organizations that offer MA regional plans in more than one MA region to apply local coverage policies across regional boundaries.

Response: We are interpreting section 1858(g) of the Act as generally preventing such an interpretation or revision to the regulation. The statute specifically allows MA regional plans to apply coverage policies only from 'any part of such region.'' It would only be where one FFS contractor had a uniform coverage policy that straddled two regions, and where an MA organization offered MA regional plans in both of those regions, that such a result would be possible.

Comment: A commenter recommended that CMS allow an MA organization offering multiple local MA plans to apply the rule in § 422.101(b)(3) across MA local plans, or if local MA plans could adopt the new rule in § 422.101(b)(4) related to MA regional plans.

Response: The specific language at section 1851(a)(2)(C) of the Act is clear in not permitting such an interpretation or revision to the regulation. The statute specifically allows an MA organization sponsoring a local MA plan to apply the coverage determination most beneficial to enrollees from the service area of that local MA plan to all enrollees of that local MA plan, and subjects that to pre-CMS review before implementation.

Comment: A number of commenters pointed out the difficulty noncontracting providers will have ascertaining the local coverage policy that will apply to a specific MA regional plan enrollee. Some commenters suggested that CMS require MA regional plans to notify both enrollees and potential noncontracting providers of the LMRP that will apply to specific MA regional plan enrollees. Others stated that providers are most familiar with LMRPs that apply in the area in which they primarily practice medicine or provide services and that it will be difficult, if not impossible, to know whether a specific service will be covered for a specific MA regional plan enrollee when LMRPs are applied from different, and possibly remote, geographic areas. Some commenters pointed out the potential impact this would have on MA regional plan enrollees who could incur financial liability for services that are otherwise Medicare-covered in the geographic location in which they are provided. Many commenters stated that the problems related to knowing what LMRP applies to a specific MA regional plan enrollee are compounded by the fact that MA regional plan enrollees, as MA PPO enrollees, have the right to access all covered benefits (albeit at potentially higher cost sharing) from out-of-network providers.

Response: We have added a new paragraph to the regulation at § 422.101(b)(5) that will require MA organizations that elect to apply local coverage policies uniformly across a local MA plan's service area, or across an MA regional plan's service area, to inform enrollees and potential providers, including through the Internet, of the applicable local coverage policy that applies to the MA plan enrollees. This means that MA organizations choosing to avail themselves of the option of applying uniform LMRPs to a local or regional MA plan must create a web site upon which to post links to or copies of the applicable LMRPs. We believe that this requirement will not create a significant burden on MA organizations and will provide convenient access for both providers and enrollees to such information. We are also making a conforming change to § 422.111(f)(11) that requires MA organizations to notify providers through the Internet that such an election has occurred and what local coverage policy will apply to MA plan members.

We proposed to add a new § 422.101(d) to provide for new cost-sharing requirements mandated by MMA related to MA regional plans. There were three specific requirements:

1. MA regional plans, to the extent they apply deductibles, are required to have only a single deductible related to combined Medicare Part A and Part B services. Applicability of the single deductible may be differential for specific in-network services and may also be waived for preventative services or other items and services.

2. MA regional plans are required to have a catastrophic limit on beneficiary out-of-pocket expenditures for in-network benefits under the original Medicare FFS program.

3. MA regional plans are required to have a total catastrophic limit on beneficiary out-of-pocket expenditures for in-network and out-of-network benefits under the original Medicare FFS program. (This total out-of-pocket catastrophic limit, which would apply to both in-network and out-of-network benefits under original Medicare, could be higher than the in-network catastrophic limit, but may not increase the limit applicable to in network services.)

MA regional plans would be responsible for tracking these beneficiary out-of-pocket limits and for notifying members when they have been met. We also proposed to require MA regional plans to track and limit incurred rather than paid out-of-pocket expenses.

Comment: Many commenters recommended that CMS explain the significance of requiring MA regional plans to track ''incurred'' rather than paid expenses related to the deductible and caps on beneficiary cost sharing.

Response: There are two reasons for requiring MA regional plans to track incurred rather than paid beneficiary cost-sharing expenses. The first is that

we foresee a potential for disputes arising between providers and MA organizations related to the ''full'' reimbursement the MA organization will owe, once a cap had been met. If ''full'' reimbursement were not required until cost sharing had been paid (rather than incurred), then disputes might arise over what amount a beneficiary had actually paid in cost sharing, and when. Administratively, it is more feasible and less burdensome for plans to track incurred cost-sharing amounts than amounts actually paid, if for no other reason than the latter would require a feedback mechanism to the MA organization whenever an enrollee makes a payment of cost sharing. Second, it is possible that in many instances a beneficiary will be unable to pay full cost sharing for a service at the time of service. Many MA organizations, for instance, require inpatient hospital copays of more than $100 per day, even when in-network hospitals are used. Beneficiaries might need to pay cost sharing to providers over a period of time. Such delays in the actual payment of cost sharing should not affect the MA organization's responsibility for timely payment of claims.

Comment: A number of commenters recommended that CMS require MA organizations to make deductible and out-of-pocket information readily available to providers to facilitate billing at the time of service. Some commenters suggested requiring MA organizations to send notices of additional financial liability to enrollees on a monthly basis. Others suggested requiring that a standardized notice be used to ensure consistent reporting across all plans. Commenters also suggested requiring MA organizations to post enrollee deductible and catastrophic cap information on the Internet, so providers could easily and quickly determine enrollee liability at the time of service.

In addition, commenters suggested that CMS require MA organizations offering MA regional plans to provide information on deductible and out-of-pocket limits related to specific MA regional plan enrollees to hospitals, similar to the method by which hospitals are notified of Medicare beneficiary eligibility and Part A deductible status under the original FFS system. Others suggested that we require MA organizations offering MA regional plans to supply deductible and catastrophic cap information when health care providers and/or hospitals notify the MA organization that an MA plan member has presented for services.

Response: In response to these comments, we have modified § 422.101(d)(4) to indicate that notification to providers of enrollee status related to a deductible (if any) and catastrophic caps is also required. To the extent an MA regional plan enrollee is not aware of his or her deductible and/or cap status, the enrollee or a provider should have reasonable access to such information at the time of service.

Comment: A number of commenters recommended that CMS add a special provision for AI/AN to § 422.101(d) that would have the affect of requiring all MA regional plans to provide ''full reimbursement'' to all I/T/U facilities that treated enrollees of that MA regional plan.

Response: The MMA did not provide for special treatment under the MA program for AI/AN beneficiaries. For this reason, we do not see a statutory basis to apply different rules to a subset of Medicare beneficiaries, such as AI/AN populations.

Comment: A commenter generally supported the requirement at § 422.101(d)(4) that MA regional plans will be responsible for tracking the incurred beneficiary cost sharing related to the deductible and the catastrophic caps on beneficiary out-of-pocket expenses. The commenter expressed disappointment that a specific dollar amount or limit had not been set related to the caps on out-of-pocket expenses in § 422.101(d)(2) and (d)(3). The commenter also asked that we provide a definition of ''incurred'' costs that ensures that all cost sharing, whether paid by the beneficiary, or on his or her behalf, is counted and tracked.

Response: We did not establish maximum deductible or cap-levels in regulation, since the statute does not set such limits. We interpret the statute to allow for flexibility in plan design, within the constraints of statutory language, to promote competition. However, under our authority at section 1852(b) of the Act to disallow the offering of an MA plan where we determine that the plan design or its benefits are likely to substantially discourage enrollment by certain MA eligible individuals, we will review deductible and cap-levels to ensure that they do not substantially discourage enrollment. Additionally, as required by section 1854(e)(4) of the Act, beginning in 2006 (and for all MA plans other than MSA plans), the actuarial value of the deductible, coinsurance, and copayments applicable on average to individuals enrolled in an MA plan related to benefits under the original Medicare program may not exceed the actuarial value of the deductibles, coinsurance, and copayments that would be applicable on average to FFS Medicare enrollees related to benefits under the original Medicare program. As provided for in statute at section 1852(a)(1)(B)(ii) and in our regulation at § 422.101(e)(2), while the catastrophic limit on in-network receipt of benefits under the original Medicare program applies to the overall cost-sharing limit that an MA regional plan can impose per § 422.256(b)(3), the out-of-network catastrophic limit is not likewise constrained.

Finally and related to the tracking of incurred costs, we will require MA regional plans to track incurred as opposed to paid enrollee cost sharing. We will require MA regional plans to provide reimbursement to providers for covered services once the deductible or caps have been incurred regardless of who has actually paid the cost sharing, or for that matter, regardless of whether the deductible or other cost sharing has been paid at all. An MA organization with financial liability to reimburse a provider for covered services may not delay reimbursement until an enrollee first pays deductible or cost-sharing amounts.

The MMA also added a new section 1859(b)(4) to the Act requiring MA regional plans to provide reimbursement for all covered benefits, regardless of whether the benefits are provided within or outside of the network of contracted providers. As PPOs, MA regional plans are permitted to impose differential cost sharing related to non-emergency services received from non-network providers. To the extent differential cost sharing is part of the benefit package, the MA regional plan will generally be responsible for its portion of payment to a non-network provider, and the enrollee will be responsible for the remainder, up to the limits discussed above. We accommodated these requirements in the proposed rule at § 422.101(e).

MA PPO Benefits

We received many comments on § 422.101(d) and (e) related to the benefits and cost-sharing protections enrollees in MA regional plans can expect to receive. We also received comments specifically related to the definition of MA PPOs provided at § 422.4(a)(1)(v), which we responded to in the subpart A preamble above. Because of the interaction of the statutory and regulatory definitions of PPO (for both local MA plans and MA regional plans, which are offered as PPOs), and the benefits they must provide, we address a number of comments related to MA PPO benefits

in this section of the preamble that have a close bearing on the definition of MA PPOs.

As we stated in the subpart A preamble of the August 3, 2004 proposed rule: ''Section 520(a)(3) of the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) added section 1852(e)(2)(D) of the Act and defined PPO plans under the MA program for purposes of quality assurance requirements. As we discussed in the preamble to the final rule with comment period titled, ''Medicare Program; Medicare+Choice,'' published on June 29, 2000 (65 FR 41070), the definition of PPOs at section 1852(e)(2)(D) of the Act was explicitly for purposes of applying quality assurance requirements in 1852(e)(2)(B) of the Act and was limited in its applicability to paragraph (2) of section 1852(e) of the Act. Before the enactment of the BBRA, PPOs had been treated under the M+C statute and regulations in the same manner as all other M+C coordinated care plans for purposes of applying quality assurance requirements. In the June 29, 2000 final rule with comment period, we incorporated this new definition into the M+C regulations at § 422.4 and by revising § 422.152.

The PPO plan definition added by section 520 of the BBRA included three elements, they were as follows: (1) has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; (2) provides for reimbursement for all covered benefits regardless of whether those benefits are provided within the network of providers; and (3) is offered by an organization that is not licensed or organized under State law as a health maintenance organization.

Because the definition of PPO plan in section 1852(e)(2)(D) of the Act only applies for the limited purpose of eligibility for PPO quality improvement requirements, we do not believe that the limitations in this definition should have been set forth in a generally applicable definition of PPO plan in § 422.4, as is currently the case. We propose to clarify in regulation that it is solely for purposes of the application of the more limited quality assurance requirements in section 1852(e)(2)(B) of the Act that PPOs must be offered by MA organizations that are not licensed or organized under State law as a HMO. For PPO-type plans that are offered by MA organizations that are licensed or organized under State law as HMOs, the quality assurance requirements that apply to all other coordinated care plans in section 1852(e) of the Act also apply to those PPO type plans.''

Based on this better interpretation of section 520(a)(3) of the BBRA, we proposed to modify the third element (related to State licensure) of the definition of MA PPO plan at § 422.4 to read as follows: ''A PPO plan is a plan that has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; and, only for purposes of quality assurance requirements in § 422.152(e), is offered by an organization that is not licensed under State law as an HMO.''

We also proposed to define MA regional plan at § 422.2 based on the definition in section 1859(b)(4) of the Act, which was added by section 221(b) of the MMA. The first and second elements of the definition of MA regional plan at section 1859(b)(4)(A) and (B) of the Act are identical to the first two elements of the definition of MA PPO plan at sections 1852(e)(3)(A)(iv)(I) and (II) of the Act , which was added by section 722(a) of the MMA. Note that the definition of MA PPO plan in section 1852(e)(3)(A)(iv)(I) of the Act is identical the definition of MA PPO plan that had appeared at section 1852(e)(2)(D) of the Act, as added by section 520(a)(3) of the BBRA. Therefore, the statute requires that both local MA PPOs and MA regional plans (which are offered as PPOs) must provide reimbursement for all covered benefits regardless of whether such benefits are provided within the network of providers.

Comment: Although some commenters supported, as a beneficiary protection, the fact that MA regional plans are required to provide reimbursement for all covered benefits, regardless of whether those benefits are provided within or outside the network of contracted providers. Many commenters suggested that statutory language requiring PPOs to provide reimbursement for all covered benefits should simply mean that PPOs need to provide out-of-network coverage for Medicare Part A and Part B services. The commenters also stated that they believe the statute never intended out-of-network coverage to apply to supplemental benefits, which are not part of the original Medicare benefit package.

Response: We disagree. The placement of the definition and other requirements related to MA regional plans in the MMA is instructive in this regard. As we noted earlier, section 221(b) of the MMA added the definition of MA regional plan, which includes the second element of the definition, ''that provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers,'' at section 1859(b)(4)(B) of the Act. Section 221(c) of the MMA establishes ''Rules for MA Regional Plans'' by inserting a new section 1858 into the Act. In both, section 1858(b)(1) of the Act related to the single deductible that MA regional plans are permitted to apply, and section 1858(b)(2) of the Act related to the catastrophic limits that MA regional plans must apply, the statute is clear in stating that only ''benefits under the original Medicare FFS program'' are included. Where the intent is to limit application of MA plan requirements to only benefits under the original Medicare program (Parts A and B), the statute states such a limitation. Because no such limitation appears in either section 1852(e)(3)(A)(iv) of the Act, related to all PPOs, nor in section 1859(b)(4) of the Act, related to MA regional plans, we cannot apply such a limitation in the regulations.

Comment: Several commenters stated that benefits such as gym, eyewear, dental discounts, discounts on hearing aids, massage, acupuncture, weight control programs, or health-related magazines are unavailable out-of-network because as a practical matter, such benefits and discounts are negotiated and offered to MA organizations primarily in consideration of the guaranteed volume the exclusive service provider believes it will receive. Many commenters stated that, to the extent such discounted benefits are available from out-of-network service providers, the basis for the negotiated discount (guaranteed volume) becomes null and void.

One commenter stated that discount arrangements such as these, which secure a larger volume of business for the entity providing the discount, provide financial profits and are a common business model not limited to the world of health insurance. The commenter also stated that in these arrangements, there is typically no payment by the plan, and no cost sharing by the enrollee.

Response: Although we fully support discounts and volume purchasing where appropriate, it is important to note that discounts are not benefits under the MA program unless they meet the definition of ''benefits'' contained in the regulations. The definition of MA benefits is found at § 422.2 and reads as

follows: ''Benefits are health care services that are intended to maintain or improve the health status of enrollees, for which the MA organization incurs a cost or liability under an MA plan (not solely an administrative processing cost). Benefits are submitted and approved through the annual bidding process.'' Note that unless an MA organization actually pays for a health care item or service, the item or service is not a ''benefit'' of the MA plan. Therefore, negotiated discounts for services for which the plan incurs no cost or liability are not MA benefits, and are not subject to the requirement that PPOs provide reimbursement for all benefits, whether or not they are provided within the network of providers. That said, it is important to note that we have termed these types of negotiated discounts ''value added items and services,'' which are discussed in Chapter 3 (Marketing) of the CMS Medicare Managed Care Manual.

Comment: Some commenters stated that MA organizations frequently subcapitate ancillary provider networks (such as dental providers) and that such subcapitated arrangements make it difficult for the MA organization to provide reimbursement for all benefits, in- and out-of-network.

Response: The statute is clear that all MA organizations offering PPOs (local and regional) must provide reimbursement for all plan benefits in- and out-of-network. A number of MA organizations subcapitate Independent Practice Associations (IPAs), Physician-Hospital Organizations (PHOs), and similar subnetworks of providers, for most (or all) original Medicare Part B and/or Part A services. Such subcapitation arrangements are permitted within the MA program, subject to § 422.208 (the physician incentive plan requirements and limitations) and other statutory and regulatory provisions. However, to the extent an MA organization wants to offer a PPO (either local or regional), it will also need to make arrangements for providing reimbursement for all out-of-network benefits in such a subcapitated environment, or it will need to make arrangements with its subcapitated contractors for providing reimbursement for out-of-network benefits directly. Two points need to be made. First, the cost sharing that an enrollee will be required to pay when obtaining covered benefits out-of-network can be higher than the cost sharing that applies when services are obtained in-network. Second, to the extent that subcapitated arrangements make the provision of reimbursement for all benefits out-of-network impractical, an MA organization might consider offering an HMOPOS product, where out-of-network coverage and reimbursement can be limited in a number of ways.

Comment: Commenters stated that it would be impossible for plans to provide reimbursement for out-of-network receipt of benefits such as 24-hour nurse hotline services or disease management services.

Response: These services are not likely to be available from out-of-network providers because of the unique nature of the services and the integration between the plan and the service provider necessary for the delivery of such services. To illustrate, a provider of in-network disease management services to a plan's enrollees is likely to need access to plan and patient information in order to provide services to enrollees. An out-of-network disease management services provider would not have such access, and so would be unlikely to be able to provide the service out-of-network. Finally, to the extent that such services are available without cost sharing from in-network providers, the imposition of cost sharing of any amount for their receipt out-of-network should deter virtually all enrollees from seeking them out-of-network.

Comment: Some commenters pointed out the difficulty inherent in requiring MA-PDs that are offered as PPOs to provide reimbursement for mail-order drugs or Part D (prescription drug) benefits received by enrollees from out-of-network providers.

Response: As a practical matter, an MA PPO plan that offers Part D coverage as an MA-PD will need to provide out-of-network coverage of Part D drugs consistent with the requirements of the Part D program and the regulations at part 423.

Comment: A commenter stated that further complications might arise were CMS to interpret ancillary services (for example, dental and eyewear) as being services subject to the catastrophic limit on out-of-pocket expenses. The concern was that once an enrollee has met the out-of-network cap, cost sharing would no longer act as a deterrent to the unrestricted and ''free'' access by PPO enrollees to these benefits from out-of-network providers.

Response: The statute and our implementing regulations at § 422.101(d)(2) and (d)(3) are clear in limiting application of the catastrophic caps to Part A and Part B benefits. To the extent dental or eyewear benefits of an MA PPO plan are not also original Medicare benefits, cost sharing can continue to apply, even after the out-of-network additional catastrophic limit in § 422.101(d)(3) has been met.

Comment: A number of commenters recommended that we revise the proposed rule to clarify that MA regional plans may establish prior authorization requirements for services obtained out-of-network and that both MA regional plans and local PPOs should be permitted to offer certain services only through network providers, where, for instance, the services have unique characteristics. The commenters stated that private sector PPO benefits are commonly offered in this manner. Therefore, the commenters believe that by providing this flexibility, CMS would allow the offering of MA PPO plans and benefits in a comparable manner to those generally available to consumers, and that this will make it possible for them to continue to offer certain services that add value for beneficiaries.

Response: Although we support the offering of added value to beneficiaries where possible, as we have previously discussed, there is a clear statutory requirement that all covered benefits of an MA PPO plan (regional or local) must be available out-of-network. The statute provides a definition of PPO that may not, in all respects, conform with business models that might be present (or even prevalent) in the commercial sector. Unlike plans serving commercial populations, the Medicare program is primarily intended to serve aged and vulnerable beneficiary populations. Therefore, the dynamics of the MA program may not match those in the commercial market. Also, for all MA plans they offer, MA organizations are required to follow FFS coverage rules related to items and services covered under FFS Medicare. Although MA organizations are permitted to adopt a single local coverage policy that will apply to all enrollees in an MA plan, in accordance with § 422.101(b), MA organizations are not permitted to impose a more stringent test related to medical necessity determinations for Medicare-covered services than the one that applies under the FFS program.

For items and services not covered by Medicare that the MA organization provides under section 1852(a)(3) of the Act, similar considerations apply. In other words, to the extent and under the conditions that a non-Medicare supplemental benefit would be available to a plan enrollee within the network of providers, such a service would also need to be available to an MA PPO enrollee out-of-network. That is not to say that differential cost sharing cannot be applied to out-of-network receipt of covered services, nor does it mean that

out-of-network cost sharing cannot be differentially applied to specific services or types of services. We believe that MA organizations offering MA PPOs (both local and regional) can accomplish their business strategies while still working within the statute.

For instance, an MA PPO can warn enrollees that to the extent that an item or service is not a covered benefit of the plan, the enrollee would be required to pay the full cost of the service. This warning might have the desired effect of encouraging the enrollee to call the MA plan before seeking care out-of-network, as a means of ensuring that a specific item or service is actually a covered benefit of the plan. Similarly, for specific services for which the plan has established substantial out-of-network cost sharing, the enrollee can be encouraged to contact the plan for pre-authorization that would reduce cost sharing. For instance, for out-of-network receipt of a specific inpatient hospital service the normal cost sharing might be 40 percent of charges. To the extent an enrollee or provider calls and receives plan pre-authorization for a specific out-of-network hospitalization of this type, the MA plan might reduce enrollee liability to 20 percent (or less) of charges. MA PPOs must be able to provide coverage and medical necessity determinations to enrollees (and providers) before the enrollee receives out-of-network services. This will act as a beneficiary protection.

A prudent enrollee will have reason to ensure that such services are medically necessary and covered by the plan before self-referring to out-of-network providers. Similarly, a prudent provider will have a means of ensuring that plan coverage will be provided. However, the idea that a gatekeeper must provide a referral or that an MA plan must pre-authorize a service before it will be covered at all, or that such a referral or plan pre-authorization is a necessary condition for receipt of any medically necessary out-of-network plan covered service is not in accord with the statutory language pertaining to MA PPOs.

Our belief is that the statute precludes requiring a medical necessity determination, a plan pre-certification or pre-authorization, or a coverage decision before receiving a covered service out-of-network. As long as an MA PPO enrollee is willing to pay the higher cost sharing associated with out-of-network care, there can be no additional barrier to receipt of plan covered benefits. If an MA organization offering an MA PPO is particularly concerned with over-utilization or inappropriate utilization of services (or of a particular service) out-of-network, the organization has the authority to impose relatively high out-of-network cost sharing overall, or related to a specific service. Also note that to the extent a referral or plan pre-authorization has been provided for in-network care, the enrollee has the right to use the referral or plan pre-authorization for receipt of the same care out-of-network (with applicable out-of-network cost sharing).

Comment: A commenter recommended that CMS offer alternative regional PPO product designs, which the commenter called ''Performance Risk PPOs.'' The commenter included a proposal that would, offer plan incentives for higher quality, better customer service and benefits, improved outcomes and program savings, and penalize plans that do not perform well on these measures. The commenter explained that such a model would offer a range of out-of-network benefits, but not all Medicare-covered services would be available out-of-network. In addition, the commenter stated that although referrals would not be required for accessing out-of-network care, pre-certification might be required.

Response: Under the definitions of regional PPO contained in the MMA, the MA regional plan must provide for reimbursement for all covered benefits, regardless of whether such benefits are provided within the plan's network of providers. Therefore, a plan of the type that the commenter proposes would not meet the statutory definition of MA regional plan. Further, as we have stated above, plan pre-certification or pre-authorization may not be a necessary condition for receipt of out-of-network covered services.

3. Supplemental Benefits (§ 422.102)

In the August 3, 2004 proposed rule, we stated that an MA plan could reduce cost sharing below the actuarial value specified in section 1854(e)(4)(B) of the Act as a mandatory supplemental benefit. Beginning in 2006, an MA plan can reduce the cost sharing that applies to plan members below the actuarial value of the cost sharing that would apply to those members if they were enrolled in the original Medicare program. This amount is not just the limit on the amount of cost sharing that an enrollee can be charged in the plan's bid for Medicare Part A and Part B services (and for which and when such plan cost sharing exceeds FFS cost sharing, a supplemental premium is necessary), but it also expresses the value of the bid-based cost sharing when the bid is below the benchmark. When we reference section 1854(e)(2)(B) of the Act in § 422.102(a)(4), we are referring to the latter value, not the former. This reduction in cost sharing can be included as a mandatory supplemental benefit and was proposed at § 422.102(a)(4).

We also proposed the following conforming changes to § 422.102:

- We removed the reference to ''additional benefits,'' as those benefits are no longer applicable to MA plans offered on or after January 1, 2006.
- We removed the reference to operational policy letters (OPLs) in § 422.102(a)(3), as guidelines related to benefits that had been contained in OPLs have been incorporated into regulation, into the Medicare Managed Care Manual, or into other instructions.

We received no comments on this section, so we finalize it as proposed.

4. Benefits Under an MA MSA Plan (§ 422.103)

For clarification purposes, we proposed to remove the extraneous word ''under'' from paragraph (a) of § 422.103.

We received no comments on this section, so we finalize it as proposed.

5. Special Rules for Self-Referral and Point of Service Option (§ 422.105)

''Point of Service'' (POS) is an option in some plans that allows enrollees to obtain non-network services, with the plan providing some limited level of reimbursement for such services. To clarify an issue that has created confusion for both beneficiaries and MA organizations, we proposed to clarify at § 422.105 that if an MA organization does not offer a POS benefit to members of a plan (or if it offers a POS benefit as an optional supplemental benefit and the member has not selected that benefit), the member cannot be financially liable for more than the normal in-plan cost sharing for covered items or services from contracted providers.

We stated that we believed that indemnifying the Medicare member in such a situation conforms with normal industry practice and also clarified our long-standing policy that members cannot be held financially liable when contracting providers fail to follow or adhere to plan referral or pre-authorization policies before providing covered services. If a plan member insisted on receiving what would otherwise be covered services from a contracted provider (but for the lack of a referral or plan pre-authorization), then the contracted provider would be required to inform the member that those services would not be covered under the plan. We proposed to require

the provider to document the medical record as to why the services are medically necessary but not available through the plan.

In addition, an MA regional plan might choose to provide for a POS-LIKE benefit where beneficiary cost sharing would be less than it would otherwise be for non-network provider services, but where it still might be greater than it would be for in-network provider services, if an enrollee follows pre-authorization, pre-certification, or pre-notification rules before receiving out-of-network services. Note that such pre-authorization, pre-certification, or pre-notification cannot be a necessary condition for receipt of, or required MA plan reimbursement for, out-of-network covered services by a PPO enrollee; however, it can act as a financial incentive (by lowering the normal out-of-network cost sharing that would otherwise apply) to an enrollee to voluntarily participate.

In this final rule, the title of this section is being changed to emphasize the fact that it contains not only rules related to POS options or benefits, but that it also contains a rule related to enrollee self-referral to plan contracted providers in all MA plans.

Comment: Many commenters recommended that we clarify the meaning of the introductory statement proposed to § 422.105(a). Other commenters suggested that the statement was misplaced, because the proposed regulation would apply to plans with and without POS offerings. Others commenters stated that in plans in which a POS option was provided as a mandatory supplemental benefit, the introductory statement we proposed to add would have no effect and would therefore be confusing.

Response: We agree with the comments regarding potential confusion and have renamed the title of this section of the regulation and reorganized it to indicate that it covers not only POS offerings, but that it also applies to all situations in which an MA plan member self-refers to a plan-contracting provider, whether or not a POS benefit is involved.

Comment: One commenter stated that while some types of services may not be covered under any circumstances, other services might not be covered by an MA plan because they are not medically necessary or appropriate for the enrollee. The commenter suggested that CMS clarify the applicability of the introductory statement to circumstances in which a service does not meet coverage criteria based on medical necessity.

Response: Many commenters responded to our request for comment in the subpart M preamble of the August 3, 2004 proposed rule related to whether or not we should permit or require (and under what circumstances) advance beneficiary notices (ABNs) to be issued by network or non-network providers to MA plan enrollees. Many of the commenters opposed such a requirement as being overly intrusive on the patient and doctor relationship and other commenters supported it as being a valid and necessary beneficiary protection. We address the specific comments related to ABNs in the subpart M preamble of this rule.

Although we decided not to incorporate an ABN requirement into the MA program at this time, we believe that there is an important beneficiary protection at stake, especially in light of the projected growth in MA PPO enrollment due to the advent of the MA regional plan program. MA organizations have a responsibility to ensure that contracting physicians and providers know whether specific items and services are covered in the MA plan in which their patients are enrolled. If a network physician provides a service or directs an MA beneficiary to another provider to receive a plan covered service without following the plan's internal procedures (such as obtaining the appropriate plan pre-authorization), then the beneficiary should not be penalized to the extent the physician did not follow plan rules. MA plan enrollees cannot be held to a higher standard than plan contracting providers. To the extent a contracting provider performs a service or refers a patient for health care services that an enrollee reasonably believes would be covered services of the plan, then an MA plan enrollee cannot be liable for more than applicable plan cost sharing for those services. To the extent an MA organization does not properly inform contracted providers, or to the extent an MA contracted provider does not properly enforce referral procedures, then to that same extent, an MA plan enrollee cannot be held financially liable for the organization's or provider's failure. Under its contract with the MA organization, a provider is contractually bound to look solely to the MA organization for reimbursement for covered services (see § 422.502(g)(1) and § 422.502(i)(3)). Similarly, MA organizations are required to communicate clear and consistent coverage guidelines and medical management procedures to contracting physicians (see § 422.202(b)).

Comment: Some commenters recommended that CMS be more flexible and not require the network contracted physician or provider to document the medical record as to why the items or services were medically necessary but not available through the plan. These commenters suggested that it was inflexible to require that such documentation appear only in the medical record.

Response: We agree with this comment that it was overly proscriptive to require that such documentation could only appear in the medical record and will permit flexibility regarding where such information is documented. We have added language at the end of § 422.105(a) that does not specify where such documentation must reside.

Comment: A few commenters asked us to clarify the issue of the provider's ability to bill the beneficiary, if all actions specified in § 422.105(a) have taken place. Commenters stated that the clarification should specify the conditions under which they are permitted to bill a beneficiary. One commenter asked whether the rules established in this section of the regulation also apply to hospitals and other types of contracted providers.

Response: The intent of our revision to § 422.105 is to clarify a beneficiary protection and not necessarily to clarify under what conditions an MA-contracting provider may or may not bill an MA plan enrollee. As mentioned above, all contracting providers are bound to look solely to the MA organization for reimbursement for services covered under the MA plan in which a Medicare beneficiary is enrolled. To the extent an MA-contracting provider provides a non-covered service to an MA enrollee, then payment for such a service is not generally within the regulatory purview of the MA program.

However, where the enrollee is notified in advance by the contracted provider that a service will not be covered unless the beneficiary receives a referral or takes some other action, and that notification is documented, and the beneficiary receives the service without obtaining the referral or taking the necessary action, then the enrollee can be billed and may be held financially liable for the service. Additionally, even if a beneficiary is informed (either verbally or in writing) that a specific service will not be covered by the MA plan in which the beneficiary is enrolled, that beneficiary is entitled to appeal such a determination, whether or not the service is actually provided after such notification. Finally, § 422.105(a) applies to all contracted providers, including physicians, hospitals, and other provider types.

Comment: One commenter suggested that CMS was proposing an odd and fundamentally misguided rule governing members of MA plans who self-refer. Another commenter stated that the requirement was unnecessary, inflexible, and burdensome for contracted providers. The first commenter stated that the proposed rule contradicted fundamental managed care principles and that the proposed rule would shift payment responsibility from the self-referring member to the contracted provider and/or the MA organization.

The first commenter asserted that enrollees who self-refer should be required to pay the entire cost of the service and should not be rewarded by having to pay only the normal, in-network cost sharing. The second commenter stated that both contracting providers and MA plan enrollees are well aware when there is a requirement to secure a referral from a PCP before receipt of specialty care. Finally, both commenters stated that the proposed rule was flawed by not contemplating, or providing exceptions for, situations in which the service is not covered by the MA plan in which the individual is enrolled, or situations in which the service is not medically necessary.

Response: We do not agree. The language in § 422.105 states that only covered items and services are subject to the regulatory provision. Covered plan services do not include services that are inappropriate or not medically necessary for a specific individual in a specific situation. The intent of the regulatory provision is to limit patient liability in situations where a contracted provider provides a covered service, but for which certain technical, non-medical conditions of coverage have not been met.

Although we agree that the enrollee should not be ''rewarded'' for failing to follow proper plan pre-authorization or referral procedures, we also believe that the contracted provider and the MA organization also should not be ''rewarded'' by shifting financial responsibility to the enrollee for covered services that are actually the financial responsibility of the MA organization. The contracting provider is, or should be, aware of the MA plan's technical requirements for referral and/or plan pre-authorization related to covered services. If the contracted provider believes the covered service is medically necessary, then the contracted provider needs to explain the plan referral/pre-authorization process and should consider assisting the enrollee in obtaining necessary plan pre-service documentation. Finally, the contracted provider needs to inform the enrollee in instances when a service will not be covered unless the enrollee obtains a referral or plan pre-authorization and in which that enrollee will have full financial liability absent such referral or pre-authorization.

6. Coordination of Benefits With Employer Group Health Plans and Medicaid (§ 422.106)

Section 222(j) of the MMA revised section 1857(i) of the Act in order to facilitate employer sponsorship of MA plans. The MMA allowed us to waive or modify requirements that hinder the design of, the offering of, or the enrollment in an MA plan offered directly by an employer, a labor organization, or the trustees of a fund established by one or more employers or labor organizations to furnish benefits to the entity's employees, former employees, or members or former members of labor organizations. Section 222(j) of the MMA further stated that such an employer-labor organization sponsored MA plan may restrict enrollment to individuals who are beneficiaries and participants in such a plan. We proposed a new § 422.106(d) to account for this new statutory authority. (The August 3, 2004 proposed rule also contained a number of clarifying, conforming, and editorial changes to this section.)

Comment: One commenter recommended that CMS use the authority provided in section 1857(i)(2) of the Act to waive requirements related to MA regional plans. The commenter wanted to know if CMS would permit employer/labor sponsored MA plans that have been created for the sole enrollment of the sponsors' own employees, retirees, or members to participate in the MA regional plan stabilization fund or in risk-sharing through risk corridors, both described in regulation at § 422.458. The commenter was concerned that these special ''incentive'' payments for organizations sponsoring MA regional plans were primarily intended to foster the growth of MA regional plans for the enrollment of all eligible Medicare beneficiaries, and that it would be inappropriate to make such special payments to organizations offering plans that are only available for enrollment to employer/labor group members.

Response: We agree and have exercised this discretion under section 1857(i) of the Act to waive program requirements that facilitate employer/labor group enrollment. For instance, we have waived the requirement that MA organizations offer MA plans for enrollment to all Medicare Part A and Part B enrollees, and have allowed MA organizations to create plans that exclusively enroll employer/labor group members. We will continue to do so. However, we will not waive the ''general'' enrollment requirement that MA plans enroll all MA eligible individuals (see section 1851(a)(1)(A) of the Act) for either MA organizations or for employer/labor MA plan sponsors, if these entities seek to offer an MA regional plan solely to employer/labor group members.

Comment: The same commenter asked whether specialized MA plans for special needs individuals could be offered as MA regional plans.

Response: The statute is clear in saying that specialized MA plans for special needs individuals can be offered as any type of MA coordinated care plan (see section 1851(a)(2)(A)(ii) of the Act). MA regional plans are a type of MA coordinated care plan (see section 1851(a)(2)(A)(i) of the Act).

Comment: One commenter asked whether CMS would exercise the waiver authority under section 1857(i) of the Act in order to allow MA organizations to offer non-actuarially equivalent prescription drug coverage to MA plan enrollees who do not purchase Part D.

Response: We will not. Section 1860D–21(a)(1)(B)(ii) of the Act states that MA organizations may not offer prescription drug coverage (other than that required under Parts A and B of Medicare) to an MA plan enrollee unless it is qualified Part D prescription drug coverage.

Comment: One commenter asked if CMS would use the waiver authority to provide for special enrollment or conversion of enrollment rules for Medicaid beneficiaries enrolled in special needs plans, similar to what CMS have provided for employer/labor group members.

Response: As previously stated, we have waived the requirement that MA organizations offer MA plans for enrollment to all Medicare Part A and Part B enrollees, and have allowed MA organizations to create plans that exclusively enroll employer/labor group members. The authority for such waivers is contained in section 1857(i) of the Act and does not apply to individuals entitled to Medicaid. Note that section 1857(i) of the Act waiver authority is exclusive in its application to employees or former employees of an employer, or members or former members of a union, or a combination thereof. Waivers for individuals entitled to Medicaid are not provided for under the waiver authority in section 1857(i) of the Act. SNPs for Medicaid eligibles are authorized in section 231 of the

MMA. Finally, note that § 422.106(a) and (b) do not discuss employer/labor groups in the context of section 1857(i) waiver authority. Regulations related to employer/labor group waiver authority are exclusively discussed in § 422.106(c) and (d).

Comment: A number of commenters asked whether CMS would apply the new waiver authority in section 222(j)(2) of the MMA to AI/AN beneficiaries. The commenters stated that such a waiver might permit I/T/Us to sponsor MA plans exclusively designed for AI/AN beneficiaries.

Response: Section 222(j)(2) of the MMA added a new paragraph to the Act at section 1857(i)(2). This new provision created the opportunity for directly-sponsored employer/labor group MA plans. Section 1857(i) of the Act waiver authority is exclusive in its application to employees or former employees of an employer, or members or former members of a union, or a combination thereof. Waivers for AI/AN beneficiaries are not provided for under the waiver authority provided in section 1857(i) of the Act.

Comment: One commenter, in relation to a comment on § 422422.560 through § 422.626 (subpart M), recommended that CMS include benefits that are separately negotiated between the MA organization and an employer/labor group in the benefits governed by the MA regulations and therefore subject to the MA appeals and grievance processes.

Response: This comment has been addressed at greater length in the subpart M preamble. However, it is important to note that for purposes of subpart C, separately negotiated benefits between MA organizations and employer groups, labor organizations, and Medicaid (and as discussed in § 422.106(a)(a) and (b)) are not part of any MA plan. Such employer/labor/Medicaid benefits are discussed only in terms of the fact that they complement the benefits of an MA plan.

Comment: A commenter requested CMS to clarify that employer groups or labor organizations that become MA organizations may retain the services of entities to assist in the development and operation of the employer-sponsored MA plan. The commenter asked CMS to implement the waiver authority under Section 1857(i)(2) of the Act in a way that does not inadvertently hinder the efficient operation of support services for employer groups and labor organizations.

Response: We agree with the commenter that our waiver authority under 1857(i)(2) of the Act should be applied to allow employers and labor organizations to offer MA plans through arrangements with entities (such as existing MA organizations) that will facilitate the offering and efficient operation of such MA plans. We have revised § 422.106(d) to clarify this point and to clarify that, as provided in section 1857(i)(2) of the Act, we may exercise this authority on our own initiative as well as upon written request from an applicant. In each case, as specified in § 422.106(d)(3), our waivers and modifications will apply to all similarly situated MA plans.

Comment: A few commenters asked for specific waivers. Some commenters recommended waivers already provided, such as a waiver that would allow MA organizations to create separate MA plans solely for employer/labor group members.

Response: As we have done in the past, we will continue to provide specifics on approved waivers in guidance and in direct communication with waiver recipients, rather than in formal rulemaking.

7. Medicare Secondary Payer (MSP) Procedures (§ 422.108)

Section 232 of MMA amended section 1856(b)(3) of the Act to remove all ambiguity related to State authority over the MA program. The Congressional intent is now unambiguous in prohibiting States from exercising authority over MA plans in any area other than State licensing laws and State laws relating to plan solvency. We proposed to amend § 422.108(f) to remove language that suggests States can limit the amount an MA organization can recover from liable third parties under Medicare secondary payer procedures.

We received no comments on this section, so we finalize it as proposed.

8. Effect of National Coverage Determinations (NCDs) (§ 422.109)

Section 1853(c)(7) of the Act requires us to ''adjust'' MA payments when a national coverage determination (NCD) or legislative change in benefits will result in a significant increase in costs to MA organizations sponsoring MA plans. We historically interpreted what constituted ''significant'' costs in regulation at § 422.109, where the costs of a coverage change are considered ''significant'' if either the average cost of providing the service exceeds a specified threshold, or the total cost for providing the service exceeds an aggregate cost threshold.

In a final rule published in the **Federal Register** on August 22, 2003 (68 FR 50839), we amended § 422.109 to refine the definition of ''significant'' cost to include a new test. By adding a new paragraph at the end of § 422.109(a)(2), we provided that, for purposes of determining whether to make an additional payment adjustment under § 422.256, the tests for reaching the ''significant'' cost threshold were to include the aggregate costs of all NCDs and legislative changes in benefits made in the prior calendar year.

Under that new test, the ''average cost'' of every NCD and legislative change in benefits for the contract year would have been added together. If the sum of these average amounts exceeded the threshold under § 422.109(a)(l), then an adjustment to payment would have been made in the following contract year under § 422.256 to reflect this ''significant'' cost. Alternatively, if the costs of the NCDs and legislative changes in benefits, in the aggregate, exceeded the level set forth in § 422.109(a)(2), an adjustment to payment would also have been made under § 422.256 on that basis.

Among the reasons for the above change was that even when the ''significant'' cost threshold had been met under the existing definition, the methodology then employed for making a payment adjustment under section 1853(c)(7) of the Act did not result in an adjustment in the capitation rate in those counties with the ''minimum'' update rate (the ''2 percent minimum update'' counties paid under section 1853(c)(l)(C) of the Act.) In accordance with section 1853(c) of the Act, the CMS Office of the Actuary (OACT) used the annual growth rate to update only the floor and blended rates, so the ''minimum'' 2 percent update rate, which was 102 percent of the prior year's rate, did not reflect the costs of new benefits effective in the middle of the previous payment year. Therefore, we decided that payments in counties in which payment was based on the ''minimum'' 2 percent update rate were not appropriately adjusted to reflect new coverage costs as required by section 1853(c)(7) of the Act.

The MMA changed the ''minimum'' percentage payment prong of the former M+C payment methodology by adding a new basis for a minimum update. The ''minimum'' percentage increase rate is changed, effective January 2004, as follows: Instead of being set at 102 percent of the prior year's rate, the minimum increase rate will now be the greater of 102 percent of the prior year's rate, or the annual MA growth percentage. This means that under the MMA payment methodology, the minimum percentage increase will now reflect the cost of mid-year NCDs and legislative changes in benefits. These

costs are now automatically built into the annual MA growth percentage and will no longer require an additional adjustment under § 422.256.

As a result of these MMA changes to the MA payment methodology we proposed in the August 3, 2004 proposed rule to remove the portion of § 422.109(a)(2) after § 422.254(f).

We also proposed clarifying language in § 422.254(f) and § 422.109(c)(3).

We received no comments on this section, so we finalize it as proposed.

9. Discrimination Against Beneficiaries Prohibited (§ 422.110)

We proposed to correct § 422.110(b) to bring it into conformance with § 422.50(a)(3)(ii). Specifically, we proposed to modify the language of § 422.110(b) to state that if an MA organization chose to apply the rule in § 422.50(a)(3)(ii), and allowed individuals who are enrolled in a health plan at the time of first entitlement to Medicare, but residing outside the MA plan's service area to remain enrolled, the MA plan must also allow this for individuals with ESRD.

We also proposed to remove § 422.110(c), since it is duplicative of a requirement now appearing in § 422.502(h).

We received no comments on this section, so we finalize it as proposed.

10. Disclosure Requirements (§ 422.111)

Section 1851(d)(2)(A) of the Act and § 422.111(d)(2) establish disclosure requirements. MA plans must provide notice to plan members of impending changes to plan benefits, premiums, and copays in the coming year so that plan members will be in the best position to make an informed choice on continued enrollment in or disenrollment from that plan. We proposed to amend this section to reflect that notice must be provided at least 2 weeks before the Annual Coordinated Election Period commences, instead of listing a specific date in order to provide flexibility in the event that the beginning date of the Annual Coordinated Election Period changes in the future.

We also proposed to remove § 422.111(f)(4), as the requirement to provide information on Medigap and Medicare Select plans is a Secretarial responsibility under section 1851(d)(2)(A)(i) and (d)(3)(D) of the Act and is to occur as part of the ''open season notification'' required by section 1851(d)(2)(A) of the Act.

In addition to an ''open season'' notification, information on Medigap and Medicare Select is available year-round from the Federally funded SHIP and the 1–800 MEDICARE telephone number. Both the local SHIP and the 1–800 MEDICARE telephone numbers are prominently displayed in MA plan literature. In addition, we stated that we would continue to require MA plans to publicize the availability of information on Medigap, Medicare Select, and other MA plans through appropriate CMS information channels (for example, *www.Medicare.gov*, 1–800–MEDICARE). This not only would remove an unnecessary administrative burden, but also would ensure that reliable, accurate, and complete information is made available to those seeking it.

To accomplish the above proposed changes, we proposed conforming organizational changes to § 422.111. We also proposed the following disclosure requirement changes:

- We removed the requirement that MAs and MSAs provide comparative information related to other MA plans.
- To prevent what might otherwise be the unreasonable result that MA regional or national plans would be required to provide comprehensive lists of contracting providers to all enrollees, we modified paragraph (b)(3). (We specifically proposed to require MA organizations, however, to provide information on contracted providers in other parts of the plan's service area upon request in § 422.111(f)(10). Note that we changed the specific wording of this paragraph to more plainly express our intent and in response to comments, as described in further detail below.)
- We modified paragraph (b)(3) to read: ''The number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services;≥
- We added a new paragraph (f)(10), which reads: ''The names, addresses, and phone numbers of contracted providers from whom the enrollee may obtain in-network coverage in other parts of the service area.''
- At § 422.111(b)(11), we proposed to require MA regional plans to provide members an annual description (at the time of enrollment and annually thereafter) of the catastrophic stop-loss coverage and single deductible (if any) applicable under the plan.
- We changed the existing paragraph (f)(11) (the new paragraph (f)(9)) related to supplemental benefits.
- We also said that we were considering a requirement that all MA organizations sponsoring MA plans would be required to maintain plan-specific information on Internet web sites. We discuss this in more detail below.

In § 422.112(a)(1)(ii), we provide an ''exception'' to the requirement in § 422.112(a)(1) related to contracted provider networks in MA regional plans. We received a number of comments on this ''exception'' and address them later in this section of the preamble. We also explain later in this preamble why we are establishing a new beneficiary notification requirement related to enrollees of MA regional plans in § 422.111(b)(3)(ii). This new MA regional plan notification requirement is intended to parallel a similar OPM requirement imposed on the FEHB Blue Cross and Blue Shield Basic Option plan, which addresses similar circumstances and situations encountered by Federal employees and annuitants when seeking health care.

We have added a new paragraph to the regulation at § 422.101(b)(5) that will require MA organizations that elect to apply local coverage policies uniformly across a local MA plan's service area, or across an MA regional plan's service area, to inform enrollees and potential providers of the applicable local coverage policy that applies to the MA plan enrollees. We make conforming changes to § 422.111.

Comment: A commenter recommended that CMS explicitly state in the disclosure requirements related to MA plans that there were additional disclosure requirements under Part D with which MA-PD plans would also need to comply.

Response: We accept this comment. Although such a requirement is implicit in § 422.111(a)(2), where we require MA plans to disclose the ''benefits offered under the plan,'' we will explicitly state the requirement at § 422.111(a)(2). To the extent an MA plan offers Part D to its MA enrollees as an MA-PD plan, it will also be required to follow the disclosure requirements in § 423.128 related to the disclosure of its Part D offering.

Comment: A commenter recommended that CMS more directly address the ''free access'' MA enrollees have to Medicare hospice services and the fact that MA enrollees have the right to continue to receive non-hospice services, unrelated to the terminal illness, from the MA plan. The commenter wanted to ensure that MA enrollees knew that they could continue to receive from the MA plan non-hospice services unrelated to the terminal illness, as long as enrollees remain members of the plan.

Response: We do not believe a specific disclosure requirement of the type the commenter requests is necessary because our existing regulations already require disclosure of Medicare hospice availability, rules related to receipt of care, and financial responsibility, in § 422.111(b)(2)(iii) and

§ 422.320(a) (formerly codified at § 422.266(a)). Otherwise, because non-hospice benefits of an MA plan continue to be available after hospice election and while an individual remains enrolled in an MA plan, such availability must be disclosed under § 422.111(b)(2).

Comment: Several commenters recommended that CMS require MA organizations to inform beneficiaries about their benefits or restrictions on those benefits. For example, one commenter suggested providing information on the average number and type of home health visits per episode that were covered by an MA plan during the prior year and beneficiaries' average cost sharing; the names of home health providers in the plan's network and the number of years the provider has operated as a Medicare home health agency.

Response: We agree that disclosure of MA plan benefits continues to be an important feature that permits beneficiaries to make informed decisions on enrollment. As previously stated, MA plans are obligated to disclose information on benefits, including applicable conditions and limitations on their receipt, the plan premiums, and the cost sharing related to specific benefits when obtained both in- and out-of-network. We also require MA organizations to disclose information on the number, mix, and distribution (including addresses) of providers from whom enrollees may obtain services. These disclosure requirements are described in regulation at § 422.111 and have not materially changed. Although MA plans are not required to specify the average number of visits or types of visits per episode from the prior year, as the comment suggests, the plans are required to provide all covered home health services, which include, at a minimum, the Medicare FFS level of benefits. We will not require MA plans to specify the number of years a home health agency has operated, nor the other specifics that the comment suggests because this would impose an additional burden upon plans that we think in unnecessary in light of the existing ways in which beneficiaries can obtain such information.

The requirement that a plan disclose the name(s) and address(es) of the contracting home health agency or agencies is already set forth in our regulations at § 422.111(b)(3), redesignated as subparagraph (i). The additional information about which the commenter suggests requiring disclosure may be available, upon request, from either the MA plan or through a direct request to the contracting home health agency or agencies.

Comment: Several commenters noted the deletion of the word ''written'' from the first sentence of § 422.111(e). One commenter stated that removing the word might allow an MA organization to meet this disclosure requirement by simply posting information on its web site.

Response: The deletion of the word ''written'' was unintentional. We have reinserted it in the regulations text at § 422.111(e). We will continue to require MA organizations to make a good faith effort to notify members in writing of changes in provider networks.

Comment: A commenter recommended that we convey the language in § 422.111(f)(10). The commenter asked if the intent of paragraph (f)(10) was to complement the requirement in § 422.111(b)(3)(i) that routine disclosure of contracting providers was limited to those from whom an enrollee would ''reasonably be expected to obtain services.'' The commenter suggested that the language in paragraph (f)(10) was imprecise, if that was our intent, since it required disclosure, upon request, of other providers ''in other areas,'' although we may have actually meant to convey the disclosure, upon request, of contracted providers ''in other parts of the service area.''

Response: We agree with this comment and have corrected the language in § 422.111(f)(10). Our intent was to make information on the availability of other contracted providers in other parts of the service area of the MA plan available to plan enrollees upon request, to the extent such information was not provided at the time of enrollment, because of the large geographic area encompassed within the service area of the MA plan.

Comment: Some commenters opposed the deletion of § 422.111(f)(7)(i) through (iv) that eliminates the requirement that MA PFFS and MSAs plans provide comparative information related to other MA plans that are available in the geographic area in which the PFFS and MSAs plans are offered. These commenters stated that potential MA enrollees should be able to easily see how these plans compare to other MA plans and original FFS Medicare.

Response: We agree that individuals considering enrollment in an MA MSA or PFFS plan should have comparative information regarding their choices for receiving Medicare coverage. All MA plans, including MA MSA and PFFS plans, must continue providing comparative information on FFS Medicare through pre-enrollment materials including the Summary of Benefits. The Summary of Benefits contains a matrix that provides a comprehensive comparison of the benefits of an MA plan with the benefits of original FFS Medicare. As we discussed in the August 3, 2004 proposed rule, we believe that the *Medicare and You Handbook* in conjunction with other CMS information channels (such as the 1–800 MEDICARE call center and direct beneficiary counseling provided through federal SHIP grants to the states) provides the best opportunity for Medicare beneficiaries considering MA plan enrollment to receive clear, impartial, and complete information on the choices available to them. Therefore, we will delete these requirements, as they represent an unnecessary administrative burden on MA MSA and PFFS plans.

Comment: Some commenters suggested including a provision in § 422.111(e) that would allow AI/AN to switch to another MA plan whenever there is a change to the provider network of the MA plan in which the AI/AN is enrolled.

Response: We cannot accommodate this request because there is no statutory basis for differentiating between AI/AN and non-AI/AN beneficiaries. However, to the extent that conditions in § 422.62(b), where special election periods are discussed, are present for *any* MA plan enrollee, the opportunity to switch plans or to return to original FFS Medicare is available.

Comment: One commenter recommended that CMS remove the annual requirement for distribution of network provider directories. The commenter stated that for a vast majority of enrollees, the provider directory is not referenced and the information could more reasonably be made available on an ''as requested'' basis after initial provision upon enrollment.

Response: Under section 1852(c)(1)(C) of the Act, MA organizations are required to provide annually, in clear, accurate and standardized form, detailed information about the number, mix and distribution of plan providers. We have interpreted this requirement in regulations to include annual disclosure of plan providers' addresses.

Comment: Most commenters supported the new language in § 422.111(b)(3)(i). A few commenters recommended that CMS define or explain the statement, ''MA organizations would be responsible for providing the number, mix and addresses ''of providers from whom

enrollees may reasonably be expected to obtain services.'' One commenter suggested that the language was unclear, subject to broad interpretation and would result in confusion and an inconsistent application by MA organizations.

Response: We believe that the standard of ''reasonable'' disclosure of network providers is both appropriate and sufficiently clear within our current regulatory standards. We believe that MA organizations are in the best position to determine what would be ''reasonable'' in this context, based on service usage and community patterns of care. In order to preserve flexibility for MA organizations to provide information appropriate to the needs of their enrollees, we do not intend to change the proposed language in § 422.111.

Comment: A number of commenters recommended that CMS apply special disclosure requirements to AI/AN beneficiaries, stating that such special disclosure requirements should include a right by AI/AN beneficiaries to select another MA plan at any time without penalty.

Response: We cannot accommodate this request because there is no statutory basis for differentiating between AI/AN and non-AI/AN beneficiaries.

Internet

In the August 3, 2004 proposed rule, we asked for comments on whether or not we should require all MA organizations for all MA plans they offer to set up an Internet web site that would make basic MA plan information and materials available to interested Medicare beneficiaries and other parties. The basic information and materials could include the Evidence of Coverage, the Summary of Benefits, and information (names, addresses, phone numbers, specialty) on the network of contracted providers. Those Internet materials and information would duplicate materials already produced in print format and made available by MA organizations relative to the MA plans they offer.

Comment: Many commenters stated that it would be difficult for providers to know whether an MA organization had chosen to adopt one of the uniform coverage policies in § 422.101(b)(3), related to local MA plans, or § 422.101(b)(4)—related to MA regional plans.

Response: As we discuss at more length earlier in this preamble related to § 422.101(b)(3) and (b)(4), we agree with this comment and therefore have added a requirement at § 422.111(f)(11) that MA organizations must make uniform coverage policies related to an MA plan readily available to members and providers, including through the Internet.

Comment: Many commenters were supportive of the proposed requirement that all MA organizations provide basic materials, such as the Evidence of Coverage, Summary of Benefits, and information (names, addresses, phone numbers, specialty) on the network of contracted providers. Some commenters suggested that CMS not be overly prescriptive in the requirements for what MA organizations post to a web site. Some suggested that the provision of information over the Internet should relieve MA organizations of their responsibility to provide identical information to enrollees in hard-copy format. One commenter suggested that CMS make plan enrollees ''opt-in,'' if they want plan information sent to their homes.

Other commenters stated that most Medicare beneficiaries do not have access to the Internet, and that regardless of whether an MA organization provides plan information electronically, we should continue to require MA organizations to send enrollees required information through the mail. One commenter stated that it did not want its member handbook or Evidence of Coverage to appear on the Internet. The commenter stated that it would prefer to have the documents available only to members. Other commenters stated that requiring an MA organization to duplicate materials such as the Evidence of Coverage or the Summary of Benefits on the Internet would be administratively redundant, costly, and burdensome to maintain. One commenter suggested leaving the decision on an Internet web site to the discretion of the MA organization. This commenter stated that although it supports use of the Internet, MA organizations should not be required to post specific documents to the Internet, since they are already provided to enrollees in hard copy.

Response: Based on these comments, we will be as flexible as possible, while still ensuring that beneficiaries receive the information necessary to make informed choices. We will require MA organizations exercising options under § 422.101(b)(3) or (b)(4) to communicate, via the Internet and through other means, the fact that a specific local coverage determination is in effect for its plan members. We have placed this requirement at § 422.111(f)(11). Use of the Internet in this way will ensure that potential providers have access to plan coverage information to the extent that it differs from the Medicare coverage policy in the geographic area in which the provider is actually treating an MA plan enrollee. Similarly, we will require MA organizations that have Internet web sites to post the Evidence of Coverage, the Summary of Benefits, and information on the network of contracted providers at § 422.111(f)(12). Because we apply this requirement only to organizations that otherwise maintain Internet web sites, we do not believe that such a requirement is overly burdensome or that it will entail a significant administrative effort. In addition, because the Evidence of Coverage and the Summary of Benefits do not change during the course of a calendar year, maintaining or updating the information in them will be a once-a-year activity, which will coincide with the update of the hard copy version of these documents. Updating of the provider directory might entail additional administrative effort; however, to the extent that MA organizations are already required to update provider information in written materials, we do not believe that extending this requirement to an electronic version of the same document would entail a great deal of additional administrative effort.

In response to the commenters that asked if the use of Internet versions of required documents would eliminate (or mitigate) the requirement for hard copy documents, we have added a final sentence to § 422.111(f)(12) that states that we will maintain our current requirement that MA organizations provide to enrollees written, hard copy materials providing information at the time of enrollment and annually thereafter as required by § 422.112(a) and (b). Most Medicare beneficiaries do not routinely use the Internet. To the extent they do and do not wish to receive hard copy plan materials, they can and will indicate such a preference. In response to commenters who did not believe it appropriate to post plan materials to the Internet, we respond that we believe it is an important feature of beneficiary choice to be fully informed regarding the benefits and features of an MA plan *before* enrollment. Plan materials, including the Evidence of Coverage, the Summary of Benefits, and a list of contracting providers are essential pre-enrollment materials that allow Medicare beneficiaries an opportunity to compare MA plans and to make an informed decision on enrollment.

11. Access to Services (§ 422.112)

There are no new access standards for MA regional plans, and existing MA standards will generally apply. We

reviewed our existing regulatory requirements related to network adequacy and proposed to remove some that are either duplicative or, in our view, overly onerous. We stated we expected competition to be the best method for ensuring network adequacy, as enrollees will favor and enroll in plans with more extensive networks and tend to avoid those without. Furthermore, Medicare beneficiaries can always choose to remain enrolled in the original Medicare FFS program.

We proposed to remove or modify some the requirements from § 422.112 of the regulation, none of which were required by statute, and some of which became unnecessary as they were replaced or superseded by requirements in the MMA:

- We proposed to delete § 422.112(a)(4), because we believed it would be redundant to suggest a specific approach to quality improvement activities in the context of, and as a means of ensuring, enrollee access to care. After reviewing and responding to comments (below), we will implement as proposed and delete § 422.112(a)(4).
- We proposed to remove the written standards requirements in § 422.112(a)(7) since they were duplicative of other provisions in the regulation. Based on a comment we received, we will not delete the requirement.

In the final rule we make editorial corrections to § 422.112(a) heading and introductory text to remove reference to ''network M+C MSA plans'' and ''additional'' services, neither of which terms have relevance in the MA program.

Comment: We received a few comments related to our proposal to remove requirements in § 422.112(a)(7). One commenter asked us to articulate what tools, other than written standards, an MA plan should use to ensure adequate access to medically necessary health care items and services. Other commenters objected to removal of written standards.

Response: Written standards are simply one aspect of an MA coordinated care plan's guarantee of access to care. Such written standards do not, in and of themselves, constitute a sufficient guarantee of access to care. To the extent that written standards are not enforced, they guarantee little. However, we agree with the commenters and believe that the requirement for written standards will, at the very least, prompt plans to affirmatively address and memorialize how they intend to provide access to care. In light of the comments we received and upon further consideration, we will retain the requirement for written access standards in § 422.112(a)(7).

Comment: One commenter recommended that CMS modify the rules to create waivers that would allow ESRD patients to be referred to nephrologists, dialysis centers, or vascular surgeons who are out-of-network if the patient prefers another physician or center, or if the referring nephrologist believes that the vascular access outcomes would be better with the out-of-network surgeon. The commenter also suggested allowing self-referrals to specialists, such as allowing ESRD patients to self-refer to nephrologists, dialysis centers, or vascular surgeons who were out-of-network. Another commenter suggested including certain benefits in the MA benefit package, such as medical nutrition therapy (MNT) benefits for diabetes and renal diseases.

Response: To respond to the first comment on the provision of benefits to ESRD beneficiaries out-of-network, PPOs are a type of coordinated care plan, as described in § 422.4(a)(1)(iii), that are required to provide reimbursement for all covered benefits regardless of whether they are provided in- or out-of-network. Therefore, a beneficiary with ESRD who is enrolled in an MA PPO plan may go out-of-network for all covered services, albeit with a potentially higher cost-sharing liability. Coordinated care plans are permitted to use mechanisms to control utilization, such as requiring referrals from a ''gatekeeper'' PCP, before an enrollee can receive in-network specialty services at in-network cost sharing levels, as codified in regulations at § 422.4(a)(1)(ii)and § 422.112(a)(2). Therefore, access to a specialist at in-network cost-sharing levels can generally be limited to contracted providers in coordinated care plans. When an individual beneficiary chooses a coordinated care plan, information is available about the availability of providers, including specialists, and under what conditions they are available in-network. Information on the routine availability of out-of-network care (either because the plan is an HMOPOS or a PPO, for instance) is also provided at the time of enrollment and annually thereafter. On the second point related to requiring MNT benefits for diabetes and renal diseases in MA plans, we remind the commenter that all MA plans are required to include all Medicare FFS benefits in their MA plan benefit packages.

Comment: One commenter recommended that CMS require all MA plans to include podiatric physicians in their networks to ensure that the necessary and vital services provided by these physicians continue to be available to patients. The commenter stated that § 422.205(a) prohibits MA organizations from discriminating against providers on the basis of license or certification.

Response: We do not see a basis for requiring MA organizations to contract with a specific provider type. As the commenter stated, our existing regulations prohibit discrimination on the basis of license or certification. Further, our existing regulations, as amended in this final rule, require MA organizations to ensure that covered services are available and accessible within an MA plan's network consistent with applicable access standards. However, § 422.205(b), which is not being amended in this rule, allows MA organizations to refuse to grant participation to health care professionals in excess of the number necessary to meet the needs of an MA plan's enrollees (with the exception of PFFS plans).

Comment: One commenter agreed that the requirements in § 422.112(a)(4) are duplicative of the proposed chronic care improvement requirements in § 422.152(c), and therefore generally agreed that it should be deleted. However, the commenter also stated that deletion of requirements at § 422.112(a)(4) should be made contingent on our addition of a requirement in § 422.152(c) that chronic care improvement programs be based on objective and evidence-based criteria, such as clinical practice guidelines.

Response: We address comments related to § 422.152(c) in the subpart D section of the preamble (below). Because chronic care improvement programs will be regulated under the provisions in subpart D of the 42 CFR part 422, we believe it remains appropriate to delete regulatory requirements concerning complex or serious medical conditions from § 422.112(a)(4).

Comment: One commenter asked whether access to covered MA plan services can be denied, if the MA plan enrollee does not pay plan required cost sharing at the time of service.

Response: The MA organization's responsibility for provision of plan covered services supersedes the member's responsibility for payment of cost sharing at the time of service. Therefore, the MA organization cannot deny provision of a medically necessary covered service for want of the payment of applicable cost sharing at the time of service.

Comment: One commenter stated that CMS should add a provision in the regulation that would apply section 1861(s)(2)(H) of the Act to MA plans offered by MA organizations.

Response: We do not agree. Both section 1861(s)(2)(H)(i) and (ii) of the Act are specific in their applicability to contracts under section 1876 of the Act. Contracts with MA organizations for MA plans are under section 1857 of the Act.

Continuity of Care

Section 422.112(b) requires all MA organizations for all MA plans they offer to ensure continuity of care through integration of health care services. Additional requirements in § 422.112(b)(1) through (b)(6) require specific methods by which MA organizations are to ensure an effective continuity and integration of health care services. Although all of the enumerated services and processes are clearly desirable, it is not as clear that the responsibility for them is appropriately or reasonably placed on organizations whose business is primarily insurance coverage. Although it may be reasonable to expect coordinated care plans to undertake these coordination, continuity, and integration requirements, it is less clear that MA PFFS plans, MSAs, and (to a lesser extent) local PPO plans and MA regional plans (which will be offered as PPOs) should also be expected to. One might argue that continuity of care rules cannot apply in the same manner to MA plans in which the enrollee is free to choose his or her own providers without restraint, such as MSAs and PFFS plans. We stated that we were considering eliminating most of the requirements in § 422.112(b) for MSAs and PFFS plans. We also stated that we were considering eliminating or modifying many of the requirements in § 422.112(b) for local PPOs and regional MA plans. Finally, we stated that we were considering the continued appropriateness of these continuity of care standards for all other coordinated care plans. We specifically welcomed input on the extent to which requirements similar to those in § 422.112(b)(1) through (b)(6) are established for commercial health insurers offering HMOs, PPOs or indemnity plans.

Based on comments we received, we will continue to apply existing continuity of care requirements in § 422.112(b)(1) through (b)(6), but we will limit their scope of applicability to coordinated care plans and then only to the services provided and coordinated by contracted, network providers.

Comment: Many commenters provided input on this issue. A large number of commenters stated that continuity of care and integration of services is a key aspect of managed care. To the extent the original FFS Medicare program has been perceived to be deficient in this aspect of health care delivery, many commenters believe that CMS should ensure that a similar ''failure'' in managed care is not allowed. A number of commenters supported the removal of continuity of care requirements related to MA MSA and PFFS plans in recognition of the fact that these types of MA plans are primarily in the business of paying claims and not in the business of coordinating health care through contracted networks of health care providers. Other commenters stated that it was especially for MA plans that did not have contracted provider networks, such as PFFS plans or MSA plans, that continuity of care requirements were most needed.

Some commenters agreed with CMS proposal to eliminate and/or reduce continuity of care requirements for open network MA plans, such as PFFS plans and PPO plans. Other commenters suggested removing all continuity of care requirements for all MA plans, saying that such requirements were duplicative of QI program activities required under section 1852(e) of the Act.

Response: Based on the comments, and because PPOs operate as both coordinated care plans and ''open network'' plans at the same time, we will modify this portion of the regulation. We will specify in § 422.112(b) that the enumerated coordination of care requirements in § 422.112(b)(1) through (6) are applicable only to coordinated care plans. We will also limit applicability of coordination of care requirements to only contracting, in-network providers, thus limiting applicability for MA PPOs to only those services provided by contracted providers. We believe such an approach strikes the appropriate balance between the need for coordination and continuity of care and the burden associated with seeking to undertake such activities in the absence of contractual relationships with providers.

Finally, we do not agree that continuity of care requirements are duplicative of QI program activities required under section 1852(e) of the Act. QI activities will generally and primarily be focused on individuals with multiple or severe chronic conditions. Access to an initial health assessment, on the other hand, as provided in § 422.112(b)(4)(i), should include all enrollees of an MA coordinated care plan, and not only those with multiple or severe chronic conditions.

Comment: A few commenters stated that CMS appeared to be deleting a paragraph (i) from paragraph (b)(4) in the regulations text at § 422.112, but had no corresponding discussion in the preamble of the proposed rule.

Response: We thank the commenters for identifying this oversight and have corrected the regulations text related to § 422.112(b)(4) to show that none of the subparagraphs is to be deleted and that renumbering is unnecessary.

Access ''Exception'' for MA Regional Plans

The MMA created a special access rule for MA regional plans in the form of an ''essential hospital'' payment. Section 1858(h) of the Act and implementing regulations related to ''essential hospitals'' are discussed in greater detail later in this section of the preamble.

We noted that in attempting to create region-wide networks, MA regional plans will be forced to bargain with hospitals that may be the only hospital (or the only hospital with a particular service or services) in a broad area. We believed that such a hospital would have a ''monopoly power'' in negotiating with plans that are, in effect, forced to contract with it in order to secure an adequate network of contracted providers with which to serve anticipated Medicare enrollees. The MMA attempted to partly address this situation through a provision that would make limited funds available to supplement payments to such ''essential hospitals.'' We proposed an additional special access requirement that also would only apply to MA regional plans at § 422.112(a)(1)(ii).

In § 422.112(a)(1)(ii), we proposed an ''exception'' to the normal access requirements that would otherwise apply to MA regional plans by adding language that provided for a relaxation of comprehensive network adequacy requirements, but only to the extent that beneficiaries were not put ''at risk'' for high cost sharing related to services received from non network providers. We believed that flexibility did not need to apply on a plan-wide basis, but rather could be applied in a county or a portion of a region where, for example, the MA regional plan was unable to secure contracts with an adequate number of a specific type of provider or providers to satisfy our comprehensive network adequacy requirements that

would otherwise apply to coordinated care plan models.

We considered two forms of beneficiary cost sharing. One was the cost sharing related to a specific item or service—for instance, a hospital coinsurance charge. Another was the ''catastrophic limits'' that MA regional plans must apply to original Medicare FFS benefits. MA regional plans are required to provide reimbursement for all covered benefits regardless of whether those benefits are received from network providers (see section 1859(b)(4)(B) of the Act and the new § 422.101(e)(1)). MA regional plans are also required to apply a catastrophic out-of-pocket limit on beneficiary cost sharing for covered in-network services and another on all covered services (in and out-of-network). See section 1858(b)(2)(B) of the Act and the new § 422.101(d)(2) and (d)(3).

We proposed to permit MA regional plans with lower out-of-network cost sharing to have less robust networks of contracted providers and to permit MA regional plans with more robust networks of contracted providers to impose higher cost sharing charges for out-of-network services. This was because to the extent the plans' networks were robust, we would not expect beneficiary access to be unduly limited by higher cost-sharing requirements when care was sought from non-network providers. However, for plans with less robust networks, we proposed to limit the plans' ability to impose higher cost-sharing requirements for out-of-network care. We believed that higher cost-sharing requirements imposed by plans with limited provider networks could unduly limit access and that more equitable cost-sharing requirements would serve as a safety valve to ensure that beneficiary access is not compromised. We discussed various methods for testing the robustness of MA regional plan provider networks. Along similar lines, we would require MA regional plans with a less robust network of contracted providers to have ''catastrophic limits'' on out-of-pocket expenditures for in-network and for all services that are closer in value. For plans with more robust contracted networks, we would allow the in-network and total ''catastrophic limits'' to differ to a greater degree.

Based on the comments we received and which we respond to (below), we will not be prescribing specific levels of cost sharing based on robustness of contracted provider networks. Rather, we will require MA organizations sponsoring MA regional plans to ensure enrollees have access to in-network levels of cost sharing for covered services. We will require MA organizations sponsoring MA regional plans to reduce cost sharing to in-network levels for the receipt of out-of-network services in cases in which covered services cannot be readily obtained from contracted, network providers.

In this part of the preamble of the proposed rule we also discussed the OPM requirement imposed on the FEHB Blue Cross and Blue Shield Basic Option plan, which addresses similar circumstances and situations encountered by Federal employees and annuitants when seeking health care. We stated that the ''exception'' process related to access to care requirements for MA regional plans might require the MA regional plan enrollee to contact the sponsoring MA organization when seeking a specific service that is not otherwise available from a contracted provider. We are adopting that proposal. We will require MA organizations sponsoring MA regional plans to designate a non-contracted provider from whom (or from which) the enrollee can obtain covered services at network cost-sharing levels, to the extent that such services are not available and accessible from a contracted, network provider. Alternatively, the MA organization can allow the enrollee to seek the service from any qualified provider and guarantee that in-network cost sharing limits will apply. We have established a new beneficiary notification requirement related to enrollees of MA regional plans in § 422.111(b)(3)(ii). We add this requirement to ensure that the access ''exception'' in § 422.112(a)(1)(ii) does not disadvantage beneficiaries seeking in-network care.

Comment: Several commenters were received on this proposed provision. Many of the commenters suggested that the ''exception'' should also apply to all local MA coordinated care plans, or even all local MA plans, while others suggested limiting it to local and MA regional PPOs.

Response: Local MA plans of all types have discretion to limit their service areas based on their network of contracted providers. Unlike local MA plans, MA regional plans are required, as a condition of offering an MA regional plan, to include the entire geographic area of an MA region in the service area of the plan. In some ways, the ''exception'' we provide at § 422.112(a)(1)(ii) for MA regional plans is comparable to the ''partial county'' provision provided for local MA plans in the service area definition at § 422.2. Under § 422.2, we permit an MA organization to contract with CMS for a local MA plan where the organization has a contracted network in only a portion of a county and when such a ''partial county'' is necessary, nondiscriminatory, in the best interests of the beneficiaries and where other conditions are met. We will also permit MA organizations to contract with CMS for an MA regional plan where beneficiaries are not put ''at risk'' even though the MA organization does not have contracts with robust networks of providers throughout the MA region. For these reasons, it is both inappropriate and unnecessary to provide such an ''exception'' for local MA plans.

Comment: Other commenters were opposed to allowing an ''exception'' to the normal access to care requirements to any MA coordinated care plan, including MA regional plans. One commenter suggested limiting the ''exception'' to only an initial start-up period, the first contract year, for instance even for MA regional plans.

Response: As noted above, we believe the ''exception'' we proposed for MA regional plan access to care requirements is essential to foster the growth of the MA regional plan program, a goal consistent with the Congressional intent in creating the program. We are concerned that in the absence of this ''exception,'' the provisions we discuss below related to beneficiary access to ''essential hospitals'' would not be sufficient to allow MA regional plans to meet access to care requirements for coordinated care plans.

The ''exception'' we provide at § 422.112(a)(1)(ii) is necessary because ''essential hospitals'' will not be contracting with MA organizations for MA regional plan members, but will be a necessary part of the MA regional plan's network in order for the MA regional plan to meet the applicable provider access requirements under section 1852 of the Act. Section 422.112(a)(1)(ii) acknowledges that some providers, such as ''essential hospitals,'' will not have a contract, but will be considered part of the network because they will be providers at which beneficiaries can seek care at in-network cost sharing levels. We do not believe it is appropriate to limit the ''exception'' to an initial start-up period, particularly because the ''essential hospital'' provision is not so limited. On the other hand, we agree that it would be appropriate to annually evaluate the ''subsection d'' hospitals that have been designated as ''essential hospitals'' by MA regional plans to ensure that the

conditions that permitted such designation continue to exist.

Therefore, we have added a requirement at § 422.112(c)(7) under which we will evaluate the continued applicability of ''essential hospital'' status on an annual basis at the time of annual contract renewal. Please see below for a more extensive discussion of ''essential hospitals.''

Comment: A few commenters suggested that CMS subject MA organizations offering MA regional plans to review by external entities and the general public to ensure that MA regional plans meet community access standards.

Response: We do not believe a mandatory external review of network adequacy is appropriate because the delay and burden associated with such a process could negate the competitive and market forces that the Congress intended should apply in the regional MA program. Ultimately, such a result could have the very effect the commenters are seeking to avoid, an adverse impact on beneficiary access. Section 1852(e)(4) of the Act provides for a private accreditation organization's external review of MA organizations in specific areas, including access to services. Nothing in section 1852(e)(4) can be construed as imposing mandatory external review on an MA organization of the type the commenters propose. Otherwise, the time frame between an organization's submission of an application for an MA contract year and CMS' approval or denial of that application would be too short to permit sufficient time for a formal, public comment period.

Comment: Many commenters expressed concern that CMS seemed to be relaxing the community access standards with the ''exception'' process we provided for MA regional plans in § 422.112(a)(1)(ii). Some commenters stated that to the extent CMS will pay MA regional plans more through various mechanisms, such as the ''stabilization'' fund, risk corridors in 2006 and 2007, and the new MA payment formula, therefore CMS also has reason to hold them to the same access standards to which CMS holds local MA plans. Other commenters supported the ''exception'' process and suggested that it be extended to local MA PPOs.

Response: As we have previously said, we will not permit local MA coordinated care plans to take advantage of the ''exception'' process in § 422.112(a)(1)(ii). The exception process is necessary precisely because we will require MA regional plans to meet community access standards. We explained in the proposed rule that to the extent an MA regional plan is unable to secure contracts with specific providers in specific areas of an MA region, beneficiaries would nonetheless be protected from excessive out-of-network cost sharing. In other words, it is exactly because we will continue to enforce community access standards that we will require MA regional plans to reduce cost sharing to in-network levels where covered services cannot be readily obtained from contracted, network providers. We establish a new beneficiary notification requirement related to enrollees of MA regional plans in § 422.111(b)(3)(ii) to reinforce this concept.

Comment: Some commenters stated that CMS should require hospitals to treat MA regional plan enrollees when they are offered the Medicare FFS payment rate that is payable under section 1886 of the Act by an MA regional plan, as long as in-network cost sharing levels are applied to enrollees that seek care at such non-contracting hospitals. One commenter stated that sole community hospitals, or hospitals serving medically underserved areas or non-urban areas should be required to treat MA regional plan enrollees if they refused to contract for FFS rates. One commenter recommended that CMS reevaluate the non-discrimination obligation of hospitals under the Medicare program and suggested that CMS establish a policy that would promote access to services at hospitals participating in the Medicare program on the same basis for all Medicare beneficiaries, regardless of whether they are MA enrollees or receiving coverage under the Medicare FFS program. One commenter recommended that CMS develop further regulations that would require providers to treat MA patients in all cases, even for elective services.

Response: We do not necessarily agree that we should establish a policy that would require Medicare participating hospitals to treat MA enrollees or to contract with MA organizations under specific terms or conditions. Were we to establish a specific price relative to FFS inpatient hospital payment rates as a baseline that would compel a hospital to treat MA plan enrollees, for instance, we would also be administering inpatient hospital pricing. We do not believe that a requirement to treat for an administered price is consistent with the overall intent of the MMA to increase plan choices for Medicare beneficiaries through competitive market forces. However, we acknowledge that MA provider contracting, especially in areas where there are few available providers, is a concern. We will continue to evaluate our current authorities outside of the MMA as a means of ensuring reasonable access at reasonable prices to medical services for all Medicare enrollees, including those electing to receive their coverage through an MA plan.

Comment: Some commenters stated that the ''exception'' CMS proposed in § 422.112(a)(1)(ii) would tend to put providers at a disadvantage vis-à-vis MA regional plans. The commenters stated that MA regional plans would offer reimbursement rates below FFS rates and as such, unilaterally dictate the terms of the contract. The commenters stated that this would be unfair to physicians and other providers. The commenters also stated that this would create an unfair playing field, especially because MA regional plan enrollees in such an area would then be required to go out-of-network at higher cost sharing levels, to receive covered medically necessary care.

Response: We disagree. MA regional plans will be required to make all covered services available at in-network cost sharing levels, even if an MA regional plan fails to reach mutually agreeable contracting terms with a specific provider or group of providers. In other words, MA regional plan enrollees will have access to medically necessary covered health services at in-network cost sharing levels. The MA regional plan must meet the access requirements either through contracted providers or through the ''exception'' process discussed above. Because section 1852(a)(2) of the Act requires MA organizations that use a contracted network to pay non-contracting providers at the Medicare FFS rate, once the MA regional plan enrollee pays in-network cost sharing, the MA organization will be financially responsible for the rest.

Comment: One commenter stated that CMS should adopt URAC, NCQA or JACHO standards related to MA PPO network adequacy requirements and privacy of beneficiary information requirements. The commenter stated that for network adequacy requirements and privacy requirements, as for all other federal regulatory requirements, to the extent that any accreditation standard of any of the three accrediting bodies applies to the same activity, compliance should be deemed for the PPO to be in compliance with the federal requirement.

Response: We do not necessarily agree. Under section 1852(e)(4) of the Act, when a private accrediting organization applies and enforces certain enumerated requirements that meet or exceed CMS standards, CMS can deem that an MA plan has met such

requirements. These enumerated requirements include access requirements under section 1852(d) of the Act and confidentiality requirements under section 1852(h) of the Act. To the extent the one of the three named parties has applied to CMS and been approved in accordance with statutory and regulatory requirements to be a private accrediting organization for external review of PPO access and/or confidentiality requirements, then deeming would be permissible. Note, however, that this deeming mechanism applies only for the purposes of CMS' enforcement of this regulation and neither CMS' enforcement of the regulation nor accreditation by an accrediting body supersedes the jurisdiction of the HHS Office for Civil Rights to enforce the HIPAA privacy rule.

Comment: One commenter asked whether the access ''exception'' in § 422.112(a)(1)(ii) for MA regional plans would preempt State licensing laws related to HMO access requirements.

Response: MA regional plans are offered as PPOs and not HMOs. We responded to a similar inquiry in the June 2000 M+C final rule with comment (65 FR 40257). An entity does not have to have a commercial license of the same type of MA plan it seeks to offer under the MA program. Rather, the entity must demonstrate that it is authorized by the State to assume the risk involved in offering the type of plan it wishes to offer. Thus, an entity that is licensed by the State to assume risk commercially as an HMO would need to demonstrate that it is authorized by the State to offer a PPO product. The access standards that would apply to such an MA product would be the MA PPO access standards.

Comment: Two commenters stated that CMS should rely on MA regional plans to demonstrate access to covered services throughout their service areas at in-network cost sharing amounts and that should CMS continue to review cost sharing levels to ensure that they are not discriminatory.

Response: We agree with this comment and will continue to review cost sharing levels as a means of ensuring beneficiary access to care and that cost sharing is not discriminatory. When we evaluate access to care for an MA regional plan that relies, in part, on the ''exception'' in § 422.112(a)(1)(ii), we will evaluate the means by which the MA regional plan proposes to ensure that access requirements are met. Such means might include the designation of ''essential hospitals'' in accordance with § 422.112(c), the designation of other noncontracting providers from which an MA plan enrollee can obtain covered plan services at in-network cost sharing levels (including the catastrophic limit described in § 422.101(d)(2)) in a timely manner, and the manner in which MA regional plan enrollees will be notified as to how they can secure in-network cost sharing when covered services are not readily available from contracted providers, in accordance with § 422.111(b)(3)(ii).

Unlike local coordinated care plans, such as MA local HMOs and MA local PPOs, where we have historically required comprehensive contracted networks of providers as a condition for meeting our access requirements, we will allow MA regional plans to contract with CMS with less robust networks of contracted providers. As long as an entity proposing to offer an MA regional plan pays noncontracted providers at the Medicare FFS rate, and as long as they can guarantee access through such payment to non-contracting providers, and as long as they limit enrollee cost sharing liability to in-network levels, then we will contract with such an entity for an MA regional plan as long as other non-access requirements are met.

Comment: One commenter stated that the ''exception'' at § 422.112(a)(1)(ii) is not in the best interest of beneficiaries and that neither the preamble nor the regulation text in the proposed rule said how promptly an MA regional plan would be required to respond to a request for access to non-network sources of care, or the basis upon which such a request could be denied, or the penalty to the MA regional plan for not acting in a timely manner on such a request, or finally, what recourse the member would have if a denial or non-response from the MA regional plan occurred.

Response: An MA regional plan would be required to provide assurances of reasonable response times, if it proposed to use the ''exception'' in § 422.112(a)(1)(ii) in such a manner. Reasonable response times proposed by the MA regional plan would need to be consistent with community patterns of care. Where a routine or follow-up specialist visit might ordinarily be available within 30 days, an MA regional plan would be expected to respond in such a manner that the MA regional plan enrollee could secure covered specialist services within a similar time frame. Similarly, as part of the MA plan's disclosure to both CMS and an MA regional plan enrollee, we would require a full explanation of the denial process (where services are readily available from contracting providers, for instance) and the appeal process the enrollee should follow in cases of disagreement. The potential penalty to the MA regional plan for not acting in a timely manner on such a request is explained in our current regulation at § 422.750 and § 422.758 for a violation of § 422.752(a)(1) and § 422.510(a)(10), respectively.

Essential Hospitals

We proposed at § 422.112(c) that if an MA organization certifies that it was unable to reach an agreement with an ''essential hospital,'' under specific circumstances we are authorized to pay additional amounts to that hospital from the Federal Hospital Insurance Trust Fund. This additional payment to the ''essential hospital'' is in addition to and does not affect the normal monthly MA payment that we would make to the MA organization. The MA organization must provide assurances that it will make payment to the hospital for inpatient hospital services in an amount not less than the amount that would be payable under section 1886 of the Act and the ''essential hospital'' must demonstrate to our satisfaction that the amounts normally payable under section 1886 of the Act are less than the hospital's costs for providing services to MA regional plan enrollees.

Comment: A number of general comments were received on potential contracting difficulties between rural providers and health plans. On the one hand, several commenters were concerned that MA organizations offering MA regional plans would not make a ''good faith'' effort to contract with hospitals, especially hospitals located in rural areas. On the other hand, several commenters suggested that MA organizations offering MA regional plans in areas with limited competition could be ''held up'' for non-competitive or predatory payment rates as a condition of securing a contract with a specific provider. The commenters on both sides recommended various solutions, such as mandating the method by which MA organizations offering MA regional plans could show they have made a ''good faith'' effort to contract with providers.

Response: In response to comments that an MA regional plan should be required to show that it made a ''good faith'' effort to contract with an ''essential hospital,'' we added a requirement at § 422.112(c)(3) that the MA regional plan will need to establish its ''good faith'' effort by showing that the designated hospital refused to contract after it was offered a payment rate no less than the amount the

hospital would receive under section 1886(d) of the Act.

We agree that in certain rural areas, difficulties may arise in obtaining contracts that will satisfy the providers or the health plans, or both. However, we do not have the statutory authority to mandate contracts between MA plans or providers, or to intervene in contract negotiations. Section 1854(a)(6)(B)(iii) of the Act prohibits us from intruding in the contractual relationships between MA organizations and health care providers. This prohibition is intended to ensure that free market conditions continue to promote competition and efficiency in the MA program. We believe that it is clear that the Congress provided incentives for MA regional plans in the form of additional payments through the stabilization fund and risk sharing in 2006 and 2007, neither of which is provided for local MA plans.

Additionally, the Congress also provided for payments for noncontracting acute care hospitals that provide inpatient hospital services to MA regional plan enrollees through the ''essential hospitals'' authority. As stated previously, we believe competition will be the best method of ensuring network adequacy because enrollees will favor and enroll in plans with more extensive networks and tend to avoid those without. Competition will also allow the more efficient health care providers to offer discounted rates to MA organizations, which will, in turn be able to pass these savings on to enrollees in the form of additional health care items and services or reduced premiums.

Finally, we believe enrollees will be attracted to MA organizations that contract with efficient providers, because costs will be lower. Clearly, the competitive forces are more complex than we can address in this forum. We have been careful not to disturb the new competitive balance created by the MMA related to MA regional plans.

Our access standards are found at § 422.112, § 422.114, and in other sections of subpart C of the MA regulation. These standards must be met before an MA organization will be allowed to offer an MA plan in an area. Continuing compliance with these requirements is an essential condition of maintaining an MA contract. For instance, CMS has the authority, provided at § 422.502(a)(3)(ii) and § 422.512(a), to deny an application or to terminate a contract if an MA organization fails to establish or maintain adequate access to care for Medicare beneficiaries. In order to meet access standards, MA organizations offering coordinated care plans will generally need to secure contracts that they have negotiated with health care providers. This will require an effort by both parties to ensure a choice of health plans with strong provider networks that will be available to all beneficiaries, including those residing in rural areas.

Comment: One commenter stated that in the State in which it operates, the contracts it has with hospitals for all lines of business (Medicare, Medicaid, and commercial) cause it to pay more on the Medicare side, that cost-shifting occurs from its Medicare line of business to its commercial line of business. The commenter expressed concern that to the extent the ''essential hospital'' provision permits an MA regional plan to ''deem'' a hospital into the MA regional plan's network, that it provides an unfair competitive advantage to MA regional plans. The commenter also suggested permitting hospitals to select a single Medicare contractor (section 1876 cost, MA local or regional plan) with which to contract, and through such a contract ''immunize'' itself from all other MA regional plans' attempts to designate it as an ''essential hospital.''

Response: We do not believe it would be appropriate or reasonable to so allow a hospital to ''immunize'' itself from designation as an ''essential hospital'' by any MA regional plan. To the extent we accepted or adopted such an interpretation, we would also be nullifying the very intent of the ''essential hospital'' statutory provision. The intent of this provision is, simply put, to ensure access to hospital care for regional MA plan enrollees. The opening clause of section 1858(h)(1) of the Act is instructive in this regard: ''For purposes of enabling MA organizations that offer MA regional plans to meet applicable provider access requirements under section 1852 with respect to such plans.'' Additionally, as we provide for in regulation at § 422.112(c), before a hospital can be designated as an ''essential hospital'' by an MA regional plan, there must be a showing by convincing evidence that such a hospital is uniquely able satisfy the access requirements for the MA regional plan. If we were to limit designation of a specific hospital as an ''essential hospital'' to the first PPO in an MA region, we would also likely limit MA regional plan competition in all MA regions with rural areas to a single MA regional plan per region. Such a result clearly was not the intent of the statute.

In addition, the ''essential hospital'' provision partly addresses hospital financing issues, to the extent that we will pay additional costs to ''essential hospitals,'' up to the amount provided in statute at section 1858(h)(3) of the Act. Thus, the MA organization would not bear these additional costs for MA regional plan enrollees.

Comment: One commenter asked for clarification on how payment will work under the ''essential hospital'' provision. While the statute is clear, the commenter stated, that the additional payment is limited to inpatient services, it is unclear to the commenter whether add-ons such as medical education or disproportionate share payments will also be made to ''essential hospitals.'' The commenter recommended that CMS encourage or even require plans to provide additional reimbursement to include these amounts, which are available under inpatient PPS, to qualifying hospitals because they would be available if the beneficiary were enrolled in FFS Medicare.

Response: IME and GME payments will continue to be made by the Medicare fiscal intermediaries (FIs) to all appropriate hospitals for all Medicare beneficiaries (including MA plan enrollees). Disproportionate Share Hospital (DSH) payments are part of the normal FFS reimbursement amount and will be the responsibility of the MA regional plan, to the extent it is making a payment under § 422.100(d)(2), because, by definition, ''essential hospitals'' are defined as noncontracting hospitals per section 1858(h)(1) of the Act. In our regulation at § 422.112(c), we clarify that ''essential hospitals'' are always noncontracting with the specific MA regional plan involved.

Comment: Some commenters suggested that to the extent an MA regional plan offers to pay a hospital no less than the amount that would be payable to the hospital under section 1886 of the Act, that CMS consider this to be evidence that the MA regional plan has made a ''good faith'' effort to contract with the hospital.

Response: We agree with the commenters and have established the FFS payment level as the baseline for MA regional MA plans in establishing that they have made a ''good faith'' effort to contract with an ''essential hospital'' at § 422.112(c)(3).

Comment: Many commenters recommended that CMS specify in regulation exactly how the ''essential hospital'' provision will work and whether or not (and how) it would apply to critical access hospitals (CAHs). Other commenters cautioned CMS not to disrupt the competitive balance between MA organizations and hospitals related to MA plan contracting. Many commenters also recommended that CMS clearly explain

that CAHs are not ''essential hospitals'' as defined in the MMA. Other commenters stated that CAHs are indeed essential providers and have been designated as such under the FFS Medicare program. Some commenters suggested requiring MA regional plans to pay CAHs the ''interim'' Medicare rate in effect at the time the service was furnished.

In addition, one commenter stated that such an ''interim'' payment rate would put parties at risk that such a payment would be more (or less) than actual costs. The commenter also suggested that CMS devise a means of ensuring that MA regional plans are properly advised on the ''interim'' payment rate, should CMS accept the commenter's proposal. Still other commenters stated that CMS should not permit MA organizations to bargain in ''bad faith'' with hospitals. However, other commenters stated that CMS should not permit hospitals to bargain in ''bad faith'' with MA organizations. In general, all expressed concern and cautioned CMS not to upset the delicate balance of competition and pointed to the scarce resources and fragile financial condition of health care delivery in rural areas.

Generally, CMS was asked not to undermine the already precarious condition of rural providers, including rural health clinics, CAHs and others, while at the same time we were encouraged to increase the availability of MA plans in rural areas. One commenter recommended that CMS put in a ''hold harmless'' or ''cost-reimbursement'' requirement for insurers that contract with critical access hospitals. The commenter was concerned that as more Medicare beneficiaries opt for participation in private insurance plans, unless CAHs receive adequate funding for the services they provide, their continued existence (and consequently continued access to medical care for the beneficiaries they serve) will be greatly jeopardized. Another commenter suggested that CMS require MA plans to provide reimbursement to CAHs using a cost-based methodology similar to that required under FFS Medicare.

Another commenter stated that as more Medicare beneficiaries enroll in MA plans that do not contract with CAHs, the marginal costs (per Medicare beneficiary) at CAHs will rise and so, consequently, will Medicare payments per FFS beneficiary to CAHs. A few commenters suggested extending the ''essential hospital'' payment to local MA plans. Other commenters called on CMS to require MA plans to pay claims from noncontracting providers in a ''timely'' manner and under the same rules that apply to original FFS claims processors, the Medicare carriers and intermediaries.

In addition, several commenters expressed confusion with the following sentence from the subpart C preamble to the August 3, 2004 proposed rule: ''In a specific case, the actual payment to an 'essential hospital' from the Federal Hospital Insurance Trust Fund would be the sum of the difference between the amount that would have been paid to the hospital under section 1886 of the Act and the amount of payment that would'' have been paid for those services had the ''essential hospital'' been a critical access hospital.''

Response: We will address the last comment first. We need to clarify that the quoted sentence from the subpart C preamble of the August 3, 2004 proposed rule simply echoes the statutory language at section 1858(h)(2)(A) of the Act. The intent of the statutory ''essential hospital'' provision and the implementing regulation at § 422.112(c) is to provide an additional payment to the ''essential hospital'' of up to 101 percent of its actual costs for providing inpatient services to a specific MA regional plan enrollee. In other words, there was never an intent to designate or allow a CAH to become an ''essential hospital'' for purposes of the MA regional plan program. The definition of ''essential hospital'' in the statute prevents such an outcome. Section 1858(h)(4) of the Act is clear in defining an ''essential hospital'' as a ''subsection (d) hospital,'' as that term is defined at section 1886(d)(1)(B) of the Act. CAHs are not included in this definition and therefore can never be ''essential hospitals'' for purposes of an MA regional plan offered by an MA organization.

In § 422.112(c)(1), we are clear in limiting the applicability of the ''essential hospital'' provision in a similar manner to only hospitals defined in section 1886(d) of the Act, and thus excluding CAHs. We have addressed concerns related to maintaining a ''competitive balance'' previously in our responses in this section of the preamble. We cannot intrude in the contracting relationships between MA organizations and providers because the statute prohibits us from doing so at section 1854(a)(6)(B)(iii) of the Act. Additionally, to the extent the statute provides the additional ''essential hospital'' payment only for inpatient hospital services provided by 1886(d) hospitals to MA regional plan enrollees, we cannot extend its applicability to local MA plans of any type.

Comment: One commenter suggested that CMS maintain a comprehensive and accessible database of Medicare FFS reimbursement rates for all providers and allow MA plans access to the database so they would be better equipped to make the correct and full payment to out-of-network providers. The commenter also stated that there should be penalties or sanctions for plans that habitually under-pay out-of-network noncontracting providers. The commenter also suggested that CMS require MA organizations to follow FFS timely payment rules, including accrual of interest when claims are not paid in a timely manner. Some commenters stated that the additional difficulties inherent in paying CAHs timely and correctly, explaining that CAHs are paid on a ''cost plus'' basis.

Response: We provide public access to the FFS fee schedules and reimbursement rates. We also assists MA organizations in pricing claims for out-of-network providers by making ''Grouper/Pricer'' software and other Medicare claims'' pricing tools available to them. However, with payment rates and computations varying by provider type, locality, provider ID, and service, and with the potential that an MA plan enrollee might access covered emergency services in any part of the United States, the task of correctly applying fee schedules that are generally updated on a quarterly basis can be daunting. When one considers the low volume of such claims that an MA organization would expect to receive and the administrative effort involved in correctly pricing them, one begins to understand that simply making such data and systems available to MA organizations does not ensure that correct payment calculations will always occur. We already have the authority to apply penalties and sanctions to MA plans that habitually fail to pay out-of-network noncontracting providers in a timely manner (see, for instance, § 422.520). MA organizations are required to follow the same timely payment requirements related to con-contracting provider claims, including interest penalties, that apply to FFS carriers and intermediaries.

Although MA organizations are required to pay noncontracting providers the amount that would otherwise be payable under original Medicare (§ 422.100(b)(2), and although Medicare providers are required to accept from noncontracting MA organizations the amount original Medicare would have made (§ 422.214), the amount original Medicare pays to CAHs is paid on a periodic interim

basis, is cost-based, and is subject to cost settlement. Additionally, section 405(c) of the MMA provides for development of alternative timing methods for the periodic interim payments already made to CAHs for inpatient services. This provision will further complicate the computation of amounts due CAHs under Medicare and will represent an additional administrative burden on MA organizations offering MA regional plans that will need to pay noncontracting CAHs based on a number of unique and changing factors. Similarly, to the extent CAHs are located in areas served by MA regional plans, they would potentially suffer a disruption in the normal cash-flow provided for them through periodic interim payments in the Act, even were MA regional plans able to provide correct reimbursement amounts in a timely manner. Although timely reimbursement for claims received from noncontracting providers by MA organizations is already required (see § 422.520(a), the timely claims-payment standard (claims must be paid within 30 or 60 days, depending on whether they are clean claims), is not a substitute for the guaranteed cash-flow related to periodic interim payments made by the Medicare FFS intermediary to CAHs.

Additionally, to the extent CAHs settle costs with CMS related to services they provide to Medicare beneficiaries, MA organization computation of payments due CAHs is further complicated, because of the potential difference between the Medicare interim payment and the final settlement.

In light of the special status provided to CAHs in section 1820 of the Act and implementing regulations, and in recognition of the unique status of CAHs related to access to care for FFS beneficiaries, we also note a special concern for them related to the MA program and specifically to MA regional plans. While we are constrained by the non-interference clause in section 1854(a)(6)(B)(iii) of the Act from requiring MA organizations to contract with CAHs, or from requiring contracts voluntarily entered into with CAHs to specify the level or manner of reimbursement, we will increase our level of monitoring of CAHs. For instance, we might review MA regional plan payment to non-contracting CAHs during our routine biennial monitoring visits. We will use our authority in section 1857(f)(2) of the Act when needed to ensure MA organization compliance with existing non-contractor timely payment requirements. We do not interpret the statute to permit CMS enforcement of contracts voluntarily entered in to by MA organizations and health care providers. Although our regulations require that all MA organization contracts with providers and suppliers contain a prompt payment provision (see § 422.520(b)), details of such prompt payment provisions and enforcement thereof would be as specified in the contract.

Comment: One commenter requested clarification regarding the ''essential hospital'' payment from the HI Trust Fund. The ''essential hospital'' must demonstrate that the amount of the MA plan payment is less than the cost of providing services to MA regional plan enrollees. The commenter asked whether this additional payment is equivalent to the full PPS rate, or to cost (which may be greater than the PPS rate), or cost plus one percent (because of the reference to CAHs at section 1858(h)(2)(A)) of the Act. The commenter also recommended that CMS provide guidance on how the hospital will demonstrate it is eligible for an ''essential hospital'' payment. The commenter is concerned that the procedures that we establish not be too cumbersome so that the additional reimbursement is not sufficient to compensate for the reporting effort.

Response: The ''essential hospital'' will need to establish that its actual costs for providing inpatient care to a specific MA regional plan enrollee actually exceeded the amount that is normally paid under FFS Medicare. The amount normally paid under FFS Medicare is the PPS payment normally made to the ''subsection d'' hospital under Part A of the Act for similar inpatient hospital services provided to an original FFS Medicare beneficiary. As we have already discussed in this part of the preamble related to § 422.100, the normal PPS payment (less the amounts paid by the fiscal intermediary under sections 1886(d)(11) and 1886(h)(3)(D) of the Act) will be the responsibility of the MA organization sponsoring the MA regional plan in which the beneficiary is enrolled. Thus, after the normal FFS amount has been paid to the ''essential hospital,'' the ''essential hospital'' can seek additional funding from CMS for up to 101 percent of the inpatient costs it actually incurred in treating a specific MA regional plan enrollee. The availability of funds to make such an additional payment to ''essential hospitals'' is limited by section 1858(h)(3) of the Act. We have clarified in the regulatory text in § 422.112(c)(6) that we will pay from funds appropriated in section 1858(h)(3) of the Act until such funds are exhausted. In other words, we will pay based on the order in which claims from ''essential hospitals'' are received. Finally, we have prescribed in regulation the method through which an ''essential hospital'' will establish that its costs for treating a specific MA regional plan enrollee exceeded the normal PPS payment amount. We will use the principles of reasonable cost reimbursement in part 412 of this chapter to determine whether costs in a specific case exceed the normal PPS payment amount in an individual case. To the extent an ''essential hospital'' can show, using methods of reasonable cost reimbursement, that the amount it reasonably expended in its treatment of an MA regional plan enrollee exceeded the normal PPS reimbursement amount for inpatient services, then CMS will make an additional payment to the ''essential hospital,'' limited by the statutorily appropriated amount in section 1858(h)(3). The statute initially authorizes $25,000,000 in 2006 and increases the annual amount available for ''essential hospital'' payments in subsequent years by the market basket percentage increase as defined in section 1886(b)(3)(B)(iii) of the Act.

Comment: One commenter recommended that CMS eliminate ambiguity and to clearly define which types of hospitals are eligible for ''essential hospital'' designation.

Response: Our regulation indicates that any ''subsection (d)'' hospital can qualify as an ''essential hospital.'' The regulation mirrors the statute in this respect. Note that ''subsection (d)'' hospitals are defined in statute at section 1886(d)(1)(B) of the Act and refer to hospitals paid under a ''prospective'' (PPS) method. We have added language to § 422.112(c)(1) to clarify this issue. Also note that we have further defined ''essential hospital'' in regulation text at § 422.112(a)(4) as one where there is no competing Medicare participating hospital in the area to which MA regional plan enrollees could reasonably be referred for inpatient hospital care. We believe MA organizations are in the best position to determine what is ''reasonable'' in this context, based on service usage and community patterns of care. However, we will evaluate such claims based on standards that will include: an evaluation of the ownership and control of other hospitals in the area; the normal patterns of community access; the physical proximity of other inpatient facilities; the referral patterns to inpatient facilities in the area; and other factors pertinent to the analysis.

Comment: A number of commenters recommended that CMS apply special rules to I/T/U hospitals so that all hospitals operated by I/T/U or the

Indian Health Service would be considered ''essential hospitals.''

Response: We cannot accommodate this request because there is no statutory basis for including all hospitals operated by Tribes or the Indian Health Service as ''essential hospitals.'' Section 1858(h) of the Act is explicit in defining ''essential hospitals'' as subsection (d) hospitals as defined in section 1886(d) of the Act. To the extent a Tribal or IHS hospital is designated by an MA regional plan under section 1858(h)(1) of the Act and to the extent all other conditions in section 1858(h) of the Act are present, then such a hospital can be an ''essential hospital.''

Comment: Some commenters recommended that CMS establish rules for ''essential hospitals'' that would require them to participate in the utilization management, discharge planning or quality improvement programs of the MA plans of the enrollees they treat.

Response: We will not separately establish such requirements related to ''essential hospitals.'' As ''subsection d'' hospitals, ''essential hospitals'' are already required to meet quality assurance, discharge planning and utilization management standards applicable to Medicare participating hospitals.

Comment: One commenter asked who would be responsible for the ''essential hospital'' payment, once the annual allocation specified in section 1858(h)(3) of the Act has been exhausted.

Response: In response to this comment, we have clarified this section of the regulation to say that once ''essential hospital'' payments exceed the limit prescribed in statute in a calendar year, no additional ''essential hospital'' payment will be due from any party. The statute is clear in allocating up to $25,000,000 for calendar year 2006 and a similar amount, adjusted for inflation, in subsequent years. We will make appropriate payments from the Part A Trust Fund on a ''first come-first served'' basis. We have specified these requirements in regulation at § 422.112(c)(6). Once the amount authorized in statute has been exhausted in a calendar year, no additional ''essential hospital'' payment is due nor can one be made by us for inpatient hospital services received by an MA regional plan enrollee in that calendar year.

Comment: One commenter asked if the in-network cost sharing requirement would still apply to services received in an ''essential hospital,'' even after the ''essential hospital'' allocation has been exhausted.

Response: To the extent an ''essential hospital'' is needed to meet the access requirements in § 422.112, we have added a requirement at § 422.112(c)(7) that in-network cost sharing applies to covered inpatient services received by an MA regional plan enrollee in an ''essential hospital.'' This is consistent with the ''exception'' in § 422.112(a)(1)(ii) and the beneficiary notification requirement in § 422.111(b)(3)(ii). The requirement for an MA regional plan to provide, or reimburse for, medically necessary inpatient hospital care (and to limit member liability to in-network cost sharing levels when reimbursing an ''essential hospital'') is independent of the ''essential hospital'' payment provision. Section 422.112(c)(7), where cost sharing is limited to in-network amounts for covered inpatient care reimbursed to an ''essential hospital'' by an MA organization for an MA regional plan member, applies even when § 422.112(c)(6) does not. Even if no ''essential hospital'' payment is due per § 422.112(c)(6) because conditions in § 422.112(c)(5) are not met (rather than due to exhaustion of the ''essential hospital'' annual allocation), in-network cost sharing for covered inpatient services at an ''essential hospital'' is still required. In other words, once a hospital is designated as an ''essential hospital'' by the plan, in-network cost sharing applies regardless of whether an ''essential hospital'' payment is due or paid.

Comment: One commenter said that to the extent the ''exception'' in 422.112(a)(1)(ii) is used, that not only normal per service in-network cost sharing should apply to services so obtained, but also that the in-network catastrophic limit on Medicare A/B services in § 422.101(d)(2) should also apply.

Response: We agree and reference the in-network catastrophic cost sharing limit in § 422.101(d)(2) as an additional limit on MA regional plan enrollee cost sharing liability in § 422.112(c)(7) when covered inpatient care is received at an ''essential hospital.''

Comment: One commenter asked whether we would permit or require MA regional plans to list ''essential hospitals'' in their provider directories. The commenter said that allowing an MA regional plan to so list ''essential hospitals'' would be inappropriate because such marketing would provide the hospitals with an advantage that should only accrue to contracting providers. We received a number of comments from other parties that objected to the listing of ''essential hospitals'' in MA regional plan provider directories on the basis that such a listing would provide the MA regional plan with an advantage that should only accrue to MA regional plans that actually have the ''essential hospital'' under contract.

Response: While we generally concur with both commenters that neither party is entitled to an undue advantage, MA regional plans are required to provide enrolled members a provider directory on an annual basis in accordance with § 422.111(a)(3). Note that as part of that requirement a description of any out-of-network coverage is also required. So, while it would not be permitted to list ''essential hospitals'' in an MA regional plan's provider directory as if they were contracting providers, it is also true that a description of their status as ''essential hospitals'' would be required.

12. Special Rules For Ambulance Services, Emergency Services, and Urgently Needed Services, and Maintenance and Post-Stabilization Care Services (§ 422.113)

We proposed to modify § 422.113(b)(2)(v) to clarify that the $50 limit for ''emergency services'' applies only to the emergency department, and that while the limit on cost-sharing for ''post-stabilization'' care at § 422.113(c)(2)(iv) continues to apply, its application would always begin upon inpatient admission. Thus, emergency cost-sharing limits would shift from being tied to the type of service (emergency services) to being tied to the site of service (emergency department). We believe that making this clarification retained cost-sharing limits for both emergency services and post-stabilization care, while eliminating the unanticipated complexities and administrative burden previously associated with this section of the regulation.

Comment: A number of comments supported the clarification that the $50 limit on cost sharing for emergency services applied only to emergency department services. Commenters supported the notion that once an MA enrollee is admitted to a hospital, normal hospital cost-sharing levels apply, even if the inpatient admission originates from the emergency department. On the other hand, many commenters recommended that CMS reexamine the $50 limit itself. Some commenters recommended that CMS set the limit higher (at $75, $100 or higher) and other commenters recommended that CMS index the emergency department cost-sharing limit for inflation.

Response: We believe that the $50 limit on cost sharing for emergency

department services continues to provide the appropriate financial disincentive to MA plan enrollees not to frivolously use emergency rooms in non-emergency situations. For instance, there is no MA plan currently imposing cost sharing for in-network physician office visits that approach $50. Similarly, MA organizations are permitted to deny emergency department services as medically unnecessary, to the extent that the member can be shown to have acted in ''bad faith'' or not as a ''prudent layperson'' in presenting at an emergency room for non-emergency services.

Finally, we do not set forth in regulation the maximum amount an MA organization can impose in cost sharing for receipt of urgently needed services. Because we have restricted the applicability of the $50 limit on enrollee cost sharing to emergency department services, we believe we have appropriately balanced the financial interests of MA organizations and MA plan enrollees requiring emergency services.

13. Access to Services Under an MA Private Fee-For-Service Plan (§ 422.114)

Section 211(j) of the MMA allows MA PFFS plans to charge higher co-pays to members who receive services outside of a PFFS plan's contracted network. This provision does not apply to PFFS plans that meet access requirements solely through ''deemed'' networks as defined in § 422.114(a)(2)(i). We proposed to add a new paragraph (c) to account for section 211(j) of the MMA.

We received no comments on this section, so we finalize as proposed.

14. Return to Home Skilled Nursing Facility (§ 422.133)

We proposed to extend the provisions in § 422.133 (Return to home skilled nursing facility) to SNF services provided in cases in which an MA organization elects, as permitted under § 422.101(c), to provide Medicare covered SNF care in the absence of a prior qualifying hospital stay. In such an instance, we proposed to require that an individual who would be eligible under section 1852(l) of the Act for admission to a ''home SNF'' upon discharge from a hospital stay, would nonetheless retain his or her right to receive ''home SNF'' benefits in the absence of such a hospital stay.

We proposed to deem that a hospital discharge has always occurred before an admission for SNF services, and therefore provide all MA enrollees full rights to the ''home SNF'' benefit.

We received no comments on this section, so we finalize as proposed.

Subpart D—Quality Improvement Program

1. Overview

The MMA amended section 1852(e) of the Act in a number of significant ways that will affect how MA organizations pursue their quality improvement activities. Below we summarize the proposed provisions and respond to the public comments. (For a more in-depth discussion of the provisions, please refer to the preamble to the proposed rule.)

Quality Improvement Program (§ 422.152)

To reflect the Congressional intent to refocus the section on quality improvement, rather than quality assurance, we changed the heading of § 422.152 to ''Quality improvement program.'' Proposed § 422.152 specified that each plan (except MA PFFS and MSA plans) offered by an MA organization must have an ongoing quality improvement program and that a chronic care program must be a part of this program.

We believe that the broad requirements in proposed § 422.152(d) for QI projects did not present an undue burden for MA organizations, as these organizations have significant experience in carrying out such projects under the current § 422.152(d) requirements that we believe are more prescriptive than those we proposed in the August 2004 proposed rule.

Our previous quality improvement requirements for M+C coordinated care plans focused on attaining improvement in specific clinical topics and included specific performance measures for improvement. As a result of the MMA amendments, we proposed that MA organizations have the flexibility to shape their QI efforts to the needs of their enrolled population. In addition, we continue, based on our interpretation of section 1852(e)(3)(B)(i) of the Act, to require MA coordinated care plans to collect, analyze, and report their performance using measurements outlined by us or to participate in surveys administered by us (for example, HEDIS, HOS, and/or CAHPS).

Proposed § 422.152(b)(4) would require MA local PPO plans that are offered by an organization that is licensed or organized under State law as a HMO, to follow the same quality improvement requirements as other MA coordinated care plans.

A. General Comments

Comment: A number of commenters made a variety of general comments about the proposed rule. These comments include: (1) require that plans disseminate educational materials to beneficiaries; (2) require that all plans review all problems that come to their attention; (3) CMS should recommend that plans seek Quality Improvement Organization (QIO) technical assistance; (4) require plans to have physician advisory committees, and that these committees advise CMS on performance measures; and (5) CMS should begin to provide information on MA quality starting in 2006.

Response: MA plans are responsible for ensuring that beneficiaries are fully informed of the benefits covered under the contract as part of its marketing material, evidence of coverage, and summary of benefits. We do not have any requirements that plans conduct educational programs. While the dissemination of educational materials may be worthwhile in improving health outcomes, we do not believe it should be mandatory. Most plans already provide QI, for example, in marketing materials. Furthermore, we post HEDIS and CAHPS data on the *www.Medicare.gov* web site. To the extent an MA plan decides to furnish educational materials to its enrollees, the plan is responsible for the type of information it wishes to furnish, and it is in the best position to determine which information is most appropriate for the enrolled population.

We agree with the commenter that plans should review all problems that are brought to their attention. Depending on the nature, extent, and substance of the problems, an MA plan may implement immediate corrective action, or may need to implement more systemic changes to address the identified problem.

We agree with the commenters and encourage plans to seek technical assistance from QIOs. Plans should review the current scope of work to determine the areas for which the QIOs can provide assistance; a draft outline of the 8th scope of work is available on our web site. Plans that seek QIO assistance will receive it on both Part C and Part D services.

We disagree with the commenters that propose that we require physician advisory committees. We do not believe this is necessary because most plans already have Medical Director committees that advise plans on QI measures. Moreover, at the national level, we have a physician advisory

committee. These bodies should ensure an appropriate level of physician input.

We agree with the commenters with respect to our providing information on quality measures. HEDIS and CAHPS data are already on our website (*www.Medicare.gov*), and the data has been available for several years

Comment: Several commenters stated that CMS should include PFFS and MSAs in all of the QI requirements. However, there were also commenters that supported the exclusion of these plans.

Response: Because section 722(a) of the MMA specifically exempts these types of plans from the majority of QI requirements, we have excluded them from the same requirements in the regulations. These plans, however, must meet the following requirements: maintain health information systems; ensure information from providers is reliable and complete; make all collected information available to us' conduct quality reviews; and take corrective action for all problems that come to their attention.

Comment: Several commenters have recommended that we provide payment incentives to MA plans for providing better quality care, also known as pay for performance (P4P).

Response: We agree with the commenters concerning the merits of P4P. We are very interested in this approach and believe that we should pay not just for providing a service but for results. P4P should stimulate care that is efficient and effective for every patient while eliminating waste. We are currently working on four P4P demonstration projects. These are as follows:

The Premier Hospital Quality Incentive Demonstration

The Premier Hospital Quality Incentive Demonstration is a 3-year project that will recognize and provide financial rewards to hospitals that demonstrate high quality performance in a number of areas of acute care. The demonstration involves a CMS partnership with Premier Inc., a nationwide organization of not-for-profit hospitals, and will reward participating top performing hospitals by increasing their payment for Medicare patients. Through the Premier Hospital Quality Incentive Demonstration, we aim to see a significant improvement in the quality of inpatient care by awarding bonus payments to hospitals for high quality in several clinical areas, and by reporting extensive quality data on our web site. Participation in the demonstration is voluntary and open to hospitals in the Premier Perspective system as of March 31, 2003.

Section 646—Medicare Health Care Quality Demonstration Program.

The MMA mandates a 5-year demonstration program to examine factors that encourage the delivery of improved patient care quality, including financial incentives, appropriate use of best practice guidelines, examination of service variation and outcomes measurement, shared decision making between providers and patients, appropriate use of culturally and ethnically sensitive care, and related financial effects associated with these factors. In the demonstration, Medicare may provide benefits not otherwise covered, but may not deny services that are otherwise covered against the wishes of beneficiaries. The demonstration is required to be budget neutral.

Section 649—Medicare Care Management Performance Demonstration.

The MMA mandates a 3-year demonstration program where physicians will be paid to adopt and use health information technology and evidence-based outcome measures to promote continuity of care, stabilize medical conditions, prevent or minimize acute exacerbations of chronic conditions, and reduce adverse health outcomes. The statute limits the program to four sites meeting eligibility criteria. Payment can vary based on performance; however total payments must be budget neutral. QIOs could help enroll physicians, evaluate their performance, and provide technical assistance.

The Physician Group Practice (PGP) Demonstration.

The PGP Demonstration rewards physicians for improving the quality and efficiency of health care services delivered to Medicare FFS beneficiaries. Mandated by Section 412 of the Benefits Improvement and Protection Act of 2000, the PGP Demonstration seeks to encourage coordination of Part A and Part B services, reward physicians for improving health outcomes, and promote efficiency through investment in administrative structure and process. Under the 3-year demonstration, physician groups will be paid on a FFS basis and may earn a bonus from savings derived from improvements in patient management. Annual performance targets will be established for each participating physician group equal to the average Part A and Part B expenditures of beneficiaries assigned to the group during a base period, adjusted for health status and expenditure growth.

We are also paying close attention to P4P for managed care plans. We are aware that MEDPAC has developed proposals along these lines in its June 2004 report. Furthermore, many private sector organizations are sponsoring such projects. See, for example, a compendium developed by The Leapfrog Group (*www.leapfroggroup.org*). In addition, the Agency for Healthcare Research and Quality (AHRQ) has sponsored an evidence based report entitled ''Strategies to Support Quality-based Purchasing: A Review of the Evidence,'' published in fall 2004, which includes managed care plans. Finally, we have a contract with the Institute of Medicine to study P4P, which will also address managed care.

B. Measures

This portion of the discussion addresses measures for all MA plans. A specific discussion of measures for PPOs appears below.

Comment: Several commenters stated that CMS should include measure reporting requirements in regulations.

Response: Based on past experience, we disagree with the commenters recommending that we include specific measure reporting systems in the regulation. We believe it is a better approach to provide specific guidance through the Medicare managed care manual rather than including specific requirements in the regulation. In this way, we have the flexibility to implement appropriate changes in the measure systems and individual measures in a more timely manner. The industry and accreditation organizations, are constantly making changes to these reporting systems. Thus, having more flexibility to change measures as well as add and delete measurements systems allows us to be more responsive to the state of the art as to measurement systems.

Comment: A commenter stated that performance assessment data is outdated and that CMS should not use HOS to rank plans because there is no benchmark.

Response: We disagree with the commenter. HEDIS, CAHPS, and HOS are updated on a regular basis. We recognize that there are no benchmarks currently available and therefore use relative ranking in the performance assessment data system. Benchmarks also refer to standards or minimum performance levels.

Comment: A commenter stated that CMS should use a standardized core set

of performance measures, clinical and non-clinical that are applied to all MA plans. The commenter suggested that CMS not require MA plans to demonstrate that QI program size and scope are proportionate to plan size.

Response: In general, we agree with the commenter that a standardized set of measures should be used across all plan types because it allows the greatest comparison among plans. The one exception as discussed later, is that we have decided to allow some variation in the early stages of the PPO program as compared to the HMO program. As also noted, MMA specifies a different set of requirements for PFFS plans and MSAs.

Comment: One commenter stated that CMS should compare quality measures of MA plans to those for the FFS Medicare program.

Response: On the *www.Medicare.gov* website, we provide consumer assessment data from CAHPS on FFS Medicare and the MA plans, as well as a comparison of an Original Medicare rate (on State and national levels) compared to the MA health plan rates on the HEDIS measure—Access to Ambulatory Health Services.

Comment: A commenter suggested that CMS reduce the burden on plans by reducing the number of measures or by conducting HEDIS by telephone.

Response: We agree that it is important to minimize the MA plans' reporting burden and do so by using data submission tools, systems, and processes that are consistent with HEDIS reporting for the plan's commercial lines of business.

We believe that it is not appropriate, however, to collect HEDIS measures by phone because information collected by phone is less reliable.

C. Special Needs Plans (SNPs)

Comment: Many commenters suggested that CMS develop special measures for specialized MA plans for SNPs. Several commenters suggested that CMS use the ACOVE measures developed by Rand. They further suggested that quality oversight should take into account the populations being served by the SNP. In addition, they suggested that CMS should ensure that SNPs have comprehensive and coordinated care.

Response: We agree with the commenters and have already indicated to several demonstration plans that have institutionalized populations and are converting to SNPs that HEDIS and HOS will not be required. Instead we will work with them to identify measures that are similar to the national nursing home quality measures reported on the Nursing Home Compare website at *www.medicare.gov* and the CHSRA quality indicators, both of which are derived from the Minimum Data Set (MDS). SNPs for dual eligibles will be required to meet the requirements of other MA plans. We are also willing to explore special measures with other types of SNPs.

We are certainly open to considering the ACOVE measures and will explore their feasibility. As to other aspects of quality oversight, we will apply the same basic types of quality requirements for all MA plans but take into account beneficiary needs for SNPs. As to comprehensive and coordinated care, SNPs will need to meet chronic care improvement program (CCIP) requirements.

Comment: A commenter recommended that SNPs should not serve dialysis patients. The commenter stated that CMS cannot monitor the quality of care provided to dialysis patients in managed care plans because dialysis providers do not bill Medicare for services to MA beneficiaries, thus, the ESRD Clinical Performance Measures data, which are extracted from billing information, are not available.

Response: We appreciate the concerns expressed by the commenter and will definitely take them into consideration. We anticipate that will be able to collect the data. However, at this time, we have not determined with certainty that we can and share the commenter's concern that we not approve the plans unless we can collect the data. In Subpart A of this preamble, we indicate that we are not setting forth a detailed definition of severe and disabling chronic condition for purposes of the definition of special needs individuals, and we will review and evaluate SNP proposals on a case-by-case basis. This evaluation will take into consideration whether we can collect sufficient quality of care monitoring data.

D. Report to the Congress

Comment: Some commenters expressed concern that CMS could not add measures without issuing a Report to the Congress as required under Section 1852(e)(3)(A). They suggested that because of several of the unique populations that might be served in SNPs, that CMS extend the Report to the Congress, and that CMS form an expert panel, enhance clinical knowledge on high risk populations, disseminate best practices, enhance coordination care, and refine payment to support outcomes.

Response: As indicated in the proposed rule, we interpret that this requirement does not prevent us from making changes within each of the existing measurement systems, such as HEDIS. Further, although we need to submit a Report to the Congress to add new systems, we do not interpret this to mean that we need the Congressional approval before we proceed to implement new systems.

E. Types of performance measures

Comment: A commenter suggested that CMS develop clearly defined, nationally recognized quality measures based on objective criteria for all facets of the Medicare program to truly achieve the MMA's goal of offering Medicare beneficiaries a meaningful choice. It is feasible that the measures be based on pharmaceutical information, medical claims, and other routine administrative information already easily accessible across the Medicare program.

Response: We will be pursuing the development of the measures and will take into consideration the commenter's suggestion.

2. Chronic Care Improvement Program Requirements (§ 422.152(c))

At proposed § 422.152(c), we would require that MA plans develop criteria for a chronic care improvement program. The criteria must–

- Include methods for identifying MA enrollees with multiple or sufficiently severe chronic conditions who would benefit from participating in a chronic care improvement program; and
- Provide mechanisms for monitoring MA enrollees that are participating in the chronic care improvement program.

Comment: A commenter recommended that CMS use the standard definition of disease management adopted by the Disease Management Association of America (DMAA) for the CCIP. The commenter also recommended that the CCIP be population based and that CMS focus on congestive heart failure (CHF), diabetes, and chronic obstructive pulmonary disease (COPD). They further suggested that CCIPs be accredited, and be evaluated on clinical quality, beneficiary and provider satisfaction, and impact on cost. Other commenters recommended that CMS provide maximum flexibility for plans as to these requirements. A commenter suggested that plans can identify patients from claims, self-reports, by providers, socio-economic data primarily using existing measures, for example, HEDIS to monitor plus other evidence-based measures. A commenter also suggested plans should use clinical variables, for example, weight, use of ACE inhibitors, health and functional status, emergency room and hospital

use, satisfaction, total costs, as measures for CCIP.

Response: We certainly encourage plans to consider the definition provided by Disease Management Association of America (DMAA), as well as the other aspects of the programs developed by DMAA. However, we believe it is premature to provide more prescriptive requirements. We will look for information on the CCIP pilot under section 721 of the MMA as well as the early stages of the MA plans' implementation of this section 722 CCIP to shape guidance for this component of the program.

3. QI Projects (§ 422.152(d))

While we proposed to delete many of the prescriptive requirements for QI projects that appeared in § 422.152(d), we still retained the basic requirements of the projects including the collection, analysis, and reporting of data. We believed, though, that MA plans should have the ability to select topic areas and proposed deleting the requirements of including the entire relevant population and having to do both national and statewide projects.

In proposed § 422.152(d)(1), we would require that QI projects be initiatives that include the entire organization and focus on clinical and non clinical areas. The projects would need to follow the current quality improvement process. We retained the provisions that QI projects must measure performance, and the interventions must be system-wide and include the establishment or alteration of practice guidelines. In addition, we propose to require that the projects focus on improving performance for the Medicare population and involve systemic and periodic follow-up on the effect of the interventions. To ensure that the measures (or quality indicators) used in QI projects are reliable and relevant for improving the health care and services furnished to MA enrollees, we proposed in § 422.152(d)(2) to require that the quality indicators be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research. The measures must also be capable of measuring outcomes, such as changes in health status, functional status, and enrollee satisfaction, or valid proxies of those outcomes. Likewise, we proposed in § 422.152(d)(3)to require that the data used in an MA plan's QI projects be valid and reliable and based on systemic ongoing collection and analysis of information. We also proposed in § 422.152(d)(4) that the interventions achieve demonstrable improvement.

Finally, in § 422.152(d)(5), we proposed to retain the requirement that MA plans report the status and results of their projects when requested by us. We believe that this reporting and review burden would be much smaller than the process used in the M+C program. We intend to provide further guidance on the reporting requirements later.

Comment: A commenter stated that QI should involve more than measure, intervene, and remeasure. The commenter also stated that it should set performance expectations, collect and analyze data, identify undesirable events, develop interventions, collect data to monitor improvement, and require that all plans meet the same QI requirements.

Response: We agree that all HMOS and PPOs should have to meet the same basic requirements as to QI projects, and the regulation requires this. However, although we will encourage plans to adopt the commenter's other recommended steps, we do not believe that it is necessary to build them into mandatory requirements. The requirements that we have already specified should be sufficient, and to add additional requirements will create unnecessary burden.

A. National projects

Comment: A commenter requested that CMS provide guidance to plans on the meaning of 'encouraging' physicians to participate in quality improvement initiatives. The commenter also proposed that CMS provide plans with the flexibility to design and conduct QI projects based on topics relevant to the plan's population. However, the commenter stated that CMS should continue to provide suggestions and examples of topics for QI projects that are relevant to the Medicare population. The commenter also suggested that CMS should provide guidance regarding meaning of ''sustained improvement,'' and consider evaluating clinical and non-clinical performance improvement using HEDIS and CAHPS 3.0H results.

Response: As to encouraging physicians to participate in QI projects, we recommend plans to coordinate their efforts with their providers. Some possible options are that the plans will send letters to their providers encouraging participation or pay them a bonus. This will be up to the plans. As indicated, we will provide suggestions as to topics for plan consideration and guidance on these topics. We will give further consideration to the suggestion of using HEDIS and CAHPS for evaluating QI projects.

Comment: Some commenters recommended that CMS require plans to participate in national projects.

Response: The MMA specifically deleted the requirement for national projects. We interpret the Congress's deletion of this requirement as an indication of its intent that participation in national projects not be required. Therefore, we are not requiring the projects, and we believe the best alternative is to encourage plans to participate voluntarily in our proposed national projects.

B. Racial-ethnic QI projects

Comment: Some commenters opposed elimination of the racial-ethnic QI projects, while one commenter supported its removal.

Response: The MMA specifically eliminated this requirement. Again, we interpret the Congress's deletion of this requirement as indicating its intent that plans not be required to pursue these types of projects. However, we encourage plans to consider pursuing such projects voluntarily. We have a current racial-ethnic national project that started in 2003 and will not be completed until 2005. We will share results of this project when it is completed. Lovelace Clinic Foundation was selected by us to develop two cultural competency guides through an AHRQ Integrated Delivery System Network Funding task order. The first manual, ''Providing Oral Linguistic Services: A Guide for Managed Care Plans,'' provides a practical step-by-step process for the improvement of oral language services to patients with limited English proficiency (LEP). The second manual, ''Planning Culturally and Linguistically Appropriate Services: A Guide for Managed Care Plans,'' assists health plans in assessing the ethnically diverse populations they may serve, and assessing the cultural competency of the managed care plan. Lovelace recently completed a report ''Evaluation of Usefulness of CLAS Guides to M+CO Plans'' which is available from AHRQ.

C. Performance levels

Comment: A commenter suggested that CMS set guidelines on the minimum percent of enrollees that are identified and managed. Others opposed the removal of requirements as to minimum performance levels, sustained improvement, and clinical-nonclinical requirements and external review.

Response: We retain our view from the proposed rule that plans should select topics areas that best meet their needs rather than being required to select both clinical and nonclinical

topics. We do not believe that it is appropriate for us to specify minimum percent identified and minimum performance level. In the preamble discussion to § 422.152(d), we proposed not to define demonstrable improvement, but indicated that we would look for some movement in the quality indicator in an upward or downward direction as appropriate.

MMA eliminated the requirement that MA organizations contract with QIOs (external review organizations) to review appeals. However, QIOs are still involved in all appeals that they currently conduct such as hospital and nursing home discharges. Elimination of this requirement just means that the MA plans do not need to contract with the QIOs or other external review organizations.

D. Project selection

Comment: A commenter suggested that CMS require all plans to participate in QI projects, as long as the projects are based on data to which the plan has reasonable access. When developing QI and data collection requirements, the commenter suggested consideration of the plan's experience in conducting the activities. Further, the commenter recommended using a standardized core set of performance measures, clinical and non-clinical that are applied to all Medicare Advantage plans. Commenters also stated that CMS should not require MA plans to demonstrate that QI program size and scope are proportionate to plan size.

Response: We believe that plans should take these suggestions into consideration, but we are not requiring them. We agree that we should not require MA plans to demonstrate that QI program size and scope are proportionate to plan size. To do so will place unnecessary restrictions on plans and would be inconsistent with what we understand to be the Congressional intent to allow for more flexibility in this area.

4. Requirements for MA Regional Plans and MA Local Plans

Section 1852(e)(3)(A)(ii) of the Act provided for us to establish separate regulatory requirements for MA regional plans relating to the collection, analysis, and reporting of data that permit the measurement of health outcomes and other indices of quality. Section 1852(e)(3)(A)(ii) of the Act further provided that these requirements for MA regional plans could not exceed the requirements established for MA local plans that are PPO plans.

In § 422.152(e)(1), we proposed a definition for the term ''local PPO plan'' as used in this section. The other requirements in this paragraph were the requirements that apply to PPOs under current regulations.

In § 422.152(f), we retained the provisions that address health information systems, QI program review, and remedial action. MA organizations will be required, for all the MA plans they offer, to maintain a health information system that collects, analyzes, and integrates the data necessary to implement their QI program. The organization will also be required to ensure that the information it receives from providers of services is reliable and complete. In addition, for each plan, there must be in effect a process for formal evaluation, at least annually, of the impact and effectiveness of its quality improvement program.

Finally, for each plan it offers, we proposed that an MA organization will be required to correct all problems that come to its attention through internal surveillance, complaints, or other mechanisms. As noted above, as a result of MMA we also made conforming changes to remove the provision that each MA organization's quality assurance program include a separate focus on racial and ethnic minorities and the requirement that for each plan it operated the MA organization would have an agreement with an external quality review and improvement organization.

The MMA provided that all the part D (Voluntary Prescription Drug Benefit) requirements are to be included as among those that could be deemed to be met through accreditation, and we accordingly proposed to add this provision to the list of deemable requirements in § 422.156(b).

Comment: Many commenters recommended that CMS use the same metrics across plan types. Others commenters recommended that CMS develop future plans to make PPOs comparable to HMOs. They suggested that CMS convene key stakeholders to develop measures. They further suggested that CMS set goals and timetables for implementing the same measures across plan types.

Response: For the most part, we will have uniform reporting requirements for HMOs and PPOs. For instance, we will require both types of plans to submit HEDIS and HOS data. Further, we will administer the CAHPS survey to both types of plans. The HEDIS measures will differ between the two plan types, as PPOs will not be required to submit HEDIS measures that require medical record review, because they have difficulty obtaining medical records from out-of-network providers. However, for PPOs, many of the HEDIS measures are available from administrative records. We are working with NCQA and other experts, MA organizations and other stakeholders to identify which HEDIS measures are most appropriate for quality performance measurement in PPO plans.

We held an open door forum on December 10, 2004, to receive input from the public on the HEDIS measures for PPOs. We expect to publish a final set of measures for field testing in January 2005. Materials from the open door forum can be found at *http://www.cms.hhs.gov/healthplans/performance/*. We expect to field test these measures in the Spring 2005, and we expect to finalize them in Fall 2005. In addition, we expect to disseminate the final list of measures for reporting, with detailed instructions, in the MA Manual in Fall 2005. In the near future, we expect that additional HEDIS measures that require PPOs to capture and submit data from medical records will also be required for reporting. We desire to measure performance and compare plans on as many dimensions of care as possible, so we plan to move progressively toward having all relevant HEDIS measures reported while allowing PPOs the opportunity to develop the capacity to collect information that requires medical record review.

After we implement NCQA's recommendations on HEDIS measures for PPOs, we will make an assessment of the possibility of making HEDIS reporting even more comparable between HMOs and PPOs

5. Deeming § 422.154

We did not have a discussion on deeming in the preamble nor proposed changes to the regulation text. Nevertheless, we did receive comments on this section and are responding to those comments.

Comment: Commenters suggested that CMS allow the American Association of PPOs (AAPPO) to be an Accreditation Organization (AO)and that CMS allow disease management associations to be AOs.

Response: Any organization that wants approval as an AO for PPOs must meet our AO requirements for PPOs.

Subpart E—Relationships with Providers (§ 422.210)

The MMA made very limited changes to existing MA program requirements concerning MA organization relationships with providers. Since these aspects of the program have

worked well, we generally proposed to keep the existing provisions of subpart E as they were. The only exceptions, are modifications to the physician incentive plan requirements to reflect changes made by MMA to section 1852(j)(4) of the Act.

Below is a summary of the proposed provisions in this subpart that were proposed in the August 3, 2004 proposed rule:

• We proposed to remove § 422.208(h) that required that, where a physician incentive plan places physicians at substantial financial risk, M+C organizations conduct ''periodic surveys of both individuals enrolled and individuals previously enrolled with the organization to determine the degree of access of such individuals to services provided by the organization and satisfaction with the quality of such services.''

• We proposed to revise § 422.210 to eliminate the requirement that information on physician incentive plans be disclosed to CMS.

Comment: A commenter supported the changes made to the reporting requirements in the August 22, 2003 final rule (68 FR 50855). Other commenters requested that CMS require plans to submit assurances that they are in compliance with the requirements.

Response: The MMA specifically requires that MA plans provide assurances to us that they are in compliance with the physician incentive plan requirements. We specified this requirement in the regulation text of the proposed rule at § 422.210 and have retained it in this final rule. Further details on the assurances will be provided in subsequent guidance. As noted in the preamble of the proposed rule, the reporting requirement had already been eliminated in a final rule published on August 22, 2003 (68 FR 50855). The assurances required by MMA are a new requirement that helps to ensure that plans are meeting the various regulatory requirements of the physician incentive plan section. Plans must provide information on their physician incentive plans when requested by us.

Subpart F—Submission of Bids, Premiums, and Related Information and Plan Approval

Under the current MA regulations, subpart F addresses payments to MA organizations, and subpart G discusses beneficiary premiums and cost sharing. Given the substantial revisions that the MMA makes to pricing and payment rules for MA organizations, we proposed to generally replace these subparts in their entirety. Subpart F will cover provisions addressing bid submissions and our review of bids and subpart G will describe the methodology and process for CMS' payment to MA organizations.

This subpart addresses provisions related not only to submission, review, and approval of bids, but also ''bid-to-benchmark'' comparisons, including how local and regional benchmark amounts are determined and how beneficiary premiums and savings are calculated; how beneficiary savings are used for beneficiary rebates and Government savings; the various premium payment options available to beneficiaries; and the options for distributing the beneficiary portion of the rebate.

We received 60 comments on subpart F in response to the August 2004 proposed rule. Below we provide a summary of the provisions of this subpart and respond to comments. (For a broader discussion of the provisions, please refer to the proposed rule.)

1. Basis and scope (§ 422.250)

Proposed § 422.250 set forth the basis and scope of the revised subpart F, noting that it was based largely on section 1854 of the Act, but included provisions from sections 1853 and 1858 of the Act. Section 422.250 indicated that subpart F addressed the bidding methodology upon which MA payments will be based beginning in 2006 and provisions for CMS' negotiation and approval of organizations' bids.

2. Terminology (§ 422.252)

The proposed definitions throughout both subparts F and G were intended to reflect the statutory definitions they implement in a simplified manner. The following terms were defined in proposed § 422.252:

• The ''annual MA capitation rate'' is the county rate. As set forth at section 1853(c)(1) of the Act, capitation rates are called ''MA local area'' rates, and references throughout the MMA to capitation rates are to county rates (or in the case of end-stage renal disease (ESRD) enrollees, to State rates).

• ''MA-PD plan,'' means an MA local or regional plan that offers prescription drug coverage under Part D of Title XVIII of the Act.

• ''Unadjusted MA statutory non-drug monthly bid amount'' is defined as the plan's estimate of its monthly required revenue to provide coverage of original Medicare Part A and Part B benefits.

• ''Monthly aggregate bid amount'' is defined as the total monthly plan bid for coverage of an MA eligible beneficiary with a nationally average risk profile. This bid is composed of: the unadjusted MA statutory non-drug monthly bid amount (also called the ''basic A/B bid''); an amount for coverage of basic prescription drug benefits under Part D (if applicable), and an amount for provision of supplemental benefits, if any.

• ''Plan basic cost sharing'' means cost sharing that would be charged by a plan for benefits under the original Medicare FFS program option before any reductions resulting from mandatory supplemental benefits.

• ''Unadjusted MA area-specific non-drug monthly benchmark amount'' is defined, for local MA plans serving one county, as the county capitation rate. For local MA plans serving multiple counties, it is the weighted average of county rates in a plan's service area, where the weights are the plan's projected enrollment per county.

• ''Unadjusted MA region-specific non-drug monthly benchmark amount'' is the sum of two components: the statutory component and the plan bid component.

• ''MA monthly basic beneficiary premium'' is the amount that an MA plan (other than an MSA plan) charges an enrollee for original Medicare benefits if its basic A/B bid is above the benchmark.

• ''MA monthly prescription drug beneficiary premium'' is the base beneficiary premium, adjusted to reflect differences between the plan bid and the national average bid, less the amount of rebate the MA-PD plan elects to apply toward a reduction of the base beneficiary premium, as described in proposed § 422.266(b).

• ''MA monthly supplemental beneficiary premium'' is the portion of the plan bid attributable to mandatory and/or optional supplemental health care benefits described in § 422.102, less any rebate applied to a mandatory supplemental benefit under § 422.266(b)(2).

• ''MA monthly MSA premium'' is the amount of the plan premium for coverage of benefits under the original Medicare program through an MSA plan, as described in proposed § 422.254(e).

As a result of our policy decision on the geographic ISAR adjustment, presented in the G preamble discussion of § 422.308(d), we are making a clarifying change to the definition of MA local area at § 422.252.

3. Submission of Bids (§ 422.254)

General rule. The MMA amended section 1854 of the Act to replace the adjusted community rate (ACR) proposal system currently in effect under the MA program with a bid

submission process. Proposed § 422.254(a) implemented section 1854(a)(1)(A) by requiring that no later than the first Monday in June, MA organizations must submit bids for each MA plan that they intend to offer in the following year (other than MSA plans, which have separate requirements), beginning for contract year 2006. Plan bids would be required to meet the requirements specified at proposed § 422.254(b), and bid submissions would be required to include the information listed in proposed § 422.254(c).

Under the previous M+C program, we permitted M+C organizations to offer new plans mid-year and to offer mid-year benefit enhancements to existing benefit packages. However, in order to maintain the integrity of the annual bidding process mandated in statute, we proposed that it is no longer appropriate to allow MA organizations to enter the program with a new plan mid-year (including service area expansions) or to offer mid-year enhancements to an existing plan (which essentially represents a redefinition of revenue needs, that is, a new bid).

Program of All Inclusive-Care for the Elderly (*PACE*) *organizations and the MMA bidding methodology*. We proposed to exempt PACE organizations from the Title II bidding process, so payments for PACE plans would be based on MA capitation rates. However, this exemption does not apply to Part D drug coverage for PACE enrollees. PACE plans will be required to submit bids for providing Part D drug benefits (although PACE bids will not be included in the national average monthly bid amount), as indicated in § 423.279(a).

ESRD enrollees. Section 1853(a)(1)(H) of the Act gives us the authority to determine if ESRD MA enrollees should be included in the MMA bidding process. We proposed at § 422.254(a)(2) that ESRD enrollees be fully incorporated into the plan's aggregate bid for contract year 2007 and succeeding years. For 2006, we proposed three options for pricing Part C benefits for ESRD beneficiaries: exclude ESRD costs from the basic A/B bid and the supplemental bid pertaining to Parts A and B benefits; exclude ESRD costs from the basic A/B bid but include them in the supplemental bid for A/B benefits; and fully include End Stage Renal Disease (ESRD) costs in the plan bid. We invited comments on specific proposed approaches. (We noted that ESRD costs must be included in the Part D bid at the outset, including the Part D supplemental bid amount.)

We noted that regardless of whether or not ESRD enrollee costs are included in the plan bid, ESRD enrollees would be subject to the same premium and cost sharing as other plan enrollees under the uniformity of premiums provision in § 422.262(c). That is, if ESRD enrollees were excluded from the plan bid, the rebate (or basic beneficiary premium, for a plan with the bid above the benchmark) would be determined based on costs for non-ESRD enrollees. ESRD enrollees would be subject to cost sharing and premium amounts based on estimated non-ESRD enrollee costs. Finally, we stated in the proposed rule that if the policy chosen were to exclude ESRD enrollees from the 2006 bids, for any plan offering a Part B premium reduction to MA plan enrollees, the amount of this reduction also would be subtracted from the payment for each ESRD enrollee.

Comment: Two commenters disagreed with any limitation on mid-year plan entry (including service area expansions) and mid-year benefit enhancement (MYBEs). One of these commenters asked if CMS' proposal were implementing statute. Another commenter stated that new mid-year plans should be allowed in a market if no other competitors existed in the market. One commenter acknowledged that an issue may exist with offering Part D benefits in any mid-year plan due to the formula used to calculate beneficiary premiums, but recommended that plans that do not offer Part D benefits should be allowed to enter at any time. This commenter added that nothing in the legislative history of the MMA supports CMS' position to limit mid-year plan entry and enhancements.

Several commenters did not state an objection to the restriction on new mid-year plan entry, but believed service area expansions (SAEs) should be allowed, to expand the availability of MA plans to Medicare beneficiaries. Finally, a number of commenters expressed concern that any restriction on offering mid-year plans, including SAEs, would undermine the ability of MA organizations to negotiate with employers or unions.

Response: We believe that the MMA both supports and requires the annual contracting methodology and the elimination of new mid-year plans, mid-year service area expansions and mid-year benefit enhancements (with exceptions that are listed below). We will require that organizations make their MA bid submissions once a year in June. We are retaining in regulation the language from the current MA regulations at § 422.306(a)(2), which states that if the submission is not complete, timely, or accurate, CMS has the authority to impose sanctions under subpart O of this part or may choose not to renew the contract.

We are doing as much as possible to support a competitive bidding process by removing uncertainty that would lead to inefficient bids, through mechanisms such as the design of the Intra-Service Area Rate (ISAR) adjustment, our models for risk adjustment of payments, and our policy on what plan expenditures we will include in risk sharing with regional plans, which by law must serve all of an MA region. (See the discussion on rebatable integrated benefits in subpart J.)

We do not believe that we should reduce the kind of ''uncertainty'' that comes from not knowing what products competitors will offer. This type of uncertainty should be a feature of a competitive bidding system. An annual plan bidding and entry process supports competitive bidding by ensuring an equal playing-field for all organizations. For example, MA organizations should not be able to design new plan benefit packages open to all beneficiaries in new service areas with post hoc knowledge of the regional MA benchmarks and national average drug bid.

However, after consideration of the public comments, we have identified certain exceptions to the end of flow contracting under the bidding methodology. (Mid-year plan entry is discussed in this comment, and MYBEs are discussed in the following comment.)

Mid-year plan entry. In general, we will not allow mid-year entry of new MA organizations, and new contracts with MA organizations for MA plans will be effective only on January 1 of each year beginning on January 1, 2006. In general, current MA organizations may not offer new plans mid-year, either in a current or new service area. We will still allow for applications to be submitted throughout the year, and we will make an eligibility determination in time for the next required bid submittal date.

However, we do not wish to discourage new plan offerings in areas where there are no MA options for beneficiaries. We also wish to support a competitive bidding process, as explained above. Therefore we will allow certain exceptions to the policy prohibiting new mid-year plans.

MA plans. The Part D bid is based on a national average of plan bids for the year, and the regional plan A/B benchmark is partly based on the average of regional plan bids for the region for the year. Accordingly, to

ensure an equal playing-field for all organizations and maintain the integrity of the Part D and MA regional benchmarks, we cannot approve mid-year regional MA plans because the regional benchmarks are established during bid review. We can only make the following exceptions for local plans. We may approve a local mid-year MA plan whose Part D bid is not included in the national average bid (that is, PFFS and cost plans offering Part D benefits, and special needs plans), if the plan will be offered in counties where there are no other PDPs (except fallback plans) or MA-PD plans. We could also approve a local mid-year MA plan that does not offer Part D benefits, if the plan is offered in an area with no other MA competitors. We believe that allowing mid-year plans could reduce the incentive to bid competitively, so we will carefully review applications.

PACE plans. New PACE organizations will be allowed to offer a PACE plan mid-year. As noted elsewhere in this preamble, PACE plans are governed by section 1894 of the Act. Under section 1894 of the Act, PACE plans must serve individuals who are ''nursing home certifiable,'' that is, require the level of care required under the State Medicaid plan for coverage of nursing facility services, and PACE plans have coverage requirements that differ from the coverage requirements for MA and MA-PD plans. Given the statutory requirements for defining the PACE-eligible individual, the PACE review and approval process is an extended process that requires intensive coordination with States and CMS. For this reason, new PACE plans will be exempt from the restriction on new-mid year plans, in order to promote coordination of Part C and Part D benefits with the benefits PACE plans are required to offer under section 1894 of the Act.

Employer/union group health plans. EGHPs not open to general enrollment will be allowed to offer new mid-year plans. Group health plans not open to general enrollment include both the ''800–series'' employer-only plan and group plans where we directly contract with the employer/union offering an MA product. However, an MA plan that enrolls both individual beneficiaries and employer/union members (in other words, a plan open to general enrollment) will be subject to the rule not allowing new mid-year plans (except under limited circumstances). As we have done in the past, we will publish separate guidance on employer/union group health plans.

Comment: Several commenters recommended that allowing mid-year benefit enhancements (MYBEs) would not affect the integrity of the bidding process, at least for original Medicare benefits. One commenter stated that plans sometimes find during the year that their benefit designs contain a problematic component, and seek to make mid-year changes. For example, an organization could discover that a plan co-payment for a preventive service was the source of widespread enrollee dissatisfaction that the plan would like to address, or the organization could learn mid-year that the cost assumptions for a particular benefit may have been higher than actual costs proved to be, and the plan would like to enrich the benefits to account for the lower costs. The commenters believe that retaining the flexibility to make mid-year changes to adjust for the circumstances could be quite beneficial to enrollees and could be done in a way to protect the integrity of the bidding process. This commenter recommended that we not allow MYBEs during the first quarter of the calendar year to remove the incentive to manipulate the process by bidding in June with the intention of making later mid-year enhancements to improve the package. Finally, several commenters requested that MYBEs be allowed for employer group plans, because MA organizations need the flexibility to enter into contracts with employer groups at any time during the year because employer groups may have plan years that differ from Medicare's calendar year cycle.

Response: We believe that in order to maintain the integrity of the bidding process, it is no longer appropriate to allow MA organizations to offer MYBEs at any time during the contract year, as they would be a de facto adjustment to the benefit packages for which bids were submitted earlier in the year. However, in response to public comments, we have designed an MYBE policy that we believe allows beneficiaries to receive the advantage of mid-year enhancements of non-drug benefits while protecting the integrity of the bidding process by reducing the incentive to overbid in June. The general rule is that we will allow MYBEs to non-drug benefits only under the following circumstances: (1) An MYBE can be effective no earlier than July 1 of the contract year, and no later than September 1 of the contract year; (2) MA organizations cannot submit MYBE applications later than July 31 of the contract year; and (3) 25 percent of the value of the MYBE will be retained by the government. The MA organization would submit, for each plan or segment, a revised bid and any supporting documentation related to the enhancement, including information on where the revenue requirements were overstated in the annual June bid submission. We will consider whether there is a current year MYBE request when analyzing a plan's bid for the following year. Continuing current practice, we will release guidance on the revised MYBE bid submission, including what types of non-drug MYBEs will be allowed and what documentation is required, in the annual Call Letter.

We consider this an interim policy for the initial years of the competitive bidding system (when drug benefit and regional plan pricing will be new terrain). We will review whether there is a continuing need for this policy.

We will allow the following exceptions to this policy of restricted MYBEs:

PACE plans will be allowed to offer MYBEs to non-drug benefits on a flow basis (unrestricted MYBEs), given the special nature of these plans and for the reasons specified above with respect to the ability of these plans to contract on a flow basis. (Under sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act, PACE plans are required to offer enrollees a package of benefits tailored to individual needs, as determined by the PACE interdisciplinary team. Because PACE enrollees may receive additional services at any point in the contract year, we note that an enrollee's access to additional benefits mid-year is in compliance with existing PACE statutory requirements and therefore in a technical sense is not the same as a mid-year expansion of benefits for MA plans.)

Employer and union group health plans. We recognize that employers and unions offering group health plans through an MA organization may operate on different bidding and negotiation timelines. Employer and union group health plans not open to general enrollment will be allowed to offer MYBEs on a flow basis. This includes both the ''800–series'' employer-only plan and the new type of employer and union plan, where we directly contract with the employer and union offering an MA product. As noted above, consistent with past practice, we will publish separate guidance on employer/union group health plans.

However, an MA plan will be subject to the restricted MYBE rule if it is a plan that enrolls both individuals and employer and union members, that is, a plan open to general enrollment. (''Plan'' in this context refers to the benefit offering of an MA organization

under an MA contract. MA organizations may offer multiple ''plans'' in a service area under one MA contract, including a mix of plans open to any Medicare beneficiary and plans open only to Medicare beneficiaries covered under an employer/union retiree plan.). Employers would still be free to enhance benefits mid-year for the part of the package that is a ''wrap-around'' to the MA plan and that is only available to employer and union members. However, it should be noted that ''wrap-around'' benefits are not technically part of the MA plan.

Comment: Several commenters were concerned that the MA bidding process is inappropriate for Special Needs Plans (SNPs), given the unique elements involved in managing the care of high risk and high cost beneficiaries. They compared SNPs to PACE organizations, which we are excluding from the Part A and B bidding process. They also indicated that the MMA explicitly excludes SNPs from the calculation of the Part D national average premium, and stated that this exclusion should be extended to bidding for Part A and B benefits. These commenters are concerned that including SNPs in the bidding process could affect participation rates by plans, thereby limiting access for beneficiaries to these types of plans. A few commenters also suggested that we could use a separate Part A and B benchmark for SNPs in recognition of the expanded benefits offered the enrollees in SNPs.

Response: First, the comparison of PACE plans to SNPs is not accurate from a statutory perspective, because PACE plans are governed by section 1894 of the Act, which is separate from the statute governing the MA program. The fact that PACE plans are governed by a separate statutory authority gives us the discretion to exempt PACE plans from the MA bidding process. However, SNPs are created under the MA statute, at section 1859(a)(6) of the Act. SNPs are coordinated care plans, per section 1851(a)(2)(A)(ii) of the Act. SNPs are governed by the payment provisions that apply to all coordinated care plans in the MA program. Section 1854(a)(6) of the Act requires all MA plans (other than MSA plans) to submit aggregate bids: a basic A/B bid, a prescription drug bid if applicable, and a supplemental bid, if any. Therefore, SNPs cannot be excluded from the bidding process. Moreover, SNP are paid under section 1853 of the Act, the same provision as other MA plans.

If the commenter is referring to Medicaid benefits when referring to the expanded benefits offered by SNP plans, we would like to emphasize that the basic A/B bid is only for coverage of original Medicare benefits.

Comment: Several commenters stated that the actuarially equivalent cost-sharing requirement will cause difficulty for SNPs serving dual eligibles because the cost-sharing payments made by State Medicaid agencies on behalf of dual eligibles are not required to equal the full Medicare cost-sharing amount.

Response: SNPs serving dual eligibles must show in their bids a level of cost sharing that is actuarially equivalent to the level of cost sharing charged to these beneficiaries under the original Medicare program option.

Comment: Several commenters asked whether and how the MA bidding methodology would apply to demonstration plans, including but not limited to those serving dual eligibles.

Response: The application of MA bidding rules to demonstration plans depends on the specific demonstration authority. Decisions about which demonstrations will be expected to submit bids will be announced in the Advance Notice of Methodological Changes for 2006 MA Payment Rates, which we expect to publish February 18, 2005 on our website at *http://www.cms.hhs.gov/healthplans/rates/default.asp*.

Comment: Many commenters recommended that we exclude the costs for MA enrollees with ESRD from the bidding methodology for 2006, both for the Part A and B bids and the supplemental bids. Commenters stated that MA organizations would have inadequate experience with the new ESRD payment methodology to submit sound bids in June 2005. A delay in including these services in the bid is also desirable to these commenters because it removes an added degree of complexity from the bidding process at a time when MA organizations are initially becoming familiar with the new and otherwise complicated requirements. One commenter also stated that ESRD enrollee costs should be omitted from both the basic A/B bid and supplemental benefits bid because payment for ESRD MA enrollees is based on a different risk adjustment methodology such that the meaning of ''1.0'' is different for ESRD than non-ESRD enrollees. The commenter added that MA plans are paid for ESRD enrollees in accord with a different ''rate book'' that is based upon state rates rather than county rates.

Response: The MMA amended section 1853(a)(1)(H) of the Act to state that we ''may apply'' the competitive bidding methodology to MA enrollees with ESRD, with appropriate adjustments made through application of the ESRD risk adjustment methodology. Since publication of the proposed rule, we have modeled bidding and payments under the new system, and have developed a way to apply the bidding method to ESRD enrollees. This ''merged bid'' method addresses commenters' concern that the ''1.0'' national average beneficiary does not mean the same under the non-ESRD and ESRD risk adjustment models. Our method involves converting non-ESRD and ESRD beneficiary risk scores (which are based on different risk adjustment models) into a common metric so that all costs for projected enrollees can be combined into a weighted average per capita benchmark and a weighted average basic A/B bid.

Therefore, beginning contract year 2007, we will require that MA organizations include costs for ESRD enrollees in their plan bids. As discussed above, ESRD enrollees must be subject to the same premium and cost sharing as other plan enrollees under the uniformity of premiums provision in § 422.262(c), for both original Medicare benefits and supplemental benefits. For this reason, we believe that the estimated costs for all enrollees should be included in plan bids. We will explain the ''merged bid'' method in the 2006 Call Letter for 2007 contracts and in the 2006 Instructions for Completing the 2007 MA Plan Bid Form.

However, we have concluded that we will not implement the merged bid method for incorporating ESRD beneficiary costs into plan bids for the 2006 contract year, because of the transition blend requirement for payments to aged and disabled MA enrollees. While 25 percent of aged/disabled MA payments must be based on the demographic model and 75 percent of payments on the risk adjustment model, 100 percent of ESRD payments must be based on the risk adjustment model. Under the bidding methodology, the transition payment blend must be reflected in the bid, since plans are paid either their bid (plus rebate) or part of their bid (benchmark, with the remainder of the bid coming from beneficiary basic premiums). We concluded, therefore, that exclusion of ESRD costs from plan bids for 2006 would reduce complexity in what will be an unfamiliar bidding process. Guidance on excluding ESRD costs from the 2006 bid will be provided in the 2005 Instructions for Completing the 2006 MA Plan Bid Form. See the subpart G preamble for information on payments for ESRD enrollees.

Comment: Several commenters recommended that we consider further delaying inclusion of costs for ESRD

enrollees in the basic A/B bid and supplemental bids in years beyond 2006.

Response: We believe that, beginning in contract year 2007, it will be feasible to implement a merged bid methodology for MA plans where non-ESRD and ESRD costs are appropriately weighted together into a single bid because 100 percent of MA bids and payments can be based on the CMS-HCC risk adjustment models. Moreover, the uniformity requirement means that it is to the MA organization's advantage to include ESRD enrollees in its bid. ESRD enrollees would be subject to the cost-sharing rules and premium amounts based on the plan's estimated non-ESRD enrollee costs. For example, if plan bids are calculated based only on lower-cost non-ESRD enrollees, MA organizations would have their supplemental premium under-funded because ESRD beneficiaries are likely to use more of certain supplemental benefits such as cost-sharing reductions and drug coverage. A significant financial impact may result from plan pricing based only on unit costs for services and expected utilization for the plan's non-ESRD enrollees.

Bid requirements

Proposed § 422.254(a) and (b) implement sections 1854(a)(1)(A) and 1854(a)(6)(A) of the Act, which set forth requirements for plan bids. MA organizations must submit an aggregate monthly bid amount for each MA plan the organization intends to offer. We proposed that each bid submission for an MA plan represents the MA organization's estimate of its average monthly estimated required revenue to provide coverage in the service area of the plan for an MA eligible beneficiary with a nationally average risk profile; that is, the aggregate bid is a standardized bid. This aggregate bid is the sum of several amounts the plan estimates are its revenue requirements: (1) the ''unadjusted MA statutory non-drug monthly bid,'' to provide original Medicare benefits (which we also call the ''basic A/B bid''); (2) the amount to provide basic prescription drug coverage; and/or (3) the amount to provide supplemental coverage, if any.

We proposed at § 422.254(b)(2) that each bid would be for a uniform benefit package for the service area (or service area segment, if applicable, for local plans). Plan premiums and all applicable cost sharing would also be uniform.

We stated in proposed § 422.254(b)(3) that the bid submission contain all estimated required revenue, including administrative costs and return on investment (profit or retained earnings). We stated that a determination that supplemental benefits are appropriately priced is essential for the integrity of the bidding process. A plan could overstate its revenue needs for covered services with the intention of maximizing those payments while under-pricing supplemental benefits to make the offering attractive to enrollees. To prevent this kind of strategy, we indicated that the accurate pricing of Part A, Part B, and Part D benefits and supplemental benefits will have equal importance in the bid review process. We will verify the reasonableness of these projections as part of the bid review process (in the same way that we will verify the reasonableness of plans' projections of enrollment numbers and enrollment mix for an optional supplemental product).

Supplemental benefits

We proposed at § 422.254(b)(3) that when estimating required revenue, a plan will include adjustments for the effect that providing any non-Medicare benefit has on utilization. We proposed that this requirement would apply to both mandatory and optional supplemental benefits. In both the Title I and Title II proposed rules, we took the position that the basic portion of the bid should represent basic benefits only; it should not reflect the utilization impact on basic benefits induced by the presence in the benefit package of supplemental or enhanced benefits. We proposed that this utilization impact should be included in the pricing of supplemental benefits (Title II) or the enhanced portion of the bid (Title I). We took this position to ensure the integrity of the bid. In other words, when a plan offers a benefit package that includes reductions in cost sharing, the pricing of such a mandatory supplemental benefit would include not only the cost of ''buying down'' the cost sharing (that is, the estimated revenue needed to cover the amounts enrollees would have otherwise paid as cost sharing), but also the cost of financing the expenditures associated with the additional utilization resulting from offering the cost-sharing benefits.

We also proposed to exercise our authority under section 1856(b) of the Act to establish a rule prohibiting MA organizations from offering, as optional supplemental benefits, reductions in Part A, Part B, and Part D cost sharing, or enhancements to Medicare Parts A and B benefits. Under the rule, MA organizations will still be permitted to offer non-Medicare benefits, for example, dental and optical services as optional supplemental benefits.

We stated in proposed § 422.254(b)(4) that the bid amount is for plan payments only but must be based on plan assumptions about the amount of estimated revenue required from enrollee cost sharing. The estimate of plan basic cost-sharing for plan basic benefits must reflect the requirement that the level of cost sharing MA plans charge to enrollees must be actuarially equivalent to the level of cost sharing (deductible, copayments, or coinsurance) charged to beneficiaries under the original Medicare program option.

Comment: A number of commenters disagreed with CMS' proposal that MA organizations develop a supplemental bid reflecting the effects on utilization of Part A and B services of providing non-Medicare covered benefits. First, most commenters stated that the benchmark, which is the maximum amount we will pay for coverage of Part A and B benefits, reflects Medicare FFS costs. Medicare carriers and intermediaries make payments for Medicare Part A and B services based on fee schedules without regard to whether the beneficiaries have supplemental coverage. According to the commenters, because most Medicare beneficiaries have some form of private or governmental supplemental coverage that has an impact on these costs, the MA benchmark also reflects this impact. The commenters believe that because ''induced demand'' is already accounted for in the benchmark, requiring plans to shift these costs to the supplemental benefit package would result in a misalignment of the relationship between the basic A/B bid and the benchmark.

Second, several commenters recommended that allocation of costs to the supplemental bid may have a tangible effect on the MA organization and on beneficiaries. To the extent that the MA plan's Part A and B bid is below the benchmark, moving these costs from the basic A/B bid to the supplemental bid increases the amount of savings, and increases the supplemental premium by the same amount. However, because we retain 25 percent of the savings, the rebate dollars will not fund 100 percent of the increase in the supplemental premium attributable to these costs. Thus, the proposed policy is likely to produce an increase in the aggregate beneficiary premium. In contrast, if utilization is included in the basic portion of the bid, basic bids will be higher and bid and premiums for supplemental benefits will be lower.

Third, commenters also were concerned that there are no existing standards to evaluate the effect that

providing non-Medicare benefits has on utilization and therefore on premiums and competition. For example, one commenter noted that frequently there are multiple impacts from a single benefit change. For example, lower primary care physician (PCP) copays may drive higher utilization among primary care physicians; however, it may also help result in lower specialist, hospital and prescription drug utilization. Several commenters concluded that it would be impossible to apply this requirement uniformly and therefore equitably.

One commenter noted another barrier to uniform application of this requirement: a large portion of an MA plan's enrollment will have supplemental coverage through a source other than the MA organization (for example, Medicaid, other government programs, employee benefit plans, Medigap plans), and these incremental, additional costs will necessarily be reflected in the level of the basic A/B bid. Therefore, this requirement would result in an uneven playing field among competitors. Finally, another commenter asked where plans will obtain data to make these adjustments and whether additional adjustments would be needed for potential adverse selection.

Response: We believe that the pricing of the supplemental benefit is critical to the integrity of the bidding process. For this reason, we proposed that when a plan offers a benefit package that includes reductions in A/B cost sharing, the price of the supplemental benefit would include not only the cost of ''buying down'' the cost sharing (that is, the estimated revenue needed to cover the amounts enrollees would have otherwise paid as cost sharing), but also the cost of financing the expenditures associated with the additional utilization resulting from offering the cost sharing benefits. We believe it was important to align pricing policies for medical benefits (in the MA rule) and drug benefits (in the Part D rule).

We recognize, however, that it can be very difficult to disentangle the effects of induced utilization from the effect of plan management of utilization of medical benefits. For Parts A and B benefits, the effect of induced demand may be insignificant. For example, it is reasonable to recommend that there is no induced demand for hospital services or skilled nursing facility (SNF) (additional hospital admissions) because of plan utilization management of those services. Thus, it is unlikely that a change in cost sharing (up or down) would create or reduce utilization of hospital or SNF services. On the Part B side, induced demand here may also be quite limited due to plan utilization management. In contrast to Part A and B benefits, there is likely to be induced demand for Part D benefits, especially for those individuals who will be receiving new coverage. Also, there is likely to be some induced demand if supplemental benefit options are provided that reduce the initial deductible or fill in part of the what is lacking in the standard Part D package. We further recognize that there are no universal actuarial standards for separating these effects. Therefore, after discussion of the public comments and further analysis, at this time we will not require that the non-drug portion of the supplemental bid be adjusted to include expenditures associated with induced demand for Medicare-covered benefits resulting from offering cost sharing reductions.

Therefore, in this final rule, we are deleting the sentence at proposed § 422.254(b)(3) that plan assumptions about revenue requirements must include adjustments for the utilization effects of non-drug cost sharing reductions. As we indicate in responses to comments below, we will not implement this aspect of estimating revenue requirements for the Part A and B benefits through rule making. However, we have the authority to refine guidance in the future on how MA organizations should estimate their revenue requirements under § 422.254(b). For the Part D benefit, the bid amount must reflect an adjustment for the effect that providing alternative prescription drug coverage (rather than defined standard drug coverage) has on drug utilization. Costs associated with any increased utilization must be included in the price of the drug portion of the supplemental bid for MA-PD plans. (See proposed § 423.265(d)(2) and the discussion in the F preamble of August 3, 2004 proposed rule for the Medicare prescription drug benefit.

As discussed below, we intend to analyze the effects of induced demand in the near future and will review this policy.

Comment: One commenter suggested that we delay implementation of this requirement concerning pricing induced demand in the supplemental package for a period of 2 years (until 2008) for both regional PPO and local plans. Another commenter was concerned about the short timeframe for a 2006 implementation of this proposal and made the following suggestions for implementation: (1) we develop a standard data set or set of utilization assumptions and distributions with which to quantify the utilization impact; and (2) plans should have the option of using those assumptions in their bid or plan-specific assumptions that are actuarially justified.

Response: As indicated above, we are withdrawing our proposal. However, we believe that improvements can be made in the accuracy of pricing supplemental benefits. We intend to conduct analysis in the near future using accumulated bidding and payment data, because we believe that over time it is possible to develop factors for the MA program that could be applied to estimate the cost of induced demand.

Comment: Some commenters stated that this requirement, coupled with the actuarially equivalent cost sharing requirement at section 1852(a)(1)(A), would cause particular difficulty for Special Needs plans (SNPs). Attribution of ''induced demand'' costs to the A/B benefit package would increase the cost of the bid and reduce potential savings, and shifting these costs to the supplemental benefit package would result in increased premium costs for SNP beneficiaries, because SNP cost structures may limit opportunities for rebates. Limited rebates also could result in cost shifting to plans or, in the case of duals, to States that cover cost-sharing amounts.

Response: As noted above, we are withdrawing this proposal. This withdrawal applies to all MA plans, including SNPs.

Comment: Two commenters disagreed with our proposed rule prohibiting MA organizations from offering, as optional supplemental benefits, reductions in Part A, Part B, and Part D cost sharing, or enhancements to Medicare Parts A and B benefits. One commenter requested that we continue to permit the flexibility of offering reductions of Parts A, B, and D cost sharing as optional supplemental benefits, because offering separate plans requires separate bids, system enhancement, and modification of enrollment and eligibility procedures. The other commenter requested that we make an exception to this rule for employer group plans.

Response: First, under Part D, optional supplemental benefits do not exist. Under § 423.265(c), we are requiring that enhanced alternative coverage be a uniform package for all enrollees. Second, in terms of Part A and Part B benefits, we would exclude from this requirement employer and union group health plans that are not open to general enrollment, which includes both the ''800–series'' employer-only plan and the new type of employer and union plan, where we directly contract with the employer and/or union offering an MA product.

However, an MA plan that enrolls both individuals and employer and union group health plan members (in other words, a plan open to general enrollment) would be subject to the restricted optional supplemental policy. Employers would still be free to fund ''wrap-around'' optional supplemental benefits that would be only available to employer/union members. The ''wrap-around'' benefits are not technically part of the MA plan.

MA organizations would still be able to provide choice by offering multiple plans within the same service area that have different mandatory supplemental benefits. Many MA organizations take this route today.

Comment: Several commenters support the proposed policy that MA bidders submit a single bid amount in 2006 based on the blending of the demographic and risk adjustment payments as required under § 422.308(c)(2)(ii)(B). The reasons cited are the administrative and analytic complexity of developing two bids to be compared against two different benchmarks.

Response: We will provide instructions for determining a blended bid, in the Instructions for Completing the MA Plan Bid Form. Information regarding payments based on blended bids will be provided in the Advance Notice of Methodological Changes for MA Payment Rates.

Actuarial equivalence

In the August 2004 proposed rule, we discussed at length how to implement the requirement at § 422.254(b)(4) to determine an actuarially equivalent amount of cost sharing. MA plans must provide Medicare-covered benefits to enrollees. The MMA amended section 1852(a)(1)(B) of the Act to include the term ''benefits under the original Medicare FFS program option,'' which are defined as those items and services (other than hospice care) for which benefits are available under Parts A and B to individuals entitled to benefits under Part A and enrolled under Part B, with cost-sharing for those services as required under Parts A and B or an actuarially equivalent level of cost-sharing as determined in this part.'' (Cost sharing refers to service-specific cost sharing for Part A and Part B benefits; it does not include a beneficiary premium.)

First, we discussed the current approach, the national uniform dollar amount. The MMA provision on determining whether a rebate is applicable is similar to a provision that continues to apply to MA plans through 2005, dealing with the determination of ''excess amounts'' used to fund extra benefits. Before 2006, when Medicare payments (based on administratively-set amounts) exceed the revenue a plan needs for providing the Medicare benefit, the plan must ''return'' the excess amount to enrollees in the form of extra benefits (or cost sharing reductions). An excess amount exists if CMS' average capitation payment for the plan exceeds the adjusted community rate, taking into account cost sharing for Medicare services that is the responsibility of the enrollees. Through 2005, all plans are required to use a uniform national figure that we provide as the amount to be subtracted from their computed revenue needs for the Medicare benefit package to determine the excess amount. The uniform national dollar amount represents our projection of the monthly actuarial value of Medicare coinsurance and deductibles (that is, the amount, on average, of cost-sharing expenses beneficiaries incur in receiving Medicare services across the nation).

We recognized that this approach does not adequately recognize geographic variations in cost sharing, cost differences among private health plans, and utilization and price differences between private plans and FFS Medicare. It distorts the statement of revenue needs of a plan. If a plan operates in a high-cost area, the national actuarial value of cost sharing may understate cost sharing in the area, while in low cost areas, cost sharing is overstated.

We proposed several alternative approaches to defining an actuarially equivalent amount of cost sharing for the basic A/B bid amount: (1) localized uniform dollar amount; (2) plan-specific approach; and (3) proportional approach. In this final rule, we also make a clarifying change to § 422.254(c)(5) to reflect the statutory requirement.

Localized uniform dollar amount

We would publish localized (for example, county-level or MSA-level) cost-sharing values, and an MA organizations would determine its basic A/B bid for a plan by subtracting the appropriate geographically weighted average of these cost sharing values for the plan's service area from the plan's stated revenue needs. The local cost sharing values would be based on actual per-beneficiary FFS cost sharing, projected to the contract year and standardized to a 1.0 risk score.

Plan-specific approach

The MA organization would use its own pricing and utilization assumptions to determine a basic A/B bid for its plan, as if the plan were offering Medicare-only benefits under Medicare cost sharing rules or an actuarially equivalent structure. A cost-sharing structure would be actuarially equivalent if the projected average cost sharing as percent of the sum of average cost sharing and projected average plan payout equals the percentage using Medicare's cost-sharing rules, based on the projected experience of the same group and using the same pricing assumptions. The average amount of cost sharing and the average plan revenue requirements for the assumed basic A/B package would then be adjusted to reflect cost-sharing and plan requirements based on an enrollee with a national average risk profile. The adjusted plan revenue requirements would serve as the organization's basic A/B bid.

Proportional approach (including national, regional, or local proportions)

Actuarial equivalence under this approach would be met if the ratio of a plan's cost sharing amount for the basic A/B bid to the total cost of plan benefits equals this proportion under original Medicare. For example, if the national average actuarial value of cost sharing under original Medicare in a year were 16.8 percent of the total (value of cost sharing plus value of benefits, using the actual 1999 figure for Medicare), then an MA plan would have to offer a basic A/B bid based upon a plan basic cost-sharing amount that is 16.8 percent of total costs. We would announce the projected percentage of total expenditures that represent cost sharing in the same way that we currently announce the national average actuarial value of Medicare cost sharing as part of the rate announcement for private health plans. To address the issue of geographic variation in cost sharing, we proposed regional or local proportions over national proportions. While a fixed national proportion recognizes variation in expenditures at the health plan level, even within FFS Medicare there is significant variation by area in the cost-sharing proportion, for example, for Part A ranging from 13 to 20 percent in 1999 (compared to the national average of 16.8 percent).

We further proposed breaking regional or local proportions into service-specific proportions of cost sharing applied to the different categories of expenditures health plans would have (for example, Part A versus Part B, or further disaggregated into inpatient, SNF, home health, physician, and/or outpatient).

We received a number of comments on the issue of actuarial equivalence, revealing a range of opinion. A few commenters recommended the local uniform dollar amount method, several recommended the plan-specific method, and some preferred the proportional method. Some commenters did not specify a choice but recognized the importance of accounting for regional variation in costs, with some expressing concern about the plan-specific method.

Comment: One commenter stated that CMS should retain the current uniform absolute dollar method. However, the commenter believes that CMS should adjust from national to local dollar amounts. The commenter believes that this aspect of the program, which is familiar to the industry, should remain constant given substantial changes to plan reimbursement under the MA program and the introduction of competitive bidding. The commenter also recommended that the plan-specific approach creates the possibility that the projections will be inaccurate and result in unfair cost-sharing burdens on members and hospitals. Thus, the proportional method may suffer from the same flaw, as it also relies on plan pricing assumptions.

The plan-specific method drew the most commentary from those in favor of and those opposed to this approach. Several commenters felt the plan-specific method would be the most precise because it was based on each plan's own utilization and pricing estimates, reflects the different mix of services in managed care versus FFS Medicare, and would be most administratively efficient since it is based on data readily available.

Several commenters objected to the plan-specific method. One commenter felt this approach would allow MA organizations to use unreasonable assumptions, and another commenter objected because it would disadvantage organizations that tightly manage care and/or have more efficient provider networks. Commenters objecting to the plan-specific approach supported beneficiary cost-sharing rules that require the same dollar amount of cost sharing across all affected plans in a local geographic area rather than any method that would allow variation by plan.

Response: There are two basic principles behind Section 1852(a)(1)(B) of the Act. First, the MA program must reflect a feature of the Medicare program, that a certain share of the cost of covered care is to be borne by beneficiaries (or third parties paying on behalf of beneficiaries), and not the government. Therefore the MA enrollee's share of costs will not be financed by government funds in the bidding system, unless rebate dollars are available. Second, for competitive bidding, the determination of whether a rebate (bid below benchmark) or a premium (bid above benchmark) is applicable to a plan must be based on an ''apples-to-apples'' comparison of the same set of benefits (Part A and Part B benefits) reflecting a specific cost-sharing structure.

Section 1852(a)(1)(B) of the Act affects how MA organizations develop their basic A/B bids. It does not determine what a plan's actual cost-sharing structure will be, because a plan can have an actuarial value of cost sharing that is less than that under original Medicare.

However, actual average per-member-per-month (PMPM) cost sharing under any plan offered by an organization cannot exceed the actuarial value of the FFS average. (This limit on actual in-plan cost sharing is a continuation of the pre-existing M+C provision except that, unlike the earlier M+C provision, the limit on the cost sharing does not include the premium.) Also excluded from this limit, and excluded from the Part A and Part B cost-sharing computation in the bid, is any cost sharing for Part A and Part B benefits that enrollees of MA regional plans obtain from non-network providers (because section 1852(a)(1)(B)(ii) of the Act specifically excludes out-of-network cost sharing (section 1858(b)(2)) from the determination of the ''actuarially equivalent level of cost-sharing with respect to benefits under the original Medicare fee-for-service program option''). We have made a change to § 422.254(b)(4) to conform the regulation to the statutory provision.

After further analysis, we do not support the use of localized dollar amounts. This approach shares a key problem with the national uniform dollar amount. An average absolute dollar amount would be too small for some plans in a local area or region (leading to shortfalls in rebates that could otherwise be used to fund supplemental benefits), yet too large for other plans (leading to bids lower than a plan's estimated revenue requirements). In either case, the distortion we are seeking to minimize would remain.

We believe the proportional approach is the best approach, based on local proportions that are service-specific. This approach supports the MMA goal of making ''apples to apples'' comparisons among basic A/B bids, which creates a level playing field because all MA organizations in a market area must apply the same standards.

This approach has the advantage over the local uniform dollar amount because plan pricing assumptions are built into the total value of the benefit package. Also, plans that efficiently manage care would be disadvantaged by local uniform dollar amounts because these amounts would overstate cost-sharing revenue, thus lowering the plan bid and resulting in larger rebates than the plan could actually ''afford.''

We believe the proportional approach is more straightforward to understand and implement than the plan-specific approach, which is crucial in the context of a bidding methodology that must build in several complex adjustments (for example, the geographic ISAR adjustment). The plan specific method is more precise (in that it reflects not only plan pricing but also plan utilization assumptions) but it is the most complicated method because it requires organizations to figure out the utilization effects of a cost-sharing structure they likely will not use in order to determine how plan payout and member cost sharing would change if the package were based on original Medicare cost sharing.

Comment: Several commenters requested that we consider using, for each local area or region, proportions by service category. The commenters believe that this refinement would yield proportions more closely reflecting the cost sharing associated with the mix of services used in these areas and could, therefore, result in a more accurate projection of the actuarially equivalent costs sharing in each geographic area.

Response: We agree with the commenters and intend to incorporate service-specific categories in the bid pricing tool. We are considering the following approach. Each year the Office of Actuary (OACT) would publish five proportions for each county representing average FFS cost-sharing: Part A inpatient hospitalization; Part A SNF; Parts A & B home health; Part B outpatient facility; Part B, all other. We will provide guidance on the proportional method and details on the service proportions in the Instructions for Completing the MA Plan Bid Form.

Comment: Two commenters also suggested that we allow MA organizations to choose whether to use the plan-specific or proportional method.

Response: We do not support the idea of allowing MA organizations to choose which method to use when estimating their MA bids. This would create further complexity in a complex bidding process. For example, it could create

confusion in bidding because each method could interact differently with the other rate and payment adjustments required under the MMA. It also would make it difficult for us to apply consistent standards in our bid review process. We want to set a single standard that applies to all MA organizations because we believe that is the intent of the statute and it ensures everyone is subject to the same rules.

Comment: Several commenters recommended that if we select the proportional method, the proportions should be established for each local area or region and also disaggregated by service category (for example, inpatient hospital cost sharing versus physician cost sharing). This refinement would yield proportions that will more closely reflect the cost sharing associated with the mix of services used in these areas and could, therefore, result in a more accurate projection of the actuarially equivalent costs sharing in each geographic area. If we select the proportional method, one commenter stated opposition to the development of proportions based on assumptions of how health plan enrollees generally use services, because it would be difficult for us to develop a distribution of services that would be consistent with the experience and practices of individual plans.

Response: We agree that further disaggregation of local or regional proportions by service category would result in proportions that are more accurate. See the discussion above for our proposed approach. Details on the method and the proportions for 2006 will be published in the Advance Notice of Methodological Changes for MA Payment Rates, which we expect to be released on February 18, 2005 on the CMS website at *http://www.cms.hhs.gov/healthplans/rates/default.asp*

Information required

Proposed § § 422.254(c) and (d) would implement section 1854(a)(6)(A) of the Act by setting out the information MA organizations must submit for coordinated care plans and PFFS plans. Proposed § 422.254(e) specified information that must be submitted for MSA plans.

Proposed § 422.254(c) established that, in addition to submitting an aggregate bid amount, MA organizations must submit the proportions of the aggregate bid attributable to coverage of Part A and Part B benefits, Part D basic benefits, and supplemental coverage. They must also identify the plan type, projected enrollment, any capacity limits, the actuarial bases for determining the bid amounts and proportions, information on the plan's cost sharing, including the actuarial value of deductibles, coinsurance, and co-payments, and information required to calculate risk corridors for regional plans for 2006 and 2007. Additional information required on drug coverage was proposed at § 423.265, which implements section 1860D–11(b) of the Act.

In the final rule, we added § 422.254(c)(9) to address information requirements for the geographic Intra-Service Area Rate (ISAR) adjustment. See the G preamble discussion of § 422.308(d) regarding our policy decision on the geographic ISAR adjustment.

Under proposed § 422.254(d), for MA organizations required to provide a monthly rebate because the plan bid is less than the plan benchmark, the organization must submit information to us about how this rebate would be allocated across the statutorily mandated options specified at § 422.266(b). All rebate dollars must be applied to a mandatory supplemental benefit.

Since MA regional plans may serve multiple regions, and each region is a separate service area, section 1854(a)(1)(C) of the Act requires us to encourage the offering of regional plans by developing procedures to allow MA organizations to file consolidated information for multi-region MA plans (including national plans). We believe our new bid pricing tool will capture MA pricing information in an efficient manner and reduce filing burden for all MA organizations, including those offering national plans. Much of the supporting documentation required for the Adjusted Community Rate Proposal (ACRP) will no longer be required. Specifically, we will no longer collect commercial pricing and corporate financial data, and the number of cost-sharing categories has been reduced. In addition, the electronic bid form includes data elements that were filed paper format for the ACRP process, for example, actuarial utilization and cost data, trends in medical expenses, and non-medical expense projections. We are committed to working with organizations to reduce duplicative information in the application, bidding, and contracting process. For example, we would expect that a single legal organization offering an MA regional plan in more than one region would submit much the same legal and organizational information for all regions, with the main differences being the provider networks. We expect the application process to be an area where paperwork burden can be reduced. Ideas for consolidating regional filings that are under development include a master contract, a single actuarial certification covering multiple bids, and consolidated supporting exhibits across regional bids where there are common elements (for example, the development of manual rates). We will continue to identify ways to consolidated filing as the program develops.

In addition, we will apply the projected revenue and medical expense values (including administrative expenses) captured by the MA bid pricing tool to calculate the risk corridor amounts used to determine risk-sharing payment adjustments for regional MA plans for contract years 2006 and 2007. See the subpart J preamble for the discussion of risk sharing on costs of providing original Medicare benefits and rebatable integrated benefits. See the Advance Notice of Methodological Changes for Medicare Advantage Payment Rates for guidance on information to submit for determination of risk sharing payments.

Finally, section 1854(a)(6)(A)(iii) of the Act gives us the authority to require information in addition to that listed above to allow us to verify the actuarial bases for plan bids. We expect to use the authority given us under this provision in two ways. First, our review of an organization's bid submissions may identify problems that would trigger our request for additional, more detailed information (for example, data the MA organization used on average utilization and pricing to model the expected distribution of costs in the plan bid). We would not want to require such detail for every plan bid in the initial submission, and we are confident that forthcoming bid submission guidance (in the annual Instructions for Completing the MA Plan Bid Form) will limit the occurrences of our requests for additional data. Second, as we did with the ACRP tool for the M+C program, we expect to make annual updates to the bid pricing tool. The updates may or may not involve changes to the information required to verify actuarial bases of the bid. We will announce the updates in the annual Call Letter.

Special rules for MSA plans

Proposed § 422.254(e)(2) would implement sections 1854(a)(3) and 1854(b)(2)(D) of the Act by indicating that bids are not required for MA MSA plans. That is, MA organizations will not complete the bid pricing tool developed for non-MSA plans. However, for MSA plans MA organizations must file a bid submission with information on coverage, the

enrollment capacity, the monthly MSA premium amount, which is the amount of revenue the plan requires to offer original Medicare benefits (analogous to the basic A/B bid for other MA plans). MA organizations must also submit the amount of the MSA deductible, and the beneficiary supplemental premium, if any. MSA plans are prohibited from offering Part D coverage (although MSA enrollees may choose to enroll in a prescription drug plan).

Comment: One commenter recommended that we consider allowing MA organizations to subsidize the Part D premium for dual eligible beneficiaries with revenue from the medical benefits part of the MA-PD plan.

Response: We believe the commenter's phrase ''the medical benefits part'' is referring to Part A and B benefits. MA organizations offering the Part D benefit may fund a reduction in the Part D premium with rebate dollars, pursuant to section 1854(b)(1)(C)(ii)(II) of the Act, and as proposed at § 422.266(b)(2). However, the resulting premium amount must be uniform for all members of the plan, in accordance with section 1854(c) of the Act. A plan may not offer an additional premium reduction only to a subset of members (for example, dual eligible beneficiaries).

Comment: One commenter asked that we clarify the ''enrollment assumptions data requirement,'' that is, how these assumptions will be used in computations and how errors in them will be corrected over time. The commenter believes that our assumption about a plan's enrollment mix will be a critical competitive factor in determining how rebate dollars are used to buy mandatory supplemental benefits and/or how beneficiary premiums for mandatory supplemental benefits are set. Our oversight on this issue will be vital to ensure a level playing field.

Response: See the discussion in the subpart G preamble on the geographic Intra-Service Area Rate (ISAR) adjustment, which takes into account the difference between the distribution of enrollment across counties in the plan's service area assumed in the plan's bid and the actual geographic mix of enrollment at the time payment is made. Also, we will release detailed guidance on the bidding methodology in the Instructions for Completing the MA Plan Bid Form and the Call Letter. Information on the payment methodology, including the ISAR adjustment, will be provided in the Advance Notice of Methodological Changes for Medicare Advantage Payment Rates, published annually on our website at *http://www.cms.hhs.gov/healthplans/rates/default.asp*.

Comment: Several commenters supported development of procedures for MA organizations to file consolidated bid information for multi-regional plans, including national plans, and believe that this will facilitate the offering of regional plans.

Response: In light of the statutory mandate to allow consolidated bids for multi-regional plans, we are committed to allowing bid consolidation where appropriate. However, in order to maintain the integrity of the bid submission and review process, section 1854(a)(1)(A) of the Act requires MA organizations to submit a bid for each MA region. However, we believe our new bid pricing tool will capture MA pricing information in an efficient manner and reduce filing burden for all MA organizations, including those offering national plans. See the discussion above for examples of burden reduction in the new bid pricing tool.

Comment: A few commenters recommended that we establish streamlined documentation requirements for MA organizations to follow in supporting the actuarial basis of their bids. The commenter requested that these requirements strike a balance between providing us with sufficient information to review the bid and ensuring that MA organizations are not burdened with onerous requirements.

Response: We support the commenters' position that the requirements built into the new bid pricing tool and supporting documentation should be thorough enough to allow a fair and accurate review of bids but should avoid undue burden. See the discussion above regarding the new bid pricing tool MA organizations will use for bid submission. Most of the supporting documentation required for the ACRP will no longer be required. For example, we will no longer collect commercial pricing and corporate financial data, and the number of cost-sharing categories has been reduced.

Comment: Several commenters are interested in having bid formats, documentation requirements for submission and criteria for actuarial substantiation as early as possible to assist in the bid preparation and to minimize the uncertainty in dealing with employer retiree groups and other contractors, including providers. One commenter stated that our negotiation and approval process will be completed later than most plans' rate quotes to employer retiree groups for the following contract year. To the extent that MA organizations must negotiate changes to retiree premiums, benefit packages and our payments after these organizations have provided rate quotes to employer groups, this destabilizes the MA organization's relationship with, and reduces its appeal to, employer groups. The commenter indicated that early and clear expectations of plans' documentation requirements for submission would help to minimize this.

Response: We have been working hard to develop all aspects of the new bidding methodology to ease the transition for all parties. In December 2004, we released for public comment drafts of the drug and non-drug bid pricing tools that will, with the plan benefit package, constitute the annual June bid submission, with the intention of developing the new program. We do recognize the special circumstances surrounding the offering of employer and union group health plans (EGHPs), and as noted above, we will release separate guidance regarding EGHPs.

Comment: One commenter strongly objected to the proposed regulatory requirement that MA organizations that have Part B-only enrollees submit a separate bid for these enrollees. Some MA organizations have only a handful of these members and the cost of preparing a separate bid is very substantial. The commenter recommended that we identify a means for bidding organizations to submit their Part B-only enrollee bid in conjunction with another bid. The commenter recommended this approach so that MA organizations are relieved of the administrative burdens of submitting two bids for their enrollee population while the underlying objectives of the bid process are still accomplished.

Response: The requirement at § 422.254(f) is substantially the same language as the previous § 422.310(a)(3) for the M+C program. Preparation of a separate adjusted community rate (ACR) for Part B-only enrollees is a long-standing policy, and we do not see a basis for changing the existing policy. We have made editorial changes to the text at § 422.254(f) to conform it to the previous § 422.310(a)(3).

There are two types of Part B-only enrollees: current members of employer or union group health plans and Part B-only enrollees ''grandfathered'' from pre–1999 risk contracts. Since 1998, only those beneficiaries who are members of employer or union groups have been allowed to elect a Part B-only plan. However, section 1876(k)(2) of the Act created ''grandfathered'' Part B-only enrollees by permitting a Part B-only beneficiary enrolled with an

organization under a section 1876 risk contract on December 31, 1998 to continue enrollment with that organization if that organization had entered into an M+C contract effective January 1, 1999.

Our operational policy has recognized that the number of ''grandfathered'' beneficiaries has been decreasing over time, and in the past we have provided guidance on grandfathered enrollees in the annual Call Letter, including an option to simplify rate filing. Call Letters from prior years with guidance on grandfathered Part B-only enrollees can be found on our website at *http://www.cms.hhs.gov/healthplans/acr/*. We will continue to provide guidance regarding this policy in the Call Letter.

Comment: A number of commenters asked questions about the procedures for bidding. For example, a few commenters asked how we will define administrative expenses in the bid pricing tool, and whether the definitions will be the same for Part C and Part D. Other examples are whether we would allow rounding of premiums after adjustments to the allocation of rebate dollars, and how MSA plans could provide risk adjustment data for payment.

Response: As in the past, we will address questions on the procedural details of bidding in the Instructions for Completing the MA Plan Bid Form and the Call Letter.

4. Negotiation and Approval of Bids (§ 422.256)

Authority to review and negotiate bids

The provisions in proposed § 422.256 would implement section 1854(a)(6)(B) of the Act, which provided us with the authority to negotiate the monthly aggregate bid amount and the proportions of the aggregate bid attributable to basic benefits, supplemental benefits, and prescription drug benefits. The MMA grants us the authority to negotiate bids that is ''similar to'' the statutory authority given the Office of Personnel Management (OPM) to negotiate with respect to health benefits plans under the FEHBP program.

Chapter 89 of Title 5 gives OPM broad discretion to negotiate prices and levels of benefits. We believe that the Congress used ''similar to'' in the statute to recognize the differences between the FEHBP and the MA program. For example, the OPM authority applies to negotiating the level of plan benefits, while MA plans must offer, at a minimum, benefits covered under the original Medicare program, which are defined in law. Also, the authority to negotiate payment rates would seem to be limited for the MA program by other provisions of the MMA (for example, statutory formulas for determining benchmarks, premium and rebate amounts, and payments to plans.)

However, MA plans are able to modify the cost sharing for Medicare Parts A and B benefits via supplemental benefits. We have the authority to negotiate the level of the supplemental benefits as part of ensuring that the bid is not discriminatory, as described in section 1852(b)(1) of the Act and implemented at proposed § 422.100(f)(2) and § 422.110. Further, in situations where we have questions about the assumptions used for a plan bid, we have the authority to negotiate with the MA organization regarding the appropriate assumptions and the resulting rebate and/or supplemental premiums, to ensure that the supplemental bid reasonably and equitably reflects revenue requirements.

Noninterference

As proposed under § 422.256(a)(2) and in accordance with section 1854(a)(6)(B)(iii) of the Act, we do not have the authority to require—(1) any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services under the Act; or (2) a particular price structure for payment under a contract to the extent consistent with our authority. Also, as under current law, we do not have the authority to review or negotiate bids for PFFS plans or any amounts submitted by MSA plans.

Standards of bid review

Proposed § 422.256(b) implements section 1854(a)(6)(B)(ii) and (iii) and section 1854(e)(4) of the Act, which together established three standards for our review of bids. First, the bid and proportions must be supported by the actuarial bases, which we determine based on information provided by the MA organization.

Second, the bid amount and proportions must reasonably and equitably reflect the plan's revenue requirements for providing the benefit package, as the term revenue requirements is used for purposes of section 1302(8) of the Public Health Service Act. We interpreted this reference to mean that the Congress intends for a plan bid to reflect the plan's estimated required revenue in providing coverage (including any profit or retained earnings), and not other factors such as the relative lack of competition in the plan's market area or the level of annual capitation rates and benchmarks in the service area.

Third, proposed § 422.256(b)(3) implemented section 1854(e)(4) of the Act by providing for a limitation on applicable cost-sharing for coordinated care and PFFS plans: the actuarial value of plan cost sharing ''applicable on average'' to plan enrollees cannot exceed the actuarial value of cost sharing ''applicable...on average'' under original Medicare. We interpreted ''applicable'' to mean the level of cost-sharing in effect after any reductions to the level of cost sharing that a plan can make by offering a mandatory supplemental benefit, as specified under section 1852(a)(1)(B) of the Act. That is, we apply this third standard of review, as specified under section 1854(e)(4) of the Act, in light of both the basic A/B bid and the application of any rebate toward reduced cost sharing of Medicare Parts A and B benefits included in the supplemental bid.

We clarified that proposed § 422.254(b)(4), which implements the requirement in section 1852(a)(1)(B)(i) of the Act), that the actuarial value of MA plan cost sharing for Medicare Part A and Part B benefits assumed in constructing the basic A/B bid must equal the actuarial value of original Medicare cost sharing, would affect how MA organizations develop their basic A/B bids. In contrast, the cap on *actual* enrollee cost-sharing liability for Medicare Parts A and B benefits is established at proposed § 422.256(b)(3), which implements the requirement in section 1854(e)(4) of the Act. Before 2006, the sum of applicable plan cost sharing for Part A and Part B services, and any cost sharing for Part A and Part B services that was collected as revenue in the form of a premium or portion of a premium, could not exceed the actuarial value of cost sharing in fee-for-service Medicare (section 1854(e)(1) of the Act). As of 2006, any Medicare cost sharing included in a premium (as well as any cost sharing that is ''bought down'' through the use of rebate dollars) is not counted towards the limit (section 1854(e)(4)of the Act).

We further clarified that, under the new bidding methodology, an MA organization cannot substitute a basic beneficiary premium for some portion of cost sharing under original Medicare. Section 1854(b)(2)(A)(i) of the Act (proposed at § 422.262(a)(1)) mandated that for plans with bids less than benchmarks, the premium for original Medicare benefits must be zero. Our understanding is that Congressional intent was to have the basic A/B bid be for a standardized package. This means MA organizations able to offer plans

with Medicare-covered benefits at a lower cost to the beneficiary than the benchmark will have a plan with zero premium for coverage of benefits under original Medicare.

However, any MA organization can choose to structure the benefit package with a mandatory supplemental benefit that includes a reduction in Medicare Part A and B cost sharing. The premium for this supplemental package, as well as the Part D or Part B premium, can be offset by any rebates for which the plan is eligible. Thus, the aggregate bid would consist of: (1) a basic A/B bid amount for benefits available for either zero premium or a basic premium depending on whether the plan's bid is above or below the benchmark; (2) a mandatory supplemental bid amount for benefits available for a premium or no premium depending on the plan's use of rebates (and an optional supplemental benefit if offered); and (3) a drug bid amount for basic benefits, also available at a premium or no premium depending on use of rebates.

Finally, we clarified that, under the MMA, an MA organization is no longer permitted to reduce the basic beneficiary premium amounts for original Medicare benefits by taking a negative adjustment on additional revenue, as was permitted under the M+C program in the ACRP process. In accordance with section 1854(a)(6)(B)(ii) of the Act, plan bids must reasonably and equitably reflect plan expected revenue requirements. MA organizations cannot submit plan bids that understate their revenue requirements for the basic A/B bid. When the basic A/B bid amount exceeds the benchmark amount, the difference is required to be charged as a basic beneficiary premium. If an MA organization were able to waive the plan's basic beneficiary premium, this would suggest that the MA organization had overstated the plan's expected revenue requirements for basic benefits. In essence, we do not have the authority under the statute to allow MA organizations to waive basic beneficiary premiums for plans with basic A/B bids greater than benchmarks.

Comment: Several commenters requested clarification on how we would interpret the bid review standard that the bid amounts and proportions must ''reasonably and equitably'' reflect the MA plan's revenue requirements for providing the benefit package. Two commenters suggested that we should ensure that adequate flexibility is maintained throughout the bid review and approval process in order to allow MA organizations to pursue legitimate business strategies that promote the availability of viable choices for beneficiaries. One commenter recommended that we consider in its bid review process whether an organization is in a start-up phase and the intensity of the marketplace competition facing the plan. Another commenter suggested that in reviewing the revenue requirements of the plan, we should take into account that a variety of factors may affect anticipated rates of return for MA plans. For example, a new MA organization may reasonably anticipate budget deficits during its early years of operation in order to offer competitive plans while its fixed costs are high in relation to the number of enrollees and its enrollment and revenues grow toward break even. In addition, due to differing marketplace dynamics and other factors, the rates of return may differ for different products. The commenter acknowledged our concern about the integrity of bids from plans lacking competition in their service area, but stated strong opposition to any requirement we may consider that would force plans to have similar ''rates of return'' on Medicare and non-Medicare products as a way to measure bid accuracy. Also, the commenters cautioned against having standards that would skew actual bid amounts in order to avoid the appearance of not operating with maximum efficiency.

Response: In the August 2004 proposed rule, we stated that we believe the Congress used the phrase ''similar to'' in section 1854(a)(6)(B)(i) of the Act (which states that our authority to negotiate bids is similar to OPM's statutory authority to negotiate concerning health plans) to signal an understanding that the FEHBP and MA programs are not identical, but have some similarities. We gave two examples of differences between the programs: (1) MA plans must offer original Medicare benefits, which are defined in law; and (2) the formulas for determining MA rates are established in law. We then gave an example of an area where the OPM-like authority to negotiate bid amounts would be relevant to the MA program: pricing of supplemental bids. We then discussed the three proposed standards of bid review: (1) bids and proportions must be supported by actuarial bases; (2) bids and proportions must reasonably and equitably reflect the plan's revenue requirements for providing the benefit package; and (3) the standard at section 1854(e)(4) of the Act (implemented at proposed 422.256(b)(3)) has been met, which limits enrollees' liability for cost sharing.

In addition to review of bid amounts and proportions under these three standards, we also are mandated to review other aspects of the annual bid submission. We must ensure that all benefits are covered, per the requirements at section 1852(a) of the Act. Section 1852(b)(1) of the Act requires us to review the plan benefit design, particularly the structure of premiums, deductibles, copayments, and coinsurance charged to beneficiaries to ensure it is not discriminatory, as implemented at § 422.110.

With regard to review of bid amounts, we will respond to the commenters' questions by discussing the statutory bases on which we formulated the first two bid review requirements. The first bid review standard, that bids be supported by actuarial bases, is mandated in two places in section 1854(a)(6)(B) of the Act. The first phrase of section 1854(a)(6)(B)(i) of the Act states that subject to the noninterference clause and the exception for PFFS plans, the Secretary has the authority to negotiate bid amounts and proportions under subparagraph (A), including supplemental benefits. Section 1854(a)(6)(A) of the Act (the subparagraph (A) reference), which specifies what information MA organizations should submit with their annual bid submission, includes the requirement that MA organizations submit information demonstrating the actuarial basis for determining the monthly aggregate bid amount. In addition, section 1854(a)(6)(B)(ii) of the Act states that the Secretary can only accept bids if they are supported by the actuarial bases provided under subparagraph (A).

Therefore, under the first review standard we may negotiate whether or not to accept a bid based on our determination that the MA organization submitted sufficient actuarial bases and that the actuarial bases support the submitted bid amounts and proportions. The specific elements for which we will require actuarial bases are not listed as part of the regulatory text, and are incorporated into the bid pricing tool. However, we expect MA organizations to submit the actuarial bases for medical costs and administrative costs (including return on investment) for all components of a plan's aggregate bid (the basic A/B bid, the bid for basic prescription drug coverage, and bids for mandatory and optional supplemental benefits). We will examine the actuarial analyses to ensure that bids have been prepared in accordance with our actuarial guidelines, and properly certified.

The second bid review standard states that bids must reasonably and equitably reflect plan costs. This is also mandated in two places in section 1854(a)(6)(B) of the Act. The latter part of the sentence at section 1854(a)(6)(B)(i) of the Act states that when exercising the requirement to negotiate regarding bid amounts, the Secretary shall have authority similar to the authority the Director of OPM has under Chapter 89 of Title 5 to negotiate with respect to health benefits under the FEHBP program. In addition, section 1854(a)(6)(B)(ii) of the Act states that the Secretary can only accept bids if they reasonably and equitably reflect the revenue requirements (as used for purposes of section 1302(8) of the Public Health Service Act).

We look to the FEHBP standard in 5 USC 8902(i) to interpret our authority to review bids in a manner similar to OPM's statutory authority. Section 8902(i) gives OPM the authority to require that rates should reasonably and equitably reflect the cost of the benefit provided. We see this provision as imposing upon us the responsibility to evaluate the appropriateness of the overall bid amount and each portion of the aggregate bid. Specifically, we intend to evaluate the reasonableness and appropriateness of the actuarial assumptions made for the aggregate bid. We would examine bids to determine whether the revenue requirements for coverage offered by the plan are reasonable, including examination of administrative costs and return on investment (profit) for reasonableness. (For a discussion of how we will evaluate the reasonableness and accurateness of the prescription drug bid, see subpart F of the preamble in the final rule for the Medicare prescription drug benefit.)

There is no cap on administrative costs under Part C (or Part D) that is similar to the cap in effect for FEHBP experience-rated plans. We assume that competition among plans will generally assure reasonable bids. The Congress, however, did not leave the determination of rates entirely to market forces. We are required to determine that the reasonable and equitable test is met and we are given negotiating authority to assure this result. The initial review of MA bid submissions will focus, in part, on low and high cost outliers, and on bids in areas with little competition. It should be noted however, that bid outliers are not necessarily inappropriate, nor are bids within the measure of central tendency automatically correct. Indeed, an outlier bid may be reasonable and appropriate after additional review and explanation while an ''average'' bid could be based on incorrect actuarial assumptions. In summary, all bids will be reviewed for their reasonableness, whether the bids include outliers or not.

A plan bid submission may meet the first review standard (because there is sufficient actuarial information and it supports the submitted bid amounts), but not meet the second review standard because a bid amount does not reasonably and accurately reflect plan costs.

Finally, the commenters requested that our interpretation of the ''reasonable and equitable'' standard allow enough flexibility for MA organizations to pursue legitimate business strategies. ''Flexibility'' seems to have different meaning for different commenters. We want to clarify that we do not intend to measure bid accuracy by forcing bids for Medicare products to have the same rates of return as non-Medicare products. We do not believe that cross-product line comparisons would be appropriate at this time.

However, we do believe that it would be appropriate to develop criteria for review among Medicare products, such as the following for employer group health plans (EGHPs). We will release separate guidance for EGHP plans.

Comment: Two commenters proposed that the standards of bid review in proposed § 422.256(b), which they see as focusing on the statutory criteria, should be applied to review not only of the basic A/B bid and non-drug portion of the supplemental bid (if any), but also to the Part D basic bid and supplemental drug bid (if any). The commenters' concern is that, although the statutory basis for review and negotiation of bids is the same in Part C and Part D, the discussion in the Part D proposed rule includes broader language suggesting that we may challenge Part D bids with administrative costs (including rates of return) that are higher than those of other sponsors or MA-PD plans. In general, the commenters opposed standards that could lead us to require that MA organizations reduce their bids due to perceptions that their MA products could be operated more efficiently.

Response: See subpart F preamble in the final rule for the Medicare prescription drug benefit, which clarifies that we are not adopting any of the OPM regulations at this time, and we will not apply the FEHBP concept of a Similarly Sized Subscriber Group (SSSG) to review of Part D bids. We believe the preamble discussions on bid review in the final rules for Parts C and D are more clearly aligned.

Comment: One commenter recommended that we revise the language at § 422.256(b)(2) ''as the term revenue requirements is used in section 1302(8) of the Public Health Service Act'' to read ''as the term revenue requirements is used for purposes of section 1302(8) of the Public Health Service Act.'' This tracks the statutory language. In addition, the commenter recommended that we explain in the preamble that the reference to ''revenue requirements'' does not indirectly require that MA organizations need to use the adjusted community rate methodology, which is found in that section of the Public Health Service Act.

Response: We agree with the commenter and have revised the proposed language at § 422.256(b)(2).

Comment: One commenter asked us to clarify that under the MMA bidding methodology, MA organizations will no longer need to include information about commercial pricing.

Response: For the purpose of bid submission, organizations will not be required to submit information about their commercial pricing experiences for purposes of trending. However, it should be noted that we are still statutorily mandated to audit a proportion of MA organizations. Within the scope of an audit, we believe that it is appropriate to request and review an MA organization's allocation of costs between its Medicare and commercial products in order to ensure that a disproportionate share of the expenses is not allocated to the MA line of business.

Comment: One commenter recommended that we prevent MA plans from ''cherry picking'' healthier beneficiaries and to review bids and plan benefit packages to ensure they are not discriminatory against sicker beneficiaries. The commenter cited studies by The Commonwealth Fund and Medpac that confirm that some MA plans have used co-payments and other devices to discourage enrollment of beneficiaries who have high utilization of services.

Response: We will be evaluating bids for their actuarial soundness based on the documentation submitted by plans to support the submitted bid amount and associated proportions. As mandated by the MMA (and earlier statutory provisions), we will also be reviewing the benefit packages of each plan to guard against discrimination. In addition, we will continue to follow the standards described in the M+C final regulation of June 2000 at § 422.110, which prohibit an organization from discriminating against beneficiaries by denying, limiting or conditioning

coverage to beneficiaries or offering of benefits to individuals eligible to enroll in a plan on the basis of any factor that is related to health status (for example, medical history or medical condition, with limited exceptions). We will be concerned about levels of cost sharing for dialysis and chemotherapy drugs, and cost sharing for medical categories (inpatient stays, outpatient facilities, and ambulatory surgical centers).

Negotiation process

Proposed § 422.256(a) would implement section 1854(a)(6)(B)(i) of the Act, which provides us the authority to negotiate with MA organizations. We have the authority to negotiate to ensure that the bid is not discriminatory; and in situations where we have questions about the assumptions used for a plan bid, we will negotiate with the MA organization regarding the appropriate assumptions and the resulting rebate and/or supplemental premiums. We expect that the process of bid negotiation between CMS and an MA organization could result in an agreement to adjust the bid's pricing, utilization, and/or enrollment assumptions. The MA organization would resubmit the bid information for the plan. The bid cannot be changed unless mutually agreed upon by the MA organization's representatives and CMS as a result of our review and negotiation process.

Comment: A few commenters are concerned that we have a uniform process for conducting bid negotiations to ensure that there is consistency across negotiating teams as well as firm deadlines for ending negotiations.

Response: We understand the concerns about the uniformity and timing of bid negotiations. We believe that the bid negotiations will be governed by the specific actuarial review principles that will be contained in the bid pricing tool. Bid negotiations will have to be complete before September in order for plans to have sufficient time to submit their plan benefit package materials for our website.

Comment: One commenter wanted to know how our deadlines for negotiation compare with the deadlines established by OPM for its FEHBP negotiations.

Response: OPM's rate filing and negotiation schedule is similar to that proposed by CMS. Rate proposals are due by May 31 each year, and by mid-August negotiations are generally complete. By law, the filing deadline for the MA program is the first Monday in June, and we expect to conclude negotiations by the end of August or early September.

Comment: Several commenters wanted to confirm that organizations unable to reach agreement with us during the negotiation process will be permitted to withdraw their bids without penalty. The ability to withdraw a bid is significant to avoid an MA organization committing to providing coverage for a year that is not sustainable financially, potentially jeopardizing beneficiary coverage and the MA organization's long term success and viability.

Response: This issue is still under consideration, and we will be issuing subsequent guidance.

Comment: One commenter stated that in the past periodically MA organizations have identified errors in their ACRP after submitting them to us for the filing deadline. The commenter requested that we retain the current policy where MA organizations are allowed to correct these errors after the filing deadline and resubmit the ACRP provided that: (1) the MA organization can demonstrate that the information in fact was in error; (2) it is clear that the error was made inadvertently; and (3) the correction is made within a relatively short period of time following the submission.

Response: We intend to retain the current practice of allowing corrections for inadvertent errors, for example, typographical errors and certain other types of errors that caused the submission to fail the initial front end edits. Guidance on this matter will be published as part of the guidance on filing the new bid pricing tool and Plan Benefit Package.

Comment: One commenter requested clarification of the timeline for bid negotiations and finalizing benchmarks for negotiation with providers.

Response: Regarding negotiations with other contractors, we believe that bidders are developing their bids on what it will cost them to provide the items and/or services in their plan benefit packages and have had discussions and negotiations with potential contractors in order to estimate properly in their bid submission. In most cases where organizations have made good faith efforts to estimate their actual revenue requirements with appropriate supporting documentation, we do not anticipate significant modifications to bid amounts and proportions during the negotiation phase of the process.

Rules for adjustment of rebate dollar allocations.

In addition to other negotiated changes, an MA organization may need to adjust the allocation of rebate dollars in a plan bid, and resubmit the bid. We described several circumstances under which we expect reallocation of rebate dollars.

First, MA organizations must submit their plan bids in June (including the estimated drug premium amount) for both local and regional MA plans before knowing the national average monthly bid amount for basic coverage. Given the preliminary nature of MA organizations' Part D premium submission, we expect that some rebate allocations to Part D premium reductions will be overestimated (excessive allocation) or underestimated (insufficient allocation). These misestimates will mean some portion of the beneficiary rebate has been credited where it is not needed or not enough has been credited to achieve the premium desired. For example, if a plan's monthly drug premium is determined to be $34, which is less than the projected premium of $35 in its initial bid submission, there was an excessive allocation of $1 of the rebate to fund the Part D premium reduction. We would require the MA organization to amend its bid submission to reallocate the excessive $1 of rebate credit to other mandatory supplemental benefits. On the other hand, if the plan monthly drug premium is determined to be $36, which is greater than the projected monthly premium of $35 in the initial bid submission, there is an insufficient allocation of $1. We would give the MA organization the option of reallocating $1 of rebate from another mandatory supplemental benefit toward the Part D premium reduction in order to eliminate the $1 Part D premium and return to the zero premium in the initial bid submission.

For this reason, we anticipated that some MA organizations will make minor technical adjustments to the benefit structures of their non-drug bid amounts (that is, the basic A/B bid and supplemental bid). The adjustments will consist of reallocation of beneficiary rebate dollars among a subset of the categories allowed by law: (1) reduction in the premium for the non-drug portion of the mandatory supplemental package (that is, reduction in cost sharing for Parts A and B benefits or reduction in the cost of additional non-Medicare covered benefits); and (2) reduction in the Part D and Part B premiums. No modifications would be allowed to the cost of the Part D supplemental benefit (reduction in Part D cost sharing or reduction in the cost for coverage of drugs not covered under Part D). Changing the reduction in Part D cost sharing would have a domino effect. It would have implications for projected

reinsurance dollars, which impacts the pricing of the bid for basic Part D benefits, which in turn could affect the national average monthly bid amount and, hence, the basic beneficiary premium, which we would have just previously calculated and published for the year, as required by section 1860D–13(a)(4) of the Act.

Second, we recognized that the June bid submission for regional MA plans will be based on unknown benchmarks not only for the drug premium but also for Medicare Parts A and B benefits. As discussed in § 422.258(c), the region-specific benchmark amount is based, in part, on a weighted average of the plan bids for Medicare Part A and Part B benefits, which we cannot calculate until after the June bid submission. This means that the exact amount of a plan's rebate is unknown and will shift to the extent that the estimated benchmark a plan uses to create its June basic A/B bid amount differs from the region-specific non-drug benchmark we establish based on plan bids. Therefore, regional MA plans will also be allowed to modify the allocation of rebate dollars, other than for Part D benefits, to arrive at the supplemental, Part B, and Part D premiums originally submitted.

We proposed the following rules for the negotiation process concerning reallocation of rebate dollars due to excessive or insufficient allocation.

- MA plans with overestimated allocations to Part D premium reduction must reallocate beneficiary rebate dollars to other mandatory supplemental benefits and can do so only for the purpose of achieving the original Part D premium in their initial bid submission.
- Local MA plans with underestimated allocations to Part D premium reduction have the option of reallocating beneficiary rebate dollars from other mandatory supplemental benefits. However, the plan could only reallocate rebate dollars for the purpose of achieving the Part D premium in the initial bid submission. In this circumstance, plans could choose not to adjust the new premium or reallocate the appropriate amount to achieve the initial premium submitted.

We proposed the following rule for regional plans, which unlike local plans will not know the exact amount of their rebate dollars at the time of the June bid submission.

- Regional MA plans may reallocate beneficiary rebate

dollars to achieve the supplemental, Part B, and Part D premiums in their initial bid submission.

- Local MA plans not offering Part D benefits (these would only be PFFS plans who have elected this option) would have all the necessary information upon which to estimate their bid amounts for their initial June bid submission, and, therefore, the MA organizations would not be allowed to modify their plan benefit structures.

Comment: A few commenters recommended that MA organizations be permitted to reallocate rebate dollars to ensure that dual eligibles would not need to pay a premium for Part D if they enroll or remain enrolled in these MA plans. The commenter believed that the MA plans that would likely use this discretion are MA Special Needs Plans (SNPs). The success of SNPs would be seriously undermined if their Part D premiums exceed the applicable low income Part D subsidy, because their dual eligible enrollment would have an incentive to disenroll from these plans. Because the Part D bids of MA special needs plans are not factored into the national average monthly bid amount and the low-income benchmark premium amount, this adjustment will have an insignificant effect on the bid and payment process.

Response: The proposed requirement is that reallocation of rebate dollars during the negotiation process must result in the supplemental, Part B, and Part D premiums originally submitted in June. We believe the commenter is requesting that this requirement be expanded to allow a change in the Part D premium from that originally submitted in order to allow an MA organization to change the plan premium to match the low income premium subsidy level in effect for the plan's service area. We would allow this. Therefore, when rebate reallocation results in a Part D premium that differs from that originally submitted in June, the new premium must match the low income premium subsidy level. The Part D premium will have to be uniform for every member of the plan.

Comment: One commenter supported our proposal to limit changes to bids to technical changes. The commenter also questioned why MA regional plans would be permitted to make changes in cost sharing that would not be allowed for MA local plans. The commenter believes that allowing more than technical changes from regional plans would destabilize the level playing field of the bidding process.

Response: Because the benchmark is calculated for regional plans after bids are submitted, unlike local plans, regional plans do not have the advantage of knowing the benchmark for estimating their rebate, cost sharing and premium amounts. Therefore, it is necessary to provide additional latitude for regional plans that is not necessary to provide for local plans. Our intent is to allow appropriate redistribution of the estimated amounts so that plans' benchmark estimates can be reconciled with the actual benchmark estimates and the necessary modifications.

5. Calculation of Benchmarks (§ 422.258)

Proposed § 422.258(a) implemented the new section 1853(j) of the Act by providing a description of how benchmarks for local MA plans are calculated. For a service area that is entirely within an MA local area (county), the MA area-specific non-drug monthly benchmark amount is equal to the monthly MA capitation rate for the local area. For a service area that is in more than one MA local area, the benchmark amount is calculated as a weighted average of the local MA monthly capitation rates, using as weights the projected enrollment in each county used to calculate the bid.

Proposed § § 422.258(b) and (c) implemented section 1858(f) of the Act by providing a description of how regional MA plan benchmarks are calculated. Each MA region will have a benchmark amount that consists of two components: (1) the statutory component (based on a weighted average of local area capitation rates in the MA region); and (2) the plan bid component (based on the weighted average of regional plans bids in the MA region). The purpose of the blend will be to be more responsive to market conditions in the region by allowing plan bids to influence the final benchmark amount.

Finally, the statutory component will be multiplied by the statutory national market share, which is the number of MA eligibles in the Nation who were not enrolled in an MA plan during the reference month (the month in the previous year for which the most recent data on MA eligibles is available) divided by the total number of MA eligibles in the nation in the reference month. The plan-bid component will be multiplied by the non-statutory market share, which is the number of MA eligible in the nation who were enrolled in an MA plan during the reference month divided by the total number of MA eligible in the nation. These components will be added to yield the MA regional benchmark.

Comment: One commenter recommended that we revise the first sentence of § 422.258(c)(4) to replace the references to ''plan(s) offered in the region'' with ''regional plans offered in the region'' to clarify the plan-bid component of the regional benchmark is

calculated based only the regional plan bids, not all of the MA plan bids in the region.

Response: We agree and have made this correction. We also made technical corrections in § 422.258(c) along the same lines to further clarify this point. Finally, we made another change to the proposed rule language at § 422.258(c)(5)(i) to clarify further how the plan bid component of the regional benchmark will be calculated. In the final rule at § 422.258(c)(5)(i), we delete the following sentence from the proposed regulatory text because it states a specific calculation for determining a plan's share of enrollment that is not mandated at section 1858(f)(5)(B)(iii) of the Act: ''In that case, each plan's share will be the plan's projected enrollment divided by the total projected enrollment among all plans being offered in the region.'' We delete this sentence to clarify that the statute allows us to apply a factor based on plans' projected enrollment but does not mandate a particular calculation.

6. Beneficiary Premiums (§ 422.262)

Proposed § 422.262(a) would implement section 1854(b)(2)(A) of the Act, and described the new methodology for calculating the MA monthly basic beneficiary premium. This premium will now be determined by comparing the unadjusted statutory non-drug bid amount (basic A/B bid) to unadjusted benchmark amount. For an MA plan with a basic A/B bid that is less than the appropriate unadjusted non-drug benchmark amount, the basic beneficiary premium is zero. For an MA plan with a basic A/B bid that is equal to or greater than the unadjusted non-drug benchmark amount, the basic beneficiary premium is the amount by which the bid amount exceeds the benchmark amount. All approved premiums must be charged; that is, plans are not allowed to waive basic beneficiary premiums.

Proposed § 422.262(b) would implement section 1854(d)(4) of the Act, which specifies that MA enrollees must be charged consolidated monthly premiums. As intended by the Congress and as a part of our efforts to simplify the process for beneficiaries, an MA enrollee will pay a single premium consisting of the sum of all premiums a particular plan charges its enrollees, which will be one or more of the following: (1) the monthly basic beneficiary premium; (2) the monthly supplemental premium; and (3) the MA monthly prescription drug premium. This process will be in addition to the Part B premium payment process already in place.

We clarified that in the case of an Medical Savings Account (MSA) plan, there are no basic beneficiary premiums because we instead make a deposit to the enrollee's MSA. MSA plans are high deductible insurance policies, not managed care plans. The only beneficiary premium for an MSA plan will be a supplemental premium.

Uniformity of premiums and cost-sharing.

The MMA did not change current law regarding uniformity of premiums. Proposed § 422.262(c) would implement section 1854(c) of the Act, which specifies that, with the exception permitted under § 422.106(d), the MA bid amount and beneficiary premiums may not vary among individuals enrolled in the plan. Proposed § 422.262(c) continues current regulations now in subpart G at § 422.304(b) that cost sharing for basic and supplemental benefits may not vary among individuals enrolled in an MA plan.

MA organizations offering local MA plans within segments of service areas must submit separate bids for those segments that may have different premiums and cost sharing. Section 1858(a)(1) of the Act which specifies that regional MA plans may not have segmented service areas.

Proposed § 422.262(f) would implement section 1854(d)(2) of the Act on beneficiary payment options. This provision gives enrollees the option, at their discretion, of paying their MA consolidated premium by: (1) having it deducted directly from their Social Security benefit amount of from their Railroad Retirement Board or the Office of Personnel Management benefit amount in the same manner that Part B premium reductions are handled; (2) setting up an electronic funds transfer; or (3) through other appropriate means CMS may identify, including payment by an employer or under employment-based retiree coverage on behalf of an employee, a former employee, or a dependent. The MA organization may not impose a charge for individuals electing to pay their premiums through a deduction from their Social Security payments. In this final rule, we have consolidated subparagraphs (3) and (4) of § 422.262(f) to clarify that the other methods we may specify for payment of premiums include those listed in the regulation.

Comment: One commenter requested that we allow intra-regional benefit plan adjustments (that is, waiver of the requirement that plan have a uniform benefit package for a service area, including plan premiums and all applicable cost sharing) to ensure that regional PPO plans are not placed at a competitive advantage or disadvantage versus local plans due to rate variations within a plan's regional service area. The commenter stated that overall, the intra-regional benefit waiver would lead to greater participation in the regional PPO program and, at the same time, would ensure local plans can continue participation in areas with traditionally low reimbursement rates, resulting in competition and increased access to health plans for beneficiaries.

Response: We do not have the authority to waive the requirement at section 1854(c) of the Act, which states that plan bids and premiums be uniform for all members of a plan. Moreover, section 1858(a)(1) of the Act explicitly disallows the application of section 1854(h) of the Act to regional plans, which signals Congressional intention that there not be variation in premium and cost sharing across segments within a region. Therefore, at this time, we cannot allow variations in the plan benefit package within the service area of regional MA plan.

Comment: Two commenters recommended that we provide an option for an MA organization to waive the amount of premium that is the difference between the MA-PD premium and the low-income premium subsidy under Part D provided for in § 423.780. The commenter believes that this waiver would fit well within a safe harbor provided for in the federal anti-kick back statute. The ability to waive premium would: (1) allow dual eligibles to be auto-enrolled into their current Medicare Advantage plan without the burden of an added premium that many of these beneficiaries could not afford; and (2) provide more flexibility for dual eligible enrollees to self-enroll into an MA-PD plan of their choosing.

Response: If the commenter's reference to the ''MA-PD premium'' is to the combined basic Part A and Part B beneficiary premium and the Part D beneficiary premium charged by an MA-PD plan, then we must emphasize that these two premiums are determined separately and under different rules. When a plan's basic A/B bid is equal to or below its benchmark, by law the plan is not allowed to charge a basic premium for basic Part A and Part B benefits. When a plan's basic A/B bid is above its benchmark, section 1854(a)(2)(A) of the Act states that this difference is the monthly basic beneficiary premium. The basic beneficiary premium cannot be waived.

Section 1854 of the Act does not provide for waiver of the basic Part A and Part B premium for dual eligibles.

Subsidies for dual eligibles for coverage of medical benefits are set forth under Title XIX of the Act. Moreover, special needs plans are subject to the same bidding rules as other MA plans, in accordance with sections 1854(a)(1)(A) and 1854(a)(6) of the Act. Therefore, we do not have the authority to waive the basic beneficiary premium for dual eligibles.

The Part D premium determination is discussed at § 423.286. We do not have the authority to waive the Part D premium for beneficiaries eligible for a premium subsidy. If those beneficiaries eligible for this subsidy enroll in a Part D plan or MA-PD plan that has a Part D premium higher than the subsidy, then they owe this difference.

Comment: A commenter recommended that during the negotiation process, MA organizations be allowed to reallocate rebate dollars to reduce the Part D premium to the level of the low-income premium subsidy benchmark.

Response: See § 422.256 and the above response to comment in this subpart of the preamble for a discussion on this issue.

Comment: Several commenters recommended that CMS and the Social Security Administration not implement the provision that beneficiaries may opt to have their premiums deducted from their Social Security benefit amounts until the systems are fully in place to ensure that payments will be made to MA organizations correctly and on a timely basis. The concern is that without sufficient operational planning for the development and testing of a new payment system, organizations will not be paid enrollee premiums accurately and timely.

Response: We do not intend to delay the implementation of a statutorily mandated provision that gives beneficiaries the option of paying MA premiums by deducting the amounts from their Social Security benefit amounts. However, we are confident that the development and testing of a new payment system for accurate and timely payment of plans is feasible by January 2006.

Comment: One commenter requested that we make clear that the MMA language at section 1854(d)(2)(C) of the Act only prohibits MA plans from imposing charges pertaining to choice of the premium payment option if beneficiaries choose to have their premiums deducted from their Social Security benefit checks. That is, the commenter wishes that we make clear to beneficiaries that the statute does not prohibit MA plans from imposing charges related to premium payment under other payment options. The commenter therefore requested that we require MA organizations to convey clearly to beneficiaries, and in writing, what are the precise charges that will apply to other premium payment options before the beneficiary makes a choice of how to pay plans premiums.

Response: MA plans may not charge fees for late payment of the plan premium or other types of processing fees because this would violate the uniformity of premiums provision at section 1854(c) of the Act. For example, we interpret the uniform premium provision to mean that plans may not provide incentives to members to pay premiums in a certain manner by offering lower processing fees (per section 1854(d)). See Subpart B for a discussion of administrative remedies for non-payment of premiums.

Comment: One commenter wanted to verify that beneficiaries may still opt to pay their MA plan premiums directly to the plan.

Response: Enrollees in the MA plans may still choose to pay their MA plan premiums directly to the plan.

Comment: Several commenters request that we remove for American Indian/Alaska Natives (AI/AN) Tribes the barriers to paying their Part B premiums under our current group payer rules, specifically rules concerning the size of the group and switching an individual from automatic deduction to group pay. The commenters maintained that without these changes, it is unlikely that AI/AN individuals, who are entitled to health care without cost sharing, will enroll in MA plans.

Response: The issue of payment of Part B premiums under our current group payer rules is beyond the scope of this rulemaking.

7. Calculation of Savings (§ 422.264)

Proposed § § 422.264(a), (c), and (e) would implement sections 1854(b)(3)(A)and (B) of the Act (for local plans) and sections 1854(b)(4)(A) and (B) of the Act (for regional plans) concerning calculation of risk-adjusted basic A/B bids and risk-adjusted benchmarks, which is the first step in determining whether an MA plan has savings. The MMA gave the Secretary flexibility to determine whether the risk adjustment factors to be applied to the benchmarks and bids are determined on a State-wide basis for local plans, a region-wide basis for regional plans, a plan-specific basis, or on the basis of another geographic area.

Proposed § § 422.264(b) and (d) implement sections 1854(b)(3)(C) and (b)(4)(C) of the Act, respectively, on how to determine the amount of savings for each local and regional MA plan (if any) by calculating the amount by which the risk-adjusted benchmark amount exceeds the risk-adjusted bid amount.

Comment: All commenters from the industry agreed plan savings should be related to the risk profile of the enrollees. One important reason for this policy is that the rebate will likely take the form of supplemental benefits or reduced cost sharing and/or premiums. MA plans with enrollees whose average risk score is higher will typically need more revenue to provide the same level of supplemental benefits as a plan whose enrollees have a lower average risk score. To accomplish this objective, the adjustment to the benchmark and the bid that is used for calculating the savings should be based on the risk score of the particular plan.

Response: We agree with the commenters. For both local and regional MA plans, the calculation of savings will be determined by applying the plan average risk adjustment factor to the basic A/B bid and benchmark. We have revised § § 422.264(c) and (e) to reflect this policy, although we have left in regulation our discretion, as provided in the statute, to select a method for calculating savings.

8. Beneficiary Rebates (§ 422.266)

Section 1854 (b)(1)(C) of the Act states that an MA plan with savings (because the basic A/B bid is less than the benchmark) must provide to the enrollee a monthly rebate equal to 75 percent of the savings amount for that plan for the year. The remaining 25 percent of the savings would be retained by the Medicare Trust Funds. If the plan basic A/B bid is equal to or greater than the benchmark, the plan has no savings and, thus, no rebate.

Proposed § 422.266(b) provided, as set forth in section 1854(b)(1)(C)(ii) of the Act, that the beneficiary rebate could be provided in the following forms: (1) some part or all of the rebate can be credited toward the provision of supplemental health care benefits (including additional health benefits not covered under original Medicare; (2) a reduction in cost sharing for Parts A, B, and D benefits, and/or a reduction in the premium for the mandatory supplemental benefits); or (3) credited toward the prescription drug premium or Part B premium.

Proposed § 422.266(b)(1) provided that all rebate dollars must be applied to a mandatory supplemental benefit. We interpret the provision at section 1854(b)(1)(C)(i) of the Act that an MA plan must provide to enrollees a rebate equal to 75 percent of savings to mean

that rebate dollars must be provided to all enrollees in a plan. Therefore, rebate dollars could not be used to fund optional supplemental benefits because this would not guarantee that the plan is providing every enrollee with the rebate dollars.

Although rebate dollars can only be used to fund a mandatory supplemental benefit, a mandatory supplemental benefit may also be funded by beneficiary premium dollars. That is, a plan with a rebate may fund a mandatory supplemental benefit with rebate dollars only or with a mixture of rebate and premium dollars.

The MA plan will be required to inform us about the form and amount of the rebate and/or the actuarial value of the supplemental health care benefits. Adjustments to the structure of the benefit package will occur during the process of negotiating and approving bids detailed in proposed § 422.256.

If an MA organization elects to provide a rebate in the form of a reduction in the beneficiary Part B premium for beneficiaries in a particular plan, we will work with the Commissioner of Social Security to provide the necessary information to the Commissioner to apply a credit (as provided for under section 1840 of the Act) to reduce the amount of the Part B premium to be charged under section 1839 of the Act for each enrollee in that MA plan.

Comment: One commenter recommended that we revise proposed § 422.266 to note that rebate dollars may be used both to pay for the Part D premium and to provide supplemental drug coverage at no cost. The commenter argued that this change is needed to clarify that MA plans have the right to use rebate dollars to fund supplemental prescription drug benefits at no cost to the beneficiary as part of the basic Part D prescription drug benefit offered by the MA plan.

Response: We agree with the commenter, with one clarification. If an MA-PD plan offers basic drug coverage under Part D, by definition at § 423.100, there is no supplemental drug benefit, and thus no supplemental drug premium toward which to apply rebate dollars. If an MA-PD plan offers enhanced alternative coverage under Part D, then the plan must charge a premium for supplemental drug coverage. Per § 422.266(b), supplemental drug coverage may consist of reductions in Part D cost sharing and coverage of drugs not covered under Part D.

Section 1854(b)(2)(C) of the Act refers to the supplemental beneficiary premium that is attributable to the provision of supplemental health care benefits, less the amount of the rebate applied to supplemental benefits. The supplemental beneficiary premium is the estimated revenue required to offer the supplemental package, which may include non-drug or drug supplemental benefits or both. Therefore, when pricing a plan benefit package, MA organizations will distinguish the cost of a Part D supplemental benefit from a non-drug supplemental benefit.

We have changed the language at § 422.266(b)(1) to clarify that rebate dollars may be used to reduce the premium for either the non-drug or drug portions of the supplemental benefit. We also have added language clarifying that plans must distinguish the amount of rebate applied to enhance original Medicare benefits from the rebate applied to enhance Part D benefits. Rebate dollars may also be used to reduce the basic Part D premium and the Part B premium.

Comment: One commenter requested that we allow MA organizations to use rebate dollars to fund stabilization of their provider networks, because recent improvements in provider compensation are not sufficient to ensure stable provider networks.

Response: Proposed § 422.266(b), which implements section 1854(b)(1)(C)(ii) of the Act establishes permissible uses of the beneficiary rebate. The statute does not allow MA organizations to apply rebate dollars to stabilize an MA plan's provider network.

9. Incorrect Collection of Premiums and Cost-Sharing for All Years (§ 422.270)

Proposed § 422.270, which is identical to the previous language in the current MA regulations in subpart G at § 422.309, sets out procedures for situations in which an MA organization collects more than the amount the plan is allowed to charge its enrollees.

Subpart G—Payments to Medicare Advantage Organizations

1. Basis and Scope (§ 422.300)

Proposed § 422.300 set forth the basis and scope for the revised subpart G, stating that it is based on sections 1853, 1854, and 1858 of the Act. It also indicated that the regulations in this subpart set forth the requirements for making payments to MA organizations offering local and regional MA plans, including calculation of MA capitation rates and benchmarks, conditions under which payment is based on plan bids, adjustments to capitation rates (including risk adjustment), and other payment rules.

2. Monthly Payments (§ 422.304)

The MMA revised the payment methodology for MA plans beginning in 2006. We provided, in proposed § 422.304(a), that, with the exception of payments to MSA plans and payments for ESRD enrollees in all other plans, we will make advance monthly payments to an MA organization for each enrollee for coverage of original FFS benefits in the plan payment area for a month, using a new bidding methodology described in this subpart and subpart F.

The amount of our payment for an MA plan (except an MSA plan) depends on the relationship of the plan basic A/B bid to the benchmark amount. Section 422.304(a) described two payment tracks:

- If the plan's risk-adjusted basic A/B bid is less than the risk-adjusted benchmark, the plan's average per capita monthly savings equals 100 percent of that difference, and the beneficiary is entitled to a rebate of 75 percent of this plan savings amount.
- If the plan's risk-adjusted plan basic A/B bid is equal to the risk-adjusted benchmark, the plan has no savings and thus no rebate, and we pay plans without rebates the benchmark for the geographic service area.
- If the plan's risk-adjusted basic A/B bid is greater than the risk-adjusted benchmark, the plan has no rebate and to meet the plan's revenue needs enrollees must pay a basic beneficiary premium equal to the difference between the unadjusted basic A/B bid and the unadjusted benchmark.

Under section 1853(a)(1)(D) of the Act, implemented in proposed § 422.304(b), MA plans offering qualified prescription drug coverage also receive payments for the direct and reinsurance subsidy payments for basic prescription drug coverage and reimbursement for premium and cost sharing reductions for low-income individuals, described at sections 1860D–14 and 1860D–15 of the Act.

Special rules for enrollees with end-stage renal disease. Proposed § 422.304(c)(1)(i) would implement section 1853(a)(1)(H) of the Act, which instructs us to continue using the ESRD payments rates and risk adjustment methodology in effect before the enactment of the MMA as the basis upon which to determine ESRD payment amounts. We believed the MMA provided us with flexibility for determining ESRD payments because of Congressional recognition that the cost and utilization patterns for ESRD beneficiaries are distinct from aged and disabled beneficiaries.

One option proposed was to pay the State capitation rate for each enrollee,

with the relevant adjustments under this part, including risk adjustment. For plans offering the Part B premium reduction, the amount of that reduction would be subtracted from the capitation payment for ESRD enrollees, too. The second option proposed was to base payment on State capitation rates, as adjusted under MMA adjustments such as the geographic ISAR adjustment at section 1853(a)(1)(F). Accordingly, ESRD enrollees would be fully incorporated into the bid process and payments for all enrollees would reflect the plan's relative weights of ESRD versus non-ESRD enrollee costs. We would consider this sufficient implementation of section 1853(a)(1)(H) of the Act because State capitation rates are the basis of payment. We invited comments on these two approaches.

Special rules for payments to MSA plans. Proposed § 422.304(c)(2) would implement section 1853(a)(1)(B)(iii) of the Act, which contains the same rules for MSA plans that existed under the previous M+C program. The only MMA change in the payment provision is that MSA plans become local MA plans, and we will make payments to MA organizations for MSA enrollees based on the non-drug benchmark amount, less 1/12 of the annual lump sum amount (if any) we deposit to the enrollee's MA MSA, as determined under § 422.314(c). This payment amount is adjusted for enrollee risk, as proposed at § 422.308(c).

RFB plans. Proposed § 422.304(c)(3) on special rules for religious fraternal benefit (RFB) society plan enrollees is unchanged from the current regulations, now in subpart F at § 422.250(a)(2)(iii).

Payment areas. Proposed § 422.304(d) would implement section 1853(d) of the Act, which changes the definition of payment area to account for the new MA regional plan program. Under the previous M+C program, a payment area was defined as a county or equivalent area defined by the Secretary (with the exception of ESRD enrollees, for whom the payment area was a State).

The MMA establishes two general types of payment areas: (1) for MA local plans, the payment area is an MA local area (defined as a county or equivalent specified by CMS); and (2) for MA regional plans, the payment area is an MA region. The payment area for ESRD enrollees continues to be a State.

Proposed § 422.304(e) would implement section 1853(d)(4) of the Act, which permits a State's chief executive to request that we use alternative payment areas. This provision retains the same language as the previous M+C provision, with the exception that the statute specifies this option applies only to local MA plans. No State has availed itself of this option since its enactment in 1998.

Comment: A number of commenters preferred that CMS pay the State rate for each ESRD enrollee, risk adjusted, seeing this approach as linked to their preference not to include ESRD enrollees in bidding. Several commenters did not state a preference for payment, noting that the concept of the second option was not clear, so they are continuing to evaluate CMS's and other options that may merit our consideration.

Response: Beginning in 2007, MA-PD plans will implement a merged bid method where ESRD and non-ESRD costs are combined. This means that MA organizations will submit a single bid for all enrollees, and will be paid according to the relationship of the basic A/B bid and the benchmark.

However, as discussed in the F preamble, for 2006 MA organizations will exclude ESRD costs from plan bids. Accordingly, for 2006 payments, we will apply the ESRD payment method in effect for 2005. For ESRD enrollees on dialysis or transplant status, we will pay the State-level dialysis rate, adjusted by the appropriate individual risk score from the ESRD CMS-HCC risk adjustment model. For functioning graft beneficiaries, we will pay the county risk rate (from the aged/disabled ratebook), adjusted by the appropriate individual risk factor from the ESRD CMS-HCC model.

Finally, as proposed in the August 2004 proposed rule, for any plan offering a Part B premium reduction to MA plan enrollees, the amount of this reduction will be subtracted from the payment for each ESRD enrollee. Future changes to how we make payments for ESRD MA enrollees will be announced in the Advance Notice of Methodological Changes for Calendar Year (CY) Medicare Advantage (MA) Payment Rates.

3. Annual MA Capitation Rates (§ 422.306)

For years before 2004, payments to MA organizations were based on the highest of three amounts: a ''blended rate'' based on a blend of national and local data on Medicare's costs for providing services to beneficiaries not enrolled in an MA plan, a ''floor amount,'' based on an amount specified in statute, subject to an update factor, and an amount representing the previous year's rate updated by a minimum percentage increase.

The MMA replaces the ''highest of three rates'' methodology in several phases. For 2004, the MMA specified a transitional methodology, where the county and State rates were the ''highest of four rates'': the floor amount rate, blend rate, minimum percentage increase rate (which was redefined to be the higher of 102 percent of the previous year's rate or the previous year's rate increased by annual MA growth percentage), or the 100 percent of FFS costs rate introduced by the MMA.

For the next phase, the MMA specified that beginning with 2005, annual capitation rates will be minimum percentage increase rates except for years when we rebase the FFS rate; in rebasing years, the rate is the higher of the minimum percentage increase rate and the FFS rate. The MMA requires us to rebase the FFS rates no less than every 3 years; that is, at least every 3 years a ''higher of two rates'' methodology is in effect. Hence, proposed § 422.306(a) would implement the revised version of section 1853(c)(1)(C) of the Act, which defines the minimum percentage increase rate.

The MMA also provides that no less than every three years, we must assign 100 percent of local per capita FFS costs as the county rate in those counties where this amount is higher than the minimum percentage increase rate. The new FFS rate is defined as the adjusted average per capita cost (AAPCC) for the MA local area, as determined under section 1876(a)(4) of the Act, based on 100 percent of FFS costs for individuals who are not enrolled in an MA plan for the year, with the following adjustments: (1) standardized for the county risk profile relative to the nationally average beneficiary; (2) adjusted to exclude costs of direct graduate medical education; and (3) adjusted to include our estimate of costs for VA and DOD military facility services to Medicare-eligible beneficiaries. We must recalculate the AAPCC rate (which we also call the ''100 percent FFS rate'') no less than once every 3 years. The statute gives us the authority to determine how often to rebase the ratebook within this 3 year window. Rebasing the FFS rates means that the Office of the Actuary retabulates the per capita FFS expenditures for each county (and for ESRD beneficiaries, for each State) so that the FFS rates reflect more recent county growth trends in FFS expenditures.

We intend to announce our decision annually in the Advance Notice of Methodological Changes for Medicare Advantage Payment Rates regarding whether we will rebase the 100 percent FFS rates for the upcoming year.

Comment: Many commenters supported annual rebasing in order to adequately pay MA organizations in

areas where the FFS costs are increasing at a rate faster than the national average. One commenter noted that CMS should rebase annually because of the high degree of volatility in local FFS costs, and stated that CMS recognizes this volatility by using a 5-year moving average when forecasting county level Medicare FFS costs.

Response: As announced in the 2005 Advance Notice of Methodological Changes, the CMS Office of the Actuary believes that it is appropriate to evaluate on an annual basis whether or not it is necessary to recalculate the basis for the 100 percent of FFS costs payment category for MA organizations. By requiring rebasing only every 3 years, the Congress determined there was no need to statutorily mandate an annual retabulation of FFS per capita expenditures for each county. Therefore, CMS will announce each year in the Advance Notice whether it intends to rebase the FFS rate. Interested parties will have the opportunity to comment each year on the announcement before it is finalized.

Comment: A few commenters noted that CMS has not implemented the existing authority for inclusion in the 100 percent FFS rate the costs associated with services provided to eligible Medicare beneficiaries at VA and DOD facilities. Two commenters claimed that the result of taking these costs into account would be a positive adjustment to MA plan payments, and that currently plans serving areas with many VA and DOD facilities were not being fully reimbursed. Commenters recommended that CMS move forward as soon as possible with implementation based on the best data available.

Response: As we previously stated in our Advance Notice of Methodological Changes for 2005, in order to incorporate the costs of services provided at VA/DOD facilities into the MA rates, it is necessary to obtain reliable data on a county level to make the adjustment. We have been unable to obtain these data, so to date the adjustment has been zero. CMS's Office of the Actuary will make an annual determination whether it has been able to obtain sufficient reliable data on the costs of services provided at VA/DOD facilities to make a non-zero adjustment to the 100 percent FFS rates.

4. Adjustments to Capitation Rates, Benchmarks, Bids, and Payments (§ 422.308)

Language proposed in § 422.308(a) remains the same as that currently in subpart F of the current regulations governing payments. Under section 1853(c)(1)(C) of the Act, the MMA makes only one change to how we must apply the national growth percentage each year to increase the minimum percentage increase rate. As we provided in proposed § 422.308(b), no adjustment can be made for changes in prior years' estimates of the national growth percentage for years before 2004.

Risk adjustment. Proposed § 422.308(c) would implement section 1853(a)(1)(C) of the Act, which requires us to adjust the payment amount for an MA plan to take into account the health status of the plan's enrollees. In order to ensure that MA organizations are paid appropriately for their plan enrollees (that is, less for healthier enrollees and more for less healthy enrollees), we will apply these adjustment factors to all types of plans (with the exception of MA RFB plans, discussed at § 422.304(c)(3)).

In 2006, 25 percent of our payment to MA organizations for aged and disabled enrollees will be based on current demographic factors, and 75 percent based on the CMS-HCC risk adjustment model. In 2007 the demographic-only payment method will be completely phased-out for MA plans, and 100 percent of payment will be risk-adjusted in 2007 and succeeding years. Note that for ESRD MA enrollees, payments to MA organizations are 100 percent risk adjusted under the CMS-HCC ESRD risk adjustment model, effective January 1, 2005. Also, for PACE organizations and certain demonstrations, the transition payment blends are one year behind that for MA organizations.

The demographic adjustment factors for aged and disabled enrollees are age, sex, institutional status, Medicaid status, and working aged status. The demographic adjustment factors for ESRD enrollees are age and sex.

Under the CMS-Hierarchical Condition Category (HCC) risk adjustment payment methodology, there are CMS-HCC models for three different populations: community-based, long-term institutionalized, and ESRD beneficiaries. Currently, the CMS-HCC factors in these models include age, sex, original reason for entitlement, Medicaid status, and disease factors. The ESRD risk adjustment model distinguishes between an enrollee on dialysis, functioning graft, and transplant status.

The statute continues to provide us the authority to add to, modify, or substitute for risk adjustment factors if the changes will improve the determination of actuarial equivalence. Additional factors would enable us to pay more accurately for different types of beneficiaries, that is, the healthier and less healthy MA enrollees.

Comment: One commenter wanted clarification of how plans that are currently paid under a risk/frailty adjustment model will be paid in 2006 and beyond.

Response: The MMA did not alter the payment methodology transition schedule for MA organizations or other types of plans that are being paid using the current risk/frailty adjustment models (PACE plans and certain demonstrations). Thus, 2006 will be the last year that the demographic method will be used to determine 25 percent of payments for MA plans. In 2006, 75 percent of payment will be based on the risk adjustment method, and from 2007 onward 100 percent of payment will be determined with the risk adjustment method. Hence, PACE organizations are on a transition schedule one year behind MA organizations and certain demonstrations will be paid on the same lagged transition schedule. In 2006, 50 percent of our payments to PACE organizations and certain demonstrations will be based on the current demographic factors and the remaining 50 percent will be based on the appropriate CMS-Hierarchical Condition Category (HCC) risk adjustment model. In 2007, 75 percent of their payment will be based on the current demographic factors and the remaining 25 percent will be based on the CMS-HCC model. In 2008 and beyond, payments to PACE organizations and certain demonstrations will be entirely based on the CMS-HCC model.

Regarding demonstration plans, the MMA did not alter the current protocol for determining a particular demonstration's payment methodology. Therefore, CMS will continue to make decisions on pricing and payment methodology for its demonstrations specific to each demonstration.

Comment: Regarding the current risk adjustment model, one commenter suggested that there are certain conditions like diabetes and cancer that have several different HCC risk adjusters of varying intensity. The concern is that chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), and other HCCs common among frail elderly have only one risk score, when it may be more appropriate to distinguish a late stage or advanced stage of illness for certain conditions to trigger a higher score.

Response: CMS continues to work on improvements to the CMS-Hierarchical Condition Category (HCC) risk adjustment model. For 2006, more diagnoses and HCCs will be included in the CMS-HCC model. We will announce the updates to the CMS-HCC model in

the Advance Notice of Methodological Changes for Medicare Advantage Payment Rates. We believe that this risk adjustment model, on average, accurately pays for Medicare enrollees.

Comment: Several commenters supported the implementation of a frailty adjuster across the MA program, but encouraged CMS to delay implementation of the adjuster for at least two years until the other significant changes to the MA program have been implemented. In light of the likely delayed implementation of a frailty adjuster for all MA organizations, another commenter believed that CMS should pursue a legislative change to pay special needs plans (SNPs) differently, in order to implement a frailty adjuster, from the rest of the MA organizations. In particular, several commenters were concerned about SNPs being paid accurately for their dual eligible enrollees.

Response: We agree that implementation of a frailty adjuster across the MA program would not be appropriate in the near future in the advent of significant changes occurring in the MA program beginning in 2006. We believe that the current risk adjustment model that includes a Medicaid eligibility adjuster pays on average correctly for dual eligible enrollees. In addition, as a part of refining the CMS-HCC model, we intend to recalibrate the current risk adjustment model so that it accurately reflects more current treatment costs. As the MA program continues to stabilize in its new form, we will be able to apply a frailty adjuster across the entire MA program. We do not have the statutory authority to apply a frailty adjuster only to special needs plans because the MMA requires CMS to pay special needs plans using the same methodology it uses for all other MA organizations.

Comment: One commenter requested that CMS encourage MA organizations to include financial incentives in their contracts with providers that are designed to encourage risk adjustment data submission, rather than using financial penalties. The commenter noted the success in California with a pay-for-performance program that includes financial incentives to IPAs and medical groups to encourage quality health care, including incentives for the submission of encounter data.

Response: In principle, we do not object to plans using financial incentives with their physicians to improve their risk adjustment data submission volume to the extent that these financial incentives do not result in MA organizations' encouraging physicians to provide unnecessary or inappropriate services in order to increase diagnosis reporting volumes. MA organizations proposing to offer providers remuneration in exchange for collecting data must ensure that such arrangements do not violate the anti-kickback statute. Parties who desire an advisory opinion about a particular arrangement may request an opinion from the HHS Office of the Inspector General (OIG). The OIG has the authority to audit financial incentives offered to providers.

We believe that physicians who submit diagnoses for purposes of risk adjustment data submission as if they were submitting claims to FFS Medicare for reimbursement will be submitting the appropriate volume.

Comment: One commenter suggested that CMS be less concerned about the burden on MA organizations of submitting risk adjustment data and more concerned about the accuracy of these data. Another commenter echoed this concern by noting that CMS' implementation of an abbreviated dataset might compromise the validity of the data submitted. One commenter praised CMS for reducing the burden on plans by implementing an abbreviated risk adjustment dataset.

Response: In 2000, we implemented a risk adjustment model based on only principal inpatient hospital diagnosis data. The industry voiced concerns that the inpatient hospital model draws on diagnoses from an acute care setting only, and therefore, is less accurate. In 2004, we implemented a more comprehensive model with a more complete list of acute and chronic diagnoses. Diagnosis data are now being collected from three settings: inpatient hospital, outpatient hospital and physician office settings. At the same time as the more accurate, comprehensive model was being implemented, we began requiring an abbreviated set of data elements to be reported in order to reduce any unnecessary administrative burden on the MA organizations. However, this abbreviated dataset does not compromise the validity of the current risk adjustment model because all relevant diagnoses affecting payment still must be submitted. Rather, the fact that we no longer collect a full set of encounters for each MA enrollee means only that we do not have accurate utilization data for future recalibration of risk adjustment models. The fact that we no longer collect a full set of encounters does not affect the validity of the current model for making payments.

Comment: One commenter asked for clarification of risk adjustment data deadlines.

Response: We will provide updated information about risk adjustment data deadlines in the MA organization training materials and other formats such as MA organization user groups designed to provide operational information including data submission deadlines. General guidelines about risk adjustment data submission deadlines can be found at § 422.310(g).

Comment: One commenter stated that any risk adjustment system should take into account the traditionally higher costs and utilization of large employer group health plans.

Response: Regarding the commenter's concern about the accuracy of the risk adjustment model for large employer group plans, data from the Medicare Current Beneficiary Survey indicate that any beneficiaries with supplemental coverage have higher costs. These data do not support the commenter's assertion that the costs and utilization of Medicare Part A and B benefits are higher for enrollees of large employer group plans than for beneficiaries with other types of supplemental coverage.

Adjustment for intra-area variations. Proposed § 422.308(d)(1) would implement section 1853(a)(1)(F)(i) of the Act, which requires us to adjust payments for regional MA plans to account for variations in local payment rates within the region the plan is serving.

Proposed § 422.308(d)(2) would implement section 1853(a)(1)(F)(ii) of the Act, which requires us to adjust payments for a local MA plan serving more than one county to account for variations in local payment rates within the plan's service area.

The proposed rule mentions four methods that could be used to adjust for relative costs in a plan's service area. Each rate reflects a different type of variation.

- *MA rates*: reflect what Congress determined to be appropriate variation in payment rates among counties. (The proposed rule suggests that this option could be used for local plans.)
- *Local average fee-for-service (FFS) costs*: reflect relative price and utilization differences among counties. (MA county rates that are 100% FFS rates also reflect price and utilization differences.)
- *Input prices*: reflect only price differences in certain service categories, for example, physician services, , not variations in practice patterns among counties.
- *Plan-provided (county-specific) factors showing relative revenue needs*

by county (which the MA organizations would provide in their annual bid submission): reflect cost variations unique to each plan.

The proposed rule stated that we may choose to apply different adjustments to local versus regional plans, because there may be different reasons for rate variation. For example, regional MA plans will be required to cover regions at least as large as a State, thereby being compelled to offer the same benefit package to urban and rural areas. This requirement could be the source of significant variation in plan costs because of service area differences in provider practice and beneficiary utilization patterns, wage indices, and other factors.

Comment: Most commenters recommended an adjustment based on the MA rates. One commenter recommended an approach where the cost index would be consistent with the costs MA plans face in their service areas. Several commenters recommended that CMS use the MA rates for a geographic adjustment at least in the initial years of the program, because the industry is familiar with the MA county rates as a means of payment. A number of commenters recommended that the method CMS selects for regional MA plans should be consistent with that for local MA plans so that the adjustment does not advantage one type of plan over the other, thus contributing to a more level playing field for all MA plans—local and regional. Another commenter remarked that the adjustment back to the local county rates is the most consistent with the constraints of the MMA, is the most feasible to implement, and contributes to a level playing field for the different types of private plans. The commenter reasoned that because the different benchmarks are all built upon the county payment rates, and because the local plans can always organize to be paid at the individual county level, payments to all the types of plans should reflect the county payment rates; otherwise, spending on MA plans would likely increase under any geographic adjustment. Finally, one commenter preferred to use county benchmarks as the basis for intra-area adjustments for local plans and an index of county benchmarks for regional plans, but added that the appropriateness of an index-type adjustment method will depend on the basis of the experience underlying the index derivation calculations.

Response: To avoid confusion with the geographic adjustment we use to calculate the 100 percent FFS rates, we will refer to this section 1853(a)(1)(F) adjustment as the geographic ISAR adjustment, reflecting its purpose.

We have chosen to interpret the ISAR adjustment provision broadly. A more narrow interpretation of ''variations in MA local payment rates'' would be that variation refers only to the administratively-set MA rates. A broader interpretation of variation is that the provision denotes underlying variations in local prices. In this sense, ''local payment rates'' means payment rates MA organizations negotiate with providers. We have taken the latter approach because the MMA defines the bid to be an amount that reflects a plan's estimated revenue requirements—that is, the average underlying costs a plan faces in its service area. This approach allows us to consider adjustment methods in addition to those based on MA county rates.

By law, a plan's bid is based on its projected enrollment. The purpose of the ISAR adjustment is to ensure that CMS pays an MA organization what its plan basic A/B bid would have been if the enrollment projections used to estimate the bid were identical to actual plan enrollment. That is, the ISAR adjustment would take into account the difference between the distribution of enrollment across counties in the plan's service area assumed in the plan's bid and the actual geographic mix of enrollment at the time payment is made. Since plan costs are not uniform across the plan's service area, the fact that the distribution of enrollment assumed in the bid is not the same as the plan's actual enrollment distribution would impact on whether the plan receives the revenue it indicated it needed in its bid to provide Medicare Part A and Part B services. The ISAR adjustment uses the distribution of actual enrollment and assumptions about relative costs across counties in the plan's service area to provide a payment amount that reflects actual enrollment.

Regardless of the specific method (whether plan-provided projected costs per county or a relative cost or price index not specific to plans), use of the ISAR adjustment to translate the plan's bid into county-specific rates would mean that if a plan's enrollment distribution turns about to be different than originally estimated in their bid, their aggregate payments would be adjusted automatically to reflect the actual mix of enrollees in of low-cost and high-cost counties. Recall that for plans with bids below benchmarks, the average payment amount is the basic A/B bid (plus the rebate); and for plans with bids greater than or equal to the benchmark, the average payment amount is the benchmark. Conceptually, converting the average payment amount into plan-specific county rates means that the bid (or benchmark)—which is an average for the whole service area—is ''disaggregated'' and allocated to each county in the service area.

For each local and regional plan, we will be using a geographic ISAR adjustment based on the MA payment rates. This approach reflects the method preferred by the majority of commenters. However, since it is our goal to encourage regional bids, we will allow regional MA plans, on a case-by-case basis, to request to have their payments geographically adjusted at the county level using a plan-determined statement of the relative costs the plan faces in different counties for the provision of Medicare-covered services, in the event that the variation in MA rates is not an accurate reflection of the variation in a plan's projected costs in its service area. We would review the plan-provided ISAR factors for reasonableness.

MA organizations would be required to provide support for their factors (such as the projected utilization and cost by service category for each county), with the understanding that we could ask for additional detail (for example, fee schedules) during bid negotiation or during an audit. We would base our determination of whether to use MA rate ISAR factors or plan-provided ISAR factors for a particular regional plan on the comprehensiveness and reasonableness of the MA organization's cost and utilization assumptions and associated documentation, and on an assessment of which approach would best reflect the plan's likely costs throughout the service area.

The rebate, described at § 422.304(a)(3), is for the provision of non-Medicare-covered benefits and is paid separately from the basic A/B bid. The rebate is not subject to geographic adjustment. Further guidance on the calculation of the ISAR adjustment factor will be provided in the Advance Notice of Methodological Changes for 2006 Medicare Advantage Payment Rates, which we expect to release February 18, 2005 on our website at *http://www.cms.hhs.gov/healthplans/rates/default.asp*.

Comment: One commenter remarked that CMS did not clearly explain its proposed method for the ISAR adjustment in the NPRM, and felt that unless we publish a proposed method for establishing regional PPO benchmark levels, participation in the regional PPO program may suffer. Another commenter requested that CMS wait until Medpac releases its report on payment rate variations before

determining how to apply the ISAR adjustment, and that CMS allow industry to comment on the proposed adjustment before implementation.

Response: First, we would like to clarify that the geographic ISAR adjustment does not establish regional benchmarks. The method for calculating regional benchmarks is established by the MMA and implemented at § 422.258. The purpose of the ISAR adjustment is to ensure that we pay an MA organization what its plan basic A/B bid would have been if the enrollment projections used to estimate the bid were identical to actual plan enrollment. Second, although we stated in the August 3, 2004 proposed rule our intention to review Medpac's upcoming study on variations in MA payment rates, we now do not believe we can wait until the final Medpac report is released, because it likely will be presented to the Congress in June 2005. We are required to announce our proposed approach to the ISAR adjustment, and other payment methodologies, in the Advance Notice of Methodological Changes for Calendar Year 2006 MA Payment Rates, which we expect to be released February 18, 2005 on the CMS website at *http://www.cms.hhs.gov/healthplans/rates/default.asp*.

Comment: A few commenters recommended that the ISAR adjustment should be considered by CMS as a tool to use in adjusting the local payment rates in rural markets, where competing with a regional plan would be cost prohibitive. One commenter suggested that the adjustment should result in localized derivations of regional benchmarks, and another commenter suggested that in counties where the local benchmark is significantly lower than the regional benchmark, payment rates to regional plans should be adjusted downward to reduce the significant competitive advantage regional plans would have over local plans, because the latter will have to charge a higher member premium for the same benefit set and cost structure. Finally, a few commenters stated their concern that it has taken many years to narrow the reimbursement gap between rural and urban areas and now is not the time to reinvent that disparity. These commenters felt this could happen under this ISAR provision because it could allow health plans to segregate rural providers within their region and offer them a substantially lower payment rate.

Response: As noted above, the ISAR adjustment will not affect regional or local benchmarks. In addition, the ISAR adjustment is not a tool to increase payments to local versus regional plans or vice versa. The ISAR adjustment is a mechanism to ensure that payments to plans reflect the plans' bids and their actual enrollment distribution.

We have worked within the construct of the statute to provide a level playing field for all plans. The MMA created incentives to encourage participation in the new regional plan program, such as possible funding from a stabilization fund and the use of risk corridors that are only available to MA regional plans, as found at § 422.438 and § 422.458 (and see subpart J). These incentives are specified by statute, so we are unable to expand the types of organization that are eligible for these incentives. It is important to point out, however, that there are special provisions available only to local plans that MA regional plans do not have available, such as the ability to target specific counties and even partial county areas for inclusion in a plan service area, and to have segmented service areas within a local plan, where premiums and cost sharing can vary across segments.

We are not clear exactly what link the commenters are positing between the ISAR adjustment and contract negotiations with rural providers where MA organizations offer payment arrangements that are lower than previous years.

Adjustment relating to risk adjustment: the government premium adjustment. Proposed § 422.308(e) would implement section 1853(a)(1)(G) of the Act, which requires us to adjust payments to plans with basic A/B bids above their benchmarks to ensure that plans are not advantaged or disadvantaged by the method of paying based on bid-to-benchmark comparisons. Under the bidding method, the beneficiary basic premium is the difference between unadjusted (''1.0 beneficiary'') bid and benchmark, yet the payment is the risk adjusted benchmark. If the MA organization received this premium and its risk adjusted payment from CMS, the combined payments would not match its revenue needs since the basic premium is not risk adjusted. Therefore, the impact that risk adjustment would have had on the basic premium will be incorporated into our payment to the organization.

Proposed § 422.308(e)(1) specified that for each regional plan, payments are adjusted so the sum of the monthly payment and any basic beneficiary premium equals the bid adjusted for enrollee risk factors and the adjustment for intra-area variations in payments in proposed § 422.308(d)(1). Note that the formula as stated at section 1853(a)(1)(G)(ii) of the Act also references the adjustment discussed in the previous paragraph—for intra-regional variations in local payment rates.

Proposed § 422.308(e)(2) specified that for each local plan, payments are adjusted so the sum of the monthly payment and any basic beneficiary premium equals the bid adjusted for enrollee risk factors. We note that, in contrast to the language for regional plans at section 1853(a)(1)(G)(ii) of the Act, the formula for local plans does not include a reference to the intra-area variation described in proposed § 422.308(d)(1). We believe this was an unintended omission for local plans, because section 1853(a)(1)(F) of the Act mandates this adjustment for both regional plans and local plans serving more than one county.

The government premium adjustment must be applied after application of the risk adjustment methodology and after taking into account adjustments for intra-area variation in local payment rates under § 422.304(d).

Comment: Two commenters supported CMS' proposal to adjust payment upward or downward to account for the fact that the basic beneficiary premium reflects the revenue needed for a beneficiary with a national average risk profile rather than the MA plan's anticipated mix of enrollees.

Response: We will refer to this adjustment as the ''government premium adjustment,'' in order to distinguish it from other payment adjustments under the MMA.

Section 1854(a)(1)(G) requires CMS to adjust payments to ensure that an MA organization is paid the revenue needed to offer an MA plan in a service area. The government premium adjustment applies to plans that have basic A/B bids greater than their benchmarks, and thus must charge a basic beneficiary premium. As described above, these plans receive their estimated required revenue to offer original Medicare benefits from two sources: capitation payments from CMS and premium payments from enrollees. Because the MMA requires that the basic beneficiary premium is the difference between the unadjusted (standardized ''1.0'') benchmark and unadjusted bid, plans with sicker than average risk profiles will not receive adequate premium payments from enrollees. The government premium adjustment would be an upward adjustment for these plans. Conversely, plans with healthier than average risk profiles will receive more premium payments than required, so they would receive a downward

adjustment. The government premium adjustment will be calculated, at the individual beneficiary level. Details on the payment formula will be provided in the Advance Notice of Methodological Changes for 2006 MA Payment Rates, which we expect to publish February 18, 2005 on the CMS website at *http://www.cms.hhs.gov/healthplans/rates/default.asp*.

Adjustment of payment to reflect the number of enrollees. Proposed § 422.308(f) implemented section 1853(a)(2)(A) of the Act, which is unchanged by MMA. Therefore, we proposed to retain the existing implementing regulatory language currently found in Subpart F. This provision requires us to make retroactive payment adjustments to account for any difference between the actual enrollees and the enrollees upon which we based advanced monthly payment.

Adjustment for national coverage determination (NCD) services and legislative changes in benefits. Section 1853(c)(7) of the Act requires that when a national coverage determination (NCD) or legislative change in benefits is established and we project this will result in a significant increase in costs, we must appropriately adjust payments to reflect these new significant costs. Because all capitation rates under the MMA now automatically build in the annual national MA growth percentage and therefore incorporate the effect of NCDs annually, we proposed to amend § 422.308(g) and remove the NCD adjustment factor.

Section 1858(c) of the Act provides for temporary risk corridors for adjusting payments to regional plans, and proposed § 422.308(h) specified data submission requirements to implement risk corridor payments. At the end of contract year 2006 and/or 2007, and before a date we specify, MA organizations offering regional plans must submit sufficient information for us to calculate risk corridor amounts.

This information includes actual allowable costs for the relevant contract year and the portion of allowable costs that are attributable to administrative expenses incurred in providing these benefits. In addition, the MA organization will be required to provide the total cost for providing rebatable integrated benefits, as well as the portion of rebatable integrated benefits' costs that are attributable to administrative expenses.

5. Risk Adjustment Data (§ 422.310)

Proposed § 422.310 reflected changes we made in the methodology for risk adjusting MA payments, under which we moved from collecting extensive encounter data to collecting targeted risk-adjustment data. The risk-adjustment data referenced in this section are data that are used in the application of the current risk-adjustment model.

We have implemented a streamlined process for MA organizations to submit risk adjustment data. MA organizations may submit risk adjustment data that conform to the requirements for equivalent FFS data. Alternatively, organizations may submit data according to an abbreviated format as specified by us. The purpose of the abbreviated format is to reduce the data submission burden on MA organizations.

In addition, our current practice is to collect data and a sample of medical records, for conducting validation studies of the risk adjustment data we receive. MA organizations will still be required to submit a sample of their medical records in a manner specified by CMS to support the validation studies. We have not and will continue not to use medical records data for any other purpose.

The risk adjustment data must be submitted according to the timeframes specified by CMS. (See the following website for information on the risk adjustment processing system: *http://www.mcoservice.com/*.) A reconciliation process will be allowed to account for late data submissions. Data that we receive after the final deadline for a payment year will not be accepted for purposes of the reconciliation.

We have modified § 422.310(e) to indicate that there may be penalties for submission of false data under the requirement for validation of risk adjustment data.

6. Announcement of Annual Capitation Rates, Regional Benchmarks, and Methodology Changes (§ 422.312)

Proposed § 422.312 would implement section 1853(b) of the Act, which was revised by the MMA to change the date for CMS' announcement of annual capitation rates to no later than the first Monday in April of each year. In addition, we must announce before September the non-drug benchmark amounts for each MA region and MA regional plan for which a bid is submitted. We must announce regional benchmarks after the plan bids are submitted in June, since per the new section 1858(f)(5) of the Act, the regional benchmark calculation includes a plan bid component based on regional plans that bid in June and also participated in the MA program in the previous year.

The deadline for our release of the Advance Notice of Methodological Changes for Medicare Advantage Payment Rates was similarly changed by the MMA to no later than 45 days before the first Monday in April.

Comment: Two commenters requested that CMS include in the Advance Notice of Methodological Changes for Medicare Advantage Payment Rates additional detail on the methodologies we use to develop and refine payment rates. The commenters specifically requested detail on the coding intensity adjustment, issues related to the data lag elimination, and implementation of the frailty adjuster.

Response: The annual Advance Notice is designed to describe the methodological changes we propose in sufficient detail to alert MA organizations to new calculations, new deadlines, and so forth. If the Advance Notice is unclear, the public is invited to request more information during the public comment period, and we then publish further detail in the annual Rate Announcement. We will be sensitive to the commenters' request as we prepare future Advance Notices of Methodological Changes.

7. Special Rules for Beneficiaries Enrolled in MA MSA Plans (§ 422.314)

Proposed § 422.314 would implement section 1853(e)(2) and (3) of the Act, which sets forth special rules for how we should make payments to enrollees' medical savings accounts. The MMA did not amend the payment provisions in section 1853(e) of the Act, so these provisions are similar to the provisions at § 422.262 in subpart F of the current MA regulations. However, we have made a change to conform § 422.314(c) with the statute at section 1853(e)(1) of the Act.

In general, we deposit into the individual's MA MSA account at the beginning of a calendar year a lump sum equal to the annual difference between the monthly MSA premium (analogous to a plan basic A/B bid) and the monthly capitation rate applied under this section for the area. The premium filed by the organization offering the MA MSA plan is uniform for all enrollees enrolled in the MA MSA plan. This results in a uniform amount being deposited into enrollees' MSAs in a given area, because the uniform premium amount will be subtracted from the uniform rate.

The advance monthly payments we make to an MA organization for each enrollee in the plan are risk adjusted under § 422.308(c), as discussed in connection with proposed

§ 422.304(c)(2) on special rules for payments for MSA enrollees.

Comment: One commenter noted a deficiency in the proposed regulations on how payment is made for enrollees in MSA plans, which prevents an MSA plan from being viable option under the MA program. The commenter summarized the problem as follows. Under the statute and proposed regulations, the total CMS payment on behalf of a beneficiary enrolled in an MSA (the sum of the deposit to the enrollee's MSA account and payment to the MSA plan) is not equal to the risk adjusted benchmark amount. Yet section 1853(a)(1)(B)(iii) requires CMS to pay the risk adjusted benchmark amount for each MSA enrollee. This problem arises because the payment to the MSA plan is risk-adjusted and the deposit to the enrollee's MSA is not. The result is that the total payment for an MSA plan enrollee could be substantially higher or lower than the risk adjusted benchmark. Beneficiaries and insurance companies cannot be reasonably sure that the Medicare payment will be adequate to cover the cost of care.

The commenter recommended that the MSA requirements be written so that: (1) the deposit to the MA MSA account is the difference between the risk-adjusted benchmark amount (based on the annual capitation rate) and the risk-adjusted MSA premium; and (2) the payment to the MSA plan is equal to the risk-adjusted MSA premium. This requirement would result in the total payment (deposit plus payment to MSA insurance plan) being equal to the risk-adjusted benchmark. The commenter recognized that this change may require legislation. Specifically, subsection 1853(e) of the Act might need to be amended to provide for risk adjustment to the contribution to the MSA account.

Response: In response to this comment, we have reviewed the proposed regulations text for MSA plans and have made a change to conform § 422.314(c) with the statute at section 1853(e)(1) of the Act. We are continuing to consider how this statutory language should be applied, and this issue will be addressed in the Advance Notice of Methodological Changes for MA Payment Rates, which we expect to release February 18, 2005.

Comment: Several commenters expressed concern about CMS' ability to risk adjust payments for MSA plan enrollees accurately. Given the complexities of risk adjustment and the absence of enrollee incentives to submit claims to their MSA plan, the commenters are concerned that risk scores for many of these enrollees will be artificially low. One commenter is concerned that in the absence of systems and incentives that encourage members to submit medical expenses to be applied against the deductible, it would not be possible to risk adjust accurately the MSA benchmark for individual health status, which is CMS' payment amount to the MSA plan sponsor. As a result, members will exceed deductibles ''prematurely'' and the plan will be responsible for all medical payments without the benefit of risk adjusted revenue.

Response: Section 1853(a)(3)(B) of the statute requires that all MA organizations submit risk adjustment data for their plans, including MSA plans. The MMA did not change this requirement. We are not sure that we understand this comment, because MSA plans are required to track each enrollee's health care expenses in order to track when the deductible has been met and the plan becomes responsible for all covered expenses. Therefore, as an integral part of managing an MSA plan, an MA organization should have access to enrollee claims or ''encounter-like'' data, which should enable them to submit the required data to CMS for risk adjustment payment purposes.

8. Special Payment Rule for Federally Qualified Health Centers (§ 422.316)

At proposed § 422.316 we would implement section 1853(a)(4) of the Act, which provides for a new payment methodology for FQHCs that contract with MA organizations. Under this methodology, the FQHCs will receive a ''wrap-around payment'' from us representing the difference (if any) between what they are paid by an MA organization, including beneficiary cost sharing, and 100 percent of their ''reasonable costs'' of providing care to patients served at the centers who are enrolled in an MA plan.

Section 1857(e)(3) of the Act, also added by MMA, requires that MA organizations that contract with FQHCs pay the FQHCs an amount that is not less than the level and amount of payment they would make for the services if furnished by an entity providing similar services that was not an FQHC. This is designed to avoid an agreement between an MA organization and an FQHC for payment of an artificially low rate, with the knowledge that the FQHC would receive supplemental payments from us resulting in a total of 100 percent cost reimbursement.

Comment: One commenter suggests that § 422.316 be revised to clarify that it applies to both written contracts and any deemed contracts as they exist under the rules that govern PFFS plans. PFFS plans would have to clearly disclose the payment rate in their written terms and conditions of payment. This would avoid discrimination against PFFS plans.

Response: PFFS plans that have ''deemed'' networks must pay what the FFS Medicare program pays to the ''provider in question,'' per § 422.114(a)(2)(i). Therefore, there would be no wrap-around payment for FQHCs treating PFFS patients under a ''deemed'' contract because the FQHC would be receiving full payment from the plan.

9. Special Rules for Coverage That Begins or Ends During an Inpatient Hospital Stay (§ 422.318)

The MMA amended section 1853(g) of the Act, which puts forth special payment rules for situations where a beneficiary's coverage by an MA plan begins or ends while the beneficiary is a hospital inpatient. The MMA amendment expands the list of hospital facilities covered under this provision to include those that have come under a Medicare prospective payment system since the Balanced Budget Act. In addition to ''subsection (d)'' hospitals, three other types of facilities are now included: rehabilitation hospitals, distinct part rehabilitation units, and long-term care hospitals. These changes were proposed at § 422.318, which otherwise retained existing language from subpart F applicable only to subsection (d) hospitals.

Comment: One commenter proposed that CMS include Critical Access Hospitals (CAHs) in the list of facilities to which this provision applies.

Response: Under section 1853(g), this rule applies only to ''subsection (d)'' hospitals and the three types of facilities the MMA specifically added. Because CAHs are not defined under section 1886(d) of the Act, this provision at § 422.318 does not apply to CAHs.

10. Special Rules for Hospice Care (§ 422.320)

Proposed § 422.320 revised the existing MA special rules for hospice care to reflect the new bidding and payment methodology in sections 1853 and 1854 of the Act, and the creation of a prescription drug benefit under Part D. Now the MA organization will be paid the portion of the payment attributable to the beneficiary rebate (minus the amount of the Part B premium reduction, if any) for the MA plan plus the amount of the subsidies related to basic prescription drug coverage for plans that offer prescription drug coverage.

Note that for PACE organizations, PACE enrollees must elect either their PACE organization or the hospice benefit as their provider of Medicare services. An enrollee who elects to enroll in hospice is thereby disenrolled from the PACE benefit. However, PACE organizations provide a service similar to hospice known as ''end-of-life-care.''

Comment: One commenter stated that beneficiaries who choose to enroll in a Medicare hospice program should also assign their Medicare Part D drug benefit to the hospice. The commenter argued that prescription drugs are usually an integral component of hospice care and should be managed by the provider. Once a health plan is not involved in the care management of a patient, then it should not be responsible for the patient's prescription drug management.

Response: When a beneficiary enrolled in an MA plan elects hospice, that beneficiary is still an enrollee in the plan, is still liable for any plan premiums and cost sharing for benefits not covered under hospice. It is possible for an enrollee who has elected hospice to require prescription drugs for conditions not related to hospice care, which are the plan's responsibility. We believe that it is appropriate for Medicare Advantage Prescription Drug (MA-PD) plans to manage the prescription drug coverage of enrollees who have elected hospice, and therefore we will pay MA-PD plans the Part D premium for all enrollees.

Comment: One commenter suggested that CMS conduct a demonstration allowing beneficiaries to elect hospice while still receiving life saving treatment as a means to overcoming the fear and perceived finality of electing hospice. The commenter cites the low rate of hospice election and short duration of services as reasons to develop some innovative approaches to identifying how to better transition beneficiaries with terminal or advanced illness into a care environment that provides needed and appropriate care, while improving quality of life.

Response: It is important to note that the current hospice benefit began as a Medicare demonstration. It was considered successful, and therefore, the Congress added hospice care as a benefit in the Medicare program. In addition, § 409 of the MMA requires CMS to conduct another hospice demonstration. The statute requires CMS to test delivery of hospice care in rural areas under which Medicare eligible individuals, without a caregiver at home, may receive care in a facility of 20 or fewer beds. Such facility will not have to offer hospice services in the community or comply with the 20 percent limit on inpatient days. In the future, we would be interested in considering other innovative ideas for increasing enrollment in hospice care throughout the country. We invite the commenter to submit a proposal on the suggestion.

11. Source of Payment and Effect of MA Plan Election on Payment (§ 422.322)

With the exception of a new provision addressing payments for Part D benefits, proposed § 422.322 is identical to § 422.268 in subpart F of the current MA regulations. Section 422.322(a)(2) was added to reflect the creation of subsidized prescription drug coverage under Part D. As required by section 1853(f) of the Act, subsidy payments to MA-PD organizations for basic drug coverage under this title are included in the payments described in § 422.322(a)(2).

Comment: Two commenters requested clarification on whether an MA organization can authorize that CMS payment be made directly to an agent of the MA organization.

Response: We believe that the commenters may be anticipating a situation under the MA program where an employer directly contracting with CMS to offer an MA plan would contract with an MA organization to manage that plan. However, section 1857(a) of the statute, which was not amended by the MMA, explicitly states that no payment shall be made under section 1853 to an organization unless that organization is under contract with the Secretary. Therefore, we do not have the authority to make any payments from the Medicare Trust Funds under section 1853 to an agent of an MA organization. The existing regulatory language in Subpart F at § 422.268(c) that implements section 1857(a) is found in proposed Subpart G at § 422.322(c).

Comment: One commenter was concerned that the proposed rules are silent with respect to provider recovery of unpaid amounts due from MA plan enrollees. The commenter recommended that CMS allow providers that treat MA enrollees the same recourse for unpaid enrollment amounts that currently exists in the regulations for the FFS program, that is, allow a cost report recovery that follows the Medicare bad debt recovery criteria. Without this recovery mechanism, providers will suffer financial harm because beneficiaries change program status, not because of any change in the service they provide.

Response: The issue of bad debt recovery criteria for providers who submit cost reports is beyond the scope of this rulemaking. We refer the commenter to 42 CFR part 413 for further information about bad debt recovery rules.

12. Payments to MA Organizations for Graduate Medical Education Costs (§ 422.324)

These provisions at proposed § 422.324 were virtually identical to the current MA provisions in subpart F at § 422.270 (we proposed some non-substantive editorial changes), and required us to make payments to MA organizations for direct graduate medical education costs that MA organizations incur in dealings with non-hospital provider settings, under specified conditions.

Comment: One commenter requested that the final rule clarify whether utilization data on MA enrollees should be considered when making determinations about FFS payment adjustments and minimum utilization standards (for example, direct and indirect medical education payment formulas and the disproportionate share payment formula). The commenter also noted that current FFS regulations apply minimum Medicare utilization standards when assigning certain designations such as rural health clinics, sole community provider or rural referral center status, and requested that MA utilization data be included when CMS makes such designations.

Response: The FFS rate determination and provider designation processes are beyond the scope of this rule making. Such decisions could be proposed and finalized in an upcoming rule-making for the relevant prospective payment system.

Subpart I—Organization Compliance with State Law and Preemption by Federal Law

The MMA amended section 1856(b)(3) of the Act and significantly broadened the scope of Federal preemption of State law. We proposed to revise § 422.402 to clearly state that MA standards supersede State law and regulation with the exception of licensing laws and laws relating to plan solvency. In other words, with those exceptions, State laws do not apply to MA plans offered by MA organizations.

We believe that the Conference Report was clear that the Congress intended to broaden the scope of preemption in the MMA. We accordingly believe that the exception for State laws that relate to ''State licensing'' must be limited to State requirements for becoming State licensed, and would not extend to any

requirement that the State might impose on licensed health plans that absent Federal preemption must be met as a condition for keeping a State license.

In addition to outlining the new scope of the preemption, we also proposed the following technical changes:

- We proposed to remove the current § 422.402(c) because

we believed it was no longer relevant given the new MMA provision.

- We clarified that States are expressly prohibited from

imposing a premium tax, or similar type of tax, on premiums paid by beneficiaries or third parties on behalf of beneficiaries to MA organizations.

Below we summarize and respond to the comments we received on Subpart I:

Comment: A commenter expresses concern that the statutory and regulatory language stating that Federal preemption does not extend to State licensing or solvency requirements is vague and may allow States to impose network access requirement on MA plans.

Response: We note that the Conference Report makes it clear that the Congress intended to broaden the scope of Federal preemption with the intention of ensuring that the MA program as a Federal program will operate under Federal rules. We have also clarified (in the preamble to the interim regulation) and we restate here that we believe that State licensing laws under Federal preemption are limited to State requirements for becoming State licensed, and cannot be extended to other requirement that the State might impose on licensed health plans that absent Federal preemption must be met as a condition for keeping a State license. We believe that under current Federal preemption authority States are limited in applying only those requirements that are directly related to becoming State licensed. For example, State-licensing requirements may include requirements such as filing articles of incorporation with the appropriate State agency, or satisfying State governance requirements. However, under Federal preemption, State licensing laws may not be extended to include rules that apply to State licensed health plans which we believe would include network adequacy requirements for MA plans.

Comment: A commenter expresses concern that if all State regulation of MA plans is broadly preempted by Federal law (with the limited exception of licensing and solvency requirements), contracting providers will not have adequate means to ensure prompt payment or access to external review of inappropriate denials of coverage or payment. The commenter recommended that CMS either narrow its interpretation of how State law may be preempted or expand its own Federal requirements for plan-provider contracting standards to include basic provider protections, such as prompt payment.

Response: As previously stated, we believe that with the exceptions of State licensing and solvency requirements the Congress clearly intends and the MMA statute provides that the MA program is to be solely under Federal and not State rules. However, we do recognize concerns regarding the effectiveness of Federal regulation of the MA program. In overseeing the MA Program, CMS will ensure appropriate oversight of MA plans.

With respect to prompt pay requirements, providers and MA organizations may enter into contracts the terms of which are established by the parties. In general the terms of these contracts including payment amounts and prompt payment standards are determined by negotiation between the parties. We specifically require in our regulations at § 422.520(b) that contracts between MA organizations and providers contain prompt payment standards which the parties have both agreed to. In the event an MA organization fails to honor its provider contract(s) in certain circumstances, we may impose intermediate sanctions or even terminate its contract with the MA organization.

Comment: A commenter asks that CMS clarify in its regulations that, with the exception of State laws that relate to State licensing and solvency, Federal preemption extends to any requirement that the State might impose, including requirements imposed as a condition of maintaining State licensure.

Response: We believe our regulations at § 422.402 are clear in regards to the broad extent of Federal preemption authority under the MMA. We have discussed in previous responses that States may not use licensure or solvency requirements as an indirect means to impose health plan regulations on MA plans. Again, we reiterate our understanding of the congressional intent that the MA program, as a Federal program operate solely under Federal rules with the exception of State licensure and solvency requirements.

Comment: A commenter acknowledges the preamble discussion in the proposed rule clarifying that State licensing laws are limited to the requirements for becoming State licensed (for example, filing of articles of incorporation with the appropriate State agency or satisfying State governance requirements) and do not extend to the requirements that a State may impose on licensed health plans that absent preemption must be met as a condition of keeping a State license. The commenter recommended that CMS make this clarification in § 422.402 of the MA regulations.

Response: We believe State licensure requirements cannot be used as an indirect way to regulate MA plans by imposing requirements not generally associated with licensure. For example, we stated that reasonable licensure requirements may include the filing of articles of incorporation with the appropriate State agency or satisfying State governance requirements. However, we chose not to establish the parameters of State licensure in our regulations as there may be other legitimate aspects of State licensure we have not noted.

Comment: A commenter stated that the proposed rule reiterates the MMA and fails to clarify the extent to which State law is preempted. The commenter maintains that the proposed regulation gives no guidance to States in determining which laws they can require Medicare plans to observe. According to the commenter, States do not know which standards they can enforce to protect consumers. As an example, the commenter cites the Knox-Keene Act in California which conditions health plan licensure on several minimum requirements. The commenter maintains that without explanation from CMS on what types of ''licensing'' laws States may enforce, California has no way of determining which parts of the State's broad statutory scheme may apply to Medicare plans and which parts are preempted. The commenter believes that CMS has not provided guidance to States on how financial solvency requirements can be separated from other parts of State licensing law which are intricately interwoven. Instead of clarifying underlying statute and policy, in the commenter's view, the proposed rule injects further confusion regarding the extent of Federal preemption of State law. The commenter requests further explanation and practical guidance on the role of the States in enforcing minimum licensure and financial solvency requirements.

Response: As we stated in the preamble to the proposed rule (69 FR 46904), we believe that under the MMA, States are preempted from applying any regulatory requirements on MA plans with the sole exception of State licensure and solvency requirements. We also believe that licensure and solvency requirements cannot be used

as an indirect method of imposing State regulatory requirements that a State might impose on non MA health plans. We recognize that there still may be questions about the extent of allowable State regulation. As in the case of the pre-MMA pre-emption provisions, we intend to address these specific type of preemption questions in cooperation with States.

Comment: A commenter stated that Federal preemption authority under the MMA means that requirements concerning these matters as fair business practices, plan and physician contracting and prompt payments which have been traditionally under State law, will now be governed by Federal law. The commenter recommended that CMS monitor the effect of Federal preemption and establish strong Federal oversight to ensure that plans are complying with Federal regulatory standards. The commenter is concerned that without strong Federal oversight, patients in MA plans may not have the same protections that apply to other individuals enrolled in health plans, including those in traditional Medicare or those enrolled in private plans governed by State law. The commenter also recommended that since most State laws applicable to health plans will be preempted by Federal law, CMS should ensure that laws and regulatory standards that protect patients and physicians in the traditional Medicare program also be applied by CMS to MA plans.

Response: We are aware of the need for strong consistent oversight of MA plans. As we have done under the previous M+C program, we will ensure that enrollees in MA plans receive the appropriate quality and access to plan covered health care services.

Comment: A commenter stated that in the proposed rule (69 FR 46913 through 46914), CMS takes the position that State contract are ''generally applicable'' to MA organizations and are therefore not preempted. The commenter also indicated that CMS explains (in the preamble to the proposed rule) that State contract and tort law does not specifically apply to health plans, and that the Congress only intended to preempt State standards contained in State statutes and regulations, and that State standards developed through case law (for example, State contract and tort law) are not preempted. The commenter expresses concern that while State contract and tort law principals may have general application, State standards developed through case law based on interpretations of State contract and tort law may be specific to health plans, and may apply State standards that would otherwise be preempted under Section 232(a) of the MMA.

The commenter concludes by stating that they believe that in enacting section 232(a) of the MMA, the Congress intended to draft a clear Federal preemption standard for the MA program, and that the primary motivation for this new preemption standard was to ease the administrative burden caused by the ambiguity in the old § 422.402. The commenter also recommended that CMS make clear that all State standards, including those established through case law, are preempted with respect to the MA program, with exceptions of State licensing and solvency laws.

Response: In response to this comment, we would clarify that all State standards, including those established through case law, are preempted to the extent that they specifically would regulate MA plans, with exceptions of State licensing and solvency laws. Other State health and safety standards, or generally applicable standards, that do not involve regulation of an MA plan are not preepmted.

Comment: A commenter expresses concern that under the rules proposed by CMS, providers who contract with MA plans will be left with virtually no protection because State prompt pay laws will be preempted. The commenter stated that while CMS has proposed adding § 422.520(b)(2), which provides that an MA organization is obligated to pay contracted providers according to the terms of the contract with the MA organization, this language does not provide sufficient protection for contracted providers. The commenter indicated that nearly every State in the country has enacted prompt pay legislation to protect providers who are often unable to negotiate sufficient prompt pay provisions in their contracts with plans. The commenter also suggested that if State prompt pay laws are preempted then CMS should revise the proposed rule to add prompt pay protection for contracted providers that is at least as strong as that given to non-contract providers.

In addition, the commenter believes that preemption of State prompt pay requirements for MA contracting providers will cause hospitals to be less willing to contract with MA plans if they are uncertain whether claims will be paid promptly and fairly.

Response: In our current MA regulations at § 422.520(b), we require that MA organizations include in its contracts with providers a prompt pay provision. However, we allow the providers and MA organization discretion to negotiate the terms of the prompt payment provisions. Since these contracts typically include payment arrangements, we believe it is appropriate and reasonable to leave the parties to the contract discretion to work out mutually agreeable terms of their contract. The contracts may include payment amounts greater than what original Medicare will pay for some services and other payment incentives for contracted providers. If an MA organization fails to honor the terms of its provider contracts under certain conditions, we have the authority to impose intermediate sanctions or even terminate its contract with the MA organization.

Comment: One commenter recommended that CMS develop guidance that builds on the preamble discussion of preemption in subpart I and Subpart M. The Congress provided broad preemption authority to ensure that the program is implemented in a uniform way for beneficiaries in States across the country. The commenter also recommended that CMS interpret the preemption authority, consistent with the Congressional intent, to maximize the uniformity of program implementation nationwide.

Response: We believe that in our previous responses, we have made it clear that our understating of Federal preemption and the Congressional intent is that the MA plans are only subject to Federal regulation with the exception of State licensure and solvency requirements.

Comment: A commenter encourages CMS to clearly communicate the provisions of the new law and regulations relating to both preemption of State law and restrictions on States imposing premium tax on funds collected from enrollees to all States. The commenter states that they have already received questions from States related to premium tax and believe a communication from CMS would help clear up any confusion the States may have.

Response: We believe the MA regulations at § 422.404 are absolutely clear that States cannot levy a premium tax, fee, or any other fee on the payment CMS makes to MA organizations (on behalf of MA enrollees) or payments made by MA enrollees to MA plans or by a third party to a MA plan on a beneficiaries behalf.

Comment: One commenter stated that CMS has not established if its expanded preemption authority applies to cost HMOs that are either: (1) observing the same rules as MA organizations (with respect to grievance and appeals for

example); or (2) offering qualifying Part D coverage. Both the Congress and CMS have stated that cost HMOs offering qualifying Part D coverage should be ''treated'' like local MA-PDs and subject to the same rules as MA-PD plans offered by MA organizations. The commenter maintains that CMS should apply the expanded preemption available to MA organizations to cost HMOs when the latter are carrying out the same programs and are subject to the same rules as the former. The commenter also believes that doing so in the final rule would be consistent with the intent of the Congress, and would ensure consistent application of Medicare managed care rules when those rules are the same for both MA members and cost HMO members. The commenter concludes by noting that without preemption, cost HMOs may be mandated by State law to cover certain drugs, or have certain cost sharing for covered drugs, inconsistent with Part D.

Response: If a cost plan offers the Part D benefit, the Part D provisions that apply under the MA program would apply to the Part D product, including the Federal preemption standards. However, other services offered by the cost plan are not subject to the new Federal preemption authority in the MMA which otherwise only applies to MA plans offered by MA organizations.

Subpart J—Special Rules for MA Regional Plans

Section 1858 of the Act, as amended by section 221 of the MMA, sets forth special rules that apply to new MA regional plans. Although MA regional plans will have many similarities with local MA plans, the Congress provided for a number of unique financial and administrative incentives designed to support the introduction of these types of plans.

These incentives will assist plans as they enter this new line of business and learn the market dynamics of serving beneficiaries across larger geographic areas. In addition, to encourage the formation of regional plans, we establish(at § 422.451) a 2-year moratorium on new local PPO plans from January 1, 2006 until December 31, 2007, unless the plan was offered before the first day of the moratorium, to implement section 221(a)(2) of the MMA.

In the August 3, 2004 rule, we proposed establishing a new subpart J to address many of the special regional PPO requirements. (Bidding and payment provisions for MA regional plans are implemented in subparts F and G of part 422.) We received more than 125 sets of comments on subpart J in response to the proposed rule; most related to the establishment of MA regions. The Secretary of the Department of Health and Human Services announced the establishment of the MA and PDP regions on December 6, 2004. The website address where the MA and PDP regions may be found is *http://www.cms.hhs.gov/medicarereform/mmaregions/*. Below we summarize the proposed provisions and respond to comments.

§ 422.451—2 year Moratorium on Expansion of local PPO plans

To encourage the formation of regional plans, we had proposed at § 422.451 to implement a 2-year moratorium on the offering of new local PPO plans from January 1, 2006 until December 31, 2007. As discussed below, in response to a comment on this final rule, we have revised our interpretation of the moratorium. We now interpret the moratorium as precluding an MA organization from offering a new PPO plan in a service area if the organization did not offer a PPO plan in that area in 2005. As discussed below, an organization that offers a PPO plan in 2005 in a service area will, under our new interpretation, be permitted to offer a different plan in the same area (for example, it could offer both an MA plan and MA-PD plan in the area). Section 221(a)(2) of the MMA provides that we cannot permit the expansion of local PPO plans during 2006 or 2007 unless the PPO was offered as of December 31, 2005. We have determined that a PPO is ''offered'' as of December 31, 2005, for purposes of the moratorium, only if it has actually enrolled beneficiaries into its plan before January 1, 2006.

Comment: A commenter believes that the Congress intended the moratorium to prohibit the expansion of local PPO service areas (for 2006 and 2007) but allow for the introduction of new local PPO plans within those PPO service areas. In support of this view, the commenter believes that the Act permits plans to ''expand enrollment'' during the moratorium, and asserts that product innovation is necessary to do that. The commenter also notes that in order to migrate existing members to new products, MA organizations will need to have several plan offerings, both with and without Part D coverage. In addition, MA organizations may want to offer MA-PD PPO plans with both the standard coverage package and enhanced packages that provide ''donut hole'' coverage. The commenter concluded that if the moratorium were interpreted as freezing the number of plans that a local PPO can offer, the effect would be to greatly restrict choices for current members of local PPO plans. The commenter believes the Congress did not intend such a result.

Response: We agree with the commenter. As noted above, we are now construing the moratorium to apply at the MA Organization level, rather than the plan level. Under this approach, an MA organization that has not offered a local PPO plan in a service area prior to the effective date of the moratorium will be prohibited from doing so, but an organization that did offer a PPO plan in the area could continue to do so, and could add other PPO plan options. We believe this change in interpretation is warranted on several grounds. First, we interpret section 221(a)(2) of the MMA as intended to prevent MA organizations from entering a new service area with a local PPO product in 2006 and 2007, not to preclude an organization already offering a PPO plan in the area from changing its benefit designs. We believe that even though the text of section 221(a)(2) contains the word ''plan,'' Congress used that word in its more colloquial sense—that is, meaning ''health plan'' rather than ''MA plan.'' As the commenter stated, support for this interpretation is found in the Conference Report, which states that MMA section 221(a)(2) establishes the moratorium ''on new local preferred provider organizations to encourage PPOs to operate at the regional level.'' Further support for this interpretation arises from the fact that were we to retain the more restrictive reading, MA organizations would be precluded from offering their enrollees the option of choosing whether to enroll in Part D. Because the organization would be required to offer an MA-PD plan in the service area, if it only offered one PPO plan in 2005, it would have to offer Part D benefits in that plan, as only that plan would be exempted from the moratorium. We believe that the Congress intended to give MA organizations the right to offer a plan without Part D benefits as long as they offered an MA-PD plan in the same area. This right would be thwarted under our earlier interpretation of the moratorium provision. We have revised the regulation accordingly. The effect of the 2006 and 2007 moratorium will be to prevent an MA organization from offering a PPO plan in a service area in 2006 and 2007 if it did not already offer one in the area, and to freeze any service area expansions of existing local PPO plans. However, during the 2-year moratorium, MA organizations offering local PPO plans, may offer additional PPO plans (within the pre-moratorium PPO services areas) to afford beneficiaries reasonable enrollment

options and to allow for the MA organization make changes in order to offer Part D coverage in a local PPO plan.

Comment: A commenter recommended that CMS allow specialized MA plans for special needs individuals or SNPs to offer new local PPO plans and service area expansions (SAEs), even during the moratorium in 2006 and 2007. The commenter believes that this flexibility is warranted because SNPs do not compete with MA regional plans.

Response: As we have discussed above, an MA organization may introduce new local PPO plans within its 2005 service areas where it has offered local PPO plans. However, an MA organization may not expand its service area beyond the boundaries of the local PPO plans the organization has established prior to the moratorium's taking effect. This will allow an organization to offer a SNP (operating as a local PPO) in its pre-moratorium PPO service areas. We think this is consistent with the Congressional intent to allow organizations offering local PPO type plans to expand enrollment within its pre-moratorium service areas.

Comment: A commenter is interested in applying to us in 2006 as a new local HMO that would become operational in 2007. The commenter states that its operational model is as an HMO. However, the commenter is licensed in its State of operation as a ''health care services contractor'' and not as an HMO. The commenter is concerned that because it is not State-licensed as an HMO, it may not fit the definition of a local HMO and will be subject to the 2-year moratorium on local PPOs.

Response: Organizations contracting with us must meet applicable State licensure requirements. Our basic regulatory requirement is that an MA organization must be State licensed to bear risk as described in the MA regulations at § 422.400. Section 422.400 indicates that it is the responsibility of the MA organization to demonstrate to us that it is operating within the scope of its State license or the State authority granted to it under § 422.400(b) (if the entity is not State-licensed as a commercial insurer) authorizes it to offer the type of MA plan or plans it intends to offer in a State. Upon meeting State licensure requirements, the organization offering an MA plan must meet MA regulatory requirements governing the type of plan being offered. As we have previously described, we will approve applications for new local PPO plans for 2006 and 2007 offered by an MA organization within the service area of local PPO plans offered by that MA organization and established prior to January 1, 2006. In addition, MA organizations may introduce other MA plan types without service area restriction (for example, HMOs or PFFS plans) that meet State licensing requirements and MA regulatory requirements.

Comment: The commenter opposes the local PPO 2-year moratorium but recognizes that it is required under the MMA. The commenter states that CMS must set an application deadline that allows for the review and approval of a local PPO application in time for the bidding deadline. Accordingly, the commenter recommends that we consider a plan as ''existing'' before 2006 even though the first effective date will not be until January 1, 2006. An MA local PPO should be considered as ''existing'' when in 2005, has been awarded a contract, has submitted a bid for 2006, and is being marketed during the annual election period which begins in November, 2005.

Response: Under MMA section 221(a)(2), the 2006 and 2007 moratorium prevents the offering of new local PPOs in a service area unless a local PPO plan was offered by that MA organization in that service area as of December 31, 2005. We have determined that this means that local PPO plans must have actually enrolled beneficiaries before January 1, 2006 to be considered ''offered'' and thus in effect before the moratorium begins. The local PPO plans that have enrolled beneficiaries prior to January 1, 2006 will establish the limits of the service area where the MA organization can introduce new local PPO plans during the moratorium.

Establishment of the MA regions (§ 422.455)

At § 422.455, we implement section 1858(a) of the Act, which requires us to establish the regions that will constitute the service areas for the MA regional plans. We were required to establish between 10 and 50 MA regions within the 50 States and the District of Columbia, and an MA regional plan will be required to serve an entire region.

The statute specified that the MA regions should maximize the availability of regional plans for Medicare beneficiaries, particularly those residing in rural areas, regardless of their health status. To assist us in developing the MA regions, we were required to conduct a market survey and analysis, including an examination of current insurance markets.

It is important to note that in accordance with section 1858(a)(2)(B)(ii) of the Act, we may periodically review MA regions and revise as necessary. We implement this provision at § 422.455(b)(2)(ii).

Combined with comments received on Prescription Drug Plan (PDP) regions, we received more than 110 sets of comments on the establishment of MA regions as found in § 422.455(b). The first sets of comments were received in follow-up to a public meeting held in Chicago, Illinois on July 21, 2004 regarding the MA and PDP regions. We also received numerous comments in response to our request for comments in the proposed rule for part 422: Establishment of the MA Program. We also received comments on PDP regions on the part 423 proposed rule: Medicare Prescription Drug Benefit. Comments and responses that relate to the establishment of PDP regions are found in Subpart C of the preamble to the final rule for part 423. Finally, we received written comments following a CMS Special Open Door Forum conference call on ''Factors for Determining MA and PDP Regions to Maximize Beneficiary Choice,'' held on Friday, October 22, 2004.

The majority of MA region comments that specified the size of the region generally favored establishing 50 State-based regions. However, about one-third of all comments supported multistate regions, though few provided the number of multistate regions they would prefer. Issues identified in support of 50 State-based regions included the large assumption of risk with the establishment of larger regions; insufficient time for plans to negotiate and develop networks in larger regions or to renegotiate provider contracts and form partnerships; limitations in capacity and infrastructure issues in the initial years; and potential difficulties in obtaining State licenses and meeting State solvency requirements.

Comment: Some commenters suggested that fewer organizations will participate as regional PPOs if larger regions are established. Commenters who favored multistate regions indicated their belief that larger regions would facilitate plan choices in areas traditionally without a choice of plans. Further, several commenters noted that 50 State-based regions would perpetuate the status quo of not providing choice of plans in certain areas, especially in rural areas. Commenters in favor of multistate regions also cited Congressional intent to provide rural beneficiaries with the same array of choices that beneficiaries in non-rural areas often have. These commenters contend that these choices would not occur with 50 State-based regions. From a market perspective, supporters of multistate regions believe that there

would be a critical mass in larger regions that are necessary to encourage new entrants into the MA market.

One commenter stated that the lack of specificity in the proposed rule made it difficult to envision how the new regional PPO option would work in practice. A number of commenters expressed concern about the compressed timeframe between our announcement of the regions and their deadline for making a decision about whether to apply as a regional PPO. Finally, a number of commenters recommended that CMS make Puerto Rico a freestanding MA region because of the unique cultural factors of Medicare beneficiaries residing in Puerto Rico.

Response: We conducted a market survey and analysis, including an examination of current insurance markets as required in the MMA. Key factors in the survey and analysis included payment rates, eligible population size per region, PPO market penetration, current existence of PPOs, MA plans, or other commercial plans, presence of PPO providers and primary care providers, and not splitting multistate Metropolitan Statistical Areas (MSAs). Additional factors were also considered, for example, solvency and licensing requirements and capacity issues. In response to comments about the lack of specificity in the proposed rule, we have taken several steps (for example, the market survey and extensive public outreach) to ensure that the public could see options for the regions, and factors used in determining these options. We also have sought public input in several contexts before the publication of the regions. The establishment of the MA PPO and PDP regions was announced on December 6, 2004, and can be found at *http://www.cms.hhs.gov/medicarereform/mmaregions/* . We understand the commenters' concerns about Puerto Rico's unique circumstances. However, the statute defines an MA region as one that is within the 50 States and the District of Columbia. Therefore, we are not authorized to include Puerto Rico or any of the other U.S. territories in an MA region. However, pursuant to the requirement to establish PDPs under section 1860D–11(a)(2) of the Act (as implemented at § 423.112), we have established PDP regions for the territories, separate from the 50 States and the District of Columbia. A separate PDP region has been established for each territory.

Risk Sharing (§ 422.458)

Section 1858(c) of the Act provided that we will share risk with MA regional plans for contract years 2006 and 2007, if plan costs are above or below a specific risk corridor. Risk sharing is intended to encourage plans to enter the regional market and to provide assistance to these plans during the start-up phase of their business.

Section 422.258(a) will implement section 1858(c) of the Act by defining the following terms:

- Allowable costs were defined as the total amount of costs incurred in a year in providing benefits covered under the original Medicare FFS program option for all enrollees and in providing rebatable integrated benefits, reduced by the portion of those costs attributable to administrative expenses incurred in providing these benefits.
- Target amount for an MA regional plan was defined as the total amount of payments made to the organization for enrollees in the plan for the year, reduced by the amount of administrative expenses assumed in the portion of the bid attributable to benefits under original Medicare FFS program option and rebatable integrated benefits.
- Rebatable integrated benefits were defined as those non-drug supplemental benefits that are funded through beneficiary rebates (described at § 422.266(b)(1)) and that we determine are: (1) additional health benefits not covered under the original Medicare program option; and (2) benefits that require expenditures by the plan.

Section 422.258(b)(2) will implement section 1858(c)(1)(B) of the Act by requiring that MA regional plans notify us, before that date in the succeeding year as we specify, of each plan's total allowable costs. As mentioned above, rebatable integrated benefits (RIBs) are the only supplemental benefits that can be included in a plan's allowable costs. We have discretion to evaluate whether certain rebatable benefits should be included in allowable costs for risk corridor calculations. We asked for comment whether reductions in cost sharing for Parts A and B benefits should be considered RIBs.

Section 422.358(c) will implement section 1858(c)(2) of the Act relating to payment adjustments. There will be no payment adjustment if the allowable costs for the plan are at least 97 percent, but do not exceed 103 percent, of the target amount for the plan. Section 422.358(c) also included the following:

- If allowable costs for the plan are more than 103 percent but not greater than 108 percent of the target amount for the plan for the year, we will increase the total monthly payments made to the organization by 50 percent of the difference between allowable costs and 103 percent of the target amount.
- If allowable costs for the plan are greater than 108 percent of the target amount, we will increase the total monthly payments to the plan by an amount equal to the sum of: (1) 2.5 percent of the target amount; and (2) 80 percent of the difference between allowable costs and 108 percent of the target.
- If the allowable costs for the plan are less than 97 percent, but greater than or equal to 92 percent of the target amount, we will reduce the total monthly payment to the plan by 50 percent of the different between 97 percent of the target amount and the allowable cost.
- If the allowable costs for the plan are below 92 percent of the target, we will reduce the total monthly payments to the organization by the sum of: (1) 2.5 percent of the target amount; and (2) 80 percent of the difference between 92 percent of the target and the allowable costs.

Section 422.358(d) will implement section 1858(c)(3) of the Act relating to disclosure of information. Each contracting MA plan must provide the information that we determine is necessary to carry out this section. Although we have the right to inspect and audit all books and records pertaining to information provided under this section, the information disclosed or obtained for purposes of this section may only be used to carry out this section.

Comment: Two commenters suggested that we clarify how MA regional plans should determine their administrative costs for purposes of determining their allowable costs and target amounts. Both commenters recommended that we develop an administratively straightforward methodology to identify administrative costs. One commenter suggested that we clearly state that the determination of administrative costs for purposes of the MA regional plan risk corridors may differ from the calculation of administrative costs for purposes of the Part D program.

Response: As stated in § 422.254 each bid submission must contain all estimated revenue required by the plan, including administrative costs and return on investment. We interpret the term administrative costs to be the costs associated with administering the program and the expected or retained earnings of health plans. For purposes of this final rule, we use the terms administrative costs and administrative expenses interchangeably. We intend to provide further guidance on defining administrative costs in the instructions

on use of the bid pricing tool. We expect that the guidance will seek to reconcile any differences in how administrative costs are calculated for purposes of Title I and Title II.

Comment: Three commenters recommended that CMS consider cost sharing reductions for Part A and B benefits as plan expenditures, and thus included as rebatable integrated benefits, rather than as foregone revenue that would be excluded from RIBs. One commenter suggested that by doing so, more risk would be shared between a plan and Medicare, thereby encouraging greater plan participation. The commenter believes that this approach would be more intuitive and less likely to result in variable cost estimations than the alternative approach. Another commenter suggested that the MA plan actuary should demonstrate and certify its estimate of the rebatable portion of the cost sharing. Another comment was made recommending that the risk sharing calculation should be modified to include full plan costs (that is, those beyond the rebate funded portion).

Response: We considered several issues when determining which uses of rebate dollars to define as RIBs. As we stated in the August 3, 2004 proposed rule, one approach could be to define RIBs as benefits that will otherwise be covered under original Medicare were it not for the imposition of deductibles, co-pays, coinsurance, and benefit coverage limits. This will exclude, for example, non-Medicare covered benefits from the category of RIBs. However, we concluded that it is difficult to draw a non-arbitrary line between integrated and non-integrated benefits. For this reason, in the proposed rule, we proposed to include additional health benefits not covered by original Medicare in the category of RIBs. In terms of cost sharing reductions for Part A and B benefits, we agree with the commenters that cost sharing reductions for Part A and Part B Benefits can be considered expenses to a plan because when an enrollee pays less, the plan pays more. In other words, when a plan uses the rebate to reduce Part A and B cost sharing, the amount that otherwise would be paid to the provider by the beneficiary must be paid by the plan. Therefore, for the purposes of determining risk-sharing payments to regional plans for 2006 and 2007, cost sharing reductions for Part A and Part B benefits will be considered plan expenditures for purposes of § 422.458(b)(2)(ii). In doing so, this allows cost sharing reductions for Part A and Part B to be considered rebatable integrated benefits provided that these reductions are funded by plan rebate dollars and not by the beneficiary supplemental premium. With regard to extending risk to full plan costs, section 1858(c) of the Act limits the risk sharing arrangement between us and plans to only allowable costs (that is, those incurred in providing Part A and Part B benefits and rebatable integrated benefits). For mandatory supplemental benefits that are non-Medicare benefits and require expenditures by the plan though are partly funded by rebate dollars, we will include only the rebate funded portion of the costs and revenues in the risk corridor calculation.

We note that several applications of rebate dollars are not considered RIBs: (1) reductions in Part D cost sharing since the statute defines RIBS an non-drug supplemental benefits in section 1858(c)(1)(d) of the Act; (2) a Part B or Part D premium reduction does not require expenditure by the plan.

State Licensing Waiver

Section 422.458(e) will implement section 1858(d), of the Act setting forth organizational and financial requirements for regional PPOs, including the provision for a temporary waiver of the MA State licensing requirement. In order to facilitate the offering of MA plans in regions encompassing multiple States, we may temporarily waive State license requirements, for example, to allow sufficient time for the processing of the application by the State or States where an application is pending.

Comment: One commenter stated that under the MMA we have the authority to temporarily waive State licensure requirements to facilitate plans in regions encompassing multiple States when a plan is licensed in at least one State. The commenter asks for clarification whether we can use our authority to grant the same waiver to local plans seeking service area expansion to bordering States. The commenter believes that in providing this authority the Congress intended to facilitate plan choices for beneficiaries. The commenter concludes by noting that the licensure waiver should apply as well to local plans seeking to become another enrollment option for enrollees in neighboring States.

Response: As the commenter indicated, section 1858(d) of the Act provides authority for us to temporarily waive State licensure requirements to facilitate the introduction of regional PPO plans if a region encompasses multiple states. However, under the statute this authority is specific to regional PPO plans. We do not believe we have the authority to extend the State licensure waiver to local plans with a service area encompassing more than one State.

Comment: Another commenter recommended that CMS be as conservative as possible in deciding how to waive State licensing requirements in the States in which regional PPOs are operating. The commenter recommended that CMS ensure regional plans serving beneficiaries in multiple States are held accountable under the State laws under which they are operating.

Response: As specified in the MMA, all MA organizations offering MA plans including regional PPO plans must be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which they offer an MA plan. We will temporarily waive the State licensure requirements only in limited circumstances. Specifically, if an MA organization offering an MA regional plan is organized and licensed under State law in at least one State in the region but has not met the licensing requirements in other States in the region, under section 1858(d) of the Act, we may temporarily waive the State licensing requirement in the other States. This waiver will only be extended to allow sufficient time for the processing of the application by the State or States where an application is pending. The statute allows for the waiver to extend for a transition period after denial of a licensure application, but does not permanently excuse a plan from compliance with state licensing requirements. Therefore, if a State denied a regional PPO's application for State licensure, we will not allow the plan to continue operating in that region beyond the transition period, unless the plan obtains licensure in all States in the region.

Comment: A commenter is concerned that organizations that lack sufficient experience in operating a PPO plan or being a capitated Medicare provider will apply to become regional PPO plans. The commenter proposes that we establish minimum requirements (beyond the filing of licensing applications) that an applicant must satisfy before we would consider a temporary waiver of the State licensure requirement. The commenter recommends that CMS impose the following requirements:

- The applicant or a sponsoring organization of the applicant must have operational experience in offering insured PPO plans;
- The applicant or a sponsoring organization of the applicant must have

operational experience with assuming risk under capitated programs;

• CMS should limit the duration of the waiver to one year from the date the waiver is granted.

Response: We anticipate that most State licensure waivers will be for less than 1 year. The exact duration of the waiver will depend on how long a State takes to process the application. In any event, as we indicated in the previous response, all regional PPO plans must become State licensed in each State in which they operate. We do not believe it is necessary for us to impose additional requirements for new PPO applicants. We have considerable experience in reviewing applications from new organizations entering the MA program. New organizations entering the program must meet the operational and regulatory requirements that apply to current plans. If a new applicant has no current experience we invest the necessary time and resources to ensure that the organization offering the plan does in fact have the capacity to offer the proposed plan and meet all regulatory requirements. We expect that we will take the same approach with any new applicant to the MA program.

Comment: A commenter recommends that if CMS do not designate single-State regions, CMS should amend the proposed rules governing preemption of State law to ease the burden of multistate licensure as much as possible. The commenter recommended that CMS apply the Federal waiver and uniform solvency standards applicable to provider sponsored organizations to regional PPO plans to promote greater regional PPO participation and access to potential beneficiaries. Alternatively, the commenter recommends that CMS engage the National Association of Insurance Commissioners and the State departments of Insurance in discussions that will result in the creation of a single, uniform MA PPO licensure application form, procedures, and solvency standards, that maximize the availability of PPO assets for use in providing direct services and care enhancement, and minimize the net worth, reserve, deposit, surplus and related requirements applicable to PPOs.

Response: Under the MMA we do not have the authority to establish regional licensure and solvency standards for regional PPO plans. Under the law, regional PPO plans must meet State licensure and solvency standards in each State in which they operate. We have added language to § 422.458(e)(1) to clarify that regional PPOs must be licensed in each State of the region, except during the period of the temporary waiver.

Comment: A commenter stated that even temporarily waiving State licensure without requiring applicants to satisfy certain minimum requirements could expose the MA program and beneficiaries to insecurity. Waiver of State licensure requirements based on a filing of an application for licensure does not constitute an assurance the organization has the essential capability necessary to operate a multistate PPO potentially serving thousands of beneficiaries. The commenter recommended that CMS establish minimum requirements, such as solvency standards, in addition to the filing of an application that a regional PPO applicant must satisfy before we even evaluates, or approves, a temporary wavier of State licensure. The commenter also recommended that any waiver be limited to 1 year from the date the waiver is granted. The commenter believes that a 1-year limit will promote stability and confidence in the MA program by terminating an unlicensed organization before their withdrawal causes disruption to beneficiaries.

Response: As we have previously discussed, we will grant a temporary State licensure waiver only in circumstances where the organization is State licensed in a least one State in the region and has submitted applications in the others. Under the waiver process, in those State(s) where it has a waiver, the organization will select the licensing rules of one State in the region and apply those rules to the States in which the organization has not met State licensure until the organization is licensed in all the States. We have made a technical change to the regulations at § 422.458(e)(2) to clarify this point. We expect that in most cases the State licensure waiver will be for less than a year. However, we will not specify the time limit, because the length of the waiver will depend on how quickly the State processes the PPO's licensure application. We note that all regional PPO plans entering the MA program (including those with a temporary State licensure waiver) must still be reviewed and approved by us and determined to be capable of meeting all regulatory requirements. We will not approve any MA plan that we have not confirmed through our application review process has the capacity to offer the proposed plan.

Stabilization Fund

Section 422.458(f) will implement the provisions in section 1858(e) of the Act providing for the creation of a Regional Stabilization Fund. The Congress has authorized an MA Regional Plan Stabilization Fund in order to promote greater stability in the regional program and provide us with a tool to respond to market fluctuations.

The Fund can be used to provide incentives for plan entry in each region, as well as for retaining plans that have already entered the market in MA regions with below average MA penetration. Initially, $10 billion will be available for expenditures from the Fund beginning on January 1, 2007, and these start-up funds will only be available until December 31, 2013. The Fund is designed to allow us to respond to market conditions on a temporary basis. If the Fund is used for either plan entry or retention for 2 consecutive years, we will report to the Congress on the underlying market conditions in the regions. These reports will give the Congress time to respond to the market conditions through changes to the regions or the underlying payment system.

The funds will be available in advance of appropriations to MA regional plans in accordance with specified funding limitations. The total amount projected to be expended may not exceed the amount available in the Fund as of the first day of that year. We will only obligate funds if our Chief Actuary, and the appropriate budget officer, certify that there are sufficient funds at the beginning of the year to cover all the obligations for that year. We will take steps to ensure that sufficient funds are available to make the payments for the entire year, which may include computing lower payment amounts or limitations on enrollment in MA regional plans receiving the payments. Expenditures from the Fund will first be made from amounts made available from the initial funding. We have made a change to § 422.458(f)(3)(ii) to conform the provision to our proposal as discussed in the August 2004 proposed rule.

Comment: Several commenters had concerns over the financial incentives made available to MA regional plans and asserted that these would disadvantage local plans by compromising their ability to compete with regional plans or the FFS Medicare program. To encourage the offering of all plan options, commenters recommended that local plans and others should also have access to these risk sharing arrangements. Several commenters proposed that CMS should use the demonstration authority to offer the same financial incentives to local plans as those offered to regional MA plans. Other commenters expressed their support for these incentives, and

asserted that these types of incentives would encourage MA regional plans to enter or re-enter certain markets.

Response: Financial incentives, such as the application of risk corridors and access to the stabilization fund, were designed to encourage new regional plans to enter the MA program and stay in the program over time. Section 1858 of the Act limits these incentives to only MA regional plans. As stated previously, regional plans are defined as those MA preferred provider organization plans available to all MA eligible individuals without regard to health status and are offered throughout the entire region. Because these incentives are provided for in the statute, we are unable to change the types of organizations that could receive them. It is important to note, that there are special provisions available only to local plans that MA regional plans do not have available, for example, the ability to choose the areas they cover, including specific counties and even partial counties, and they are not required to cover an entire region. Further, the MMA contemplated competition between plans so that beneficiaries will have greater choice of high-quality, low-cost regional and local plans. The statute specified the payment methodology for both local and regional plans. Additional responses to bidding and payment comments may be found in the preamble for subparts F and G.

Comment: One commenter stated that the stabilization fund discriminates against local plans because a portion of local plan savings would subsidize the regional plans.

Response: The commenter is incorrect. Seventy-five percent of the savings accrued when an MA plan bid falls below the benchmark, is rebated to the beneficiary in the form of extra benefits. For local plans, the remaining 25 percent of the difference between the bid and the benchmark returns to the Medicare Trust Funds. For regional plans, the remaining 25 percent of the difference is split: 12.5 percent of the difference returns to the Medicare Trust Funds, and 12.5 percent of the difference goes toward supplementing the stabilization fund.

6. Plan Entry Funding

At § 422.458(f), we make available plan entry incentives for either a 1-year national bonus payment or multi-year adjustments in regional payments (but not both). Funding will only be available for a single year, but more than one organization can receive the incentive in the same year.

As found in § 422.458(f)(4)(ii), the national bonus payment will be: (1) available to an organization only if it offers plans in every MA region; (2) available to all MA regional plans of the organization regardless of whether any other MA regional plan is offered in any region; and (3) equal to 3 percent of the benchmark amount otherwise applicable for each MA regional plan offered by the organization, subject to funding limitations.

If a national bonus payment is not made, a regional payment adjustment can be made. The regional payment adjustment is an increased payment for an MA regional plan offered in an MA region that did not have any MA regional plans offered in the previous year. The adjusted payment amount will be determined based solely on plans' bids in the region and that the adjusted payment amount be available to all plans offered in the region.

We did not receive any public comments on this section. We are implementing this section as proposed.

7. Regional Payment Adjustment

Subject to funding limitations, we will determine the period of time that funds are available for regional payment changes to encourage plan entry. If funding is provided for a second consecutive year under this provision, we will submit a report to the Congress describing the underlying market dynamics in the region and recommend changes to the payment methodology. Multi-year funding will be made available to all MA plans offered in a region, but if this multi-year increased amount is made available to MA plans in a region, funding will not be available for plan retention in the region in the following year.

We did not receive any public comments on this section. We are implementing this section as proposed.

8. Plan Retention Funding

In addition to using the Fund to encourage plans to enter regions that might otherwise go unserved, we may also use the fund to encourage plans to remain in regions if market conditions are causing plan withdrawals. At § 422.548(f)(5), incentives for plan retention could take the form of an increased payment to plans in regions that meet specific requirements.

We intend to use this provision to ensure that all MA organizations offering regional plans in a region receive appropriate incentives to remain in the region. As specified at § 422.548(f)(5)(ii), the payment will be an amount determined by the Secretary that does not exceed the greater of: (1) 3 percent of the benchmark amount applicable in the region; or (2) an amount that, when added to the benchmark, results in a ratio such that the additional amount plus the benchmark for the region divided by the adjusted average per capita cost (AAPCC) equals the weighted average of benchmarks for all regions divided by the AAPCC.

The payment would be available if: (1) one or more plans inform us that they are going to discontinue service in the region in the succeeding year; (2) we determine that if those plans were not offered, fewer than two MA organizations will be offering MA regional plans in the region in the year; (3) for the previous year, we determine that the proportion of beneficiaries enrolled in MA regional plans in the region is less than the national average of MA regional plan enrollment; and (4) funds have not already been awarded for 2 consecutive years.

We did not receive any public comments on this section. We are implementing this section as proposed.

Subpart K—Application Procedures and Contracts for Medicare Advantage Organizations

1. Overview

Subpart K sets forth the provisions relating to the application procedures and contract determinations that are entered into by MA organizations including a description of terms that must be included in the contract, the duration of the contract, provisions regarding the nonrenewal or termination of a contract, and minimum enrollment, reporting, and prompt payment requirements of the MMA.

In this final rule, in order to make more clear the requirements for MA plans under part 422 and any additional requirements for MA plans offering a prescription drug benefit under part 423, we have amended section § 422.500 by revising the section heading to read ''Scope and definitions≥; designating the undesignated introductory text as paragraph (b) and adding the heading ''Definitions≥; and adding a new paragraph (a), ''Scope,'' which specifies the scope of the subpart K requirements.

We also incorporated the application requirements and evaluation and determination procedures from subpart A (§ 422.6 and § 422.8) into subpart K at newly redesignated § 422.501 and § 422.502, respectively. As a result we have revised the title of subpart K in this final rule to read as follows ''Application Procedures and Contracts for Medicare Advantage Organizations.''

In addition, we have eliminated the proposed § 422.502(b)(3)(iv)(G), regarding self-reporting requirements.

However, we have specified at § 422.503(b)(vi)(H), that MA-PDPs must follow the requirements in part 423 (the requirements for the Part D prescription drug benefit) concerning a comprehensive fraud and abuse plan. Note that the fraud and abuse requirement in part 423 applies only to the Part D prescription drug benefit offered by the MA organization. Please see our discussion of this requirement at section 4 of this preamble.

The MMA added a new section 1857(e)(3)(A) of the Act, which applies only to Federally Qualified Health Centers (FQHCs)and requires that the contract between CMS and MA organizations include a provision that any written arrangements between an MA organization and an FQHC include a level of payment that would be equal to what the MA organization would pay other providers for similar services. This requirement was codified at proposed § 422.527. We received two comments asking for some clarifications on the reimbursement of FQHCs which we do address here.

We also responded to commenters expressing concern that they would be unable to properly prepare for beneficiary enrollment if the contract process and the bid process were consecutive. Other commenters, for the same reason, asked that we streamline the application and contracting process. We welcomed these suggestions and have made changes accordingly, which we discuss below.

We made a number of technical and clarifying changes. In § 422.502(b)(1), for example, we clarified that the completion of an application is a condition necessary to contract as an MA organization, clarified the distinction between the contract and process for purposes of redeterminations at § 422.501(c)(2), and, at § 422.503(b)(4)(ii), § 422.503(b)(4)(vi)(F), § 422.503(b)(6) and § 422.503(b)(6)(i), made several terminology changes (for example, we changed ''terminated'' to ''non-renew''). We received 25 comments on subpart K. Below we summarize and respond to these comments. Please refer to the proposed rule for additional discussion of the specific provisions of the requirements we proposed for subpart K. Note that public comments on the proposed MA rule and the proposed rule establishing the prescription drug benefit under part 423 are often related and we draw on comments from both proposed rules for our responses here. These comments often lead to changes in both rules and we identify the changes affecting both rules, as appropriate. Because of the similarity of many aspects of both rules and the comments we received related to both we refer interested readers to our final rule establishing the prescription drug benefit.

2. Application Requirements (§ 422.501)

Comment: Several commenter submitted comments on the proposed regulation for MA organizations as well as the proposed rule establishing the Medicare prescription drug benefit asking CMS to make every effort to produce the final regulations as early as possible in January 2005, and to streamline our application process in a way that that does not increase administrative burden for MA plan applicants as well as, specifically, all Part D plan sponsors (which includes MA organizations offering a prescription drug benefit). Several commenters expressed concern that the contract and bid determination processes for MA organizations, as well as, more generally, sponsors of Part D plans, if occurring consecutively, would not leave enough time for plans to be ready for business by January 2006. The commenters requested that CMS permit the contract determination process to run concurrently with the bid application process (subpart F).

Response: We will permit contract applicants to enter into the bid determination process concurrently with the contracting process prior to the execution of a contract. The contract will be pre-qualified and left unsigned until a successful bid negotiation has been approved by us. We are also clarifying at § 422.501(c)(2) that these are distinct processes and, further, that determinations concerning the contract only are appealable under subpart N of part 422 (the bid application requirements are in subpart F). We have made other changes to streamline the contract application process including, for example, the elimination, as a requirement, of a separate notice of incomplete or missing application information which we had proposed in § 422.502(e). Additional ways that we will streamline the contract application process are included in § 422.502(a)(2). We made similar changes to the requirements of part 423. We discuss these and other changes below.

Comment: A commenter recommended that CMS confirm the scope of State licensure requirements that apply to entities offering MA PPO plans, as State licensing laws may restrict an HMO's ability to offer a PPO plan, and sought CMS' confirmation that a State licensed indemnity insurer authorized under State law to provide PDP coverage meets the definition of a Regional Plan provider.

Response: Section 422.400(c) is clear in saying that State law controls whether the MA organization is licensed or authorized to offer the type of MA plan it proposes to offer. As we explained in the preamble discussion in subpart A of the proposed rule, the fact that MA organizations offering local PPOs that are (or are not) licensed as HMOs is pertinent to the MA program solely for purposes of the application of quality improvement standards in section 1852(e) of the Act, and has no specific bearing on whether an MA organization has State authority to actually offer an HMO or PPO under the MA program. Whether an MA organization (licensed either as an HMO or otherwise) can offer a specific type of MA plan continues to rest upon State licensure or authority to offer such a type of MA plan.

3. Evaluation and Determination Procedures (§ 422.502)

Comment: One comment pointed to the differing timelines for evaluation and determination of applications set forth under the Medicare+ Choice rules (and now under MA plans) from those proposed for PDP Sponsors under Part D and requested clarification. Another commenter asked that CMS streamline its application process in a way that does not increase administrative burden for MA organizations wishing to apply to offer MA-PD plans or for other Part D plan sponsor applicants.

Response: We have modified the timeline for evaluation and determination of applications for both applicants to be MA organizations and PDP sponsors at § 422.502 (and made similar changes to the requirements of part 423 for other Part D plan sponsors). We believe that maintaining a single application and evaluation procedure and a single set of contract requirements for both MA and PDP programs brings simplicity, consistency, and reduced administrative burden for those entities that are managing both programs. If an application is determined to be both incomplete, and failing to meet requirements necessary to become an MA organization resulting in an intent to deny issuance, we will notify the applicant concurrently of both determinations. For a notice of intent to deny, based on an incomplete (for example, applicant already received an incompleteness notice and did not provide the required information) or non-responsive application, we will allow applicants 10 days to cure their application before issuing a denial notice, if still justified.

We remain committed to providing successful applicants a reasonable time to begin operations by the first of the year in their selected service area(s). We also want to ensure all potential applicants are given every chance to contract with us. In the event we determine that an application is incomplete, we afford a means for the applicant to ''cure'' the contract application. However, under the MMA with a bidding process added, and the absence of a ''rolling application'' program used under the M+C process, we needed to modify these determination timelines.

In order to respond to concerns that the determination application process as it was set up could compromise a plan's ability to effectively prepare for the beginning of a contract we are consolidating the proposed § 422.502 by removing paragraphs (e), (f), and (g). The change eliminates, as a separate and distinct step in the review process, notification that an application is incomplete. In the final rule, § 422.502 now provides that if an applicant's contract is submitted and found to be both incomplete, as well as unqualified (resulting in the issuance of an Intent to Deny Notice), the period to remedy the application will be 10 days from the date of the notice.

Also, in the final rule in § 422.502(c)(2)(ii), we are changing the amount of time that an applicant has to remedy an application after receiving an intent to deny notice from 60 days suggested in the proposed rule to 10 days. We believe this change is in accordance with the comments we have received to on both rules to streamline the process for each, bring the MA requirements under part 422 and the prescription drug benefit requirements under part 423 in to line, and to reduce confusion and administrative burden. Additionally, if after the initial review of the applications, we determine that an application is missing information necessary for us to make a determination we will attempt to notify the applicant that this is the case. This is not a requirement, however, and we are stating in the preamble of this final rule that applicants receiving notification that their application is incomplete but who have not yet received an intent to deny notice respond back to us with a cured application within two days of receiving the notice. The two days are thus a guide, but ultimately we are constrained by the total amount of time to review applications. As a result, an applicant that takes longer than two days to remedy its incomplete application, risks our issuing a notice of intent to deny before the applicant submits the requested information. We believe that the amount of time given to applicants to furnish information is a procedural rule that is not subject to notice and comment. In addition, applicants will still receive the same 10 days included in the proposed rule to revise their applications if they fail to respond within 2 days, and then receive an intent to deny notice from us.

As discussed above, we are making every effort to accommodate plans in the contract application process. We believe that the availability of choices will enhance opportunities to lower program costs. However, we must balance this goal with the need to ensure that only qualified plans are selected to contract with us.

With the exceptions noted, we are accepting the language from the proposed rule for this section.

4. General Provisions (§ 422.503).

Comment: In the proposed rule at § 422.503(b)(vi)(G)(2), CMS suggested that MA organizations include provisions that would require a MA organization to report misconduct it believes may violate various criminal, civil or administrative authorities. Numerous comments, both for and against, were received regarding these mandatory self-reporting of misconduct requirements. Most of the comments, however, objected that the rule as written was vague and overbroad, with no basis in statute. Other comments directed CMS to eliminate the proposal, stating that current compliance requirements were sufficient.

Response: In response to these comments, we are eliminating from this regulation an explicit requirement that MA organizations report to CMS violations of law, regulation, or other wrongdoing on the part of the organization or its employees/officers. While we are not requiring MA organizations to engage in mandatory self-reporting, we continue to believe that self-reporting of fraud and abuse is a critical element to an effective compliance plan; and we strongly encourage MA organizations to alert CMS, the OIG, or law enforcement of any potential fraud or misconduct relating to the Part D program. If after reasonable inquiry, the MA organization has determined that the misconduct has violated or may violate criminal, civil or administrative law, the MA organization should report the existence of the misconduct to the appropriate Government authority within a reasonable period, that is, within 60 days after the determination that a violation may have occurred.

The failure to disclose such conduct may result in adverse consequences to MA organizations, including criminal prosecution. For example, Title 42 U.S.C. Section 1320a–7b(a)(3) punishes as a felony the knowing failure to disclose an event affecting the initial or continued right to a benefit or payment under the Medicare program. The Federal civil False Claims Act, 31 U.S.C. Section 3729(a)(7) states that any person who knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government, is liable to the United States for a civil penalty plus trebled restitution for the damages sustained by the government. In addition, both DOJ and the OIG have longstanding policies favoring self-disclosure.

As discussed earlier, we believe that establishing procedures to ensure prompt responses to potential fraud violations should be one of the elements in an effective compliance plan. While we are eliminating the mandatory self-reporting requirements, we expect all MA organizations offering a Part D plan to comply with the requirement for a comprehensive fraud and abuse plan as found under § 422.503(b)(4)(vi)(H). (Note: we are not reproducing our discussion on the fraud and abuse requirements here as this is a requirement specifically for MA organizations offering a prescription drug benefit. Please see our discussion in our final rule establishing the prescription drug benefit.) In summary, we have elected to recommend reporting fraud and abuse as part of the compliance plan as required as a condition of contracting as an MA organization. Plans that self-report violations will continue to receive the benefits of voluntary self-reporting found in the False Claims Act and Federal sentencing guidelines. In the future, we will examine mandatory self-reporting of health care fraud and abuse across all Medicare providers and contractors.

5. § 422.504 Contract Provisions

Comment: A commenter questioned the need for proposed § 422.504(h) which would require MA organizations to comply with certain specific Federal laws and rules, other laws applicable to recipients of Federal funds, and all other applicable laws and rules. The commenter argued that these requirements were on their face seemingly inconsistent with our regulatory provisions exempting Federal plans from procurement standards and preempting State laws other than those

relating to licensure. Furthermore, nothing suggests a rationale for naming some laws and not others. The same commenter also suggested that the provisions might more appropriately be replace with one focused on plans committing themselves to compliance with Federal standards aimed at preventing or ameliorating waste, fraud, and abuse.

Response: We agree that our efforts are best focused on requirements to prevent fraud, waste, and abuse and on issues that we are responsible for enforcing such as the HIPAA Administrative Simplification rules. We have, therefore, made the suggested changes to reflect this focus at § 422.504(h). These changes are in no way meant to imply that MA organizations need not comply with other Federal laws and regulations as applicable, only that the enforcement of these Federal laws and regulations is the responsibility of Federal agencies other than ours. We have made a similar change in the regulations establishing the prescription drug benefit program under part 423.

Comment: A commenter responding to our proposed rule establishing the prescription drug benefit under part 423 asked us to clarify whether the retention periods all refer to MA organizations offering Part D plans. Another commenter asked that our records retention policy for Part D plan sponsors parallel the statute of limitations that applies to the False Claims Act, that is, a maximum of 10 years from the time of the violation.

Response: We agree with the commenter that our retention requirements should more closely follow the statute of limitations that apply to the False Claims Act. And, in response to the other commenter, we are using this standard for retention requirements under both parts 422 and 423. As a result, in the final rule at § 422.504(e)(4), we are requiring that records be maintained for 10 years from the last contracting period or audit, whichever is latest, to conform to the statute of limitations for the discovery of violations under the False Claims Act.

We recognize that 10 years is the upper limit under the False Claims Act but we believe that this period will best enable us to have access to pertinent records should this be necessary. Also, the 10-year retention policy is in line with requirements concerning the prescription drug rebates under the Medicaid program (see 42 CFR 447.534(h)). We believe, as is the case with the Medicaid rule, that in order to ensure that we have the proper oversight for investigating the complex payment and other relationships associated with the delivery of prescription drugs under a program such as Part D, the 10-year retention requirement is necessary. We are making the change to parts 422 and 423 in order to maintain uniformity between requirements for MA organizations and other Part D sponsors. With the exception noted, we are accepting the language from the proposed for this section.

6. Prompt Payment by MA organization (§ 422.520)

Comment: A commenter recommended that we remove the distinction between contracted and non-contracted providers under § 422.520(a)(3) referring to prompt payment terms for non-contractors, fearing that we relinquish any authority to enforce prompt payment control for contracted providers. A commenter asked that the 60-day period for non-contracted providers to be paid be shortened to 30 days.

Response: In response to the first commenter, we do not believe it is necessary to add language concerning contract and non-contract providers. We believe that § 422.520(b)(2) makes it clear that the MA organization is obligated by the terms of its contract with the provider and that such a contract is the proper vehicle for any prompt payment terms.

In response to the second commenter, we believe that a limit of 60 calendar days strikes a reasonable balance by allowing time for the processing of payment without causing providers hardship.

Comment: We received comments asking that we include Independent Physicians Associations (IPAs) and Medical Groups under the prompt payment standards. Other suggestions included establishing timely payment requirement for capitations paid to IPAs and Medical groups; standards for documentation that should be included with capitation payments and/or deductions; establishment of a 90-day limit on an MA plan's ability to retroactively assign or terminate beneficiaries to or from a capitated IPA or Medical group; establishment of a time limit on how far back an MA plan is allowed to make a capitation deduction (not longer than 12 months; allow capitated IPA and medical groups to renegotiate their capitation rate if new benefits are by law and/or added by an MA plan; requiring MA plans to provide on a quarterly basis a detailed accounting of the status of any risk arrangements or risk pools(for example hospital, and pharmacy) in a mutually agreed to electronic format.

Response: Non-contracted IPAs and Medical Groups are already included in the prompt payment requirements in section 1857(f)(1) of the Act and in § 422.502. The billing ''agent'' or entity is immaterial. We have not specifically regulated the content of contracts between providers and MA organizations. We have long supported the notion that allowing the ''free'' market to determine the contractual terms, including payment amounts and timeliness, as well as related matters was best left to the interested parties (MA organizations and providers), who could best represent their own self-interest. While we support many of the items suggested and would support their inclusion in provider/MA organization contracts, we do not believe it is appropriate to require that they appear there.

We have adopted the language of the proposed rule in this final rule.

7. Agreements with Federally Qualified Health Centers (§ 422.527)

Comment: One commenter recommended that we add language clarifying under § 422.527(b) that payment in full to an FQHC does not preclude the FQHC from receiving the wrap-around payment provided by statute and in § 422.316.

Response: We agree with the commenter that we are responsible for the difference between what the MA plan pays to the FQHC and what its fee for service cost are, described above as a wrap-around. Our proposed language at § 422.527 concerned primarily the contract between CMS and the plan. However, in order to clarify how our payments to FQHCs are determined when a beneficiary in an MA plan receives treatment from an FQHC that has a written agreement with the MA organization offering the plan, we have revised § 422.527 of the final rule by adding new paragraph (c) to specify that financial incentives and withholds are not considered in determining the payments made under § 422.316(a).

Comment: The same commenter asked that we clarify that in the final rule that we will not include a financial incentives, ''such as risk pool payments, bonuses or withholds'' received by a FQHC from an MA—when determining payments made by CMS.

Response: In response to the commenter, we are clarifying in § 422.527(c) that financial incentives such as risk pool payments and bonuses as well as financial withholds are not considered in determining payments made to FQHCs by CMS. The language

at section 1833(a)(3)(B)(ii) of the Act, as added by section 237(a)(B)(ii) of the MMA, specifically excludes these financial incentives or withholds when determining the base amount used to be used in calculating payments by CMS.

With the exception of the changes noted, we are adopting the language of the proposed rule for this section.

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

In the proposed rule, we indicated that we would study the modification of existing change of ownership (CHOW) provisions in order to reduce the administrative burden of these requirements and to increase the effectiveness of these provisions. In particular, we requested and received comments regarding situations which constitute a CHOW and how the CHOW provisions should be applied to large companies with multiple business units. These provisions are essentially the same as those requirements found in Title I subpart L for Prescription Drug Plan sponsors. Several commenters specifically requested that we maintain consistency between the provisions for subpart L in Title I and Title II.

After reviewing the comments that we received, we recognize that given the infinite variety of business arrangements and transactions it may be necessary to provide guidance via interpretive documents (for example, FAQs,) and on a case by case basis as to whether a given arrangement constitutes a CHOW and requires an entity to adhere to the CHOW requirements. Contracting organizations should be aware that although we are committed and sensitive to reducing the administrative burden on businesses with multiple legally related entities, we will be alert to situations where these organizations may be looking to avoid compliance with the CHOW provisions so as to evade Medicare liabilities and obligations.

In this final rule we note that contracted MA organizations must adhere to the Privacy Rule on sharing patient health information in the course of a CHOW and novation agreement. MA organizations are not permitted to share protected enrollee health information with a new owner that is not, or will not, become a covered entity absent authorization from its enrollees.

General Provisions (§ 422.550)

Comments: Two commenters requested that CMS clarify that the transfer of the MA line of business from one entity to another constitutes an asset transfer for which CMS will permit a novation agreement.

Response: We agree that the transfer of a MA line of business from one entity to another would constitute a CHOW, such that a novation agreement would be permitted and, in fact, required.

Comment: A commenter recommended that the change of ownership requirements under § 422.550 and § 422.552 exempt change of ownership transactions between two separate subsidiaries of the same parent corporation from the financial information, financial impact and novation agreement requirements of the CHOW provisions. Instead, the commenter suggested that such entities provide written certification detailing that a legally binding transfer of the MA obligations has occurred.

Response: We asked specifically for comments with regard to multiple business units so as to ensure that our rules reflect the realities of today's business world and are not unduly burdensome. While transactions between two subsidiaries of the same parent corporation may not in all cases constitute a CHOW, and, therefore, the business units would not need to adhere to the requirements of the CHOW provisions, we decline to create a separate certification procedure for such business units in the event that a CHOW does occur, as suggested by the commenter. Our ultimate responsibility is to the beneficiaries and objective is to ensure that an entity cannot under any circumstance evade its responsibilities to the Medicare program. What is relevant is whether the transaction leaves the same entity responsible for the MA contract and all inherent responsibilities remain unchanged. Any transfer of functions and/or assets that results in a change of the responsible party or parties for the MA contract must comply with the CHOW provisions under Subpart L.

Asset Sale (§ 422.550(a)(2))

Comment: Two commenters recommended that the title of the subparagraph identified as ''Asset sale,'' be revised to read ''Asset Transfer.''

Response: The suggestion has been adopted in the final regulation. In the proposed rule we were looking for comment on how to best characterize a CHOWs for those businesses with multiple business units, recognizing that a business would not always be selling its assets, but may sometimes simply be transferring a business asset.

Notice Period (§ 422.550(b))

Comments: Two commenters recommended that CMS consider extending the 60 day Notice period that MA organizations are required to provide before a change of ownership. The commenters stated that circumstances may arise when it is not possible to give such notice, for example, State approval pending, and a final determination date by the State is indefinite. Additionally, they recommended adding a good clause exception to the rule when such circumstances occur.

Response: The MMA was passed, in part, to encourage and ease MA plans into the new Medicare market place. Towards that end we will, on a case by case basis, have the flexibility to extend the 60 day notice period if a situation arises that warrants such an exception. We do not feel at this time we need to add a clause that specifies a good cause exception.

Subpart M—Grievances, Organization Determinations, and Appeals

1. Introduction

The MMA did not make any revisions to the statutory requirements in sections 1852(f) and (g) of the Act regarding MA grievances and appeals. Thus, we generally proposed to maintain the existing regulatory requirements in subpart M of part 422, with the inclusion of minor changes needed to conform these subpart regulations to MMA terminology and other provisions. We also reviewed the existing MA grievance and appeal requirements to identify needed refinements. Finally, we proposed changes to the part 417 regulations, which apply only to section 1876 cost contractors and section 1833 health care pre-payment plans (HCPPs) that would establish uniform grievance and appeal procedures for all Medicare managed care plans.

We received 30 comments on subpart M in response to the proposed rule. Below we summarize our proposals and respond to public comments. (For a detailed discussion on our proposals, please refer to the August 3, 2004 proposed rule. (69 FR 46,866, 46,909).

2. Background

Section 1852(f) of the Act provides that an MA organization must provide meaningful procedures for hearing and resolving grievances between the organization (including any other entity or individual through which the organization provides health care services) and enrollees in its MA plans. Section 1852(g) of the Act addresses the procedural requirements concerning coverage (''organization'') determinations and reconsiderations and other appeals for MA organizations. Only disputes concerning ''organization

determinations'' are subject to the reconsideration and other appeal requirements under section 1852(g) of the Act.

In general, organization determinations involve whether an enrollee is entitled to receive a health service or the amount the enrollee is expected to pay for that service. All other disputes are subject to the grievance requirements under section 1852(f) of the Act. For purposes of this regulation, a reconsideration consists of a review of an adverse organization determination by either the MA organization itself or an independent review entity. We use the term ''appeal'' to denote any of the procedures that deal with the review of organization determinations, including reconsiderations, hearings before administrative law judges (ALJs), reviews by the Medicare Appeals Council (MAC) and judicial review.

For the grievance, organization determination, and appeal requirements, an MA organization must establish procedures that satisfy these requirements with respect to each MA plan that it offers. These requirements generally are the same for all plan types —including coordinated care plans such as HMOs and PPOs, non-network MSA plans, and PFFS plans. However, note that for MA-PD plans, separate rules apply for drug benefits, as set forth under part 423, subpart M.

Sections 1833(a)(1)(A) and 1876(a)(5)(B) of the Act reference reasonable cost reimbursement contracts for HCPPs and HMO/CMPs. Section 1876(c)(5) of the Act sets forth the procedures HMO/CMP organizations must follow with regard to grievances, organization determinations, and appeals. Section 417.840 of our regulations requires HCPPs to apply the administrative review procedures set forth for HMO/CMPs. Section 1869 of the Act provides the right to a hearing and to judicial review for any individual dissatisfied with a determination regarding his or her Medicare benefits.

3. General Provisions, Grievances, and Organization Determinations (§ 422.560 through § 422.576)

Section 940(b)(2)(A) of MMA amended section 1852(g)(5) of the Act to incorporate the provisions of section 1869(b)(1)(E)(iii) of the Act, which also was added by MMA. This new clause provides for inflation adjustments to the ''amount in controversy'' required to pursue a hearing and judicial review. It makes these provisions applicable in determining the amount in controversy under section 1852(g)(5) of the Act ''in the same manner as they apply to the dollar amounts specified in section 1869(b)(1)(E)(i).'' Therefore, revisions to the provisions in section 1869 of the Act governing the calculation of the amount in controversy apply to MA appeals.

The existing MA regulations incorporate 42 CFR part 405, subparts G and H, and 20 CFR part 404, subparts J and R. Note that in an interim final rule we expect to publish shortly, we intend to create a new subpart I of part 405 to implement significant revisions to section 1869 of the Act. To accommodate these changes, we proposed minor changes to the cross-references for MA appeals at § 422.560(a)(3), § 422.561, and § 422.562 accordingly. We are finalizing these changes in this final rule. We note that under § 422.562(d), the provisions of part 405 apply to the extent that they are appropriate. This means, for example, that the provisions to implement the time and place for a hearing before an ALJ under section 1869 of the Act, if and when finalized, would apply to MA appeals. Thus, we have added a reference to § 422.602(b) that the time and place for a hearing before an ALJ will be set in accordance with § 405.1020. Although that section has not yet been published in final form, we expect that it will be published prior to the effective date of this rule. Readers may refer to 67 FR 69311, 69331 (Nov. 15, 2002) for an explanation of the proposals and a discussion of the possibility of using video-teleconferencing in ALJ hearings. On the other hand, the provisions that are dependent upon qualified independent contractors would not apply since an independent review entity conducts reconsiderations for MA appeals.

We also clarified the definitions of an authorized representative and an enrollee under § 422.561, which are consistent with part 405. We have removed ''authorized representative'' and replaced it with ''representative'' to clarify that a representative means an individual appointed by an enrollee or other party, or authorized under State or other applicable law, to act on behalf of an enrollee or other party involved in the appeal. Unless otherwise stated in this subpart, the representative will have all of the rights and responsibilities of an enrollee or party in obtaining an organization determination or in dealing with any of the levels of the appeals process, subject to the applicable rules described in part 405 of this chapter.

In accordance with section 1852(g)(1) of the Act, § 422.566 begins by specifying that an MA organization must have a procedure for making timely organization determinations regarding the benefits an enrollee is entitled to receive and the amount, if any, that an enrollee must pay for a health service. We clarified at proposed § 422.566(b)(4) that a reduction in services was an action that constituted an organization determination that an enrollee may appeal. Notice requirements would continue to apply whenever an enrollee disputed the reduction, under § 422.568(c).

Standard timeframes and notice requirements for organization determinations (§ 422.568)

The only substantive change we proposed in § 422.568 was the elimination of the practitioner's notice requirement set forth in § 422.568(c). This section required that at each patient encounter with an MA enrollee, a practitioner must notify the enrollee of his or her right to receive, upon request, a detailed written notice from the MA organization regarding any decision to deny services to an enrollee. Instead of requiring practitioners to provide general notices to enrollees at each patient encounter, we proposed instead to require MA organizations to provide specific written notice for MA organization denials. We believed that MA organizations could provide general information about enrollees' rights in physician office settings in the plan's Evidence of Coverage (EOC). Requiring practitioners to issue notices to enrollees has proven to be administratively burdensome and impossible to monitor.

We also proposed conforming changes to § 422.570(d)(2)(ii) and § 422.572(b) to require that an MA organization must inform an enrollee of the right to file an ''expedited'' grievance, if the enrollee disagrees with the MA organization's decision not to expedite a request for an expedited organization determination.

Timeframe and notice requirements for expedited organization determinations.

Under § 422.572(c), we proposed to eliminate the requirement that oral notice of an expedited determination be followed up with written confirmation in cases of fully favorable determinations. Notice would be required only for decisions that are fully or partly adverse to the enrollee, and thus could engender an appeal.

Comment: Several commenters supported the elimination of the practitioner's notice set forth in § 422.568(c). Some commenters agreed that the practitioner's notice was not a practical means of notifying enrollees of their appeal rights; they supported use of the EOC to provide information about enrollee rights in situations where

physicians make coverage determinations in their offices. One commenter contended that the practitioner's notice was burdensome for providers to deliver and in effect absolved plans of any accountability for their utilization review decisions.

Two commenters stated that the EOC was not a viable substitute for communicating appeals information to enrollees. The commenters believe that the EOC would not be as effective as a notice provided in a practitioner's office regarding how an enrollee could get a coverage determination from the plan. These commenters thought our proposal would disadvantage enrollees, because they do not routinely refer to the EOC. In lieu of the requirement to provide a written notice to each enrollee, one commenter recommended that CMS require practitioners to display posters in their offices to inform enrollees about their rights.

Response: In our view, the EOC is an appropriate alternative to requiring practitioners to deliver notices regarding enrollees' rights to receive coverage determinations from their plans. We believe that enrollees have a responsibility to refer to their EOC to obtain general information regarding coverage determinations. Furthermore, we believe that enrollees have relationships with their physicians built on trust, and enrollees often play an active role in the treatment decisions that affect them. Therefore, in the absence of a delegated arrangement, we are not placing the burden on practitioners to deliver notices to enrollees on their right to receive detailed coverage notices at each patient encounter.

We will work with MA organizations to ensure that the EOC contains information on an enrollee's right to receive a detailed explanation if he or she believes that a practitioner has denied care that the enrollee believes he or she is entitled to receive, or care the enrollee believes should continue. For these situations, the EOC will direct the enrollee to request an organization determination. We will also work with consumer advocates to determine other ways to educate enrollees about their rights.

Comment: Four commenters supported CMS' proposal to explicitly specify in § 422.566(b) that a reduction of services constitutes an organization determination that an enrollee may appeal.

Response: We believe that this approach essentially clarifies existing policy, under which a reduction in service is an appealable issue. Thus, if an enrollee disagrees with an MA organization's decision to reduce a course of treatment, the MA organization must consider the disputed reduction of service a new request for an organization determination. A request for a new organization determination allows the enrollee to receive notice, appeal rights, and access to the MA appeals system under § 422.570 and § 422.584.

4. Requests for Reconsiderations (§ 422.582)

The only substantive change we proposed regarding standard reconsiderations pertained to the manner in which a party to an organization determination would request an appeal. Proposed § 422.582(a)(1) and (a)(2) allowed a party to request a standard reconsideration orally or in writing. In addition, proposed § 422.584(e) required an MA organization to give notice in accordance with the broader provision of § 422.590, since there are notice requirements other than those contained in § 422.590(d).

As we proposed for expedited organization determinations under § 422.570(d)(2)(ii), proposed § 422.590(a) and § 422.590(d)(2) required an MA organization to inform an enrollee of the right to file an ''expedited'' grievance if the enrollee disagreed with the MA organization's decision not to expedite a request for an expedited reconsideration. This is a right that already was established under the grievance provision at § 422.564(d)(2) (re-codified under this final rule at § 422.564(f)(2)); thus, we needed to make a conforming change.

Comment: One commenter took exception to the expedited grievance process currently in § 422.564(d) (re-codified in this rule at § 422.564(f)), (and by extension, the conforming changes at proposed § § 422.570(d)(2)(ii) and 422.572(b)), arguing that this process was not beneficial because it allowed the same organization determination to be considered along two separate tracks simultaneously. The commenter stated that an MA enrollee has the right to request an expedited review of a plan's organization determination, and that the review is automatically granted if supported by a physician's assertion that the life or health of an enrollee would be adversely affected by a decision not to expedite the review. Thus, even without the benefit of an expedited grievance process, a decision would still be made by the plan (albeit in a longer period), and the enrollee would not be in jeopardy while waiting for the plan's decision. The commenter recommended that CMS delete this provision from the regulation in its entirety because, in the commenter's view, it is redundant and inefficient. It would also remove the need for conforming changes.

Response: We agree with the commenter that we should not create redundant processes. However, we do not believe that § 422.564(d) (now § 422.564(f)) is duplicative of the appeal procedures. An expedited grievance process provides important protections for enrollees who are unable or prefer not to obtain a physician's certification that applying the standard time frame would have adverse consequences for the enrollee. In addition, an MA plan could determine that it needs an extension to process a standard or expedited organization determination or reconsideration request. By allowing an expedited grievance to proceed under those circumstances, the decision about the grievance would not be the organization determination, but the plan's appropriate use of its discretion to extend the time frame. Thus, we specified at § 422.564(d) (now (f)) that an MA organization must notify the enrollee within 24 hours of receiving a grievance about the MA organization's refusal to expedite a review. Similarly, if an enrollee believes an MA organization's decision to invoke an extension to the organization determination or reconsideration time frames is incorrect, an expedited review would ensure that any inappropriate procedural actions under the appeals process are resolved and that the appeal proceeds without delay. Therefore, we are retaining the provision that in the current § 422.564(d) (now § 422.564(f)), and making the required conforming changes at § 422.570(d)(2)(ii) and § 422.572(b) as previously proposed.

Comment: A commenter supported CMS' decision to revise § 422.572(c) to no longer require MA organizations to provide written notice for fully favorable decisions. The commenter also recommended that the MA organization should communicate fully or partially favorable decisions to the provider, who would then notify the enrollee of the organization's decision.

Response: While we agree that the revision at § 422.572(c) will eliminate the unnecessary burden to issue written notices in cases of fully favorable decisions, we believe that written notifications remain appropriate for partially favorable decisions, which may result in appeals. Moreover, notwithstanding any arrangements an MA organization negotiates with its providers, the MA organization is ultimately responsible for ensuring that its decisions are communicated to

enrollees. We believe that decisions involving whether to initiate a service constitute the majority of an MA organization's communication with enrollees. Therefore, in the absence of a delegated arrangement, we do not believe that it is appropriate or practical to require all individuals or entities that provide health care services to give routine notices to a plan's enrollees.

Comment: Two commenters opposed CMS' proposed revision at § 422.582(a) that would allow a party to request a standard reconsideration orally or in writing. One commenter recommended that CMS delete the proposed provision because oral requests would increase the number of meritless reconsiderations and overburden the reconsideration process. The commenter believed that this provision would lead to confusion and undocumented assertions in the process. The commenter further believed that written requests ensure that MA organizations effectively and efficiently focus on an enrollee's ultimate issue. Additionally, the commenter noted that the MA organization would be required to reduce oral requests to writing, which would transfer the burden of generating a written request from the enrollee to the MA organization. If the provision for oral appeal requests is retained, the commenter recommended that they be allowed only in person. Another commenter believed that MA organizations would need guidance on how to process oral requests, particularly in the case of a request from a purported authorized representative. Finally, a commenter stated that CMS should not permit oral requests in order to be consistent with private sector regulatory requirements.

Response: Based on our review of the comments, we agree with the commenters that oral appeal requests could present problems for both MA organizations and the appealing parties, particularly when one individual attempts to translate an oral request into writing on behalf of another. We believe that an unintended consequence of our proposed change is the potential for essential information to get misconstrued. Thus, rather than requiring MA organizations to accept oral requests, we will continue to provide guidance on how an MA organization may choose to accept an oral request for reconsideration, and the steps it can take to validate the request. This will enable plans the flexibility to create such a process if they choose to do so. Therefore, we have revised the text at § 422.582(a) to reflect that an MA organization may adopt a policy under which it accepts oral requests for standard reconsiderations. We would expect that MA organizations would accept oral requests in instances where there is a clear and compelling reason to do so. An example of a clear and compelling reason to accept an oral request would be in the case of an illiterate or an incapacitated enrollee on the basis that they would not be able to request a reconsideration in writing.

5. Administrative Law Judge (ALJ) Hearings, Appeals to the Medicare Appeals Council, Judicial Review, and Provisions Affected by Part 405 (§ 422.600 through § 422.612)

Section 931 of the MMA requires that the ALJ hearing function now conducted by the Social Security Administration (SSA) be transferred to the Department of Health and Human Services by no later than October 1, 2005. In light of this impending change, we are revising § 422.582 and § 422.602 to eliminate any reference to SSA as a location for enrollees to file appeals. If an enrollee inadvertently files an appeal request with SSA after the transfer, its field offices will ensure that the request is transferred to the appropriate appeals entity. We have modified § 422.602(a) to require that a party must file a written request for an ALJ hearing with the entity specified in the independent review entity's (IRE's) reconsideration notice.

6. Noncoverage of Inpatient Hospital Care—Notice and QIO Review (§ 422.620 and § 422.622)

We proposed at § 422.620(b) to specify that an MA organization (or an entity delegated by the organization) must obtain the concurrence of the physician responsible for the enrollee's in-patient care before discharging an enrollee. This provision would clarify an omission in our April 4, 2003 final rule where we inadvertently failed to include a corresponding change that physician concurrence is necessary for discharging the enrollee rather than for issuing the notice. Therefore, an MA organization's obligation to provide a notice of non-coverage when an enrollee objects to a discharge would not be contingent upon a physician concurrence because the discharge decision already would have been made.

We also proposed to revise § 422.620(c) to require that if an MA organization lowers the enrollee's level of care in an inpatient hospital setting, for example, from acute to skilled, but the enrollee is not discharged from the facility, the MA organization must specify the enrollee's new level of care in the notice. This change would be consistent with § 422.620(a)(1)(ii), which requires the MA organization to provide a notice to the enrollee when it no longer intends to continue coverage of the inpatient hospital stay, but is not ''discharging'' the enrollee from the facility.

Comment: Several commenter recommended that CMS clarify that an enrollee's right to receive a notice of non-coverage is linked to physician concurrence to the extent that the physician must concur with the MA organization's decision to discharge the enrollee or change the enrollee's level of care. Several commenters continued to believe that an MA organization could not issue a notice without the physician's concurrence. One commenter thought that the propose rule suggested that it is the MA organization rather than the physician that ultimately discharges the enrollee. The commenter maintained that since a hospital cannot discharge an enrollee without physician concurrence, CMS should prohibit an MA organization from ending coverage without a physician's concurrence. Another commenter stated that the final rule should prevent MA organizations from shifting financial liability to hospitals without securing the attending physician's concurrence to discharge the enrollee.

One commenter stated that a benefit determination based on medical necessity guidelines to discontinue unnecessary inpatient coverage does not require physician concurrence. Another commenter thought that if physician concurrence were required to issue the notice of non-coverage, then enrollees would be unable to initiate the appeals process in a timely manner. This commenter recommended that CMS delete the entire provision and only require plans to issue a notice of non-coverage to the enrollee when it decides to no longer pay for acute care.

Another commenter, concerned about a hospitalized enrollee's reaction to receiving a notice of non-coverage from the MA organization, thought that CMS should withdraw the proposal, citing the trauma, confusion and stress to the enrollee. Instead, the commenter believed that the hospital staff familiar with the specific medical circumstances related to the enrollee's confinement should provide the notice.

Response: Medical guidelines alone cannot substitute for a physician's judgment about the medical condition of the patient under the physician's care. We agree with the commenters that physicians ultimately have the authority to discharge enrollees or change the level of care in hospital settings.

However, the MA organization is required to issue a notice of non-coverage if an enrollee objects to the discharge decision, or when an enrollee's level of care changes in an acute facility. Since the attending physician must agree to the discharge or the change in level of care, the MA organization can provide the notice without further physician involvement. Thus, we are merely clarifying under § 422.620(b) that a physician concurrence is required before discharging an individual or changing the level of care in an inpatient setting.

We disagree with the commenter that argued if a physician concurrence were required to issue the notice, then enrollees would be unable to initiate timely appeals. The timeframe for filing does not begin until the enrollee receives the notice. We further disagree that we should delete the entire provision at § 422.620 and only require plans to issue notices when they decide to no longer pay for acute care. If an enrollee disagrees with being discharged from the hospital, then the enrollee is entitled to a notice explaining his or her appeal rights under the law.

Finally, if an MA organization believes that its provision of the notice to an enrollee in an acute facility would create stress, trauma and confusion, then the MA organization has the option to delegate to the hospital the responsibility to provide the notice of non-coverage on behalf of the MA organization.

Advance Beneficiary Notices in the MA Program

In the August 3, 2004 proposed rule, we solicited comments on whether to permit or require network and non-network providers to furnish enrollees advance beneficiary notices (ABNs) when they access non-Medicare covered services, or when they face potential liability for out of network services that would be otherwise payable by the MA plan if proper referral were obtained.

Comment: Several commenters vehemently opposed requiring providers to furnish ABNs to enrollees who wish to obtain non-Medicare covered services. They stated that CMS could not enforce any requirements on non-network providers to advise enrollees of potential liability. The commenters believed that ABNs would be burdensome for physicians, providers and MA organizations, and could lead to delays in care for enrollees. Another commenter stated that CMS, instead, should educate providers about their responsibility to contact the MA organization when enrollees seek out of network or non-Medicare covered services.

Several commenters stated that ABNs in original Medicare have inherent problems, such as providers that issue blanket ABNs, which then become meaningless to the enrollee. A commenter noted that although the ABN was only a one-page document, there were 30 pages of instructions for the provider to complete the form, thus the use of ABNs would be confusing.

One commenter indicated that it was premature to propose the use of ABNs in managed care. Instead, CMS should establish a database with information, so that physicians could have access to coverage information for each plan. Otherwise, it would be too burdensome for physicians to know the different benefits and coverage of each plan. The commenter further recommended that if CMS determined that ABNs were necessary, then we should ensure that MA organizations provide clear information to physicians' offices on the appropriate use of ABNs.

Another commenter recommended that CMS should allow providers to issue ABNs only after they have requested and received an adverse organization determination from the MA organization. If an enrollee waived the right to have the provider request an organization determination, nothing would preclude the enrollee from appealing the MA organization's denial for the service.

Other commenters, however, were in favor of CMS allowing the use of ABNs in managed care. One commenter reported that not all providers of MA organizations have contracted networks, and even among those that do, enrollees still utilize non-network providers. The commenter stated that the MA organization could be unaware that the enrollee received any services until he or she presents a claim. ABNs would inform enrollees about potential costs at the time the enrollee seeks services, thereby providing protection from unintended liability. Another commenter thought ABNs should be required when enrollees access non-Medicare covered services, and that an out of network provider should be required to get an organization determination prior to providing services.

Response: We will continue to study this issue and will pursue subsequent notice and comment rulemaking before implementing any standard use of ABNs under the MA program. In addition, we will work with interested parties to determine how best to educate enrollees and providers on financial liability matters, including the possibility of permitting optional use of an ABN-like notice.

8. Appeal Procedures for Cost Plans and HCPPs.

We proposed under § 417.600(b) that the same rights, procedures, and requirements relating to beneficiary appeals and grievances set forth in subpart M of part 422 of this chapter also apply to organizations offering Medicare cost plans. In proposing this change, we took into account that a key difference between cost plans and MA plans is that virtually all organizations offering cost plans employ a billing option available under § 417.532(c)(1) that reduces a cost plan's financial liability for certain Medicare-covered services. Under this billing methodology, hospitals and SNFs that furnish services to cost plan members can obtain direct reimbursement from Medicare fiscal intermediaries for these services. For services paid for under this methodology, the claims appeal procedures available under original Medicare regulations in part 405 would be the appropriate recourse when a Medicare fiscal intermediary denies a claim. However, for other services, including any service or payment denial resulting from an organization determination under a cost plan, as defined in § 417.606, enrollees would appeal through the cost plan's appeals process. The plan's appeal procedures would also apply in the rare situation when a fiscal intermediary approved a claim for hospital or SNF services, but the cost plan refused to pay the covered portion of the enrollee's cost sharing associated with the services.

As noted above, the cost plan appeals process would follow the same rules that apply to MA organizations, as set forth in subpart M of part 422. Although the appeal procedures set forth in part 417 and part 422 are largely similar, it is important to note that the part 422 grievance provisions and recent changes to the notice and appeal requirements for inpatient hospital, SNF, home health agency (HHA) and comprehensive outpatient rehabilitation facility services would apply to cost plans for the first time. These changes primarily involve § 422.564, § 422.620, § 422.622, § 422.624 and § 422.626 which were set forth in the April 4, 2003 final rule, Improvements to the Medicare+Choice Appeals and Grievance Procedures.'' (See 68 FR 16,652). The effect of those changes would be that plans would have more specific guidelines for processing grievances, and enrollees would be entitled to the same notice and appeal rights in cases of terminations of Medicare services

furnished by hospitals, SNFs, HHAs and CORFs.

Comment: Commenters generally supported CMS' proposal to require cost plans and HCPPs to follow the Medicare Advantage grievance and appeal requirements, particularly in light of the unique billing arrangement utilized by the majority of cost plans. One commenter stated that CMS should reflect in its final rule that cost plans may elect billing option one, a payment methodology where a fiscal intermediary pays certain Part A services instead of the cost plan. Another commenter wanted CMS to make sure that the cost plan's appeals process would apply in the unusual circumstance where a fiscal intermediary approved a claim, but the cost plan denied payment of the enrollee's cost sharing portion. Other commenters wanted CMS to allow sufficient time for cost plans that do not have MA experience to transition to the MA rules. Some commenters recommended an effective date of January 2006. Another commenter requested that the transition to MA rules apply as of the first day of the contract year following publication of the final rule.

Response: We did not receive any comments on the applicability of the notice and appeal requirements to cost plans when Medicare services end in SNFs, HHAs and CORFs, under § 422.624 and § 422.626. Nevertheless, we agree with the commenters that there should be one managed care appeals process for all plan types. As proposed, all part 422 rules now apply to cost plans and HCPPs. Thus, we have deleted all part 417 grievance, organization determination, and appeal provisions, and replaced them with § 417.600(b) and § 417.840 to require cost plans and HCPPs to apply the MA procedures under part 422, subpart M. Additionally, we have made a conforming change to § 417.832(c) dealing with representation of parties, and added a new provision at § 417.832(d) dealing with administrative law judge hearings, Medicare Appeals Council review, and judicial review that references part 405, as applicable to those provisions. However, for those cost plans that elect to bill under original Medicare, any denied claim by the fiscal intermediary or carrier must be subject to the appeals process under original Medicare. We also agree that if a plan denies payment of an enrollee's cost sharing amount, then the enrollee must file an appeal under the MA appeal procedures.

As recommended by commenters, we will require that cost plans and HCPPs must transition to the MA grievance and appeals processes under part 422 no later than January 1, 2006. This should give plans, providers and original Medicare contractors an ample opportunity to make a seamless transition.

9. Federal Preemption of Grievances and Appeals

Section 232(a) of the MMA changes the presumption from one in which State laws are not preempted unless they conflict with Federal laws or fall into specified categories to one in which State standards are presumed preempted unless they are licensing or solvency laws. In light of the comprehensive nature of the appeals process already established, we did not believe that the new preemption standard would have any effect on coverage appeals provisions. Our regulations would continue to defer to State law on the issue of authorized representatives of enrollees in the organization determination, grievance and appeals processes. We were concerned, however, with State grievance requirements now preempted, and believed that we needed to reexamine our Federal grievance requirements. Therefore, we solicited comments on whether we should adopt the grievance provisions proposed in our January 24, 2001 proposed rule that would require MA organizations to establish notice and timeliness procedures. (See 66 FR 7593.) Alternatively, we asked whether we should impose, as a Federal MA requirement, that MA organizations meet State grievance requirements.

Comment: Most commenters, including both those representing MA organizations and consumers, favored adopting the specific grievance requirements first proposed in the January 2001 proposed rule. They indicated that establishing national standards would eliminate confusion for plans, particularly regional PPOs, and protect beneficiary interests. They indicated that plans should not be subject to multiple and conflicting State laws governing grievances. One commenter generally supported the grievance rules but recommended that CMS make two changes. The first modification would be that MA organizations must process grievances ''as expeditiously as the enrollee's health requires, but no later than 60 days.'' The second change would prohibit plans from taking extensions to the timeframes.

Two commenters thought that CMS should not only require the originally proposed standards for grievances, but also require plans to adhere to individual State grievance processes as well. One of the commenters believed that requiring plans to follow State processes would restore the status quo before enactment of MMA, while the other commenter thought that beneficiaries would have better protections by having access to both Federal and State grievance procedures.

Response: We agree with the commenters that establishing a uniform set of grievance standards would reduce confusion and burden for MA organizations. We also believe that one set of rules will ensure greater beneficiary understanding of their grievance rights and achieve consistency among plan operations. Thus, we are implementing at § 422.564 the specific Federal requirements for grievance procedures that basically mirror those set forth in our January 2001 proposed rule. We disagree with the commenter that MA organizations should be required to follow both State and Federal grievance processes. We believe that such an approach would be inconsistent with section 232(a) of the MMA, which preempts State grievance requirements.

Under MA grievance requirements, organizations must notify enrollees of decisions as expeditiously as the enrollee's case requires, but no later than 30 calendar days after receiving a complaint. MA organizations may extend the timeframe by up to 14 calendar days if the enrollee requests the extension, or if the organization justifies a need for additional information and the delay is in the interest of the enrollee. We believe that the timeframes should be according to the enrollee's case as opposed to the enrollee's health since not all grievances involve medical care. For example, an enrollee may complain that a network physician does not offer convenient hours for office visits. In addition, we believe that most MA organizations will be able to respond to most grievances within 30 days. Even if an MA organization needs to extend the timeframe, we believe that a 60-day standard is too long for an MA organization to respond to an enrollee's grievance.

If an enrollee makes a grievance orally, the MA organization may respond to it orally or in writing, unless the enrollee requests a written response. If an enrollee files a written grievance, then the MA organization must respond in writing. In addition, an MA organization must provide information to enrollees on their right to request a review by a Quality Improvement Organization (QIO) if the grievance

involves a quality of care issue. For any complaint involving a QIO, the MA organization must comply with the requirement at § 422.564(c), and cooperate with the QIO in resolving the complaint. MA organizations must establish a 72–hour expedited grievance process for complaints involving certain procedural matters in the appeals process. Finally, MA organizations must create a system to track and maintain records on all grievances.

We note that under MMA, enrollees would still have access to various State remedies available in cases in which an issue is unrelated to the MA organization's status as a health plan. As noted above, cost plans and HCPPs must follow the grievance, organization determination and appeal procedures under MA. However, general preemption rules continue to apply to cost plans and HCPPs.

10. Employer Sponsored Benefits and Appeals

When an employer, by contracting with an MA plan, provides health benefits in addition to those covered under Part C of Title XVIII of the Social Security Act to their retirees, such employer may have established a group health plan governed by both title I of the Employee Retirement Income Security Act of 1974 (ERISA), as amended, and State law (to the extent such State law is not preempted by ERISA). In addition, when MA plans offer benefits covered under Part C, they also fall under the requirements of part 422 with respect to Part C benefits. Therefore, we solicited comments on whether, and to what extent, the application of parallel appeal procedures in this context might be a problem for plans, employers and/or eligible individuals.

Comment: Almost all commenters supported utilizing only the MA procedures for claims involving integrated ERISA and MA benefits. One commenter noted that enrollees probably do not distinguish between ERISA and CMS approved benefits when they are integrated, and therefore, a single appeals process would be less confusing. Another commenter agreed, recommending that to the extent any benefits received by an individual are part of an underlying MA, MA-PD, or PDP group plan, including benefits separately negotiated between the MA, MA-PD or PDP organization and an employer or labor organization, those benefits should be governed by the MA or PDP regulations on grievances, organization determinations, and appeals rather than subjecting the beneficiary to two separate processes. Commenters also noted that although the ERISA and MA rules contain some differences, they generally provide similar enrollee protections.

Three commenters agreed that adopting and applying a single, uniform MA appeals process for all benefits would be easier for the enrollee to understand. Other commenters stated that parallel appeal processes for enrollees with Medicare and ERISA benefits were costly, redundant, and burdensome to administer, with the potential for conflicting determinations. Only one commenter promoted a continuation of parallel appeal procedures, but only to the extent that parallel procedures afforded enrollees with more protection than would be available in the absence of parallel procedures.

One commenter argued that the benefits under the two separate programs must be adjudicated according to the rules for each program. The commenter stated that it was not clear whether the outcome of a CMS decision would preclude an enrollee from filing an ERISA appeal, and that a decision made by CMS could affect the need for appeal under ERISA when the ERISA plan had secondary payer status. The commenter added that given that the benefits provided to the Medicare beneficiary in this instance involve two different laws, there is no statutory authority for us to adjudicate appeals relating to an ERISA plan, just as there is no statutory authority for the DOL to adjudicate appeals relating to Medicare benefits. This commenter recommended that DOL and CMS work together to develop a process that would allow the plan sponsor of a retiree health plan to delegate its authority for appeals to the same entity considering Medicare appeals, provided that DOL is satisfied that this process would satisfy ERISA claims and appeal procedures.

Response: After reviewing the public comment and conferring with representatives of DOL, we have concluded that changes (not only to the CMS regulations but also to the DOL regulations) are needed to properly address this issue. Accordingly, we have added § 422.560(c), which is intended to give ERISA plans the option, according to regulations of the Secretary of Labor, of electing the MA process rather than the procedures under 29 CFR § 2560.503–1 for claims involving supplemental benefits provided by contract with an MA organization. In this regard, DOL has agreed to work with CMS to develop such regulations. The language in § 422.560 is intended to demonstrate our commitment to make the entire MA process available in this context. The provision in § 422.560 would not take effect in the absence of regulations by the Secretary of Labor.

Subpart N. Medicare Contract Determinations and Appeals

1. Overview

Subpart N ''Medicare Contract Determinations and Appeals'' went into effect under Part C of Title XVIII, and as such was not part of the proposals in the proposed rule of August 3, 2004. However, we found that we needed to make a change to the requirements under Title II subpart N.

Section 1860D–12(b)(3)(F) of the Act directs that the ''procedures for termination'' in section 1857(h) of the Act be incorporated into requirements for PDP sponsors. Therefore, we proposed under Title I that a single set of procedures relating to contract determinations and appeals would apply to both MA organizations and PDP sponsor contractors and that the requirements in § 423.641 through § 423.669 (applicable to PDP sponsors) would mirror the requirements at § 422.641 through § 422.698 for the MA program. We asked for comments on this proposal and did not receive any negative comments. Whenever practicable the regulations mirror each other. We assume that commenters believed that it should be simpler to adhere to a uniform set of contract requirements.

We found that in order to maintain one set of contract requirements—and be responsive to commenters asking for a streamlined application process and a single timeline—we needed to add a cutoff date to the contract determination process under subpart N. This new rule clarifies the timeline for valid contracts, in the event of a redetermination, and we have added this provision at § 422.654(c). This provision specifies that in the case of a favorable redetermination, including favorable decisions as the result of a hearing or Administrative review, that such determinations be made by July 15 for the contract in question to be effective on January of the following year. We have made a corresponding change to the PDP sponsor regulations by adding § 423.647(c).

Subpart O—Intermediate Sanctions

In the proposed rule, we proposed a technical correction to § 422.752(a)(8). The word ''entity'' was inadvertently left out of the regulations text of that amendment. We proposed revising paragraph (a)(8) to read ''[e]mploys or contracts with an individual or entity who is excluded from participation in

Medicare under section 1128 or 1128A of the Act (or with an entity that employs or contracts with such an individual or entity) for the provision of any of the following.'' We did not receive any comments on these clarifications and will adopt them in this final rule.

We note that while we did not propose other changes to the requirements at § 422.750 through § 422.760, an interim final rule with comment period was issued at the end of December, 2004 to correct technical errors in the regulatory text made in a final rule for MA plans that was issued on August 22, 2003 and that was entitled ''Modifications to Medicare Rules'' (68 FR 50840).

In addition, in the course of reviewing and responding to comments that we received regarding the corresponding regulatory provisions for Title I and the Part D program, we discovered that while we did not need to propose changes to the substance of the regulatory provisions, we needed to make certain revisions to the regulatory text at this subpart in the interests of clarity and accuracy. We are, therefore, making the following changes in this final rule:

At § 422.752(b), we are deleting the references to § 422.756(c)(1) and (c)(3) that are listed under procedures for imposing sanctions. We are replacing them with references to § 422.750(a)(2) and (a)(4). The purpose of this correction is to include a reference to the provision that details the kinds of sanctions that we may impose, rather than the provision that details the procedures for imposing sanctions.

At § 422.752(a) we clarified our authority to impose more than one sanction at a time by deleting the word ''any'' and replacing it with the phrase ''one, or more''. Therefore, § 422.752(a) will now read as follows: ''All intermediate sanctions. For the violations listed in this paragraph (a), we will impose one, or more, of the sanctions. . .''

Also, at § 422.752(a)(8) we have added the word ''excluded'' to the parenthetical clause in the interest of clarity. The parenthetical will now read, ''or with an entity that employs or contracts with an excluded individual or entity.''

At § 422.756(f)(2) a reference to ''part 1005 of this chapter'' was incorrect and we have replaced with a reference to ''part 1003 of this chapter,'' since part 1003 is the correct reference to the OIG procedures for imposing sanctions whereas part 1005 includes the appeal procedures for sanctions.

At § 422.756(f)(3) we have deleted the clause ''in accordance with the provisions of part 1005 of this chapter'' of this chapter. Since this subparagraph discusses our authority to impose CMPs, as opposed to the OIG's authority, we realized that this reference was incorrect.

At § 422.758, in the introduction and at paragraph (c), we made some editorial changes to better clarify the basis for civil money penalties issued by CMS.

IV. Provisions of the Final Rule

For the most part, this final rule incorporates the provisions of the proposed rule. Those provisions of this final rule that differ from the proposed rule are as follows:

Effective Date of Initial Regulations (§ 417.402)

In paragraph (c)(2) we have added the word ''calendar'' prior to ''year'' to clarify our intent.

Applicability of Requirements and Procedures (§ 417.832)

We have made a conforming change to paragraph (c) of § 417.832 to reflect that the provisions of subpart I of part 405 dealing with the representation of parties apply to organization determinations and appeals.

We have added a new paragraph (d) at § 417.832 to indicate that the provisions of subpart I of part 405 dealing with administrative law judge hearings, Medicare Appeals Council review, and judicial review are applicable, unless otherwise provided.

Definitions (§ 422.2)

We have amended the definitions of ''prescription drug plan (PDP)'' and ''Prescription drug plan (PDP) sponsor'' to make them consistent with the Medicare Prescription Drug Benefit Program proposed rule.

We have revised the definition of ''service area'' to clarify that CMS may consider whether a contracting provider network meets the access and availability standards set forth in § 422.112 for all MA coordinated care plans and network MA MSA plans.

We have clarified the definition of ''institutionalized'' for the purpose of SNPs to provide information on what is meant by a long term care facility (SNFs, ICF, ICF/MR and Inpatient Psychiatric hospitals). We have also expanded the definition to include a special needs individual who is expected to reside in a long-term care facility for 90-days or longer based on as assessment of the potential for such a stay as long as the assessment is of a type approved by CMS .

We have defined a SNP that enrolls a disproportionate percentage of special needs individuals as one that enrolls a greater proportion of the target group than occur nationally in the Medicare population.

We have included in its definition that a SNP is required to provide Part D coverage.

We further clarified the definition of a SNP as a plan that has been designated by CMS as meeting the requirements of a MA SNP for institutionalized or dual eligible individuals or those individuals with a severe or disabling chronic condition as determined on a case-by-case basis using criteria that include the appropriateness of the target population, the existence of clinical programs or special expertise to serve the target population, and whether the proposal discriminates against sicker members of the target population

Additionally, we have added a technical amendment to correct the term ''Religious and Fraternal Benefit (RFB) Society'' to read ''Religious Fraternal Benefit (RFB) Society''.

Types of Plans (§ 422.4)

We have amended paragraph (a)(1)(iv) to clarify the types of MA plans and Part D prescription drug coverage.

We have also added a new paragraph (c) regarding rules for MA plans' Part D coverage. This paragraph clarifies the requirements for MA coordinated care plans, MA MSAs, and MA PFFS plans. In addition, a new paragraph (c)(2) states the MSAs cannot offer drug coverage, other than that required under Parts A and B of Title XVIII of the Act. Finally, in paragraph (c)(3), we have added language that MA organizations offering private fee for service plans can choose to offer qualified Part D coverage meeting the requirements in § 423.104.

Eligibility to Elect an MA Plan (§ 422.50)

In § 422.50, we have added a new paragraph (a)(2)(iii) to allow SNPs to serve ESRD individuals.

We have amended paragraph (a)(5) to provide that beneficiaries may make elections by completing an enrollment form by completing another CMS approved election mechanism offered by the MA organization.

Coordination of Enrollment and Disenrollment through MA Organizations (§ 422.66)

We have revised § 422.66(d)(5) to allow us to offer, as an option in the future, the ability of an MA plan to process a ''seamless'' enrollment upon an individual's entitlement to Medicare.

Disenrollment by the MA Organization (§ 422.74)

We have added a new paragraph (b)(2)(iv) to show that in certain cases, loss of special needs status is a basis for required disenrollment from a SNP that enrolls only special needs individuals.

We have amended paragraph (d)(1)(i) by adding paragraphs (d)(1)(i)(A), (B), and (C) to clarify what ''reasonable efforts'' to collect unpaid premiums must be taken in prior to the disenrollment of an individual from an MA plan.

We have revised the definition of ''disruptive behavior'' in paragraph (d)(2)(i) to focus on the behavior that substantially impairs the plan's ability to arrange or provide care for the individual or other plan members.

We have added a new paragraph (d)(2)(ii) ''Basis of disenrollment for disruptive behavior.

We have amended paragraph (d)(2)(iii) to require the MA organization to provide reasonable accommodations for individuals with mental or cognitive conditions.

We have amended paragraph (d)(2)(iv) ''Documentation'' to provide an MA organization the option to decline future enrollment of an individual who has been disenrolled for disruptive behavior.

We have revised proposed paragraph (d)(2)(v) ''CMS review of the proposed disenrollment'' to also require MA organizations to provide a ''reasonable accommodation'' to individuals in exceptional circumstances.

We have removed proposed paragraph (d)(2)(vi) ''Reenrollment in the MA organization'' and paragraph (d)(2)(vii) ''Expedited process''.

Requirements Related to Basic Benefits (§ 422.101)

We have revised paragraph (b)(4) to clarify its intent.

We have added a new paragraph (b)(5) to require MA organizations that elect to apply local coverage policies uniformly across a local MA plan's service area, or across an MA regional plan's service area, to inform enrollees and potential providers of the applicable local coverage policy that applies to the MA plan enrollees.

We have modified § 422.101(d)(4) to indicate that notification to providers, as well as members, of enrollee status related to a deductible (if any) and catastrophic caps is required.

Special Rules for Self-Referral and Point of Service Option (§ 422.105)

We have renamed the title of this section and reorganized the section in order to clarify its scope and applicability.

Coordination of Benefits with Employer or Union Group Health Plans and Medicaid (§ 422.106)

We have modified § 422.106 to clarify the intent.

Disclosure Requirements (§ 422.111)

To be consistent with language elsewhere in this regulation, we have added a conforming amendment, revising paragraph (b)(9) to change references to ''Quality assurance program'' to ''Quality improvement program.

We have amended paragraph (e) by reinserting the word ''written'', as its removal was unintentional.

We have corrected the language in § 422.111(f)(10) to clarify our initial intent.

We have added a requirement at § 422.111(f)(11) requiring all MA organizations to make uniform coverage policies related to an MA plan readily available to members and providers, including through the Internet.

We have also added a new paragraph (f)(12) requiring MA organizations that have Internet web-sites to post the Evidence of Coverage, the Summary of Benefits, and information on the network of contracted providers.

Access to Service (§ 422.112)

In paragraph (a) introductory text, we removed obsolete terminology from both heading and introductory text.

We have revised paragraph (b) introductory text related to ''continuity of care.''

We have removed the instructions that would have removed paragraph (b)(4)(i) and redesignated paragraphs (b)(4)(ii) and (b)(4)(iii). The inclusion of this amendment in the proposed rule was an error.

We have amended paragraph (c) introductory text by adding ''noncontracting'' before ''hospital''.

We have amended paragraph (c)(1) to clarify the types of hospitals that are eligible to be designated an ''essential hospital''.

We have amended paragraph (c)(3) to clarify ''good faith''.

We have added a new paragraph (c)(4) in order to include ''competition text'' in regulation, where no MA organization will be permitted to designate a hospital as an ''essential hospital'' where there is a ''competing hospital'' in the area.

We have added a new paragraph (c)(7), under which we will evaluate the continued applicability of ''essential hospital'' status on an annual basis at the time of annual contract renewal.

Compliance Deemed on the Basis of Accreditation (§ 422.156)

We revised paragraph (b)(1) to change the term ''Quality assurance Program'' to ''Quality improvement program'', in order to be consistent with changes elsewhere in this regulation.

Terminology (§ 422.252)

We have made a clarifying change to the definition of MA local area to be consistent with the intent of § 422.308.

Submission of Bids (§ 422.254)

We amended paragraph (a)(1) by adding ''and, for plans with rebates as described at § 422.266(a), the MA organization must provide the information required in paragraph (d) of this section.''

We have added a new paragraph (a)(3), to retain language from the current MA regulations at § 422.306(a)(2), which says if the bid submission is not complete, timely, or accurate, CMS has the authority to impose sanctions under subpart O of this part or may choose not to renew the contract.

We have revised paragraph revise (b)(2) to read ''as the term revenue requirements is used for purposes of section 1302(8) of the Public Health Service Act'' to track the statutory language.

We have amended paragraph (b)(3) by removing the proposed sentence stating that plan assumptions about revenue requirements must include adjustments for the utilization effects of cost sharing reductions.

We have revised paragraph (b)(4) to conform the regulation to the statutory provision.

We have made a clarifying change to paragraph (c)(5) to reflect the statutory requirement that in the bid submission, MA organizations provide the actuarial bases for determining the amount of cost sharing for a plan.

We have added a new paragraph (c)(9) to address information requirements resulting from our policy decision on the geographic ISAR adjustment, presented in the G preamble discussion of § 422.308(d).

We have added paragraph (f) to clarify that separate bids must be submitted for Part A and Part B enrollees and Part B-only enrollees for each MA employer group health plan offered.

Review, Negotiation, and Approval of Bids (§ 422.256)

We have amended paragraph (b)(2) for clarity and to better reflect the statutory language on standards of bid review.

Calculations of Benchmarks (§ 422.258)

We have corrected paragraph (c)(4) to clarify the plan-bid component of the regional benchmark is calculated based only on regional plan bids, not an all of the MA plan bids in the region.

We made an additional change to the proposed paragraph (c)(5)(i) to clarify further how the plan bid component of the regional benchmark will be calculated.

Calculation of Beneficiary Premiums (§ 422.262)

We have amended paragraph (f)(1) to add the Railroad Retirement Board and the Office of Personnel Management.

We consolidate paragraphs (f)(3) and (f)(4) to clarify that the other methods CMS may specify for payment of premiums include those listed in the regulation.

Calculation of Savings (§ 422.264)

We have amended paragraphs (c) and (e) to more accurately reflect the policy that for both local and regional MA plans, the calculation of savings will be determined by applying the plan average risk adjustment factor to the basic A/B bid and benchmark, although we have left in regulation the statutorily mandated discretion for CMS to select a method for calculating savings.

Beneficiary Rebates (§ 422.266)

We have changed the language in paragraph (b)(1) to clarify that rebate dollars may be used to reduce the premium for either the non-drug or drug portions of the supplemental benefit. We also add language clarifying that plans must distinguish the amount of rebate applied to enhance original Medicare benefits from the rebate applied to enhance Part D benefits.

We have amended paragraph (c) by adding ''MA organizations must distinguish, for each MA plan, the amount of rebate applied to enhance original Medicare benefits fro the amount of rebate applies to enhance Part D benefits.''

Adjustments to Capitation Rates, Benchmarks, Bids, and Payments (§ 422.308)

We have amended the language in paragraph (e) to refer to the adjustment as the ''government premium adjustment,'' in order to distinguish it from other payment adjustments under the MMA.

Risk Adjustment Data (§ 422.310)

We have modified § 422.310(e) to indicate that there may be penalties for submission of false data under the requirement for validation of risk adjustment data.

Special Rules for Payments to Federally Qualified Health Centers (§ 422.316)

We have amended (a) to clarify what amount CMS will pay an FQHC by adding ''less the amount the FQHC would receive for the MA enrollee from the MA organization and taking into account the cost sharing amount paid by the enrollee.''

Moratorium on New Local Preferred Provider Organization Plans (§ 442.451)

We have revised this section to better reflect Congressional intent to give MA organizations the option of introducing new PPO plans in those service areas where they have already established a local PPO plan prior to the start of the local PPO moratorium of 2006 & 2007.

Risk Sharing with Regional MA Organizations for 2006 and 2007 (§ 422.458)

We have added language to § 422.458(e)(1) to clarify that regional PPOs must be licensed in each State of the region, except during the period of the temporary waiver.

We have also made a technical change in paragraph (e)(2) to clarify what State licensing rules an organization must apply until the organization is licensed in all states, under the waiver process.

Scope (§ 422.500)

This section sets forth application requirements for entities seeking a contract as a Medicare Organization offering, an MA plan. MA organizations offering prescription drug plans must, in addition to the requirements of this part, follow the requirements of 42 CFR part 423 specifically related to the prescription drug benefit.

Application Requirements (§ 422.501)

We have added a new § 422.501(c)(2) to clarify that a CMS determination that an entity is qualified to act as an MA sponsor is distinct from the bid negotiation that occurs under subpart F of part 422.

Evaluation and Determination Procedures (§ 422.502)

In paragraph (c)(2)(ii), we are changing the amount of time that an applicant has to remedy an application after receiving an Intent to Deny Notice from 60 days to 10 days.

We have eliminated paragraphs (e), (f) and (g

General Provisions (§ 422.503)

In § 422.503, we have eliminated the mandatory self reporting requirements that we proposed, but we have added a new requirement at § 422.503(b)(4)(vi)(H) that MA-PDPs have a comprehensive fraud and abuse plan.

Contract Provisions (§ 422.504)

We have made changes in paragraph (h) to reflect our focus on requirements to prevent fraud, waste and abuse and on issues that we are responsible for enforcing, such as the HIPAA administrative simplification rules.

Agreements with Federally Qualified Health Centers (§ 422.527)

We have amended paragraph (c) to clarify that financial withholds are not considered in determining payments made to FQHCs by CMS.

General Provisions (§ 422.550)

We have added an amendment to amend § 422.550(a)(2) by revising the heading to read, ''Asset Transfer'' instead of ''Asset Sale''.

Basis and Scope (§ 422.560)

In response to comments on whether and to what extent, the application of parallel appeal procedures might be a problem for plans, employers, and eligible individuals, we have added a new paragraph (c) related to ERISA standards.

Definitions (§ 422.561)

We have clarified the definitions of ''Enrollee'' and ''Authorized representative'' in this section. We have removed ''Authorized representative'' and replaced it with ''Representative'' to clarify that a representative means an individual appointed by an enrollee or other party, or authorized under State or other applicable law, to act on behalf of an enrollee or other party involved in an appeal.

Grievance Procedures (§ 422.564)

We have added new paragraphs (d) and (e) related to the method for filing a grievance and the grievance disposition and notification process and we have redesignated the existing sections.

Timeframes and notice requirements for expedited organization determinations.

We have made a conforming change in paragraph (b) of § 422.572 to reflect the enrollee's right to file an expedited grievance if he or she disagrees with an MA organization's decision not to expedite an organization determination.

Request for a Standard Reconsideration (§ 422.582)

We have revised the text in paragraph (a) to denote that an MA organization may adopt a policy under which it accepts oral requests for standard considerations. Additionally, in accordance with part 405, subpart I, we have removed paragraph (a)(2) to eliminate the SSA as a filing location for standard reconsideration requests.

Timeframes and Responsibility for Reconsideration (§ 422.5900)

We have made a conforming change in paragraph (a) of § 422.590 to reflect the enrollee's right to file an expedited grievance if he or she disagrees with an MA organization's decision not to expedite a request for an expedited reconsideration.

We have revised paragraph (a) of § 422.602 that previously read that a party must file a written request with ''the appropriate ALJ hearing office'' to read that a party must file a written request for a hearing with ''the entity specified in the IRE's reconsideration notice'' in accordance with part 405, subpart I that eliminates alternate filing locations.

Reconsideration: Applicability (§ 422.648)

We have added a new paragraph (c) to § 422.648. This provision specifies that in the case of a favorable determination, including favorable decisions as a result of a hearing or Administrative review, that such

determinations be made by July 15 for the contract in question to be effective in January of the following year.

Basis for Imposing Sanctions (§ 422.752)

We have amended paragraph (a) in § 422.752 to clarify CMS' authority to impose more than one sanction at a time.

We have also amended paragraph (b), by deleting references to § 422.756 (c)(1) and (c)(3) and replacing them with references to § 422.750(a)(2) and (a)(4). This clarifies that we are cross referencing the basis for sanctions with the kind of sanctions that could result, not the procedure for imposing sanctions.

Procedures for Imposing Sanctions (§ 422.756)

We have amended paragraph (f)(2) to corrected a reference to ''part 1005 of this chapter'' to correctly reference ''part 1003 of this chapter,'' since 1003 includes the OIG procedures for imposing sanctions whereas 1005 are appeal procedures.

Maximum Amount of Civil Money Penalties Imposed by CMS (§ 422.758)

At § 422.758 we added some language that better clarifies the basis for Civil monetary penalties (CMPS) issued by CMS. At § 422.758(a) we added language that clarifies the existing basis for the Office of the Inspector General to support the imposition of this CMP. At § 422.752(a)(8) we added the word ''excluded'' for clarification.''

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether OMB should approve an information collection, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The collection requirements referenced in sections one and two below are currently approved under OMB approval number 0938–0753 (CMS–R–0267, Medicare Plus Choice Program Requirements Referenced in 42 CFR 422.000 through 422.700), with a current expiration date of October 31, 2005.

Section one below outlines the collection requirements referenced in this regulation that have not been modified by the proposed regulatory changes. Section number two references requirements in this regulation that have been technically revised, but do not affect the currently approved burden estimates. Table three below references new collection requirements.

It should be noted that all of the collection requirements summarized and discussed below are open for public comment and will be submitted to OMB for approval.

1. Currently Approved Collection Requirements Not Affected By Proposed Regulation:

Section 422.54 Continuation of enrollment for MA local plans

(b) The intent by an enrollee to no longer reside in an area and permanently live in another area must be verified by the plan through documentation that establishes residency, such as a driver's license, voter registration.

(c)(2) The enrollee must make the choice of continuing enrollment in a manner specified by CMS. If no choice is made, the enrollee must be disenrolled from the plan.

Section 422.60 Election process

(b)(1) MA organizations may submit information on enrollment capacity of plans.

(c)(1) The plan election must be completed by the MA eligible individual (or the individual who will soon become eligible to elect an MA plan) and include authorization for disclosure and exchange of necessary information between the U.S. Department of Health and Human Services and its designees and the MA organization. Persons who assist beneficiaries in completing forms must sign the form, or through other approved mechanisms, indicate their relationship to the beneficiary.

(e)(3) The MA organization must give the beneficiary prompt notice of acceptance or denial in a format specified by CMS.

(e)(4) If the MA plan is enrolled to capacity, it must explain the procedures that will be followed when vacancies occur to the potential enrollee.

(e)(5) Upon receipt of the election, or for an individual who was accepted for future enrollment from the date a vacancy occurs, the MA organization transmits, within the timeframes specified by CMS, the information necessary for CMS to add the beneficiary to its records as an enrollee of the MA organization.

(f)(3) Upon receipt of the election from the employer, the MA organization must submit the enrollment within timeframes specified by CMS.

Section 422.66 Coordination of enrollment and disenrollment through MA organizations

(f)(2) Upon receipt of the election from the employer, the MA organization must submit a disenrollment notice to CMS within timeframes specified by CMS.

Section 422.80 Approval of marketing materials and election forms

(a)(i) At least 45 days (or 10 days if using marketing materials that use, without modification, proposed model language as specified by CMS) before the date of distribution the MA organization has submitted the material or form to CMS for review under the guidelines in paragraph (c).

Section 422.506 Nonrenewal of contract

(a)(2)(ii) Each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective. This notice must include a written description of alternatives available for obtaining Medicare services within the service area, including alternative MA plans, Medigap options, and original Medicare and must receive CMS approval prior to issuance.

Section 422.564 Standard timeframes and notice requirements for organization determinations

(e)(3)(ii) All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO.

Based on the results of prior sampling of managed care enrollees, we extrapolate that approximately 17 percent of MA enrollees would likely experience some dissatisfaction with their MA organizations. Since we estimate that there would be approximately 6.7 million MA enrollees in 450 plans, we estimate that approximately 1,139,000 enrollees likely would experience some dissatisfaction with their MA organizations in a given year.

Based on previous grievance requirements analysis (See 66 FR 7593 through 7600), we estimate that approximately 455,600 enrollees, that is,

40 percent of the total number of dissatisfied enrollees, will file an oral or written grievance. We further estimate that another 60 percent will request a grievance orally, that is, 273,360. Of those requests, we believe that approximately 10 percent of enrollees will request a follow-up written response, that is 27,336 enrollees.

We estimate that it will take MA organizations 15 minutes to prepare and furnish each written response, and that MA organizations will be required to provide an estimated 27,336 written notices following oral requests. The total annual burden associated with this requirement is 6,834 hours.

Section 422.568 Standard timeframes and notice requirements for organization determinations

(a) When a party has made a request for a service, the MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination.

(c) If an MA organization decides to deny service or payment in whole or in part, or if an enrollee disagrees with an MA organization's decision to discontinue or reduce the level of care for an ongoing course of treatment, the organization must give the enrollee written notice of the determination.

Section 422.590 Timeframes and responsibility for reconsiderations

(d)(2) When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension.

Section 422.600 Right to a hearing

(a) If the amount remaining in controversy after reconsideration meets the threshold requirement established annually by the Secretary, any party to the reconsideration (except the MA organization) who is dissatisfied with the reconsidered determination has a right to a hearing before an ALJ.

Section 422.608 Medicare Appeals Council (MAC) review

Any party to the hearing, including the MA organization, who is dissatisfied with the ALJ hearing decision, may request that the MAC review the ALJ's decision or dismissal.

Section 422.612 Judicial review

(b) Any party, including the MA organization, may request judicial review (upon notifying the other parties) of the MAC decision if it is the final decision of CMS and the amount in controversy meets the threshold established in paragraph (a)(2) of this section.

(c) In order to request judicial review, a party must file a civil action in a district court of the United States in accordance with section 205(g) of the Act. See part 405 of this chapter for a description of the procedures to follow in requesting judicial review.

2. Currently Approved Collection Requirements Technically Modified By Proposed Regulation: Not Affecting Burden:

Section 422.50 Eligibility to elect an MA plan

(a)(5) Completes and signs an election form or completes another CMS approved election method offered by the MA organization and provides information required for enrollment.

Section 422.66 Coordination of enrollment and disenrollment through MA organizations

(b)(1)(i)Elect a different MA plan by filing the appropriate election with the MA organization.

(b)(1)(ii) Submit a request for disenrollment to the MA organization in the form and manner prescribed by CMS or file the appropriate disenrollment request through other mechanisms as determined by CMS.

(b) (3) (ii) Provide enrollee with notice of disenrollment in a format specified by CMS.

(b) (3) (iii) In the case of a plan where lock-in applies, include in the notice a statement.

(d) (5) The individual who is converting must complete an election as described in § 422.60(c)(1), unless otherwise provided in a form and manner approved by CMS.

Section 422.74 Disenrollment by the Medicare Advantage Organization

(c)(1) A notice must be provided to the individual before submission of the disenrollment transaction to CMS.

(d)(1)(i) The MA organization can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount that meets the requirements of this section.

(d)(1)(ii)The MA organization provides the enrollee with notice of disenrollment that meets the requirements set forth in paragraph (c) of this section.

(d)(2)(ii)An organization may disenroll an individual whose behavior is disruptive as defined in 422.74(d)(2)(1)(i)only after it meets the requirements described in this section and CMS reviews and approves the request.

(d)(2)(iii) The beneficiary has a right to submit any information or explanation that he or she may wish to submit to the MA organization.

(d)(2)(iv) The MA organization must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraphs (d)(2)(i) through (d)(2)(ii) of this section and any extenuating circumstances. The MA organization may request from CMS the ability to decline future enrollment by the individual if the organization obtains approval from CMS.

Section 422.111 Disclosure requirements

(d)(2) For changes that take effect on January 1, the plan must notify all enrollees 15 days before the beginning of the Annual Coordinated Election Period defined in section 1851(e)(3)(B) of the Act.

(e) The MA organization must make a good faith effort to provide written notice of a termination of a contracted provider at least 30 calendar days before the termination effective date to all enrollees who are patients seen on a regular basis by the provider whose contract is terminating, irrespective of whether the termination was for cause or without cause. When a contract termination involves a primary care professional, all enrollees who are patients of that primary care professional must be notified.

Section 422.112 Access to services

(a)(1)(i) Maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served. These providers are typically used in the network as primary care providers (PCPs), specialists, hospitals, skilled nursing facilities, home health agencies, ambulatory clinics, and other providers.

(a)(1)(ii) MA regional plans, upon CMS pre-approval, can use methods other than written agreements to establish that access requirements are met.

Section 422.152 Quality improvement program

(b)(3)(i) Plans must measure performance using the measurement tools required by CMS, and report its performance to CMS. The standard

measures may be specified in uniform data collection and reporting instruments required by CMS.

(b)(3)(ii) Make available to CMS information on quality and outcomes measures that will enable beneficiaries to compare health coverage options and select among them, as provided in § 422.64(c)(10).

(d)(5) The organization must report the status and results of each project to CMS as requested.

(e)(2)(i) MA organizations offering an MA regional plan or local PPO plan as defined in this section must measure performance under the plan using standard measures required by CMS and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS.

(f)(i) and (iii) For all types of plans that it offers, an organization must maintain a health information system that collects, analyzes, and integrates the data necessary to implement its quality improvement program and make all collected information available to CMS.

Section 422.570 Expediting certain organization determinations

(d)(2)(ii) The plan must inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision not to expedite.

Section 422.572 Timeframes and notice requirements for expedited organization determinations

(c) If the MA organization first notifies an enrollee of an adverse expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

Section 422.582 Request for a standard reconsideration

(a) A party to an organization determination must ask for a reconsideration of the determination by making an oral or written request to the MA organization that made the organization determination or to an SSA office.

(c)(2) If the 60-day period in which to file a request for reconsideration has expired, a party to the organization determination may file a request for reconsideration with the MA organization.

Section 422.602 Request for an ALJ hearing

A party must file a written request for a hearing with the appropriate ALJ office, which meets the requirements of this section.

Section 422.620 How enrollees of MA organizations must be notified of noncovered inpatient hospital care

(c) When appropriate, a written notice of non-coverage must be issued no later than the day before hospital coverage ends. The written notice must include the elements set forth in this section.

As noted above, while the requirements in this section have been modified, the associated burden has not changed.

3. New/Revised Collection Requirements Proposed In This Regulation: Affecting burden:

Section 422.80 Approval of marketing materials and election forms

(a)(3) The MA plan meets the performance requirements established by CMS The MA plan may distribute the designated marketing materials 5 days following their submission to CMS with an certification that the marketing materials meet the model language guidelines specified by CMS.

The burden associated with this requirement is the time and effort necessary for the plan to submit the designated marketing materials to CMS five days prior to distribution.

We estimate it will take 350 plans approximately 12 hours to provide the materials to CMS on an annual basis.

Section 422.101 Requirements relating to basic benefits

(b)(5) An MA organization an MA local plan or regional MA plan as described in this section must make information on the selected local coverage policy readily available to the enrollees and health care providers.

The burden associated with this requirement is the time and effort necessary for the plan to make information on the selected local coverage policy readily available to the enrollees and health care providers. We estimate that it will require 350 MA plans 1 hour each on annual basis to make the necessary information available.

(d)(4) MA regional plans are required to track the deductible (if any) and catastrophic limits in paragraphs (d)(1) through (d)(3) of this section based on incurred out-of-pocket beneficiary costs for original Medicare covered services, and are also required to notify members and health care providers when the deductible (if any) or a limit has been reached.

The burden associated with this requirement is the time and effort necessary for the plan to notify members when the deductible (if any) or a limit has been reached. While this requirement is subject to the PRA, we believe this requirement meets the requirements of 5 CFR 1320.3(b)(2), and as such, the burden associated with this requirement is exempt from the PRA.

Section 422.106 Coordination of benefits with employer group health plans and Medicaid

(d)(1) To facilitate the offering of MA plans by employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity's employees, former employees (or combination thereof) or members or former members (or combination thereof), of the labor organizations, those MA plans may request, in writing, from CMS, a waiver or modification of those requirements in this part that hinder the design of, the offering of, or the enrollment in, those plans by those individuals.

The burden associated with this requirement is the time and effort necessary for the plan to submit a waiver to CMS. We estimate that on an annual basis it will take plans 2 hours to submit the waiver to CMS. However, we do not anticipate more then nine waiver requests on an annual basis. As such, this requirement is not subject to the PRA as stipulated under 5 CFR 1320.3(c).

Section 422.111 Disclosure requirements

(f)(10) The names, addresses, and phone numbers of providers from whom the enrollee may obtain in-network coverage in other areas.

The burden associated with this requirement is the time and effort necessary for the plan to notify member of the names, addresses, and phone numbers of providers from whom the enrollee may obtain in-network coverage in other areas. While this requirement is subject to the PRA, we believe this requirement meets the requirements of 5 CFR 1320.3(b)(2), and as such, the burden associated with this requirement is exempt from the PRA.

Section 422.112 Access to services

(c) An MA regional plan may seek, upon application to CMS, to designate a noncontracting hospital as an essential hospital as defined in section 1858(h) of the Act that meets the conditions set forth in this section.

The burden associated with this requirement is the time and effort necessary for the plan to submit the required materials to CMS. We estimate

that on an annual basis it will take 100 plans 8 hours to submit the materials to CMS.

Section 422.254 Submission of bids and rebate information

(a)(1) No later than the first Monday in June, each MA organization must submit to CMS an aggregate monthly bid amount for each MA plan (other than an MSA plan) the organization intends to offer in the upcoming year in the service area (or segment of such an area if permitted under § 422.262(c)(2)) that meets the requirements in paragraph (b) of this section. With each bid submitted, the MA organization must provide the information required in paragraph (c) of this section and, for plans with rebates as described at 422.266, the MA organization must provide the information required in this section.

The burden associated with this requirement is the time and effort necessary for the plan to submit the required bid materials and rebate information to CMS. 350 MA organizations offering 400 plans 100 hours per plan bid and rebate submission to CMS for a total annual burden of 40,000 hours.

(b) For MSA plans, MA organizations must submit the following information: the monthly MSA premium, the plan deductible amount, and the beneficiary supplemental premium, if any. Since CMS does not review or approach MSA plan submissions, we estimate that the submission burden is half that for other MA plans. Under the M+C program, no MSA plans were offered. We estimate that under the MA program 5 organizations will offer an MSA plan and require 50 hours for submission of the above information, for a total annual burden of 250 hours.

Section 422.270 Incorrect collections of premiums and cost-sharing

(b) An MA organization must agree to refund all amounts incorrectly collected from its Medicare enrollees, or from others on behalf of the enrollees, and to pay any other amounts due the enrollees or others on their behalf.

The burden associated with this requirement is the time and effort necessary for the MA organization to provide written assurance to CMS that they will refund all amounts incorrectly collected from its Medicare enrollees or representatives. We estimate that on an annual basis it will take 350 MA organizations 30 minutes to submit a written agreement to CMS.

Section 422.304 Monthly payments

(e)(2) A State's chief executive may request, no later than February 1 of any year, a geographic adjustment of the State's payment areas, as outlined in this section, for MA local plans for the following calendar year.

The burden associated with this requirement is the time and effort necessary for a State to provide a written request for geographic adjustment to CMS. Under the M+C program, we received inquiries from 2 states and requests from none. Thus, we estimate that on an annual basis we may receive 2 State submissions. As such, this requirement is not subject to the PRA as stipulated under 5 CFR 1320.3(c).

Section 422.310 Risk adjustment data

(b) Each MA organization must submit to CMS (in accordance with CMS instructions) all data necessary to characterize the context and purposes of each service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner. CMS may also collect data necessary to characterize the functional limitations of enrollees of each MA organization.

The burden associated with this requirement is the time and effort necessary for a plan to submit the required risk adjustment data to CMS. We estimate that on an annual basis it will take 350 MA organizations 121 hours each to submit the required data to CMS.

(d)(1) MA organizations must electronically submit data that conform to the requirements for equivalent data for Medicare FFS when appropriate, and to all relevant national standards. Alternatively, MA organizations may submit data according to an abbreviated format, as specified by CMS and which meet the requirements of (d)(2) and (d)(3) of this section.

The burden associated with this requirement is the time and effort necessary for a plan to gather the required data and submit the required risk adjustment data to CMS. The estimate for submission of the abbreviated format data is included in the above estimate.

(e) MA organizations and their providers and practitioners will be required to submit medical records for the validation of risk adjustment data, as required by CMS.

The burden associated with this requirement is the time and effort necessary for a plan to submit the required validation data to CMS. We estimate that on average 350 MA organizations will each submit 29 medical records to CMS, requiring 1 hour per record, for a total annual burden of 9800 hours.

Section 422.314 Special rules for beneficiaries enrolled in MA MSA plans

(b) An entity that acts as a trustee for an MA MSA must Register with CMS, certify that it is a licensed bank, insurance company, or other entity qualified, under sections 408(a)(2) or 408(h) of the IRS Code, agree to comply with the MA MSA provisions of section 138 of the IRS Code of 1986; and provide any other information that CMS may require.

The burden associated with this requirement is the time and effort necessary for an entity to certify and submit the required materials to CMS as outlined in this section. We estimate 5 MA organizations will submit the required information on an annual basis. As such, this requirement is not subject to the PRA as stipulated under 5 CFR 1320.3(c).

Section 422.320 Special rules for hospice care

(a) An MA organization that has a contract under subpart K of this part must inform each Medicare enrollee eligible to select hospice care under § 418.24 about the availability of hospice care if a Medicare hospice program is located within the plan's service area, or it is common practice to refer patients to hospice programs outside that area.

The burden associated with this requirement is the time and effort necessary for a plan to disclose to each Medicare enrollee about the availability of hospice care. We estimate that on an annual basis it will take 350 plans 1.14 hours to distribute the required materials to enrollees. While this estimate may appear low, we believe that this disclosure requirement will be standardized and incorporated into the plans marketing material routinely disseminated to enrollees.

Section 422.458 Risk sharing with regional MA organizations for 2006 and 2007

(d)(1) Each MA organization offering an MA regional plan must provide CMS with information as CMS determines is necessary to implement this section.

The burden associated with this requirement is the time and effort necessary for a plan to submit the required information to CMS. We estimate that on an annual basis it will take 30 to 100 plans, 40 hours to submit the required information to CMS.

(d)(2) Pursuant to the existing § 422.502(d)(1)(iii) (section 1857(d)(2)(B) of the Act), CMS has the right to inspect and audit any books and records of the organization that pertain

to the information regarding costs provided to CMS under paragraph (b)(2) of this section.

This requirement is exempt from the PRA as stipulated under 5 CFR 1320.4.

Section 422.501 Application requirements

(b)(1) In order to obtain a determination on whether it meets the requirements to become an MA organization and is qualified to provide a particular type of MA plan, an entity, or an individual authorized to act for the entity (the applicant) must complete and submit a certified application, in the form and manner required by CMS, that meets the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for a plan to submit the required application to CMS. We estimate that on an annual basis it will take 350 plans 40 hours to submit the required application to CMS.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare and Medicaid Services

Office of Strategic Operations and Regulatory Affairs,

Attn: John Burke (CMS–4069–P)

Room C5–13–28, 7500 Security Boulevard,

Baltimore, MD 21244–1850;

and

Office of Information and Regulatory Affairs,

Office of Management and Budget,

Room 10235, New Executive Office Building,

Washington, DC 20503,

Attn: Christopher Martin, CMS Desk Officer,

[CMS–4069–F],

Christopher_Martin@omb.eop.gov.

Fax (202) 395–6974.

VI. Regulatory Impact Analysis

We received comments on the proposed rule regulatory impact analysis in six subject areas. The comments pertained to (1) our not having examined the impact of the Comparative Cost Adjustment program under section 241 of the MMA, set to begin in 2010; (2) an error in our projection of the value of extra benefits that enrollees of MA plans will receive; (3) a question regarding the number of insurers licensed to operate nationally or in multiple states; (4) the manner in which we classify entities as being either regional plans or local plans; (5) concerns about the competitive advantages that regional plans may have over local plans; and (6) our not having discussed the effect of these rules on American Indian and Alaska Native populations. Our responses to those comments are addressed in the appropriate sections below. None of these comments suggested the need for major changes in our analysis, and we have accordingly modified it primarily to reflect final decisions and to use updated economic projections (in addition to correcting the projection error pointed out in public comments).

A. Overall Impact

We have examined the impacts of this rule under Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) and Executive Order 13132 on Federalism.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impact and equity). A regulatory impact analysis (RIA) must be prepared for any rule with an effect on the economy of $100 million or more in any one year. Since this rule will be the most significant step in implementing the MA program, we are classifying it as an economically ''significant'' rule for purposes of E.O. 12866 and as a ''major'' rule for purposes of the Congressional Review Act (5 U.S.C., section 804(2)). Accordingly, we have prepared this RIA in accordance with OMB Circular A–4, combined with a Final Regulatory Flexibility Analysis (FRFA), pursuant to the Regulatory Flexibility Act), in which we analyze the overall effects of the Medicare Advantage program, including effects not addressed in this rulemaking (for example, rate increases that went into effect in March, 2004). Although the MMA is a highly detailed statute that delineates most important provisions of the MA program, there are alternatives available to us in implementing several important provisions of the statute. We analyze in detail those areas for which regulatory alternatives are available.

Although we have included or summarized most of the required analysis in this section of the preamble, the explanation of the basis for the rule and analysis of some regulatory options are presented elsewhere in the preamble. We note that the preamble to the companion rulemaking concerning the Part D drug benefit also contains an RIA and a FRFA, and some effects of the legislation (for example, on Medigap plans) are analyzed in more detail in that preamble.

The MMA provides for increasing the role of private plans in providing Medicare benefits to beneficiaries. The statute made changes to the payment system that increase Medicare payment rates to private plans as of 2004, and for subsequent years. A new private plan option is introduced, the regional Medicare Advantage plan, structured as a PPO, which will be required to offer services over a wide geographic area. To encourage the formation of such plans, the MMA provides financial incentives above and beyond the payment rate increases applicable to all plans. There are other financial incentives discussed in what follows and elsewhere in the preamble. In addition to increased payments to plans, the MMA will provide benefits to beneficiaries and to entities (such as employers and States) that would otherwise be financially responsible for the cost of beneficiaries' medical care. The benefits to beneficiaries and plans are the result of transfer payments from the Federal Government which we project will total $18.3 billion in the period 2004 to 2009 (as a result solely of the Title II provisions of the MMA), as described in more detail in what follows.

The main purpose of this rule is to implement the statutory provisions of Title II of the MMA, which deal with the Medicare Advantage program. Insofar as the rule implements provisions of the law, we are providing a general discussion of the impact of the law and our basis for projections of the impact. These impact projections reflect the statutory scheme in its entirety, not just the relatively minor effects attributable to discretionary provisions in the regulations. Although the statute prescribes Medicare Advantage rules and procedures in considerable detail, it specifically affords CMS discretion to make decisions on a number of issues regarding how the law will be implemented. The preamble and this impact analysis discuss these types of issues in greater detail. The rule also introduces changes to Medicare private health plan requirements that, in most cases, are intended to streamline the administration of the program and make contracting less burdensome for health plans while not impinging on the rights of enrollees. (Note that this analysis does not extend beyond the year 2009; that is, the Comparative Cost Adjustment (CCA) demonstration program of subtitle E of the MMA is not

discussed. The CCA regulations will be proposed at a later date.)

Comment: One commenter expressed disappointment in the approach of dealing with the impact of the law and regulations only through 2009, without discussing the Comparative Cost Adjustment (CCA) program set to begin in 2010 (under section 241 of the MMA). The commenter is interested in knowing what our thinking is with regard to the CCA program.

Response: As discussed in the notice of proposed rule making, any necessary regulations for the CCA program will appear sometime in the future as proposed rules, at which time there will be opportunity for public comment. We would also note that our experience with the bidding system that begins in 2006 will help inform our thinking about the CCA program when we begin active planning for it.

1. Objectives of the Final Rule

The primary goal of the MMA is to expand the health plan choices available to Medicare beneficiaries, allowing beneficiaries to meet their medical needs at a lower cost. There is also the expectation that Medicare health plan enrollment will increase. The expansion of health plan choice is envisioned as occurring at many levels: areas of the country that previously did not have private plans available should see new plans enter the market; areas where there are plans should see an increase in the number of competing plans; and beneficiary choice should be enhanced by the introduction of new types of plans, including specialized plans, and, most importantly, regional plans that are structured as preferred provider organizations. In keeping with the overall objectives of the law, the rule seeks to implement the law in ways that will promote plan participation (and, as a consequence, lead to increased enrollment in private plans). The introduction of regional plans and the choice of the PPO model for such plans are designed to lead to greater plan participation. The rationale for the introduction of regional plans and the use of the PPO model are discussed in the impact analysis of the August 3, 2004 proposed rule (69 FR 46919).

General Impact. In general, the law and regulations will have a positive impact on beneficiaries and private health plans. Transfer payments from the Federal Government will go towards the provision of additional health benefits to enrollees of health plans and reduced out-of-pocket costs, including reduced Part B and Part D premiums for these enrollees. The law will result in increased revenue for participating private plans for the provision of the basic Medicare benefit and the provision of additional health benefits. We also anticipate a positive impact for employers and unions as sponsors of retiree coverage, as discussed in more detail below.

There are revenue effects on States arising directly from the law (the prohibition on premium taxes) and arising indirectly as a result of beneficiary movement towards private plans and away from traditional FFS Medicare with Medigap coverage. The latter effect is relevant to Medigap insurers. The effects on States and insurers are discussed more fully in what follows.

2. Provisions of the Law

The MMA introduces major changes in the payment rules for private plans. These changes are discussed in detail in the preamble text for subparts F and G of these regulations. For local plans, the MMA increased MA payment rates beginning in 2004, by using county FFS rates (minus direct medical education payments) as a minimum payment level and rebasing the rates periodically, by removing a budget neutrality limitation on payment at a national/local blended rate, and by providing for higher yearly payment rate increases (while maintaining minimum payment rate increases).

Payment to plans are risk adjusted for health status (in addition to risk adjustment for demographic factors such as age), with 30 percent of payment being subject to health status risk adjustment in 2004, 50 percent in 2005, 75 percent in 2006, and 100 percent in 2007 and thereafter. When payments are risk-adjusted, a greater proportion of such payments are directed to chronically ill and older beneficiaries with predictably high costs. Note that CMS is currently implementing health status risk adjustment in a ''budget-neutral'' manner, with savings re-invested in plan payments. That is, the difference in payment between the total health status-adjusted payment rates and the rates adjusted only by demographic factors is paid to the health plan ''sector,'' in 2006, but the funds are distributed among plans based on the relative health status of each plan's enrollees.

Through 2005, there is no change to the payment rules related to how plans must use any excess funds (Medicare payments greater than the amount a health plan requires to provide the Medicare benefit). Currently such funds must be returned to enrollees in the form of reduced cost sharing, or the provision of extra (non-Medicare) benefits. Plans also have the option of using the excess funds to reduce all or a portion of an enrollee's Part B premium, but in that case, the Government retains 20 percent of the reduction in plan payments while reducing the Part B premium that is usually collected through a beneficiary's Social Security payment. Another option for the disposition of excess funds is to make deposits to a ''stabilization fund'' to be used in a subsequent contract year for reductions in cost sharing or for financing of extra benefits-an option that the MMA eliminates as of the end of the 2005 contract year.

Currently and through 2005, the determination of whether there are excess funds is done through the ''adjusted community rate'' approval process (a CMS review of proposed benefits and premiums and the revenue required to provide the benefit package). The MMA does away with the ACR review process and instead institutes a bidding process. As of 2006, plans will present bids that are to be compared against benchmarks to determine whether enrollees will receive rebates or be required to pay a premium to the health plan. For local plans, the benchmark is based on what today are county payment rates. For regional plans, the benchmark represents a weighting of these same county rates and the actual plan bids. CMS will evaluate the bids for reasonableness and actuarial soundness, and can negotiate over the bid amounts and proposed supplemental benefits. In 2006 and thereafter, to the extent that the bid is less than the benchmark, that difference (comparable to the current ''excess funds'') determines plan rebates. The Government retains 25 percent of this difference, and the remaining 75 percent is to be used for beneficiary ''rebates,'' which can take the form of extra benefits, reduced cost sharing, reduced health plan premiums for mandatory supplemental benefits, or reduced Part B and/or Part D premiums. To the extent that the plan bid is greater than the benchmark, that difference becomes the premium the plan must charge enrollees for ''basic'' benefits.

The limitation on cost sharing for Medicare services that previously existed is modified in the MMA. Prior to the MMA, for coordinated care plans, the combination of the actuarial value of cost sharing for Medicare-covered services, plus any premium or portion of a premium representing a charge in lieu of Medicare cost sharing, could not exceed the average level of cost sharing that beneficiaries face in FFS Medicare. As of 2006, premium amounts that are in lieu of cost sharing are not counted

in determining whether the limit is exceeded (which is the rule as it is currently applied to PFFS plans). In addition, the comparison is made to local values of cost sharing in FFS Medicare rather than to the current use of national values. (The cost sharing for Medicare Part A and B services that enrollees of MA regional plans obtain from non-network providers is not counted in determining whether the cost sharing limit on Medicare services has been exceeded.)

The MMA also makes structural changes in the Medicare private plan contracting program. The most important of these statutory changes is the introduction of regional MA plans that will be structured as PPOs, and which would first become available in 2006. While local plans may choose the counties in which they wish to operate as MA plans, regional plans must cover an entire region. On December 6, 2004, we designated 26 regions for MA regional plans and 34 regions for PDP plans. Information on the regions and the basis for their selection can be found at www.cms.hhs.gov/medicarereform/mmaregions. To facilitate the ability of regional plans to operate in multiple States, plans that are licensed in at least one State in the region can qualify for a waiver of the licensing requirements in the other States in the region for a period of time pending an organization's becoming licensed in each State (see the preamble text for subpart J). In the first 2 years of formation of regional plans, there is a moratorium imposed on the formation or expansion of local PPOs.

Regional plans have various statutory incentives to participate, including:

- Sharing risk with the Government in 2006 and 2007,
- Access, beginning in 2007 through the end of 2013, to a ''stabilization fund'' of $10 billion (plus half of the 25 percent of regional plan rebate dollars that would otherwise go to the Government). The stabilization fund will be used to encourage plan entry (including a bonus for plans operating in the entire Nation) or to prevent plans from discontinuing contracts; and
- Access to additional funding payable to ''essential'' hospitals (as described in the subpart G preamble text).

As described elsewhere in this regulation, we are also taking other regulatory steps to support regional plan participation, such as allowing plan payments to be adjusted based on geographic variations in a plan's costs within a region, and providing flexibility in network adequacy standards (as outlined in the preamble discussion of subpart G).

Other structural changes affecting Medicare health plans include provisions for plans that can exclusively or disproportionately serve special needs individuals, special treatment of enrollees with ESRD (paid outside of the bidding system in 2006–see subpart G), authority for direct contracting between CMS and employers or unions for coverage of retirees (see § 422.106), and removal of certain limitations that had been imposed on medical savings account plans. There are also provisions calling for the termination of cost-reimbursed contracts with health plans if certain conditions are met (see discussion of changes to part 417).

In the following section we list those areas in which we will exercise discretion, either because the law entails a choice of options or because we have elected to exercise regulatory discretion.

3. Discretion Resulting from Statutory Provisions

Designation of Regions. The most important feature of the MA program that the statute leaves to the discretion of the Secretary is to determine the boundaries for the regions in which regional MA plans will operate. As permitted by the statute, the regions for MA are different from the PDP regions, as explained in the announcement of the regional configurations and as discussed in the impact analysis for Title I of the MMA (concerning PDPs). The biggest difference between the two sets of regions is that the size of the eligible population necessary to support economic viability is somewhat larger for MA than PDP plans. All PDP regions are ''nested'' within (included in) MA regions to simplify planning and administration. Some of the issues relating to the configuration of regions were discussed in the alternatives considered section of the proposed rule (see 69 FR 46937). The estimates contained in the analysis found in the proposed rule (see 69 FR 46928, Table 2, for example) were for illustrative purposes and were based on an assumption that there would be 15 regions. The projected numbers in this final rule are based on the MA regions designated by CMS. The configuration of the regions affects the projections because of the expected benchmark levels in each region and the projected bids from health plans in the regions.

Statewide Versus Plan-Specific Risk Adjustment. CMS is given the authority to use a statewide, area-wide, or a plan-specific, risk adjustment methodology for determining rebates. The effects of each and the factors to consider in choosing one or the other approach were discussed in the alternatives considered section of the proposed rule (see 69 FR 46942). The consequence of choosing the option of the plan-specific approach is briefly discussed below, in the alternatives considered section of this final rule.

4. Regulatory Discretion

The statute spells out in detail most major and many minor parameters of Medicare reform. However, in certain matters, the statute describes a structure or uses terminology that is open to interpretation but which is a necessary component of the statutory scheme. There are also other areas where we believe further interpretation is needed, or where there appear to be internal inconsistencies in the statute that need to be resolved. The following issues are of this nature, and each is noted here briefly, with some of the issues discussed in further detail in the section on alternatives considered.

Actuarial Value of Medicare Cost Sharing. When plans present bids for Medicare-covered services the bid may include only Medicare-covered services and must reflect cost sharing at Medicare levels or with ''actuarially equivalent'' cost sharing. The options for defining ''actuarially equivalent'' in this context are discussed in detail in the preamble text of subsection F in this final rule and in the proposed rule (where the uniform, plan-specific, and proportional amount methods of determining actuarial equivalence are discussed).

Treatment of Induced Demand as a Supplemental Cost. As was discussed in the proposed rule, to the extent that we were to use the ''plan-specific'' approach to determining cost sharing that is actuarially equivalent to that of traditional Medicare, an additional issue arises, having to do with the additional expenditures arising from ''induced demand'' (higher utilization because of lower cost sharing). We have decided not to use the plan-specific approach, relying instead on a proportional approach to determining cost sharing as a component of the bid for Medicare A and B services. Therefore we are unable to quantify any induced demand that may exist (that is, any difference in A and B expenditures between the bid and actual utilization under a plan's benefit design which is attributable to reduced cost sharing). In the alternatives considered section, below, we discuss the consequence of this choice.

Prohibiting Use of Rebate Dollars for the Purchase of Optional Supplemental Benefits. This final rule prohibits rebate dollars from being used for the purchase of optional supplemental benefits, as

explained in the preamble text for subpart F.

Intra-Area Geographic Adjustment to Payments. The statute specifies that ''if applicable'' (1853(a)(1)(B)(i)), CMS ''shall adjust'' payments ''in a manner to take into account variations in MA local payment rates'' (1853(a)(1)(F) for regional plans and for local plans operating in more than one local payment area. This issue is discussed in more detail in the ''alternatives considered'' section. We will be using a geographic adjustment based on MA county payment rates, but in exceptional situations, for regional plans, we will allow the use of a plan-determined statement of the variation in the relative cost to the plan of providing Medicare-covered services.

5. Provisions Of The Rule Not Based On Specific MMA Changes

As discussed throughout the preamble of this final rule and the proposed rule, we have made a concerted effort to improve, and wherever possible simplify and reduce the burden of, existing regulations. In general, as previously noted, these provisions reduce the burden on health plans while enhancing beneficiary protections or not adversely affecting the rights of enrollees. Among the changes that are being made that are not a result of the MMA statutory provisions are (a) new beneficiary protections related to coverage of services when network providers can see patients on a ''point-of-service'' basis (§ 422.105); (b) revisions to the rules limiting beneficiary cost sharing related to emergency episodes (§ 422.113); (c) the elimination of requirements on MA plans that are duplicative of activities already conducted by CMS regarding information about beneficiary health care coverage options (elimination of § 422.111(f)(4) and (f)(6), and portions of (f)(7)); (d) the elimination of certain access to care provisions (changes made at § 422.112); (e) use of alternative election mechanisms other than forms (§ 422.50(a)(5)), and alternative notice options (§ 422.60(e)); (f) allowing MA organizations to submit requests to restrict enrollment for capacity reasons at any time during the year (§ 422.60(b)); (g) providing more flexibility in the procedures for disenrolling beneficiaries for failure to pay premiums (§ 422.74(d)(1)) and rules related to disenrollment due to disruptive behavior (§ 422.74(d)(2)); (h) formal adoption of a ''file and use'' approach to approval of marketing materials (§ 422.80) for contractors that have demonstrated a record of compliance with marketing rules; (i) changes in requirements regarding information plans provide to enrollees about participating providers (§ 422.111(b)(3), for example); and, in § 422.133 , extending the right under section 1852(l) of the Act for admission to a ''home skilled nursing facility'' in the event that a health plan admits an enrollee to a skilled nursing facility without a prior qualifying hospital stay. In addition, various changes are made in subpart D that are consistent with a ''quality improvement'' approach to quality standards.

B. Basis for Estimating Impacts

The extent of the impact of the MMA will depend on whether the goals of the law are realized. We believe that the payment changes and structural changes of the MMA will lead to higher levels of plan participation, and, as a consequence, enrollment in coordinated care plans will increase over the next several years and over the longer term. We expect the absolute level of Medicare health plan enrollment to increase because of the greater availability of plans, and we expect the rate of enrollment in such plans (''penetration'') to increase because plans will be able to offer plan designs that will allow beneficiaries to meet their medical needs at a lower cost, and MA organizations will be able to offer generous benefit packages that Medicare beneficiaries will find attractive. However, there is a great deal of uncertainty involved in making projections of plan participation and beneficiary enrollment levels. The factors contributing to uncertainty include uncertainty about market decisions health plans might make, how changes in health care markets and costs will affect plan participation and beneficiary enrollment, whether MA plan offerings will satisfy the enrollment preferences of Medicare beneficiaries, how MA plans will fare in competition with the new PDP plans, and other factors. For the MMA, the designation of MA regions and how the marketplace will react to the regional designations is also a factor contributing to uncertainty.

We have revised the enrollment, expenditure, and distribution of funds estimates contained in the proposed rule (summarized in the proposed rule, in Tables 2, 4, and 12, found at 69 FR 46928, 46930, and 46951). The revisions reflect revised bid and benchmark estimates based on the designation of regions; and revised enrollment estimates based in part on the results of discussions with the Technical Review Panel on the Medicare Trustees Reports (information about the panel and its findings can be found at *http://aspe.hhs.gov/health/medpanel/2004/*, in particular the minutes of the October 15, 2004 meeting). The enrollment estimates (and associated expenditures for MA) were revised downward for the 2004 to 2009 period that is the subject of the projections contained in this final rule. While enrollment in MA had been projected to reach 33 percent of the Medicare population by 2009 in our proposed rule projections, we are revising the penetration projection to be lower in 2009–it is now projected to be about 24 percent-but we continue to expect enrollment to reach 33 percent by 2016, with enrollment in 2016 being evenly divided between local MA plans and regional plans.

The proposed rule contained a lengthy discussion of the history and current state of the MA program (and its predecessor programs, such as Medicare+Choice). The discussion contained data on beneficiary access to MA plans over the years and penetration levels in the past, the types of beneficiaries who currently enroll in such plans (for example, lower-income individuals are more likely to enroll in MA), the categories of beneficiaries less likely to enroll; and a discussion of any conclusions that can be drawn from the history of the program in terms of health plan decisions to participate in the program and beneficiary decisions on enrollment in Medicare health plans (69 FR 46921 through 46925 of the proposed rule). The discussion was intended to provide historical and anecdotal evidence to support the enrollment projections found in the proposed rule. For this final rule, we are providing an update of some of the data.

As of January 2005 there are 174 MA coordinated care plans (CCPs), and such plans were available to 65 percent of the Medicare population (compared to 61 percent of the population at the end of 2004, and compared to a historical high of 74 percent). There are applications pending for 19 additional CCPs. Including PFFS plans, if all pending new contract applications and service area expansion requests are approved, 86 percent of Medicare beneficiaries will have access to at least one Medicare private plan.

The current data demonstrate a significant increase in plan participation in MA, associated with an increase in enrollment in CCP plans of about three percent between January and December of 2004 (to 4.7 million). (In addition, enrollment in PPO demonstration plans increased 34 percent to 111,000; and enrollment in PFFS plans increased 93 percent, to 51,000.)

With regard to MSA plans, we remain uncertain, as noted in the proposed rules, about participation and enrollment in MSAs. The MMA changed the MSA provisions of the BBA with a view towards facilitating the offering of such plans. However, we are unable to determine whether the MMA provisions will result in such plans being introduced and the extent to which beneficiaries might enroll in such plans.

Comment: Several commenters remarked that the impact analysis showed that very little of the additional payments to health plans resulting from the MMA would be used to fund extra benefits for plan enrollees.

Response: The commenters have pointed out what is an error in the impact analysis published in the notice of proposed rule making of August 3, 2004. We are correcting the error in this final rule. While the projections of Tables 2 and 4 of the proposed rule (69 FR 46928 and 46930, respectively) show that only about six percent of total new expenditures arising from the MMA would be used to fund extra benefits, the correct percentage, over the period 2004 through 2009, should be a much higher figure-in the range of 50 percent, as explained below in the section on effect on beneficiaries. The remainder of the payment increases will support maintaining and enhancing provider networks and stabilization of the plans' financial status in Medicare. (The erroneous projected percentage was based on the percentage of total MA payments in 2004 through 2009 that we project will be used for extra benefits, not the percentage of only the incremental dollars that plans will receive in 2004 through 2009 because of the MMA provisions.)

Comment: One comment questioned a statement in the impact analysis of the proposed rule to the effect that there were a number of insurers that are licensed as insurers in every State in the Nation, or which are licensed in multiple States. The commenter noted that they were aware of several national and multi-state insurers but inquired whether CMS had in mind any other insurers beyond the ones named in the comment.

Response: The CMS information on the number of insurers that are multi-state or national insurers was based on information available at the web site of the National Association of Insurance Commissioners (www.naic.org), showing the licensure status, by State, of health insurance companies. We have not done an exhaustive analysis to determine the total number of such companies. Our purpose was merely to point out, as the commenter noted, that there are a number of organizations that are potential MA regional plan contractors.

Projections Provided in the Impact Analysis. The methodology used to project the impact of the law and regulations is partly explained in the section on effects on beneficiaries. The projections in this final rule, which are different from those in the proposed rule, are based on the CMS designation of 26 MA regions. For projection purposes, a model is used that assumes three regional plans in each region, with each plan at a different level of efficiency (though this is not to suggest that this would be the number of regional/national plans in each region). With regard to the number of MA local plans, the projections of enrollment do not involve assumptions about any specific number of local plans. Instead a certain level of enrollment is assumed for local plans based on the benefits they are expected to offer. It was assumed that there would be sufficient capacity among local plans to enroll all beneficiaries that are expected to join such plans. The estimates of plan bids are based on the proprietary information submitted to CMS by current Medicare Advantage plans (coordinated care plans as well as demonstration PPO plans). Beneficiary behavior is modeled with utility functions that predict the choices they will make among available health plan options. As previously mentioned, we recognize the high degree of uncertainty entailed in such projections. The projections represent our best estimate of the impact given the assumptions stated.

C. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies identify any Federal mandates resulting from rules that may result in the expenditure by State, local, and tribal governments of $100 million or more (adjusted for inflation and currently about $110 million). If this threshold is met, a detailed analysis is required. This rule does not contain any such mandate, and other direct effects on State, local, and tribal governments will be minimal. There will, however, be an indirect effect on State premium tax revenues due to the increased enrollment in MA plans and reduced enrollment in certain Medigap policies. These indirect effects, however, are not the result of these rules, but of increased plan payments and prohibitions on sale of those Medigap policies implemented independently of these regulations.

Title II of the MMA contains several provisions that have a direct impact on States. Section 232(a) of the MMA amends section 1856(b)(3) to preempt all State standards other than licensure and solvency as they apply to MA plans. Section 232(b) of MMA amends section 1854(g) to expand a prohibition on State taxes for MA plans to apply to both CMS' payments to MA plans and to enrollee premium payments to MA plans. In addition, section 221(c) of MMA allows for temporary waiver of State licensure in States covered by regional MA plans where those plans cover a multi-State area.

Medicare law prohibiting State taxes on section 1853 payments to M+C organizations, that is, payments made by CMS to health plans contracting with Medicare, was established by the Balanced Budget Act 1997. That prohibition did not apply to enrollee premium payments made to M+C plans.

Section 232(b) of the MMA has expanded the prohibition on State taxes for MA plans, addressed in statute at section 1854(g), to apply to both section 1853 payments to MA plans and to section 1854 enrollee premium payments to MA plans. This provision was effective on the date of enactment of the MMA and is, therefore, not subject to the Regulatory Accountability provisions of the UMRA, which apply only to effects resulting from promulgation of rules. Section 422.404(a) is revised to reflect this change. We do not anticipate that the added prohibition on taxation of enrollee premiums to have a significant cost impact on States. Enrollee premiums to Medicare health plans are a small proportion of total payments to health insurers. Thus, State loss of tax revenue from Medicare enrollee premiums would also be small. Therefore, even if it were subject to UMRA, the prohibition of taxation by States of Medicare enrollee premiums would not approach the UMRA threshold.

We also recognize, however, that there is an indirect effect of the MMA law because of the expected enrollment shift from taxable Medigap insurance, and employer-sponsored private supplemental coverage, to non-taxable MA plans. This indirect effect would vary by State and would be dependent on a variety of factors, including the State's tax rate on health insurance premiums, the extent of Medigap enrollment in a State, the extent that Medigap enrollees choose to shift to MA plans in that State, as well as other resulting factors such as changes in Medigap premiums that could result from enrollment shifts. Due to these

factors, estimates of the indirect effect of enrollment shifts away from taxable Medigap and employer-sponsored supplemental plans combined with the prohibition on State taxation of Medicare enrollee premiums would involve great uncertainty and would necessarily be speculative.

D. Federalism

MMA provisions may have qualitative impacts on how States regulate and interrelate with health insurers serving Medicare enrollees due to the expanded preemption of State laws and possible temporary waiver of State licensure for multi-State MA regional plans. Law relating to Federal preemption of State standards for Medicare-contracting health plans has undergone several revisions in recent years. While Federal preemption of State standards was initially established into Medicare law by the Balanced Budget Act of 1997, a general preemption authority existed under Executive Order prior to that time. Federal preemption of State standards for Medicare-contracting health plans was expanded by Congress in 2000 and expanded again by Congress in 2003.

Prior to 1997, Federal law did not contain specific preemption requirements for Medicare-contracting health plans. However, section 1876 Federal requirements could preempt a State law or standard if State provisions were inconsistent with Federal standards based on general constitutional Federal preemption principles, consistent with the provisions of Executive Order 12612 on Federalism, since superseded by Executive Order 13132. Section 1876 requirements did not preempt a State law or standard unless the State law or standard was in direct conflict with Federal law. See the June 26, 1998 **Federal Register** notice (63 FR 35012) for further discussion on the history of general Federal preemption of State law prior to the BBA.

The BBA established for the M+C program at section 1856(b)(3) of the Act a general preemption authority in which State laws or standards would be preempted when they were inconsistent with M+C standards in the same manner that the previous Executive Order applied, and this law also established a specific preemption of State laws and standards in three areas: benefit requirements, requirements relating to inclusion or treatment of providers, and coverage determinations (including related appeals and grievance procedures). This meant that a general preemption applied if State laws, regulations, or other standards were inconsistent with Federal standards and, furthermore, in the specifically preempted areas, meant that State standards were preempted regardless of whether or not those standards were inconsistent with Federal standards.

In 2000, section 614 of BIPA maintained the general preemption authority and expanded specific preemption requirements by amending benefit requirements to include cost-sharing requirements and by adding a fourth specific preemption for requirements relating to marketing materials and summaries and schedule of benefits regarding a M+C plan. Thus, the list of areas of specific preemption effective since 2001 were: benefit requirements (including cost-sharing requirements), requirements relating to inclusion or treatment of providers, coverage determinations (including related appeals and grievance procedures), and requirements relating to marketing materials and summaries and schedule of benefits.

In 2003, section 232(a) of the MMA amended section 1856 for MA plans by eliminating the general and specific preemption distinctions from section 1856 and expanded Federal preemption of State standards to broadly apply preemption to all State law or regulation (other than State licensing laws or State laws relating to plan solvency). Section 422.402 of the regulation is thus revised. Note that State laws on secondary payer are also preempted by Federal law and a change is made in regulation at § 422.108(f) to reflect that States are prohibited from limiting the amount that MA organizations can recover from liable third parties under Medicare Secondary Payer provisions. The Congress indicated its intention to fully preempt State laws in the Conference Report for the MMA emphasizing that Medicare is a Federal program and that State laws should not apply. Section 232(a) of MMA was effective on enactment.

We do not perceive that there will be a significant cost impact on States from section 232(a) of MMA to broaden Federal preemption authority to preempt all State law and regulation (other than State licensing laws or State laws relating to plan solvency). The specific preemptions already in effect were broad areas where States were most likely to have enacted laws or developed other regulations or standards for health insurance. Apart from those specific preemptions, general preemption already applied where State provisions were inconsistent with Federal standards such that other State standards in conflict with Federal standards were also already preempted.

Areas of State law that will newly be preempted by full preemption of State laws (other than licensing and solvency) do exist, however, and will affect State residents who are Medicare beneficiaries. State governments will be affected in that State governments will no longer be responsible for enforcing preempted laws, which will likely reduce costs to States. A discussion of the diverse types of State laws that previously fell under general preemption is addressed in some detail in the response to public comments in the preamble to a June 29, 2000 final rule implementing the BBA's preemption law. (See 65 FR 35012 through 35014 of the June 29, 2000 **Federal Register** for a further discussion of the types of State laws that may be affected, which includes grievances and quality complaint reviews conducted by State governments.)

In reality, determinations of which State laws have been subject to general preemption often has not been made unless specific questions or disputes have arisen that resulted in a court review of applicability of law to specific cases. The MMA revision relieves uncertainty of which State laws are preempted by ''preempting the field'' of State laws other than State laws on licensing and solvency.

As required by Executive Order 13132, because of the implications for the States of the Federal preemption of State laws enacted in the MMA, we will consult with the States regarding the effect of the preemption provision on the role the States will play with respect to the regulation of Medicare plans, and the effect the preemption will have on State agencies and on beneficiaries enrolled in Medicare health plans. As noted in the preamble discussion of subpart I, there are issues to resolve with the States in order to clarify the breadth of preemption provisions with respect to State licensure laws, and which State statutory and regulatory provision may be considered licensing standards which are not preempted by the MMA provision. The comments and responses presented earlier in this preamble make clear that the role of State regulation of these plans is severely circumscribed. Some State-specific questions may subsequently arise, and some of these may be common across several States. In such cases we will undertake appropriate consultations with the States and, if necessary, issue interpretive guidance.

E. Effect on Beneficiaries

The MMA increases the value of benefits that enrollees of MA plans have and will increase the availability of such

benefits. When MA plans can bid at levels below the relevant benchmark, they can offer Medicare enrollees coverage of benefits beyond what Medicare covers (such as eyeglasses, hearing aids, or dental care), reduction in out-of-pocket expenditures for covered services (either as reduced cost sharing, on average, compared to FFS Medicare, or reduced expenditures for supplemental premiums compared to Medigap, for example), and reductions in expenditures for the Medicare Part B and Part D premiums. As a result of the MMA provisions, we project that in the period 2004 through 2009, Medicare beneficiaries enrolling in MA plans will see benefits beyond basic Medicare Parts A and B coverage which represent approximately 50 percent of the incremental dollars that are the government transfers to plans listed in Table 1. We are unable to provide a more precise figure because of the type of modeling used to determine projected expenditures and enrollment. The 50 percent estimate is based on the disposition of the incremental MMA dollars that MA plans received in March of 2004, at which time plans were asked to resubmit adjusted community rate proposals to CMS to account for the extra money received mid-year. We analyzed the benefit changes resulting from these mid-year filings and found that, for non-employer-sponsored plans, 58 percent of the additional funds were used to provide enrollees with extra benefits (or were deposited in a stabilization fund to be used for that purpose in 2005). Remaining funds were used to strengthen MA benefits in other ways, for example, maintaining or enhancing provider networks or financial stability for the MA plan. Expressed in dollars per enrollee, of the $38 per enrollee per month that was added to plan payments by the MMA in March of 2004, $22 was used to finance extra benefits or reduce out-of-pocket costs, and most of the remainder was used for provider networks (which will be particularly important to create attractive PPO plans). Employer group plans, which represent a little under 20 percent of MA enrollment, had a higher proportion of incremental dollars used for extra benefits-about 80 percent of the incremental dollars were used for that purpose-but, unlike non-group plans, a substantial proportion of the incremental dollars (over three-fourths of the funds) were deposited for use in 2005 (compared to five percent for non-group enrollees), and are included in the 80 percent figure. On average, therefore, across both types of coordinated care plans (employer group plans and plans for individual Medicare enrollees), about 60 percent of the 2004 MMA incremental dollars were used to finance extra benefits for MA enrollees. We assume that in future years this percentage will decrease slightly (a) because of the 2006 provision whereby the Government retains 25 percent of savings generated by local plans, and (b) because regional plans will incur relatively higher costs for the provision of Medicare A and B services (for example, because of higher out-of-network costs) and will consequently have less money available to return to enrollees in the form of rebates.

Because of the MMA payment increases effective March 2004, beneficiaries enrolled in private plans have already seen reduced out-of-pocket expenditures and increased benefits. Our analysis of MA benefit packages in 2004 after the MMA payment increases shows that enrollees of MA plans had out-of-pocket costs (including Medigap premiums) that were $700 less per year than for an individual in traditional FFS. This corresponds to a 14 percent savings for MA enrollees, relative to traditional Medicare. Individuals in poorer health had estimated savings in out-of-pocket costs of up to $1,909 a year in comparison to the alternative of traditional Medicare without Medigap coverage. (Savings are also substantial for MA relative to traditional Medicare with Medigap, average $1,647 per year).

F. Effect on Health Plans and Insurers

Health plans will see significant increases in transfer payments from the Federal Government as a result of the MMA. Plan payments will increase significantly, allowing plan revenues and profits to rise as enrollment increases with the offering of better benefits, better networks, and more stable plan availability. Organizations that currently contract with Medicare will have new market opportunities as regional plans and opportunities to expand their participation as local plans (other than as PPOs at a local level, which are prohibited from being newly formed, or expanding into a new service area, for an interim transition period, 2006 and 2007). Organizations that are not currently participating in Medicare will have a more favorable market environment for participating as local or regional plans.

The Federal Government transfer payments to health plans over and above what would have been paid in the absence of the law, as a result of the Title II provisions of the MMA, are expected to total $18.3 billion. To determine the administrative costs associated with these expenditures, we have relied on the adjusted community rate proposals of current MA coordinated care plans and demonstration PPOs, which report administrative cost figures as a percentage of Medicare payments. On average, ten percent of total plan revenues-consisting of Government payments and member premiums-will be used for plan administration in each type of plan (local and regional). The benefits to health plans will vary geographically, depending on benchmarks and the cost of doing business for the plans. The administrative cost figure cited here for the plans includes projected start-up costs for new organizations becoming Medicare contractors. The estimates of benefits related to MA plans for 2004 through 2009 are shown in Table 1. The data in the table reflect projections we have made about the number of plans participating, their bids and (consequently) their level of benefits, and the level of expected beneficiary enrollment. These projections are based on (a) what we know about the expected benchmarks in each of the 26 MA regions; (b) the current premium and benefit packages of MA plans and PPO demonstration plans, and their costs for the packages as submitted to CMS; and (c) the current patterns of enrollment in health plans in Medicare and the commercial sector. As noted previously, projections are based on a model that assumes three regional plans in each region, and that there will be a sufficient number of local plans to meet beneficiary demand for enrollment in local plans. In general, in terms of the proportion of funds used to provide extra benefits to enrollees, we expect local MA plans to be able to have more revenue available than regional PPO plans for the provision of extra benefits and reduced out-of-pocket expenditures. This is due to the cost of doing business in the areas where the regional PPOs will draw much of their enrollment (for example, the higher costs in rural areas), and the PPO structure, which involves the use of network providers as well as non-network providers. However, we would also expect that in many areas, there will only be regional plans available, and no local MA coordinated care plans. In addition, some beneficiaries will prefer the availability of out-of-network options in the regional PPOs, as is the case for many non-elderly Americans who prefer PPOs. As noted elsewhere, areas where there are only regional plan options and no coordinated care MA plans are likely to have higher benchmarks that are a vestige of the ''floor'' payment status of

such counties. Although PPO plans may face higher costs in operating in such areas, the higher benchmarks will enable them to offer enriched benefit packages (compared to traditional FFS Medicare). The projections of Table 1 show the distribution of dollars to all plans. The distribution is subject to regional variation (as is currently the case), so that in some areas, for example, beneficiaries will have more offerings and better benefit packages available to them as a result of plans having more funds to provide extra benefits, reduced cost sharing, lower premiums, or more extensive networks. Some plans may offer very few extra benefits but would still be attractive to enrollees and would be viewed by beneficiaries as more advantageous than FFS Medicare with Medigap coverage, for example.

The dollar figures shown in Table 1 reflect the projected additional Medicare Part A and B expenditures incurred solely as a result of the MMA provisions. That is, the expenditures are the incremental program expenditures that are incurred because of the MMA provisions, including any difference in expenditures that result when beneficiaries enroll in a private plan rather than receiving care in FFS Medicare.

Comment: Several commenters stated that the impact analysis projections are misleading in how types of plans are classified-that is, the basis for determining whether a plan is a regional plan or a local plan, and what kinds of organizations will be receiving payments as MA plans. The commenters noted that some local plans cannot become regional plans because they are not able to provide services across an entire region, while some local plans are sponsored by organizations that would also be (or could become) regional plans. The commenters believe that payments to local plans that are operated by organizations that operate regional plans (or could operate such plans) should be classified as payments to regional plans rather than payments to local plans. *Response:* While we acknowledge that the commenters' observations reflect the situation in the health care market-which is that not all organizations can be regional plans-we have provided separate projections for regional and local plans on the basis of the statutorily defined differences between the two types of MA contractors. In addition, we separated the two categories because we believe there is a value to the public in knowing what our expectations are with respect to the new types of plans-MA regional plans-introduced by the MMA.

The Congress recognized that it is not feasible for some organizations that are current MA contractors to become regional plans, and Congress did not preclude regional plan sponsors from also operating local plans. In various sections of the conference report it is noted that regional plans were designed to be able to provide services over a wide geographic area, and in particular to provide choices in rural areas that historically have not had coordinated care plans available to Medicare beneficiaries (see pages 96 through 98 of the MMA Conference Agreement, for example). It is recognized that regional plans would be larger-scale plans than some current local plans. We would also note that the possibility envisioned in the statute of a national plan eligible for stabilization fund payments demonstrates that Congress was aware that there could be plans that operate on a much larger scale than many local plans.

TABLE 1: PROJECTED PAYMENTS TO MA PLANS RESULTING FROM TITLE II PROVISIONS OF THE MMA, YEARS 2004 TO 2009, IN MILLIONS (INCREMENTAL AMOUNTS IN ABSENCE OF MMA TITLE II PROVISIONS); PROJECTED TOTAL PLAN ENROLLMENT, 2004 TO 2009, IN THOUSANDS (TOTALS MAY NOT SUM DUE TO ROUNDING)

	Year 2004	Year 2005	Year 2006	Year 2007	Year 2008	Year 2009	TOTAL, Years 2004–2009
Enrollment Projection, Local Plans	4,752	4,855	4,980	5,648	6,234	6,539	
Enrollment Projection, Regional Plans			1,686	2,637	3,097	3,604	
Total Value of Transfer Payments, Local Plans	1,738	2,618	2,143	1,632	1,259	1,023	10,414
Total Value of Transfer Payments, Regional Plans			746	2,498	2,372	2,312	7,928
Total Value of Transfer Payments to Plans, Both Types of Plans	1,738	2,618	2,889	4,130	3,631	3,335	18,342

As between regional and local plans, and the choice that an organization can make, regional plans, as described elsewhere, have a number of financial incentives. Local plans have the advantage of being able to selectively market to Medicare beneficiaries in that they can make decisions on a county basis. Local MA plans can choose whether or not to serve a particular county, and they can also vary benefits and premiums by county under one contract by segmenting larger service areas to as small a unit as a single county. The uniform benefit requirement applies to local plans at the service area or segment level, while regional MA plans, as previously noted, must have a uniform benefit in the entire region (for each of the plans that an MA regional organization offers in a region, each of which must be offered on a region-wide basis). One organization may offer both local and regional plans.

Although we have emphasized the additional benefits that we expect plans to be able to offer, the transition to a competitive bidding process more similar to that used by FEHB and large employers to obtain high-quality, stable plan participation should also help provide broader plan participation. As part of this process, Medicare has replaced the adjusted community rate process and its requirement that plan profit levels must be the same as for a plan's commercial product, and has

eliminated the limit on premiums related to reducing cost sharing for Medicare-covered benefits, plans can potentially manage their profit levels by developing more competitive benefit packages at a lower cost. Plans with bids exceeding the benchmark can also be assured of having adequate revenue to operate as Medicare plans (though they must offer sufficient additional benefits or quality to attract beneficiaries despite their higher premium). These provisions may also lend stability to the program in allowing plans to make adjustments to revenue needs from one year to the next without facing statutorily imposed limits on their ability to generate needed revenue.

There are a number of statutory and regulatory provisions which reduce burden on Medicare plans while maintaining and strengthening beneficiary protections, including the statutory changes that eliminated the reporting requirements relating to physician incentive plans, and the major changes in the quality assurance standards for plans. As discussed elsewhere, this rule also has several administrative changes that will reduce plan burden, including elimination of plan disclosure requirements that are redundant, and provisions that streamline the appeals procedure as regards notices to beneficiaries.

In terms of estimating the impact of these changes, the physician incentive plan (PIP) burden reduction was previously codified in the final rule entitled ''Medicare Program: Modifications to Managed Care Rules'' on August 22, 2003 and effective September 22, 2003. In the regulatory impact statement of that rule (68 FR 50853 and 50854) we stated: ''We find that overall the economic impact of this final rule is positive, due to...the reductions in regulatory burden due to...the reduction of the physician incentive reporting requirements...The data available do not allow us to determine the distributional effects...We have not considered alternatives to lessen the economic impact or regulatory burden of this final rule because the regulatory burden is reduced...'' We have no new data at this time that would alter the analysis and conclusions drawn in the prior rule.

With regard to the ''file and use'' policy, we are codifying in regulation a previously existing program tolerance which has been successful. The ''burden reduction'' actually associated with ''File and Use'' is minimal for two reasons. The first is that it represents a ''tolerance'' already in use; so additional burden reduction is non-existent. Second, File and Use is simply permission to publish (or use) certain marketing materials prior to CMS review and approval. To the extent that MA plans ''earn'' (or qualify for) File and Use status, the advantage gained and the burden reduction available to them is that MA plans qualifying for File and Use will not need to wait for CMS approval prior to using specific marketing materials. Finally, CMS does not currently collect data nor does it have information on the distributional impact of the currently existing File and Use program, so it is impossible to project the precise impact that File and Use will have on organizations qualifying for it.

We remove certain plan disclosure requirements from § 422.111(f). These disclosure requirements all are information that MA organizations must provide ''upon request.'' We have no data that would help us quantify the actual level of burden reduction. Therefore, the level of administrative burden mitigation is likely negligible.

Other Effects. Although most Medicare health plans and organizations that can participate as MA plans stand to benefit from the MA provisions, Medigap insurers may face price pressures and see declining enrollment if MA enrollment increases to the level that CMS projects. It should be noted that many of the insurers that offer Medigap coverage are companies that also operate health plans and are already, or can become, local or regional MA plans.

Medicare Advantage PFFS plans are another class of insurer that may see changes in the competitive environment. To date, such plans have operated primarily in ''floor'' counties (counties in which, because of the BBA and BIPA payment rules, health plan payment rates are higher than estimated FFS Medicare costs). PFFS plans generally have not competed directly against coordinated care plans. PFFS plans offer generally less generous benefit packages than MA coordinated care plans (involving higher levels of cost sharing and premiums), but they do offer some level of supplemental coverage for individuals (including drug coverage in many such plans), and they offer an advantage that some beneficiaries prefer, which is that there is not a limited network of providers that must be used to obtain covered care. As a consequence of the MMA, where there are regional MA plans, regional plans are likely to have a competitive advantage over Medicare PFFS plans that had usually targeted areas in which there were no MA local plans. MA regional plans must offer coverage for out-of-network care, and they are likely to be able to offer a significant level of extra benefits because of the financial incentives in the MMA. (As stated elsewhere in the preamble, regional MA plans may not be PFFS plans; regional plans must operate as a PPO model.)

G. Effects on States

States may see benefits from Title II of the MMA if more Medicaid beneficiaries who are also entitled to Medicare A and B coverage (the dual eligible population) enroll in private Medicare plans. Because MA enrollees are likely to receive non-Medicare-covered benefits (such as vision care) as well as lower copayments for Medicare-covered benefits, dual eligible enrollees would receive benefits that the States would otherwise have had to pay for. States may benefit from reduction of the Part B premium which the State would otherwise pay for dual eligibles. It should be noted that to date, the enrollment level of dual eligibles in Medicare plans is not as high as it could be (see Edith G. Walsh and William D. Clark, ''Managed Care and Dually Eligible Beneficiaries: Challenges in Coordination,'' Health Care Financing Review, fall 2002, volume 24, number 1). A number of factors could contribute to greater enrollment of dual eligibles in MA plans: the extension of plan availability across an entire State (as part of a regional plan), the likelihood of Part B premium rebates (which the State would be entitled to), and the designation in the law of dual eligibles as a category for purposes of determining whether an MA plan is a specialized plan. Dual eligible individuals do not have the same incentives to enroll in MA plans as other low-income Medicare beneficiaries. In certain circumstances, a State may require the enrollment of dual eligibles in MA plans (if, for example, the plan is also a Medicaid health plan and the State has a waiver permitting mandatory health plan enrollment for Medicaid beneficiaries).

The direct effect on the States of the expansion of the premium tax prohibition is discussed in the section on unfunded mandates. The MMA changed the law to exempt from State premium taxes the premiums paid by beneficiaries, as well as Federal payments to plans (which the law already exempted). This provision by itself has a relatively minor effect on State revenues, given the prevalence of zero-premium MA plans and given the expected trend in MA benefit packages towards more zero-premium products. However, an indirect effect of the premium tax prohibition is that, to the

extent that there are reductions in the number of beneficiaries who hold Medigap policies, States may lose premium tax revenue that would have been derived from Medigap policies (the entire premium of which is generally taxed). As previously discussed, it is unclear what the impact will be if there is such an effect, given the trend of greater numbers of beneficiaries with Medigap coverage and rising Medigap premiums.

H. Effect on Employers and Unions as Sponsors of Retiree Coverage

Historically, Medicare-contracting health plans that contracted with employer or union groups to provide benefits had to comply with the same Medicare regulatory requirements that apply to all Medicare-contacting health plans. In 2000, section 617 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) added a new authority at section 1857(i) of the Act, effective 2001, that provided CMS broad authority to waive or modify requirements that hinder the design of, the offering of, or the enrollment in M+C plans under contracts between M+C organizations and employers, labor organizations, or the trustees of a fund established to furnish benefits to an employer's current or former employees or to a labor organization's current or former members.

Three types of waivers have been approved under the BIPA authority which are discussed in an August 22, 2003 **Federal Register** notice (68 FR 50845). The three types of waivers are: (1) M+C organizations are allowed to offer employer-only plans that are not open to individuals and plan marketing materials do not have to be submitted for CMS review and approval; (2) M+C organizations are allowed to ''swap'' benefits not covered by Medicare of approximately equal value when an employer asks for a benefit package different from what is offered on the individual market; and (3) M+C organizations are allowed to raise the co-payments for certain benefits but to provide a higher benefit level or a modification to the premium charged as long as projected beneficiary liability is actuarially equivalent. These waiver authorities also will continue for MA organizations.

Section 222(j) of the MMA adds another authority for employer or union sponsored plans, effective 2006, at section 1857(i)(2) of the Act CMS may waive or modify requirements that hinder the design of, the offering of, or the enrollment in an MA plan offered directly by an employer, a labor organization, or the trustees of a fund established by employers or labor organizations to furnish benefits to current or former employees or to current or former members of labor organizations. This authority is added in the rule at § 422.106(d). We have received a number of inquiries from employers and labor organizations expressing interest in this direct contracting option.

We believe that there is likely to be a significant increase in the number of retirees whose employer or union provides retiree coverage through an MA plan because of the additional payments MA plans will receive (so that benefits that otherwise would have been financed by the employer or union can be financed by Medicare payments), and because regional plans will be available that can cover wider geographic areas and meet the needs of employers with retirees residing throughout a large geographic area, or dispersed across many geographic areas.

As of January 2002, about 18 percent of enrollees in Medicare+Choice plans were employer- or union-sponsored retirees (see Geoffrey R. Hileman, Kerry E. Moroz, C. William Wrightson, and Suhn K. Kim, ''Medicare+Choice Individual and Group Enrollment: 2001 and 2002,'' Health Care Financing Review, fall 2002, volume 24, number 1). There are 1.1 million beneficiaries residing in counties in which only employer-sponsored retirees or dependents may enroll in MA plans operating in those counties. MA plans may find this particular market segment attractive for a number of reasons, including: the efficiency of marketing to a large group; the advantage of having a group will have been previously insured; and the ability of offering enrollees a seamless continuation of coverage between active worker status and retiree status. The regional PPO model may also facilitate the ability of plans to serve this population to the extent that retirees no longer reside near their place of work.

According to a 2003 Hewitt-Kaiser Family Foundation survey of large employers, 21 percent of employers with 1000 or more employees require new Medicare-eligible retirees to pay 100 percent of the plan premium. The survey also found that, with regard to future trends, ''Serious consideration is also being given to only providing access to health benefits and asking retirees to pay 100 percent of costs; 26 percent of firms said that they are very or somewhat likely to make such a change.'' (Frank B. McArdle, et al., ''Large Firms' Retiree Health Benefits Before Medicare Reform: 2003 Survey Results.'' Health Affairs, web exclusive, January 14, 2004.) MA plans are a likely vehicle for employers to offer health plans under these circumstances. In fact, the 2004 Kaiser/Hewitt Survey on Retiree Health Benefits report indicates the continuing trend of having retirees pay 100 percent of their premiums and also shows that, among the changes large private sector employers made in 2004, ten percent of such employers are offering MA plans (the report is available at *http://www.kff.org/medicare/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=49652*; see in particular exhibit 22, at page 53). These trends would suggest that we will see an increase in MA enrollment of retirees with employer group or union-sponsored coverage (for beneficiaries of both types, those for whom the sponsor contributes to the cost of the coverage and those whose coverage involves only an offering of coverage).

I. Effect on the Federal Government

The benefits to beneficiaries and private health plans are the result of transfer payments from the Federal Government to plans, or, in the case of reductions in the Part B and Part D premiums, transfer payments to beneficiaries. For the period 2004 through 2009, the total amount of such transferred funds is projected to be $18.3 billion above what would otherwise have been incurred in the absence of the Title II provisions of the law. The preceding figure assumes a private plan penetration rate of 24 percent by 2009. The total expenditure figure assumes that $5.1 billion of the stabilization fund dollars for regional MA plans are used in the period 2004 through 2009. We have not separately projected an administrative cost to the Government for the administration of Title II of the MMA separate from administration of all portions of the MMA taken together.

There were several issues with a potential budgetary impact that were discussed in the notice of proposed rule making. The section on alternatives considered in the proposed rule examined the impact on expenditures in choosing between statewide and plan-specific risk adjustment to determine rebate amounts (beginning at page 46942). The conclusion of that analysis was that expenditures under either approach (plan-specific or area-wide) depended on the risk profile of plan enrollees, and that it was not possible to quantify the effect: ''Wide swings in the level of rebate dollars are possible under either method, but we cannot quantify the effect at this time without knowing the risk distribution of enrollees for

2006 and the respective bids of the health plans.'' As discussed in the preamble, in part as a reflection of comments received, CMS has chosen the plan-specific option. (See the preamble of the final rule and the alternatives considered section of the proposed rule, previously cited, for a discussion of the considerations that led to this decision.)

Another issue that has an effect on expenditures is the payment adjustment relating to risk adjustment for bids that exceed the benchmark. The regulatory text at § 422.308(e), discussed in subpart G of the preamble, would implement section 1853(a)(1)(G) of the Act, which requires CMS to make certain plan payment adjustments to take into account the health status of a plan's enrollees. For plans bidding above the benchmark, this provision would allow the total revenue a plan receives for its actual enrollees to more closely match the plan's required revenue. The 1853(a)(1)(G) provision requires CMS to adjust plan payments in recognition of the amount that a health plan receives as a basic premium from its enrollees. The basic member premium that plans actually will charge is the premium for a ''1.0'' beneficiary-that is, it is determined based on the revenue needs for a person with average health status. For a plan with a risk score above 1.0 (that is, the plan has enrollees that are sicker than average and utilize more services), there would be an additional payment from Medicare to provide the plan with revenue that covers the shortfall between the basic premium determined for a 1.0 enrollee, and the actual revenue necessary from member premiums. (Under the current system, but not after 2005, in such a case enrollees would be charged a higher plan premium to cover the needed revenue that matches their enrollees' actual utilization patterns.)

A similar adjustment would be made for plans with risk scores below 1.0. A plan with a risk score below 1.0 would have determined its basic premium for a 1.0 person, and enrollees will be charged that level of premium. This provides the plan with more revenue than it needs. Consequently, the section 1853(a)(1)(G) provision would call for a reduction in Medicare's payment to the plan in recognition of the additional revenue that comes from member premiums that are determined for a 1.0 beneficiary.

The budgetary impact of this provision depends on the number of plans that would have bids above the benchmark, and the health status of enrollees in such plans. One would assume that the majority of organizations deciding to enter the Medicare market would like to be able to offer extra benefits at no cost, or at little cost, to prospective enrollees. Therefore there may be few plans that bid above the benchmark, and those that do so would try to limit the basic premium to an amount that would attract a sufficient number of beneficiaries. However, bids above the benchmark may arise (a) in certain areas-for example, in areas where there may be only one or two plans, or (b) in certain competitive situations-for example, when the reason for a bid above the benchmark is that the plan offers coverage that is expensive but has features that appeal to beneficiaries (such as a wide network of providers, particular ''marquee'' providers in the network, especially lower copayments, or generous out-of-network coverage).

With respect to the risk profile of plans that may be bidding above the benchmark, currently private plan enrollees are somewhat healthier on average than Medicare beneficiaries in traditional FFS. If plans bidding above the benchmark have healthier-than-average enrollees, the budgetary impact of the 1853(a)(1)(G) provision would actually be net program savings as beneficiaries bear some extra cost in their plan premium. If today's patterns of enrollment continue, there may be such program savings: looking at the subset of plans that currently charge a premium for Medicare-covered services compared to plans that have no premium charge for Medicare-covered services (a rough type of proxy for determining whether a bid will be above the benchmark), the risk status of enrollees of plans in which there is no premium is below 1.0 but closer to 1.0 than among plans charging a premium. The latter group of plans have risk scores that are also below 1.0, but the risk scores are about 10 percent lower-that is, risk scores show that enrollees are healthier-than the risk scores of plans that have no premium charge for Medicare-covered services.

On the other hand, as Medicare increases the proportion of plan payments that are risk-adjusted to 100 percent, plans will have even greater financial incentives to offer benefit packages that appeal to less healthy beneficiaries. Consequently, moving to full risk adjustment would be expected to lead to a reduction of any differences in health status in MA plans, including the higher-premium plan.

In summary, the 1853(a)(1)(G) risk adjustment provision, which may have limited applicability if few plans bid above the benchmark, may result in program savings.

J. Administrative Costs

The expenditures shown in Table 1 include administrative costs for MA plans. For both local and regional plans, administrative costs are assumed to comprise ten percent of the total incremental expenditures shown in Table 1. This includes both costs to administer the program and the profit or retained earnings of health plans. Administrative costs for local plans and regional plans are considered to be roughly the same based on the reported administrative costs of current MA plans that are PPOs and HMOs.

K. Analysis of Effects on Small Entities

The Regulatory Flexibility Act (RFA) requires us to determine whether a rule will have a ''significant economic impact on a substantial number of small entities.'' If so, the RFA requires that a Final Regulatory Flexibility Analysis (FRFA) be prepared. Under the RFA, a ''small entity'' is defined as either a small business (as defined by the size standards of the Small Business Administration, or SBA), a non-profit entity of any size that is not dominant in its field, or a small governmental jurisdiction. The SBA size standard for ''small entity'' health insurance plans is annual revenue of $6 million or less.

The direct effects of Medicare Advantage fall primarily on insurance firms and on individual enrollees. The competitive market created by Medicare Advantage is likely to have long run indirect effects on health care providers, such as hospitals, physicians, and pharmacies, depending on the extent to which MA plans attract enrollees. However, those effects will result from the workings of market choices made by enrollees, plans, and providers, not from specific provisions of this rule. (There is an MMA provision for paying certain ''essential hospitals'' higher rates for participation in the MA program, which we analyze below.) Therefore, we primarily analyze effects on the insurance industry (including HMOs as insurers) in this FRFA.

We do not believe that these rules will create a significant economic impact on a substantial number of small entities. We have prepared the following analysis in part to provide a factual basis for our beliefs regarding the impact of this regulation on small entities; we also consider this analysis a voluntary FRFA. Under longstanding HHS policy we prepare a FRFA if significant impacts of a rule on small entities are positive rather than negative. We also prepare a FRFA if we cannot be certain of a conclusion of no ''significant impact'' on less than a

''substantial number.'' In this case, the statutory reform is so major and the number of regulatory changes so large that we cannot be certain of our conclusion. Finally, we generally prepare a FRFA if there is likely to be substantial interest on the part of small entities. Essentially all of the insurance firms affected by the statute and this final rule exceed size standards for ''small entities'' within the meaning of the RFA and implementing SBA guidelines, which state that an insurance firm is ''small'' only if its revenues are below $6 million annually. We note that under prior law (continued unchanged for Medicare Advantage), no health insurance plan is normally eligible to participate in Medicare Advantage unless it already serves at least 5,000 enrollees, or 1,500 enrollees if it primarily serves rural areas. At the 5,000–enrollee level, no plan would fall below the SBA revenue cutoff assuming, very conservatively, yearly revenue of $2,000 per enrollee. While a very small rural plan could fall below the threshold, we do not believe that there are more than a handful of such plans. In the InterStudy Competitive Edge HMO Directory for 2000, discussed below, we found only one rural HMO with a continuing enrollment level below 1,500. Therefore, the statutory limits generally prevent any insurance firm defined as ''small'' pursuant to the RFA's size standards from participating in the program. However, a substantial fraction of the insurance firms affected by this final rule are ''small entities'' by virtue of their non-profit status. The analysis in this section, taken together with the other regulatory impact sections, and the preamble as a whole, constitute our FRFA for the Medicare Advantage provisions of Title II of the MMA. We note that there is a related FRFA in the companion final rule on the Part D Drug Program of Title I of the MMA.

1. The Health Insurance Industry

The 1997 Economic Census: Finance and Insurance (the latest available edition when the proposed rule was being developed) states that there were 944 firms classified as ''Health and Medical Insurance Carriers'' under the North American Industry Classification System. Of these, 851 firms operated the entire year. Using Census data, these firms had total revenue of $203 billion, operated through about 3,200 establishments, and had about 328,000 employees. Of the 851 firms that operated the entire year, 342 had revenues of less than $5 million. Taking into account subsequent inflation, this corresponds closely to the $6 million threshold established by the SBA as the current cutoff for small businesses in this insurance category. Thus, approximately 40 percent of the industry as counted by the Census is ''small'' using the SBA definition. These small firms had total revenue of about $440 million, rather less than one half of one percent of total health insurance revenue. As discussed below, we do not believe that any of these small firms underwrite comprehensive health insurance policies, or are actual or potential participants in the Medicare Advantage market.

In contrast, the Census found that the largest 50 firms, or 6 percent, accounted for 75 percent of all health insurance revenue. While these data cannot be reconciled directly with other statistics on numbers and size of health insurance companies, they clearly indicate that the market for comprehensive health insurance policies, covering the lives of about 200 million Americans, is dominated by several hundred companies, few of which, and most likely none of which, are ''small'' by SBA revenue standards.

Another source of industry data, much richer in detail, is found in the InterStudy Competitive Edge. This annual report covers only HMOs. The discussion that follows uses the 2000 edition as reflecting most of the changes of the 1990s, but still close enough in time to the Census information to be roughly comparable. In 2000, there were 560 HMOs. While these were all separately incorporated, many were subsidiaries of larger corporations. For example, the report lists 40 United HealthCare plans, 22 Aetna and 32 Prudential plans (all owned by Aetna), 31 Cigna plans, 10 Humana plans, and 9 Kaiser plans. Ninety-seven of these HMOs enrolled 200,000 or more people (enrollment is a standard industry measure of size). The InterStudy data, using an enrollment cutoff of 3,000 to correspond roughly to the SBA $6 million threshold, shows that only 5 HMOs were continually operating entities (not entering or exiting the industry) with revenues below the SBA small entity threshold.

Of the approximately 200 contracts under the current MA program (this figure excludes demonstration contracts), only a handful have enrollment of fewer than one thousand or annual Medicare revenue of under $6 million assuming, conservatively, revenues of $6,000 per enrollee (Medicare enrollees cost, and are reimbursed, more than double working age persons). Of course, these plans have other revenues from non-Medicare clients, and we are unaware of any current MA organizations with revenues below the SBA threshold. (Note that the number of current MA contracts includes separate Medicare contracts held by a single firm in different parts of the country-as in the case of PacifiCare, for example, which has ten contracts in eight States.)

These data show that few, if any, health insurance firms with revenues of $6 million or less underwrite comprehensive insurance in the national insurance market. Furthermore, discussions with Bureau of the Census staff indicate many and probably most of the small firms classified as insurers do not underwrite health care costs (that is, provide comprehensive health insurance), but are firms offering dental or medical discounts through small provider networks or offering indemnity-type policies paying, for example, a few hundred dollars a day for each day spent in a hospital. They would not even be licensed by States to offer comprehensive or group insurance policies. Therefore, we have no reason to believe that the changes to the Medicare Advantage program that will take effect for the 2006 contract year will have any positive or negative effect on ''small'' insurance firms, with the possible exception of Medigap insurers.

Some of these small firms may be Medigap insurers. For this limited group, the MMA has major consequences. Specifically, existing categories of Medigap policy that cover prescription drugs will become illegal to sell to new enrollees, and several new Medigap categories will be created. (These changes, however, are specified in the statute and are not subject to regulatory discretion.) Furthermore, Medigap insurance is a unique type of product that does not involve accepting insurance risk for the full cost of health benefits, since Medicare itself remains the primary insurer. Therefore, it is unlikely that any consequential number of firms operating solely in the Medigap market would expect to operate in the Medicare Advantage market. Effects of the MMA on Medigap are discussed in more detail the economic effects analysis in the companion Title I rule.

The definition of small entities under the RFA also encompasses not-for-profit organizations that are not ''dominant'' in their field. (HHS interprets ''dominant'' to mean national dominance.) There are many large HMO companies that are non-profit. As of 2000, about 37 percent of HMO enrollment was in non-profit firms, and 152 of 558 HMOs, or 27 percent, were non-profit (InterStudy Competitive Edge HMO Industry Report for 2000). None of these firms is nationally ''dominant'' in

the health insurance industry although many firms achieve large market share in particular health care markets.

About half of these firms already compete in the Medicare MA market, and most are potential entrants or re-entrants as Medicare Advantage plans. According to the InterStudy data, about one third of HMOs currently participating in MA are non-profit. Some HMOs, profit or non-profit, may be potential entrants in the new regional MA markets. This will partly depend on how rapidly the non-profit firms grow by merger or make other market adaptations, such as adding PPO networks. However, relatively few HMO plans (in contrast to parent company or linked HMOs), operating through local HMO networks, are likely to be able to compete in a region encompassing large areas or several States and multiple health care markets.

2. The Local Medicare Advantage Market and Small Entities

Under MA, there are two distinct (though overlapping) markets: local and regional. All existing MA HMO plans participate on a local area basis, typically covering the several counties encompassed in a metropolitan area. Because HMOs are most common in metropolitan areas, and especially in the largest metropolitan areas, existing plan availability and enrollment is concentrated in these areas. As discussed previously in this analysis, only about one fifth of U.S. counties, though over 60 percent of the eligible population, have an MA coordinated care plan available. The MMA makes one major change for local plans by significantly improving payment rates. This statutory change is already in effect and is not addressed in these rules. These rules will have beneficial effects on local plans, by reducing some administrative burdens, but the changes in this final rule, singly and collectively, do not rise to the level of ''significant economic impact'' on local HMOs (though the payment increases in 2004, already in effect as a result of the statute, did have an effect of that magnitude).

The other major changes of Medicare Advantage include the creation of a new regional plan structure to become operational in 2006, designed for and limited to PPO plans. The regional structure is intended to ensure that the entire beneficiary population, not just those residing in major urban centers, has access to alternative plans. As discussed elsewhere in this analysis, we assume that as a result of these changes private plans may attract as much as one-third of all Medicare enrollment by 2016.

Starting in 2006, local HMOs will face two new sources of competition. First, they will find themselves seeking to attract enrollees from a pool of eligible applicants who will now have Part D drug benefits as enrollees in FFS Medicare. Second, they will be competing against regional MA plans serving their areas. Regional plans will have some advantages specified in the statute, including access to the stabilization fund and, temporarily, to risk sharing with the government. It is possible that some existing local plans will lose some enrollment. The local HMOs will, however, have important assets including integrated benefit packages (as compared to free-standing PDPs), quite likely drug benefits at premiums lower than PDP premiums, and extra benefits (including rebates of the Parts B and D premiums) not available in FFS and possibly more generous than those available in regional MA plans. The local plans will have an existing customer base and pre-existing networks in the areas where most beneficiaries live. Most compete in major metropolitan areas where Medicare payment rates are higher than in other areas that a region would encompass. Finally, many and perhaps most local plans are subsidiaries of large insurance firms that offer multiple product lines. These firms retain the ability to ''mix and match'' their product offerings to best advantage. Regardless, whether and how much any given plan loses or gains will primarily depend on its overall attractiveness (benefits, services, provider panels, out of network benefits, and premiums) compared to its competitors. Nothing in these rules, as such, either favors or disfavors local plans when competing against regional plans.

While it is impossible to predict the precise situations that these HMOs will face, or their responses, there are some lessons available from the FEHB Program experience. In that program, about 200 local HMOs co-exist in competition with about a dozen national PPO plans. Most HMOs compete in big city markets against 15 or 20 plans, both PPO and HMO. While HMO enrollment in the program has declined slightly in recent years, and almost half of all HMOs have left the program since their peak participation in the early 1990s (reflecting mainly industry consolidations), HMOs currently enroll about 35 percent of all Federal employees, and 9 percent of retirees, down only slightly from the peak levels of 39 percent and 10 percent, respectively, a decade ago.

3. The Regional Medicare Advantage Market and Small Entities

Starting in 2006, health insurance firms both profit and non-profit (and hence ''small entities'' under the RFA) will be able to compete as regional plans. A firm may compete in as many regions as it chooses, up to and including the entire nation. The chief constraint is that a plan must demonstrate that it has a region-wide network of providers.

We know of one group of potential regional competitors who may be affected by regional boundary decisions-insurance plans that operate on a state-specific basis, notably Blue Cross/Blue Shield plans. In recent years many Blue Cross/Blue Shield plans have merged within and across State lines. However, there still remain several dozen of these plans that operate on a state-delineated basis. The regional MA boundaries established in December, 2004 attempt to accommodate these and other plans that face significant practical constraints in operating across state line. Of course, many considerations affected decisions on regional boundaries, including beneficiary access, viable economic size, and existing medical and PPO markets. Our primary objectives were to give all Medicare beneficiaries the opportunity to enroll in an MA plan, to give them the greatest amount of choice by encouraging competition, and as a result to provide price competition and affordable costs for enrollees. These considerations, and the resulting boundary decisions, are described on the CMS Web site at *www.cms.hhs.gov/medicarereform/mmaregions*.

A local plan may encompass all or most of a State, and/or operate in more than one State if it so chooses. Of course, regional plans have some advantages, but local plans have others. Since the statute preempts State standards for benefits, coverage, and provider networks, leaving effectively only licensure and solvency standards as State-imposed requirements, we anticipate no important problems for plans (though regional plans may have to seek licensure in States in which they currently do not operate, or would have to seek a waiver as permitted by the MMA). There is another problem that could be important to a plan far larger than the SBA size standard but nonetheless smaller than the plans serving hundreds of thousands or millions of enrollees. Organizing the full resources needed to compete effectively in the Medicare context will require substantial investments in acquiring and maintaining actuarial expertise, legal expertise, effective marketing, network

building, benefit design, cost-control, disease management, formulary design, claims processing, financing, and so forth. There are economies of scale in health insurance (like many other businesses), and these presumably favor larger firms, all other things equal, up to some point. We are not aware of any industry studies that seek to measure the minimum size necessary for health insurance firms to compete effectively in local, regional, or national markets and request information on this question. However, to the best of our understanding any such barriers to entry or cost competitiveness are likely to fall well within the size of most firms competing today in such large systems as M+C, the FEHB Program, or the private employer market. In summary, the MA program, by having both a regional and local model, provides opportunity for health insurance entities of all types and most sizes (but probably not below the ''small'' insurance entity cutoff level defined by the SBA, which is lower than appears viable for a comprehensive, risk-bearing insurance plan), and offering many different kinds of plans, to participate. That participation is more likely to take the form of local plans in the case of smaller and non-profit entities. However, the overriding objective of the regional plan model is to give beneficiaries access to and choice among integrated private plans that can offer comprehensive health insurance encompassing Medicare parts A, B, and D. This model is dictated in almost all its important details in the statute.

Comment: Several commenters felt that the impact analysis did not discuss the negative impact on local MA plans of having to compete with regional plans, which have various financial incentives to ensure participation. For example, local plans operating in a rural area would be at a disadvantage because their benchmarks could be lower than the benchmarks applying to regional plans. The commenters also suggested that CMS work with the Department of Justice and the Federal Trade Commission to ensure that anti-competitive practices are not permitted, given that the MMA creates new health insurance markets with participating plans that, the commenters state, would have the market power to unfairly limit competition.

Response: As we noted above in response to another comment regarding how to classify plans as local or regional, in order to address the issue of limited access to coordinated care plans in rural areas, the MMA has created the MA regional plan option, which is likely to be an option that is primarily offered by larger health plans or insurers. In the year 2003, only about 13 percent of Medicare beneficiaries residing in rural areas had access to a Medicare coordinated care plan. That is, only 13 percent of the rural population was served by a local coordinated care plan. If the MMA is successful in the goal of expanding access to rural areas, ideally 100 percent of rural enrollees will have access to a coordinated care plan because of new regional MA option.

The manner in which the MMA seeks to expand access to coordinated care plans in rural areas involves certain incentives for plans willing to participate under the terms set out by the law, and it involves certain ''trade-offs'' that were felt necessary to ensure participation. One such trade-off is the willingness of the Congress to increase payments through the use of the stabilization fund in order to ensure maximum access to MA plans across a wide geographic area. Only plans that are willing to serve a wide geographic area have access to the stabilization fund. Local plans do not have access to the fund, unless they are willing to participate as regional plans. Similarly, regional benchmarks may be higher than local benchmarks in certain areas. However, organizations for which a regional benchmark applies are assuming risk for a large population across a wide geographic area, must offer a uniform benefit package across the entire area, and cannot selectively discontinue contracting on a county-by-county basis (or even selectively drop portions of counties, as local plans are permitted to do under certain circumstances). Regional plans are required to operate as preferred provider organizations throughout a large service area. Requiring plans to operate under such a model, as opposed to a more tightly knit network model, would tend to raise costs for the plan and would result in a lower level of extra benefits for enrollees. The PPO model also adds to the level of risk assumed by the health plans because of the uncertainty surrounding the utilization and costs for out-of-network services that such plans must reimburse.

As we have stated above, we would hope that there is room for competition to occur in all types of areas of the country between local plans and regional plans. With regional and local plans each having some advantages, and open competition among multiple plans of each type expected in most areas, we cannot predict likely ''winners.'' Our expectation is that plans of both types will succeed in most areas.

With respect to anti-competitive practices, CMS has worked with the Department of Justice and Federal Trade Commission in the past on competition issues in the provider and health plan markets, and we will continue to work with those agencies in the future.

4. Hospitals

An additional program under Medicare Advantage directly affects hospitals. HHS has long taken the approach of treating all hospitals as presumptive ''small entities'' within the meaning of the RFA, mainly because of the dominance of the non-profit model in the hospital industry (about 80 percent) and also because most of the rest have revenues under the $29 million SBA size threshold for hospitals.

The MMA facilitates the inclusion of hospitals in regional networks in cases in which a plan and a hospital cannot reach agreement regarding the hospital's provision of services under the plan. As described in more detail under the Subpart C preamble section, if the hospital's participation is ''essential'' to meeting a plan's network adequacy requirement, and the hospital can demonstrate to us that its costs are higher than the normal Part A payment it receives, then the MA plan can pay the normal amount and the network adequacy fund will pay the difference. The total amount available nationally for this purpose is $25 million in 2006 (rising annually at the hospital market basket rate).

This provision will most likely apply to small towns and rural areas, particularly if such areas are served by only one hospital. It is impossible at this time to predict the frequency with which this situation will arise, since that depends on future bargaining among plans and hospitals, and on hospitals' ability to demonstrate excess costs. Since the hospitals benefiting would otherwise serve Medicare enrollees at Medicare rates, the financial effects of this program on hospitals should never be negative, and qualifying hospitals will obtain higher payments. Likewise, by allowing regional plans to meet their network requirements at a reasonable cost the effects on them are positive. We note that over 700 rural hospitals are already paid at rates somewhat higher than would otherwise be applicable under Medicare's hospital payment rules. Some of these would be candidates for ''essential'' hospital payments (although the eligibility criteria are different). Although there are 700 such hospitals, they are small hospitals in sparsely inhabited rural areas and account for only about one

percent of Medicare hospital payments. The pattern under the essential hospital program is likely to be similar.

5. Medical Savings Accounts

These regulations also change the rules for Medical Savings Accounts (MSAs), which are high deductible plans. This provides new opportunities for insurance firms to participate in Medicare Advantage. High deductible plans are increasingly being offered in the under age 65 market by large insurance firms. As discussed previously in this Preamble, we are implementing the statutorily defined changes (at section 233 of the MMA), which are intended to make MSAs a viable option for beneficiaries. We are also amending the existing rules in several places to remove requirements that would be inappropriate if applied to MSAs.

6. Employer Sponsored Plans

The MMA adds new authority for employers and unions to sponsor plans for their employees and former employees, or members. Previously they could sponsor plans through an M+C organization; the statute gives them the flexibility to sponsor plans directly. The statute and the regulation provide for waiver or modification of any requirement under Part C or Part D that would hinder the design of, the offering of, or the enrollment in employer or union-sponsored plans.

7. Other Requirements in the Regulatory Flexibility Act

The RFA lists five general requirements for a FRFA and four categories of burden reducing alternative to be considered. It also defines as a small entity a ''small governmental jurisdiction'' whose area has a population of less than fifty thousand. We anticipate no consequential effects of these regulations on small governmental jurisdictions. We know of no relevant Federal rules that duplicate, overlap, or conflict with the rule (which in any event amends an existing rule that is not duplicated or overlapped by other rules). The analysis above, taken together with the rest of this preamble, addresses all these general requirements.

We have also sought both to avoid imposing new burdens, and to ameliorate existing burdens, as discussed throughout this analysis. Throughout this preamble we identify a number of changes that would lessen the burden of the existing MA rules.

Comment: In response to our desire to know of any small businesses or entities affected by these regulations whose concerns might not have been addressed, a number of commenters stated that CMS failed to address issues related to the health care needs of AI/AN.

Response: This concern is addressed in various sections of the preamble language dealing with specific issues as they relate to AI/AN (specifically in subparts A, B, C and F). As noted in those sections, where the statute permits us to do so, we have taken into consideration issues raised by commenters having to do with the special needs of AI/AN populations, their use of IHS providers and the reimbursement rules and cost sharing requirements for such providers, and outreach issues related to such populations.

The preamble to subpart A addressed the comments asking (1) that IHS services be included within the definition of basic services; (2) that we include as SNPs those plans that would enroll only AI/AN beneficiaries; and (3) that we recognize that IHS, I/T/U Programs will face high costs related to outreach, education and enrollment because of the MMA. As stated in the preamble, we are unable to accept the commenters suggestions for the first two issues because there is no statutory authority to expand the definition of basic services as suggested, and there is no statutory authority for establishing AI/AN special needs plans. With regard to the third issue, we recognize this concern and state that we will continue to work with the IHS and other partners in identifying effective outreach and education strategies appropriate to AI/AN populations.

Comments on subpart B asked that (1) we make exceptions for AI/AN beneficiaries when plans are closed for enrollment because of capacity waivers; (2) allow AI/AN beneficiaries to switch among types of plans outside of open enrollment periods; (3) have plans contact I/T/U if a plan intends to involuntarily disenroll an AI/AN enrollee; and (4) specify that outreach workers employed by IHS or tribal organizations not be prohibited from going door-to-door to assist AI/AN individuals in making health plan choices because of the prohibition on door-to-door marketing. With regard to the first item, we do not believe it is appropriate to have exceptions to capacity waivers for particular categories of individuals because of the nature of capacity waivers, which are granted when an organization establishes that its provider network capacity is such that enrollment must be limited to a certain number of individuals. With respect to SEPs, the subpart B preamble language explains that specific SEPs are included in regulations if they are based on statutory provisions. Periodically, we establish SEPs based on special circumstances, and there may arise situations in which AI/AN populations may be subject to SEPs. On the question of involuntary disenrollment, the preamble states that the notification is to the individual who is the subject of the proposed disenrollment, and that to bring in other parties would be beyond the scope of the statutory provision. With regard to the prohibition on door-to-door marketing, the preamble notes that we understand this concern and will work with the IHS and tribal organizations to address the concern.

Subpart C comments included requests that there be rules requiring ''full reimbursement'' of IHS facilities and that there be a blanket waiver of cost sharing requirements for AI/AN enrollees of MA plans. Neither of these requests is possible within the scope of the statute. However, the rules that apply, for example, to non-network providers and the amount that must be paid to such providers, apply to IHS providers. With regard to cost sharing, although blanket waivers are not permissible, under current law and regulations cost sharing can be waived in individual cases under certain circumstances.

The subpart C preamble also discusses a comment asking that we use the waiver authority of section 1857(i)(2) of the Act, as expanded by section 222(j)(2) of the MMA, to permit direct contracting with I/T/Us to sponsor MA plans exclusively designed for AI/AN beneficiaries. As stated in the subpart C discussion, the waiver authority applies only to employer- or union-sponsored health plans.

In the subpart F preamble we note that we are considering possible options to facilitate the ability of AI/AN Tribes to use the option of allowing groups to pay the part B premium for individuals, which is suggested as a means of making it more likely that AI/AN beneficiaries will enroll in MA plans.

L. Alternatives Considered

In this section we discuss the impact of several issues in which we have made a choice among various policy options. We refer readers to the Notice of Proposed Rule Making, and other documents available from CMS, for a fuller discussion on the issue of the designation of regions. Readers are referred to the NPRM for a discussion of the effect of our decision to use a plan-specific versus statewide, area-wide or region-wide risk adjustment to

determine plan rebates, and the effect of the payment adjustment relating to risk adjustment for bids that exceed the benchmark. Below is a discussion of the impact of our decision regarding the determination of the actuarial value of Medicare cost sharing as part of a health plan's bid, as well as a discussion of the potential impact of different approaches to intra-area geographic adjustment of payments when plans serve more than one county.

Designation of Regions

The impact analysis for the proposed rule of August 3, 2004, noted that a major area in which CMS was given discretion was in the matter of designating the configuration of MA and PDP regions. The proposed rule impact analysis included a discussion of some of the issues related to the designation of MA regions (69 FR 46937). On December 6, 2004, CMS announced the MA and PDP regions. The listing of the regions and material discussing the rationale for choosing the regions can found at *http://www.cms.hhs.gov/medicarereform/mmaregions/*. That site also contains links to sites containing research findings related to the designation of regions, and information concerning public meeting that were held on the subject of the regions (for example, *http://www.cms.hhs.gov/medicarereform/mmaregions/All_Info_Materials.pdf*). The impact analysis of the companion Title I final regulations contain an explanation of why there is a larger number of PDP regions than MA regions.

As we have discussed in the explanation of projections, the enrollment and expenditure figures of Table 1 represent our best estimate of the effects of the law and regulations based on the regions as they have now been designated. The proposed rule assumed 15 regions, but with a greater number of MA regions, there is likely to be a smaller level of enrollment in regional plans.

Plan-Specific Versus Statewide, Area-Wide or Region-Wide Risk Adjustment to Determine Plan Rebates; Payment Adjustment Relating To Risk Adjustment For Bids That Exceed The Benchmark

As noted previously in section I (Effect on the Federal Government), these issues were discussed at length in the proposed rule, with the conclusion being that the impact could not be quantified without knowing the risk distribution among the plans and their bids. Another issue that has an effect on expenditures is the payment adjustment relating to risk adjustment for bids that exceed the benchmark, previously discussed in section I, Effect on the Federal Government.

Actuarial Value of Medicare Cost Sharing as Part of Bid

As explained in the preamble of this final rule in the discussion of subpart F, a number of alternatives were considered in determining how to compute an actuarially equivalent value of Medicare cost sharing as a component of a plan's bid for the basic Medicare benefit package (coverage of Medicare A and B services). Under the provisions of section 1854(a)(6)(A)(ii)(I) of the Act, one component of the bid is the proportion of ''such bid amount.attributable to.the provision of benefits under the original Medicare fee-for-service program option (as defined in section 1852(a)(1)(B)).'' Under section 1852(a)(1)(B), ''benefits under the original Medicare fee-for-service program'' are defined as ''those items and services (other than hospice care) for which benefits are available under parts A and B to individuals entitled to benefits under part A and enrolled under part B, with cost-sharing for those services as required under parts A and B or an actuarially equivalent level of cost-sharing as determined in this part.'' A number of alternatives are discussed in the preamble of the final rule and the proposed rule under subpart F.

One alternative discussed would use a plan-specific determination of cost sharing which would have included a computation of any induced demand resulting from reduced cost sharing. That is, for purposes of comparison to the benchmark, a bid would have been made based on the cost sharing structure of FFS Medicare. To the extent that the Medicare cost sharing structure acts as a limit on utilization, a plan would require less revenue to provide Medicare A and B services as compared to a benefit package with a cost sharing structure less restrictive than that of FFS Medicare (the extreme case being, for example, a benefit package with no cost sharing on Part A and B benefits). The former, lower amount-the bid based on Medicare cost sharing-would be the amount to be compared to the benchmark to determine whether there were any savings that would be retained by the Government (25 percent of the savings, for local plans) or which would have to be passed on to the plan's enrollees (75 percent of the savings). If an organization decided to offer a benefit package with, for example, no cost sharing for Medicare-covered services, the proposed rule suggested that the supplemental benefits associated with such a benefit package would include not only the dollar value of reduced cost sharing (that is, the charges that would otherwise be the responsibility of the beneficiary are borne by the health plan), but also the dollar value of any additional utilization of Part A and B services which would not have arisen if there had been a Medicare-like cost sharing structure. In other words, because the benefit package being offered is ''richer'' or more costly than the benefit package that the Government asks plans to bid on (the Medicare Part A and B package with a specified level of cost sharing), one hundred percent of that cost must be borne by the plan and/or its enrollees. The cost to the beneficiary of such a package could be reduced by available rebate dollars, but the computation of the total rebate dollars would be based on a comparison between the benchmark and the plan-specific determination of the presumably lower-cost ''benefits under part A and.part B, with cost-sharing for those services as required under Parts A and B.''

The alternative chosen-which is to use a proportional method to determine the actuarial value of cost sharing for Part A and B services associated with a bid-does not involve a determination of induced utilization. The proportional method assigns cost sharing values to a bid in manner that is intended to closely approximate Medicare FFS cost sharing with respect to the expenditures for services that would be plan expenditures versus those (the cost sharing) that are beneficiary expenditures. It is not entirely clear whether having chosen this method rather than the plan-specific approach has the effect of reducing the amount of savings the Government would have retained. And if there is such a difference, we do not believe we are able to provide a reasonable dollar estimate of the effect.

With regard to whether induced demand is an issue that would affect the determination of Government savings as just described, a number of commenters stated that induced demand does not arise in managed care plans because utilization is limited to necessary and appropriate services through the plan's utilization management practices. That is, changes in cost sharing would neither reduce nor increase utilization; they would only shift the source of provider revenue from the plan to the enrollee. As discussed in the preamble, this argument may be clearer for hospital services received through a plan, when discretionary hospitalizations may be limited because physicians admit patients, but for other service such as specialist physician services in ''open access'' plans there

would presumably be a utilization effect if, for example, copayments for specialist physician visits are far higher than copayments for primary care providers and a beneficiary is making a choice between visiting a specialist versus a primary care provider.

As we note in the preamble, CMS will continue to examine the issue of the relationship between cost sharing and plan bids, and we may refine our approach in the future.

Geographic Adjustment of Payments

Subpart G of the preamble contains a discussion of the manner in which we will implement the geographic adjustment of payments called for in section 1853(a)(1)(F) of the Act ''to take into account variations in MA local payment rates under this part among the different MA local areas.'' Under the bidding system effective in 2006, variations in payment rates among counties have to be taken into account through an adjustment process that is somewhat different from what occurs today when Medicare Advantage plans operate in more than one county. As previously noted, we will be using a geographic adjustment based on county-level MA payment rates, but will allow regional MA plans, on a case-by-case basis, to request to have their payments geographically adjusted at the county level using a plan-determined statement of the relative costs the plan faces in different counties for the provision of Medicare-covered services. What follows is a general discussion of the two methods and the possible budget implications of one method versus another.

Under the system in use in 2005 (as in prior years), the ''geographic adjustment'' consists simply of paying the county MA rate adjusted by the demographic and risk characteristics of the individual beneficiary. To the extent that a plan's health care expenditures vary by county, this method of ''geographic adjustment'' entails a certain level of risk for a health plan with respect to any unanticipated costs incurred for (a) the provision of Medicare A and B benefits, to the extent that the plan's costs of providing A and B benefits vary from county to county, and (b) the provision of required extra benefits to the extent that the cost of such benefits vary by county, or-what is more likely-to the extent that the Medicare A and B cost and revenue projections, which form the basis of the determination of savings and the valuation of extra benefits, vary from actual A and B costs and revenues because of the actual enrollment distribution. The geographic adjustment system of 2006 and thereafter will have a different budgetary impact because of the manner in which rebates are paid for, and the impact may differ from today's methodology depending on the method used to accomplish the geographic adjustment.

Today's method of ''geographic adjustment'' is illustrated in Table 2. In this example, an organization is operating in three counties with the same benefit package offered in all counties. The first section of Table 2 shows the plan's projected enrollment, revenue needs, and ability to provide extra benefits based on the projected enrollment (the kind of information contained in the adjusted community rate proposal the plan submits to CMS under today's system). Although in one county, County A of the example, the plan's projected cost of providing the Medicare A and B benefit package exceeds the Medicare payment level ($520 in costs versus a payment of $500), the ability of the plan to provide the Medicare A/B benefit package in other counties at a ''cost'' below the level of the MA payment rate in the county enables the organization to provide extra benefits to each of its expected enrollees. That is, enrollees in one county are cross-subsidizing the costs of enrollees in other counties. Had this organization only contracted for County C, residents of that county would have received $100 in extra benefits. However, because there are three counties involved, and a certain enrollment distribution is assumed, County C enrollees will receive less in extra benefits, but they will receive the same amount as any other enrollee of the plan in the three-county area. This geographic cross-subsidization enables residents of some counties (in this case, the first two counties listed in Table 2) to receive extra benefits financed by revenues generated in a different county (County C, which enables County A residents to receive extra benefits, and enables County B enrollee to receive better benefits than they would otherwise receive under a single-county contract).

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Table 2: "Geographic Adjustment" of MA Payments in 2005 and Plan Benefit Package Obligations

I. Plan Adjusted Community Rate Submission Under 2005 Rules: $40 in Savings = $40 in Extra Benefits

	MA Rates	Projected Enrollment	Projected Medicare Payment	Plan A/B Per Capita Revenue Needs in County for A/B Benefits	Total Plan Revenue Needs for A/B Benefits	Total Plan Revenue Needs for A/B Benefits and Extra Benefits (at $40 Per Enrollee)	Total CMS Payment for A/B Benefits and Extra Benefits = MA Rate in County
County A	$500	4	$2,000	$520	$2,080	$2,240	$2,000
County B	$500	3	$1,500	$480	$1,440	$1,560	$1,500
County C	$800	5	$4,000	$700	$3,500	$3,700	$4,000
Totals:		12	$7,500		$7,020	$7,500	$7,500
Per Capita:			$625		$585	$625	$625
Plan Savings for Extra Benefits, Per Capita (Difference Between Projected Payments and A/B Revenue Need):					$40		

IIa. Plan Payment with MA-Based Geographic Adjustment, Enrollment Different from Projection; More Enrollment from County with Higher Margin

	MA Rates	Projected Enrollment	Actual Plan Enrollment	Plan A/B Per Capita Revenue Needs in County for A/B Benefits	Total Plan Revenue Needs for A/B Benefits	Total Plan Revenue Needs for A/B Benefits and Extra Benefits (at $40 Per Enrollee)	Total CMS Payment for A/B Benefits and Extra Benefits = MA Rate in County
County A	$500	4	1	$520	$520	$560	$500
County B	$500	3	1	$480	$480	$520	$500
County C	$800	5	10	$700	$7,000	$7,400	$8,000
Average	$600	Totals:	12		$8,000	$8,480	$9,000
Weighted Average	$750	Per Capita:			$667	$707	$750
					Plan excess revenue per capita:		$43

IIb. Plan Payment with MA-Based Geographic Adjustment, Enrollment Different from Projection; More Enrollment from County with No Margin (Counties Where Plan Revenue Need for Medicare A/B Coverage Exceeds Payment)

	MA Rates	Projected Enrollment	Actual Plan Enrollment	Plan A/B Per Capita Revenue Needs in County for A/B Benefits	Total Plan Revenue Needs for A/B Benefits	Total Plan Revenue Needs for A/B Benefits and Extra Benefits (at $40 Per Enrollee)	Total CMS Payment for A/B Benefits and Extra Benefits = MA Rate in County
County A	$500	4	10	$520	$5,200	$5,600	$5,000
County B	$500	3	1	$480	$480	$520	$500
County C	$800	5	1	$700	$700	$740	$800
Average	$600	Totals:	12		$6,380	$6,860	$6,300
Weighted Average	$525	Per Capita:			$532	$572	$525
					Plan revenue shortfall per capita:		-$47

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Table 2 serves to illustrate the ''risk'' to the Government, and the risk to the plan, in the current system. If the actual enrollment had turned out to be the distribution in section II.a. of Table 2, the Government would have paid the plan more money because of the actual enrollment distribution coming from each county. In this example, the plan would have had excess revenue beyond that needed to provide the Medicare A and B benefits and the promised level of extra benefits. Had the plan predicted this enrollment distribution going into the contract year in its ACR submission, beneficiaries would have been entitled to extra benefits valued at $83 per month. (Under the current system, there is a limit to the Goverment's ''risk exposure'' in the case just described because county level payments for any enrollee cannot exceed the MA payment rate in each county.)

Section II.b. of Table 2 shows a situation in which, because of the actual enrollment distribution, the plan incurs a loss both in the provision of A and B benefits and in providing the promised level of extra benefits. Plans can seek to protect themselves from this kind of risk by reducing their obligation to provide extra benefits. The plan can have an adjusted community rate filing showing that its required revenue matches the MA payment rates in each county, for example (though the stated inability to provide extra benefits may dampen enrollment, and the statement of revenue needs might be challenged in the ACR audit process). However, even with that approach to minimizing risk, if the figures in section II.b. of Table 2 accurately represent the plan's costs in each county, the plan will incur a loss just in providing Medicare A and B benefits, with the enrollment mix shown in the example. To avoid that kind of risk, what the MA organization might do is either not include the first county in its service area, or segment that county. Segmenting the county-establishing a separate ''plan'' for the county-enables the organization to exclude the county's enrollees from the computation of extra benefits for the other counties and to have a separate determination of the Medicare benefit package to be offered in the individual county. (Such service area segmentation is not available to regional plans in the competitive bidding system, but the approach can still be used by MA local plans in 2006 and thereafter.)

The examples of Table 2 show extreme cases in which the actual enrollment ends up being significantly different from the projected distribution of enrollment by county. Once a plan has at least one year's experience as a contractor, there is a better basis for reviewing the enrollment projections of a plan to ensure that the projections are reasonable and that the plan is appropriately determining the level of benefits it should be providing to its enrollees. This will also be true in the new system as of 2006, when one aspect of the bid review process will be an evaluation of the reasonableness of a plan's projections. However, there is always likely to be some level of uncertainty in predicting a plan's enrollment distribution by county. The issue of geographic adjustment is especially important for regional plans that will be required to have a uniform benefit package and premium in a large region.

The purpose of the equivalent of a bid under the ''old'' system was solely to determine whether there were any extra benefits available to beneficiaries, and what their Medicare premium would be. A bid under the new system serves that same purpose but it also can be thought of as the primary basis of payment for the provision of Medicare A and B services. Any rebate, for the provision of non-Medicare-covered benefits, is paid separately from the bid, and is not subject to geographic adjustment In the competitive bidding system of 2006 and thereafter, the Government is ''at risk'' for the cost of the rebate to the extent that the rebate amount would have been higher or lower because a plan's projected enrollment mix does not match its actual enrollment mix. Under the prior system, plans could be said to be at risk for the promised value of extra benefits incorporated in their bid: even though there might be significant changes in the county of residence of their actual enrollment compared to their projected enrollment, only the county-based Government payments could change. When the Government payments changed in tandem with the relative change in costs faced by the plan, the plan would remain whole with respect to its revenue needs for the provision of Medicare A and B benefits and, potentially, for the provision of any additional benefits. (Whether the plan would remain whole would also depend on the types of additional benefits being provided-for example, a fixed cost benefit such as a dollar reduction of the Part B premium, or a benefit with variable costs, such as the buy-down of cost sharing that can take the form of reduced coinsurance. Under the new system, the Government also limits its risk exposure by retaining 25 percent of plan savings.)

For geographic adjustment in 2006, one of the alternatives considered, an adjustment based on the MA payment rates, is similar to today's system. This method allows us to adjust the service area-wide bid to arrive at the county MA rate, less the value of any rebate when a rebate is required. The rebate value that reduces the MA rate is ''apportioned'' across all counties based on the plan's projected enrollment and based on the overall expected revenue that enabled the plan to offer a rebate (which is a function of the MA payment rate totaled across all counties, based on the enrollment projected in each county). When a plan provides a rebate, this method pays a percentage (always less than 100 percent) of the county MA payment rate, even though in a particular county the plan's costs of providing the Part A and B benefit might exceed the county MA payment. In that respect, this method is similar to the current method, which limits the Government's risk exposure to the level of the MA payment, or benchmark, in a given county.

This adjustment is illustrated in Table 3. The bid is adjusted by the county-level, enrollment-weighted MA factors shown in Table 3. This operation ''returns'' the bid to the appropriate MA rate for that county, taking into account the level of rebate dollars determined on a plan-wide basis. (Note that unless the plan projects the same level of enrollment in each county of its service area, the MA factors for the plan are not the same as the simple relationship among MA payment levels in the plan's service area.)

Under this method of geographic adjustment based on MA payment rates, the Government never pays more than the MA rate in a given county for the provision of Medicare A and B benefits. However, it is possible under the competitive bidding system for the Government to have higher per capita expenditures for an MA enrollee in a given county as compared to today's MA payment methodology, because of the manner in which rebate dollars are paid. In the competitive system of 2006 and thereafter, the bid to benchmark comparison-a comparison based on projected enrollment-determines the rebate dollars (in the same manner that savings were determined in 2005, by comparing projected payment rates to projected revenue needs for Medicare A and B services). In 2006 and thereafter, regardless of the plan's actual enrollment distribution by county, the Government is obligated to pay the per capita amount of rebate dollars directly to the plans as a separate payment stream (or the Government withholds the amount for reduction of the Part B premium). That is, the rebate amount, as determined based on projected

numbers, is a fixed amount and is not geographically adjusted. In 2005 and earlier years, there was no separate payment of savings dollars. Savings were financed out of the county MA rate, with plans receiving 100 percent of the MA payment rate as the payment for the provision of both A and B benefits. The MA payment also financed the provision of any extra (non-Medicare) benefits the plan was obligated to provide if its projected average MA payment rate exceeded its adjusted community rate for the provision of Medicare A and B benefits. (For simplicity, these examples represent the situation of a multi-county local plan with enrollment of beneficiaries with a 1.0 risk score. A similar methodology would also apply to regional plans.)

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Table 3: Geographic Adjustment of MA Payments in 2006 Based on County MA Rates

Ia. Plan Bid: $30 in Extra Benefits (75% of $40 in Savings)

	MA Rates	Unweighted MA Index (or Index at Equal Enrollment Distribution in All Counties)	Projected Enrollment	Enrollment-Weighted MA Index	Medicare Advantage Service Area Benchmark Computation	Plan A/B Per Capita Revenue Needs in County for A/B Benefits	Total Plan Revenue Needs for A/B Benefits = Plan Bid	Total Plan Revenue Needs for A/B Benefits and Extra Benefits (at $30 Per Enrollee)
County A	$500	0.83	4	0.80	$2,000	$520	$2,080	$2,200
County B	$500	0.83	3	0.80	$1,500	$480	$1,440	$1,530
County C	$800	1.33	5	1.28	$4,000	$700	$3,500	$3,650
Average	$600	Totals:	12		$7,500		$7,020	$7,380
Weighted Average	$625	Per Capita:			$625		$585	$615
						Savings Per Enrollee:	$40	
						Rebate:	$30	

Ib. Plan Payment with MA-Based Geographic Adjustment, Enrollment as Projected

	MA Rates	Per Capita Bidj-Based Payment for A/B Services (MA Rate Times Bid/Benchmark Ratio)	Actual Enrollment	Rebate Dollars to Plan, Per Enrollee	Payment Per Capita with Rebate Dollars	Total Plan Payment in this County	Total Plan Revenue Needs for A/B Benefits = Plan Bid	Total Plan Revenue Needs for A/B Benefits and Extra Benefits (at $30 Per Enrollee)
County A	$500	$468.00	4	$30	$498.00	$1,992	$2,080	$2,200
County B	$500	$468.00	3	$30	$498.00	$1,494	$1,440	$1,530
County C	$800	$748.80	5	$30	$778.80	$3,894	$3,500	$3,650
Totals						$7,380	$7,020	$7,380
Per Capita:						$615	$585	$615

IIa. Plan Payment with MA-Based Geographic Adjustment, Enrollment Different from Projection; More Enrollment from County with Higher Margin

	MA Rates	Per Capita Bidj-Based Payment for A/B Services (MA Rate Times Bid/Benchmark Ratio, or Bid Times Enrollment-Weighted MA Index)	Actual Plan Enrollment	Rebate Dollars to Plan, Per Enrollee	Payment Per Capita with Rebate Dollars	Total Plan Payment in Each County	Total Plan Revenue Needs for A/B Benefits, Based on Actual Enrollment	Total Plan Revenue Needs for A/B Benefits and Extra Benefits (at $30 Per Enrollee)
County A	$500	$468.00	1	$30	$498.00	$498	$520	$550
County B	$500	$468.00	1	$30	$498.00	$498	$480	$510
County C	$800	$748.80	10	$30	$778.80	$7,788	$7,000	$7,300
Average	$600	Totals:	12			$8,784	$8,000	$8,360
Weighted Average	750	Per Capita:				$732.00	$666.67	$696.67
						Plan excess revenue per capita:		$35.33

IIb. Plan Payment with MA-Based Geographic Adjustment, Enrollment Different from Projection; More Enrollment from County with No Margin (Counties Where Plan Revenue Need for Medicare A/B Coverage Exceeds Payment)

	MA Rates	Per Capita Bidj-Based Payment for A/B Services (MA Rate Times Bid/Benchmark Ratio, or Bid Times Enrollment-Weighted MA Index)	Actual Plan Enrollment	Rebate Dollars to Plan, Per Enrollee	Payment Per Capita with Rebate Dollars	Total Plan Payment in Each County	Total Plan Revenue Needs for A/B Benefits, Based on Actual Enrollment	Total Plan Revenue Needs for A/B Benefits and Extra Benefits (at $30 Per Enrollee)
County A	$500	$468.00	10	$30	$498.00	$4,980.00	$5,200	$5,500
County B	$500	$468.00	1	$30	$498.00	$498.00	$480	$510
County C	$800	$748.80	1	$30	$778.80	$778.80	$700	$730
Totals:			12			$6,256.80	$6,380	$6,740
Per Capita:						$521.40	$531.67	$561.67
						Plan revenue shortfall per capita:		-$40.27

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A different alternative method for geographic adjustment that was mentioned in the impact analysis of the NPRM, would emphasize the bid-based nature of the new system (that is, plans are to be paid their bids for the provision of Medicare A and B services) and would recognize variation in plan costs among counties, as stated by the plans, for the provision of Medicare A and B benefits. Under this method, illustrated in Table 5, we would adjust the bid by a county-level cost factor to arrive at the payment for each plan in each county. Under either system, the MA-based system or the plan-determined cost factor system, total payments to a plan in a given year would be the same to the extent that the plan's actual enrollment distribution across counties matched the projected enrollment distribution that formed the basis of any rebate determination. When the actual enrollment distribution differs from the projection, the Government payment to a plan might exceed the MA rate in a given county if the plan states that its costs in the county exceed the MA rate. However, in at least one county, we would pay less than the MA rate (and less than the MA-rate-based geographically adjusted amount of the alternative previously described, given that there has to be at least one county below the MA rate in order for the plan to have a rebate). This bid-based method of payment based on plan-determined relative costs makes plans whole with respect to their revenue needs for the provision of Medicare A and B services, unlike the MA-based system which can pay more or less than the plan needs for the provision of A and B services. With regard to rebate dollars, either method results in the plan being paid the stated cost of providing the required rebate, which should make the plan whole with respect to these expenditures unless there is geographic variation in the cost of providing the rebate (for example, cost sharing reductions as a rebate).

Table 4: Geographic Adjustment of MA Payments in 2006 Using Plan-Determined A/B Cost Factors

Ia. Plan Bid: $30 in Extra Benefits (75% of $40 in Savings)

	MA Rates	Enrollment-Weighted MA Index (Included for Comparison to Plan A/B Revenue Need Index)	Projected Enrollment	Medicare Advantage Service Area Benchmark	Plan A/B Per Capita Revenue Needs in County for A/B Benefits	Plan-Specified A/B Revenue Need Index (Ratio of County Revenue Needed to Bid)	Total Plan Revenue Needs for A/B Benefits = Plan Bid	Total Plan Revenue Needs for A/B Benefits and Extra Benefits (at $30 Per Enrollee)
County A	$500	0.80	4	$2,000	$520	0.89	$2,080	$2,200
County B	$500	0.80	3	$1,500	$480	0.82	$1,440	$1,530
County C	$800	1.28	5	$4,000	$700	1.20	$3,500	$3,650
Average	$600	Totals:	12	$7,500			$7,020	$7,380
Weighted Average	$625		Per Capita	$625	$585		$585	$615
						Savings Per Enrollee:	$40	
						Rebate:	$30	

Ib. Plan Payment with Plan Revenue Need Index Geographic Adjustment, Enrollment as Projected

	MA Rates	Per Capita Bid-Based Payment for A/B Services (Bid Times Plan A/B Revenue Need Index)	Actual Enrollment	Rebate Dollars to Plan, Per Enrollee	Payment Per Capita with Rebate Dollars	Total Plan Payment in this County	Total Plan Revenue Needs for A/B Benefits = Plan Bid	Total Plan Revenue Needs for A/B Benefits and Extra Benefits (at $30 Per Enrollee)
County A	$500	$520.00	4	$30	$550.00	$2,200	$2,080	$2,200
County B	$500	$480.00	3	$30	$510.00	$1,530	$1,440	$1,530
County C	$800	$700.00	5	$30	$730.00	$3,650	$3,500	$3,650
Totals						$7,380	$7,020	$7,380
Per Capita:						$615	$585	$615

IIa. Plan Payment with Plan Revenue Need Index Geographic Adjustment, Enrollment Different from Projection; More Enrollment from County with Higher Margin

	MA Rates	Per Capita Bid-Based Payment for A/B Services (Bid Times Plan A/B Revenue Need Index)	Actual Plan Enrollment	Rebate Dollars to Plan, Per Enrollee	Payment Per Capita with Rebate Dollars	Total Plan Payment in Each County	Total Plan Revenue Needs for A/B Benefits, Based on Actual Enrollment	Total Plan Revenue Needs for A/B Benefits and Extra Benefits (at $30 Per Enrollee)
County A	$500	$520.00	1	$30	$550.00	$550	$520	$550
County B	$500	$480.00	1	$30	$510.00	$510	$480	$510
County C	$800	$700.00	10	$30	$730.00	$7,300	$7,000	$7,300
Average	$600	Totals:	12			$8,360	$8,000	$8,360
Weighted Average	$750	Per Capita:				$696.67	$666.67	$696.67
						Plan excess revenue per capita:		$0.00

IIb. Plan Payment with Plan Revenue Need Index Geographic Adjustment, Enrollment Different from Projection; More Enrollment from County with No Margin (Counties Where Plan Revenue Need for Medicare A/B Coverage Exceeds Payment)

	MA Rates	Per Capita Bid-Based Payment for A/B Services (Bid Times Plan A/B Revenue Need Index)	Actual Plan Enrollment	Rebate Dollars to Plan, Per Enrollee	Payment Per Capita with Rebate Dollars	Total Plan Payment in Each County	Total Plan Revenue Needs for A/B Benefits, Based on Actual Enrollment	Total Plan Revenue Needs for A/B Benefits and Extra Benefits (at $30 Per Enrollee)
County A	$500	$520.00	10	$30	$550.00	$5,500.00	$5,200	$5,500
County B	$500	$480.00	1	$30	$510.00	$510.00	$480	$510
County C	$800	$700.00	1	$30	$730.00	$730.00	$700	$730
Totals:			12			$6,740.00	$6,380	$6,740
Per Capita:						$561.67	$531.67	$561.67
						Plan revenue shortfall per capita:		$0.00

Table 5 below summarizes the examples of Tables 2, 3 and 4. The two different possible methods of geographic adjustment for 2006 discussed above have different results, but in each case there is a divergence only when the actual enrollment differs from the projected enrollment distribution, as previously noted. In certain cases, the plan-determined index produces higher total Government expenditures than the MA payment-based index, while in other cases the opposite is true. Only the plan-determined index makes a plan whole with respect to its reported cost of providing benefits on a county-by-county basis. As is the case with today's payment system, enrollment distributions different from those projected in advance result in either revenue gains or revenue shortfalls. Compared to the current system of payment, the plan-determined index would appear to be particularly advantageous to plans in ensuring the avoidance of risk based on errors in enrollment projections. As previously noted, however, the MA-based index prevents Government payments in any county which would exceed the benchmark-which is a possibility for the plan-specified approach. Again, as previously noted, for there to be any projected rebate, there has to be at least one county in which plans costs (whether revealed or not) are below the benchmark, with such margins being used to cross-subsidize other counties.

One concern with the plan-specified system is the issue of whether it is more subject to gaming than the MA index approach. Either approach is gameable based on misstatements of enrollment projections in order to maximize profits. However, manipulation of the enrollment distribution, if it occurs, would likely be an issue only in the first year of contracting.

Table 5: Summary of Results in Tables A, B, and C

	Government Expenditures	Plan Excess Revenue or Shortfall Per Capita (Shortfall Is Negative Number)	Difference in Government Payments Compared to Plan-Specified Index Adjustment (If Negative Number, Government Expenditures Lower for Row Category)	Plan Index Pays More?	Difference in Government Payments Compared to MA Index Adjustment (If Negative Number, Government Expenditures Lower for Row Category)	MA Index Pays More?
Plan-Determined Index Results						
Projected Payment Using Plan-Determined Cost Index	$ 7,380.00	$ -				
Plan-Determined Index, More Enrollment Coming from Higher Margin Counties	$ 8,360.00	$ -			$ (424.00)	yes
Plan-Determined Index, More Enrollment Coming from Lower (Negative) Margin County	$ 6,740.00	$ -			$ 483.20	no
MA Geographic Index Results						
Projected Payment Using MA Geographic Index	$ 7,380.00	$ -				
MA Geographic Index, Enrollment Coming from Higher Margin Counties	$ 8,784.00	$ 35.33	$ 424.00	no		
MA Geographic Index, More Enrollment Coming from Negative Margin County	$ 6,256.80	$ (40.27)	$ (483.20)	yes		
Year 2005 Payment System Results (No 25 Percent Reduction of Savings; Savings Amount Not Paid Separately)						
Year 2005 MA Payments, Enrollment Coming from Higher Margin Counties	$ 9,000.00	$ 43.33	$ 640.00	no	$ 216.00	no
Year 2005 MA Payments, Enrollment Coming from Negative Margin County	$ 6,300.00	$ (46.67)	$ (440.00)	yes	$ 43.20	no, but plan shortfall is less with 2006 MA index

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The public comments on the method of geographic adjustment almost without exception favored the use of the MA rates as the basis for adjustment. Commenters stated that they favored using the MA rates because it promotes a level playing field among plans and because current plans are familiar with adjustments made on this basis (which is similar to today's method of adjustment). While we have accepted these comments and have decided to use the MA rates for geographic adjustment, we also believe that it is important to provide the option to regional plans, on a case-by-case basis, of using a plan-determined index for geographic adjustment. The purpose of allowing this is to encourage regional bids. As we have noted, local plans can fashion their own service areas and can pick and choose which counties they want to serve. In most cases, local plans are operating as Medicare plans in areas in which they have commercial operations and are therefore familiar with the market conditions that they face. This enables local plans to be able to project their costs (in relation to MA rates) and to make more reliable projections of enrollment in a given area. For regional plans, the law requires that they assume risk over a wide geographic area, because a regional plan must serve an entire MA region and not a subset of counties in the region. Regional plans are likely to be entering areas in which they have not had any Medicare involvement and may not have had any significant commercial presence (for example, in rural areas, where fewer people have employer group coverage).

M. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a–4.pdf*), in Table 6 we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of Title II of the MMA that are the subject of this regulation. The table provides our best estimate of the dollar amount of these transfers, expressed in 2001 dollars, at three percent and seven percent discount rates.

All expenditures are classified as transfers to health plans. As previously explained, a large share of these expenditures would be used for the provisions of extra

benefits and reduced cost sharing for beneficiaries enrolled in private plans. (Note that this information, as it appeared in Table 12 of the August 3, 2004 proposed rule did not contain annualized figures. The figures were total figures for the 2004 to 2009 period.)

TABLE 6. ACCOUNTING STATEMENT: CLASSIFICATION OF EXPENDITURES, 2004 THROUGH 2009 (2001 DOLLARS, IN MILLIONS)

Three Percent Annual Discount Rate	
TRANSFERS	
Annualized Monetized Transfers	2,742
From Whom To Whom?	Federal Government To Private Plans
Seven Percent Annual Discount Rate	
TRANSFERS	
Annualized Monetized Transfers	2,711
From Whom To Whom?	Federal Government To Private Plans

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, Reporting and recordkeeping requirements

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 417–HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 1. The authority citation for part 417 continues to read as follows:

Authority: Sec. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), sec. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e 9), and 31 U.S.C. 9701.

Subpart J—Qualifying Conditions for Medicare Contracts

■ 2. Amend § 417.402 by—

A. Revising paragraph (b).

B. Adding paragraph (c).

The revision and addition read as follows:

§ 417.402 Effective date of initial regulations.

* * * * *

(b) No new cost plan contracts are accepted by CMS. CMS will, however, accept and approve applications to modify cost plan contracts in order to expand service areas, provided they are submitted on or before September 1, 2006, and CMS determines that the organization continues to meet regulatory requirements and the requirements in its cost plan contract. Section 1876 cost plan contracts will not be extended or renewed beyond December 31, 2007, where conditions in paragraph (c) of this section are present.

(c) *Mandatory HMO or CMP and contract non-renewal or service area reduction.* CMS will non-renew all or a portion of an HMO's or CMP's contracted service area using procedures in § 417.492(b) and § 417.494(a) for any period beginning on or after January 1, 2008, where-

(1) There were two or more coordinated care plan-model MA regional plans in the same service area or portion of a service area for the entire previous calendar year meeting the conditions in paragraph (c)(3) of this section; or

(2) There were two or more coordinated care plan-model MA local plans in the same service area or portion of a service area for the entire previous calendar year meeting the conditions in paragraph (c)(3) of this section.

(3) *Minimum enrollment requirements.* (i) With respect to any service area or portion of a service area that is within a Metropolitan Statistical Area with a population of more than 250,000 and counties contiguous to the Metropolitan Statistical Area, 5,000 enrolled individuals.

(ii) With respect to any service area or portion of a

service area that is not within a Metropolitan Statistical Area described in paragraph (c)(3)(i) of this section, 1,500 individuals.

Subpart Q—Beneficiary Appeals

■ 3. Section 417.600 is revised to read as follows:

§ 417.600 Basis and scope.

(a) *Statutory basis.* (1) Section 1869 of the Act provides the right to a redetermination, reconsideration, hearing, and judicial review for individuals dissatisfied with a determination regarding their Medicare benefits.

(2) Section 1876 of the Act provides for Medicare payments to HMOs and CMPs that contract with CMS to enroll Medicare beneficiaries and furnish Medicare-covered health care services to them.

(3) Section 234 of the MMA requires section 1876 contractors to operate under the same provisions as MA plans where two plans of the same type enter the cost plan contract's service area.

(b) *Applicability.* (1) The rights, procedures, and requirements relating to beneficiary appeals and grievances set forth in subpart M of part 422 of this chapter also apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

(2) In applying those provisions, references to section 1852 of the Act must be read as references to section 1876 of the Act, and references to MA organizations as references to HMOs and CMPs.

§ 417.602 through § 417.638 [Removed]

■ 4. Sections 417.602 through 417.638 are removed.

Subpart U—Health Care Prepayment Plans

■ 5. Amend § 417.832 by-

A. Revising paragraph (c).

B. Adding paragraph (d).

The revision and addition read as follows:

§ 417.832 Applicability of requirements and procedures.

* * * * *

(c) The provisions of part 405 dealing with the representation of parties apply to organization determinations and appeals.

(d) The provisions of part 405 dealing with administrative law judge hearings, Medicare Appeals Council review, and judicial review are applicable, unless otherwise provided.

■ 6. Section 417.840 is revised to read as follows:

§ 417.840 Administrative review procedures.

The HCPP must apply § 422.568 through § 422.619 of this chapter to

organization determinations that affect its Medicare enrollees, and to reconsiderations, hearings, Medicare Appeals Council review, and judicial review of those organization determinations.

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 7. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 8. Revise the heading of part 422 to read as set forth above.

Subpart A—General Provisions

■ 9. Amend § 422.1(a) by adding the following statutory basis in numerical order:

§ 422.1 Basis and scope.

(a) * * *

1858—Special rules for MA Regional Plans.

* * * * *

■ 10. Amend § 422.2 by-

A. Removing the definitions of ''ACR,'' ''Additional benefits,'' ''Adjusted community rate,'' and ''M+C.''

B. Revising the definitions of ''Basic benefits,'' ''Benefits,'' ''Mandatory supplemental benefits,'' and ''Service area.''

C. Adding the definitions of ''Institutionalized,''

''MA,'' ''MA local area,'' ''MA local plan,'' ''MA-Prescription drug plan,'' ''MA regional plan,'' ''Prescription drug plan (PDP),'' ''Prescription drug plan (PDP) sponsor,'' ''Special needs individual,'' and ''Specialized MA plans for special needs individuals.''

D. In the definitions of ''M+C eligible individual,'' ''M+C organization,'' ''M+C plan,'' and ''M+C plan enrollee,'' ''M+C'' is removed each place it appears and ''MA'' is added in its place.

E. Amending the definition of ''Religious and Fraternal Benefit (RFB) Society'' by removing the words ''Religious and Fraternal'' and by adding the words ''Religious Fraternal'' in their place.

■ The revisions and additions read as follows:

§ 422.2 Definitions.

* * * * *

Basic benefits means all Medicare-covered benefits (except hospice services).

Benefits means health care services that are intended to maintain or improve the health status of enrollees, for which the MA organization incurs a cost or liability under an MA plan (not solely an administrative processing cost). Benefits are submitted and approved through the annual bidding process.

* * * * *

Institutionalized means for the purpose of defining a special needs individual, an MA eligible individual who continuously resides or is expected to continuously reside for 90 days or longer in a long-term care facility which is a skilled nursing facility (SNF) nursing facility (NF); SNF/NF; an intermediate care facility for the mentally retarded (ICF/MR); or an inpatient psychiatric facility.

* * * * *

MA stands for Medicare Advantage.

MA local area is defined in § 422.252.

MA local plan means an MA plan that is not an MA regional plan.

MA-Prescription drug (PD) plan means an MA plan that provides qualified prescription drug coverage under Part D of the Social Security Act.

MA regional plan means a coordinated care plan structured as a preferred provider organization (PPO) that serves one or more entire regions. An MA regional plan must have a network of contracting providers that have agreed to a specific reimbursement for the plan's covered services and must pay for all covered services whether provided in or out of the network.

Mandatory supplemental benefits means health care services not covered by Medicare that an MA enrollee must accept or purchase as part of an MA plan. The benefits may include reductions in cost sharing for benefits under the original Medicare fee for service program and are paid for in the form of premiums and cost sharing, or by an application of the beneficiary rebate rule in section 1854(b)(1)(C)(ii)(I) of the Act, or both.

* * * * *

Prescription drug plan (PDP). PDP has the definition set forth in § 423.272 of this chapter.

Prescription drug plan (PDP) sponsor. A prescription drug plan sponsor has the definition set forth in § 423.2 of this chapter.

* * * * *

Service area means a geographic area that for local MA plans is a county or multiple counties, and for MA regional plans is a region approved by CMS within which an MA-eligible individual may enroll in a particular MA plan offered by an MA organization. Each MA plan must be available to all MA-eligible individuals within the plan's service area. In deciding whether to approve an MA plan's proposed service area, CMS considers the following criteria:

(1) For local MA plans:

(i) Whether the area meets the ''county integrity rule'' that a service area generally consists of a full county or counties.

(ii) However, CMS may approve a service area that includes only a portion of a county if it determines that the ''partial county'' area is necessary, nondiscriminatory, and in the best interests of the beneficiaries. CMS may also consider the extent to which the proposed service area mirrors service areas of existing commercial health care plans or MA plans offered by the organization.

(2) For all MA coordinated care plans, whether the contracting provider network meets the access and availability standards set forth in § 422.112. Although not all contracting providers must be located within the plan's service area, CMS must determine that all services covered under the plan are accessible from the service area.

(3) For MA regional plans, whether the service area consists of the entire region.

Special needs individual means an MA eligible individual who is institutionalized, as defined above, is entitled to medical assistance under a State plan under title XIX, or has a severe or disabling chronic condition(s) and would benefit from enrollment in a specialized MA plan.

Specialized MA Plans for Special Needs Individuals means a MA coordinated care plan that exclusively enrolls or enrolls a disproportionate percentage of special needs individuals as set forth in § 422.4(a)(1)(iv) and that, beginning January 1, 2006, provides Part D benefits under part 423 of this chapter to all enrollees; and which has been designated by CMS as meeting the requirements of a MA SNP as determined on a case-by-case basis using criteria that include the appropriateness of the target population, the existence of clinical programs or special expertise to serve the target population, and whether the proposal discriminates against sicker members of the target population.

■ 11. Amend § 422.4 by-

A. Revising the section heading.

B. Revising paragraph (a)(1)(iii).

C. Redesignating paragraph (a)(1)(iv) as paragraph

(a)(1)(v).

D. Adding a new paragraph (a)(1)(iv).

E. Revising newly redesignated paragraph (a)(1)(v).

F. Removing paragraph (a)(2)(ii).

G. Redesignating paragraph (a)(2)(iii) as paragraph (a)(2)(ii).

H. Adding a new paragraph (c).

■ The revisions and additions read as follows:

§ 422.4 Types of MA plans.

(a) * * *

(1) * * *

(iii) Coordinated care plans include plans offered by health maintenance organizations (HMOs), provider-sponsored organizations (PSOs), regional or local preferred provider organizations (PPOs) as specified in paragraph (a)(1)(v) of this section, and other network plans (except MSA and PFFS plans).

(iv) A specialized MA plan for special needs individuals (SNP) includes any type of coordinated care plan that meets CMS'SNP requirements and either—

(A) Exclusively enrolls special needs individuals as defined in § 422.2; or

(B) Enrolls a greater proportion of special needs individuals than occur nationally in the Medicare population as defined by CMS.

(v) A PPO plan is a plan that has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; and, only for purposes of quality assurance requirements in § 422.152(e), is offered by an organization that is not licensed or organized under State law as an HMO.

* * * * *

(c) *Rule for MA Plans' Part D coverage.*

(1) Coordinated care plans. In order to offer an MA coordinated care plan in an area, the MA organization offering the coordinated care plan must offer qualified Part D coverage meeting the requirements in § 423.104 of this chapter in that plan or in another MA plan in the same area.

(2) *MSAs.* MA organizations offering MSA plans are not permitted to offer prescription drug coverage, other than that required under Parts A and B of Title XVIII of the Act.

(3) *Private Fee-For-Service.* MA organizations offering private fee-for-service plans can choose to offer qualified Part D coverage meeting the requirements in § 423.104 in that plan.

§ 422.6 [Removed]

■ 12. Remove § 422.6.

§ 422.8 [Removed]

■ 13. Remove § 422.8.

§ 422.10 [Redesignated as § 422.6]

■ 14. Redesignate § 422.10 as § 422.6 and amend newly redesignated § 422.6 by-

A. Revising the section heading.

B. Revising paragraph (a).

C. Revising paragraph (b).

D. Revising paragraph (d)(2)(ii).

E. Revising paragraph (e).

F. Revising paragraph (f)(1).

G. Revising paragraph (f)(2)

H. Revising paragraph (f)(3).

■ The revisions read as set forth below:

§ 422.6 Cost-sharing in enrollment-related costs (MA user fee).

(a) *Basis and scope.* This section implements that portion of section 1857 of the Act that pertains to cost-sharing in enrollment-related costs. It sets forth the procedures that CMS follows to determine the aggregate annual ''user fee'' to be contributed by MA organizations and PDP sponsors under Medicare Part D and to assess the required user fees for each MA plan offered by MA organizations and PDP sponsors.

(b) *Purpose of assessment.* Section 1857(e)(2) of the Act authorizes CMS to charge and collect from each MA plan offered by an MA organization its pro rata share of fees for administering section 1851 of the Act (relating to dissemination of enrollment information), and section 4360 of the Omnibus Budget Reconciliation Act of 1990 (relating to the health insurance counseling and assistance program) and section 1860D–1(c) of the Act (relating to dissemination of enrollment information for the drug benefit).

* * * * *

(d) * * *

(2) * * *

(ii) For fiscal year 2006 and each succeeding year, $200 million, the applicable portion (as defined in paragraph (e) of this section) of $200 million.

(e) *Applicable portion.* In this section, the term ''applicable portion'' with respect to an MA plan means, for a fiscal year, CMS's estimate of Medicare Part C and D expenditures for those MA organizations as a percentage of all expenditures under title XVIII and with respect to PDP sponsors, the applicable portion is CMS's estimate of Medicare Part D prescription drug expenditures for those PDP sponsors PDP sponsors as a percentage of all expenditures under title XVIII.

(f) *Assessment methodology.* (1) The amount of the applicable portion of the user fee each MA organization and PDP sponsor must pay is assessed as a percentage of the total Medicare payments to each organization. CMS determines the annual assessment percentage rate separately for MA organizations and for PDPs using the following formula:

(i) The assessment formula for MA organizations (including MA-PD plans):

C divided by A times B where—

A is the total estimated January payments to all MA organizations subject to the assessment;

B is the 9-month (January through September) assessment period; and

C is the total fiscal year MA organization user fee assessment amount determined in accordance with paragraph (d)(2) of this section.

(ii) The assessment formula for PDPs:

A is the total estimated January payments to all PDP sponsors subject to the assessment;

B is the 9-month (January through September) assessment period; and

C is the total fiscal year PDP sponsor's user fee assessment amount determined in accordance with paragraph (d)(2) of this section.

(2) CMS determines each MA organization's and PDP sponsor's pro rata share of the annual fee on the basis of the organization's calculated monthly payment amount during the 9 consecutive months beginning with January. CMS calculates each organization's monthly pro rata share by multiplying the established percentage rate by the total monthly calculated Medicare payment amount to the organization as recorded in CMS's payment system on the first day of the month.

(3) CMS deducts the organization's fee from the amount of Federal funds otherwise payable to the MA organization or PDP sponsor for that month.

* * * * *

Subpart B—Eligibility, Election, and Enrollment

■ 15. Amend § 422.50 by-

A. Revising the section heading.

B. Adding introductory text.

C. Amending paragraph (a)(2)(i) by removing the word ''and'' from the end of the paragraph.

D. Amending paragraph (a)(2)(ii) by removing the period from the end of the paragraph and by adding ''; and'' in its place.

E. Adding paragraph (a)(2)(iii).

F. Revising paragraph (a)(5).

■ The revisions and addition read as follows:

§ 422.50 Eligibility to elect an MA plan.

For this subpart, all references to an MA plan include MA-PD and both MA local and MA regional plans, as defined

in § 422.2 unless specifically noted otherwise.

(a) * * *

(2) * * *

(iii) An individual with end-stage renal disease may elect an MA special needs plan as defined in § 422.2, as long as that plan has opted to enroll ESRD individuals.

* * * * *

(5) Completes and signs an election form or completes another CMS-approved election method offered by the MA organization and provides information required for enrollment; and

* * * * *

■ 16. Add § 422.52 to read as follows:

§ 422.52 Eligibility to elect an MA plan for special needs individuals.

(a) *General rule*. In order to elect a specialized MA plan for a special needs individual (Special Needs MA plan, or SNP), the individual must meet the eligibility requirements specified in this section.

(b) *Basic eligibility requirements*. Except as provided in paragraph (c) of this section, to be eligible to elect an SNP, an individual must:

(1) Meet the definition of a special needs individual, as defined at § 422.2;

(2) Meet the eligibility requirements for that specific SNP; and

(3) Be eligible to elect an MA plan under § 422.50.

(c) *Exception to § 422.50*. CMS may waive § 422.50(a)(2) concerning the exclusion of persons with ESRD.

(d) *Deeming continued eligibility*. If an SNP determines that the enrollee no longer meets the eligibility criteria, but can reasonably be expected to again meet that criteria within a 6-month period, the enrollee is deemed to continue to be eligible for the MA plan for a period of not less than 30 days but not to exceed 6 months.

(e) *Restricting Enrollment*. An SNP must restrict future enrollment to only special needs individuals as established under § 422.2.

(f) *Exceptions*. (1) As specified in § 422.4, CMS may designate certain MA plans that disproportionately serve special needs individuals, as defined in § 422.2 as SNPs.

(2) Individuals already enrolled in an MA plan that CMS subsequently designates as an SNP may continue to be enrolled in the plan and may not be involuntarily disenrolled because they do not meet the definition of special needs individuals in § 422.2.

■ 17. Amend § 422.54 by-

A. Revising the section heading.

B. Revising paragraph (a).

C. Revising paragraph (b).

D. Revising paragraph (c)(1)(ii).

E. Revising paragraph (c)(2).

F. Revising paragraph (d)(3).

■ The revisions read as follows:

§ 422.54 Continuation of enrollment for MA local plans.

(a) *Definition*. *Continuation area* means an additional area (outside the service area) within which the MA organization offering a local plan furnishes or arranges to furnish services to its continuation-of-enrollment enrollees. Enrollees must reside in a continuation area on a permanent basis. A continuation area does not expand the service area of any MA local plan.

(b) *Basic rule*. An MA organization may offer a continuation of enrollment option to MA local plan enrollees when they no longer reside in the service area of a plan and permanently move into the geographic area designated by the MA organization as a continuation area. The intent to no longer reside in an area and permanently live in another area is verified through documentation that establishes residency, such as a driver's license or voter registration card.

(c) * * *

(1) * * *

(ii) Describe the option(s) in the member materials it offers and make the option available to all MA local plan enrollees residing in the continuation area.

(2) An enrollee who moves out of the service area and into the geographic area designated as the continuation area has the choice of continuing enrollment or disenrolling from the MA local plan. The enrollee must make the choice of continuing enrollment in a manner specified by CMS. If no choice is made, the enrollee must be disenrolled from the plan.

(d) * * *

(3) Reasonable cost sharing. For services furnished in the continuation area, an enrollee's cost-sharing liability is limited to the cost-sharing amounts required in the MA local plan's service area (in which the enrollee no longer resides).

* * * * *

■ 18. Amend § 422.56 by-

A. Revising the section heading.

B. Revising paragraph (a).

C. Revising paragraph (b).

■ The revisions read as follows:

§ 422.56 Enrollment in an MA MSA plan.

(a) *General*. An individual is not eligible to elect an MA MSA plan unless the individual provides assurances that are satisfactory to CMS that he or she will reside in the United States for at least 183 days during the year for which the election is effective.

(b) *Individuals eligible for or covered under other health benefits program*. Unless otherwise provided by the Secretary, an individual who is enrolled in a Federal Employee Health Benefit plan under 5 U.S.C. chapter 89, or is eligible for health care benefits through the Veteran's Administration under 10 U.S.C. chapter 55 or the Department of Defense under 38 U.S.C. chapter 17, may not enroll in an MA MSA plan.

* * * * *

■ 19. Amend § 422.60 by-

A. Revising paragraph (b)(1).

B. Revising paragraph (b)(3).

C. Revising the heading of paragraph (c).

D. Revising paragraph (c)(1).

E. Revising paragraph (d).

F. Revising paragraph (e).

G. Revising paragraph (f)(1).

H. Revising paragraph (f)(3).

■ The revisions read as follows:

§ 422.60 Election process.

* * * * *

(b) *Capacity to accept new enrollees*. (1) MA organizations may submit information on enrollment capacity of plans.

* * * * *

(3) CMS considers enrollment limit requests for an MA plan service area, or a portion of the plan service area, only if the health and safety of beneficiaries is at risk, such as if the provider network is not available to serve the enrollees in all or a portion of the service area.

(c) *Election forms and other election mechanisms*. (1) The election must comply with CMS instructions regarding content and format and be approved by CMS as described in § 422.80. The election must be completed by the MA eligible individual (or the individual who will soon become eligible to elect an MA plan) and include authorization for disclosure and exchange of necessary information between the U.S. Department of Health and Human Services and its designees and the MA organization. Persons who assist beneficiaries in completing forms must sign the form, or through other approved mechanisms, indicate their relationship to the beneficiary.

* * * * *

(d) *When an election is considered to have been made*. An election in an MA plan is considered to have been made on the date the completed election is received by the MA organization.

(e) *Handling of elections*. The MA organization must have an effective system for receiving, controlling, and processing elections. The system must

meet the following conditions and requirements:

(1) Each election is dated as of the day it is received in a manner acceptable to CMS.

(2) Elections are processed in chronological order, by date of receipt.

(3) The MA organization gives the beneficiary prompt notice of acceptance or denial in a format specified by CMS.

(4) If the MA plan is enrolled to capacity, it explains the procedures that will be followed when vacancies occur.

(5) Upon receipt of the election, or for an individual who was accepted for future enrollment from the date a vacancy occurs, the MA organization transmits, within the timeframes specified by CMS, the information necessary for CMS to add the beneficiary to its records as an enrollee of the MA organization.

(f) *Exception for employer group health plans.* (1) In cases in which an MA organization has both a Medicare contract and a contract with an employer group health plan, and in which the MA organization arranges for the employer to process elections for Medicare-entitled group members who wish to enroll under the Medicare contract, the effective date of the election may be retroactive. Consistent with § 422.250(b), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

* * * * *

(3) Upon receipt of the election from the employer, the MA organization must submit the enrollment within timeframes specified by CMS.

■ 20. Amend § 422.62 by-

A. Revising the section heading.

B. Revising paragraph (a).

C. Revising paragraph (b) introductory text.

D. Revising the heading of paragraph (d).

E. Revising paragraph (d)(1).

F. Removing paragraph (d)(2)(i)(A).

G. Redesignating paragraph (d)(2)(i)(B) as paragraph (d)(2)(i)(A).

H. Redesignating paragraph (d)(2)(i)(C) as paragraph (d)(2)(i)(B).

■ The revisions and addition read as follows:

§ 422.62 Election of coverage under an MA plan.

(a) *General: Coverage election periods*—(1) *Initial coverage election period for MA.* The initial coverage election period is the period during which a newly MA-eligible individual may make an initial election. This period begins 3 months before the month the individual is first entitled to both Part A and Part B and ends on the later of—

(i) The last day of the month preceding the month of entitlement; or

(ii) If after May 15, 2006, the last day of the individual's Part B initial enrollment period.

(2) *Annual coordinated election period.* (i) Beginning with 2002, the annual coordinated election period for the following calendar year is November 15th through December 31st, except for 2006.

(ii) For 2006, the annual coordinated election period

begins on November 15, 2005 and ends on May 15, 2006.

(iii) During the annual coordinated election period, an individual eligible to enroll in an MA plan may change his or her election from an MA plan to original Medicare or to a different MA plan, or from original Medicare to an MA plan. If an individual changes his or her election to original Medicare, he or she may also elect a PDP.

(3) *Open enrollment and disenrollment opportunities through 2005.* Through 2005, the number of elections or changes that an MA eligible individual may make is not limited (except as provided for in paragraph (d) of this section for MA MSA plans). Subject to the MA plan being open to enrollees as provided under § 422.60(a)(2), an individual eligible to elect an MA plan may change his or her election from an MA plan to original Medicare or to a different MA plan, or from original Medicare to an MA plan.

(4) *Open enrollment and disenrollment during 2006.* (i) Except as provided in paragraphs (a)(4)(ii), (a)(4)(iii), and (a)(6) of this section, an individual who is not enrolled in an MA plan, but who is eligible to elect an MA plan in 2006, may elect an MA plan only once during the first 6 months of the year.

(A) An individual who is enrolled in an MA-PD plan may elect another MA-PD plan or original Medicare and coverage under a PDP. Such an individual may not elect an MA plan that does not provide qualified prescription drug coverage.

(B) An individual who is enrolled in an MA plan that does not provide qualified prescription drug coverage may elect another MA plan that does not provide that coverage or original Medicare. Such an individual may not elect an MA-PD plan or coverage under a PDP.

(ii) *Newly eligible MA individual.* An individual who becomes MA eligible during 2006 may elect an MA plan or change his or her election once during the period that begins the month the individual is entitled to both Part A and Part B and ends on the last day of the 6th month of the entitlement, or on December 31, whichever is earlier, subject to the limitations in paragraphs (a)(4)(i)(A) and (a)(4)(i)(B) of this section.

(iii) The limitation to one election or change in paragraphs (a)(4)(i) and (a)(4)(ii) of this section does not apply to elections or changes made during the annual coordinated election period specified in paragraph (a)(2) of this section or during a special election period specified in paragraph (b) of this section.

(5) *Open enrollment and disenrollment beginning in 2007.* (i) For 2007 and subsequent years, except as provided in paragraphs (a)(5)(ii), (a)(5)(iii), and (a)(6) of this section, an individual who is not enrolled in an MA plan but is eligible to elect an MA plan may make an election into an MA plan once during the first 3 months of the year.

(A) An individual who is enrolled in an MA-PD plan may elect another MA-PD plan or original Medicare and coverage under a PDP. An individual who is in original Medicare and has coverage under a PDP may elect a MA-PD plan. Such an individual may not elect an MA plan that does not provide qualified prescription drug coverage.

(B) An individual who is enrolled in an MA plan that does not provide qualified prescription drug coverage may elect another MA plan that does not provide that coverage or original Medicare. An individual who is in original Medicare and does not have coverage under a PDP may elect an MA plan that does not provide qualified prescription drug coverage. Such an individual may not elect an MA-PD plan or coverage under a PDP.

(ii) *Newly eligible MA individual.* An individual who becomes MA eligible during 2007 or later may elect an MA plan or change his or her election once during the period that begins the month the individual is entitled to both Part A and Part B and ends on the last day of the 3rd month of the entitlement, or on December 31, whichever is earlier subject to the limitations in paragraphs (a)(5)(i)(A) and (a)(5)(i)(B) of this section.

(iii) The limitation to one election or change in paragraph (a)(5)(i) and (a)(5)(ii) of this section does not apply to elections made or changes made during the annual coordinated election period specified in paragraph (a)(2) of this section or during a special election period specified in paragraph (b) of this section.

(6) *Open enrollment period for institutionalized individuals.* After 2005, an individual who is eligible to

elect an MA plan and who is institutionalized, as defined by CMS, is not limited (except as provided for in paragraph (d) of this section for MA MSA plans) in the number of elections or changes he or she may make. Subject to the MA plan being open to enrollees as provided under § 422.60(a)(2), an MA eligible institutionalized individual may at any time elect an MA plan or change his or her election from an MA plan to original Medicare, to a different MA plan, or from original Medicare to an MA plan.

(b) *Special election periods.* An individual may at any time (that is, not limited to the annual coordinated election period) discontinue the election of an MA plan offered by an MA organization and change his or her election, in the form and manner specified by CMS, from an MA plan to original Medicare or to a different MA plan under any of the following circumstances:

* * * * *

(d) *Special rules for MA MSA plans*—(1) *Enrollment.* An individual may enroll in an MA MSA plan only during an initial coverage election period or annual coordinated election period described in paragraphs (a)(1) and (a)(2) of this section.

* * * * *

■ 21. Amend § 422.66 by-

A. Revising the section heading.

B. Revising paragraph (b)(1)(i).

C. Revising paragraph (b)(1)(ii).

D. Revising paragraph (b)(3)(ii).

E. Revising paragraph (b)(3)(iii) introductory text.

F. Revising paragraph (d)(5).

G. Revising paragraph (e).

H. Revising paragraph (f)(2).

■ The revisions and additions read as follows:

§ 422.66 Coordination of enrollment and disenrollment through MA organizations.

* * * * *

(b) * * *

(1) * * *

(i) Elect a different MA plan by filing the appropriate election with the MA organization.

(ii) Submit a request for disenrollment to the MA organization in the form and manner prescribed by CMS or file the appropriate disenrollment request through other mechanisms as determined by CMS.

* * * * *

(3) * * *

(ii) Provide enrollee with notice of disenrollment in a format specified by CMS; and

(iii) In the case of a plan where lock-in applies, include in the notice a statement explaining that he or she—

* * * * *

(d) * * *

(5) *Election.* The individual who is converting must complete an election as described in § 422.60(c)(1) unless otherwise provided in a form and manner approved by CMS.

* * * * *

(e) *Maintenance of enrollment.* (1) An individual who has made an election under this section is considered to have continued to have made that election until either of the following, which ever occurs first:

(i)The individual changes the election under this section.

(ii)The elected MA plan is discontinued or no longer serves the area in which the individual resides, as provided under § 422.74(b)(3), or the organization does not offer or the individual does not elect the option of continuing enrollment, as provided under § 422.54.

(2) An individual enrolled in an MA plan that becomes an MA-PD plan on January 1, 2006, will be deemed to have elected to enroll in that MA-PD plan.

(3)An individual enrolled in an MA plan that, as of

December 31, 2005, offers any prescription drug coverage will be deemed to have elected an MA-PD plan offered by the same organization as of January 1, 2006.

(4) An individual who has elected an MA plan that does not provide prescription drug coverage will not be deemed to have elected an MA-PD plan and will remain enrolled in the MA plan as provided in paragraph (e)(1) of this section.

(5) An individual enrolled in an MA-PD plan as of December 31 of a year is deemed to have elected to remain enrolled in that plan on January 1 of the following year.

(f) * * *

(2) Upon receipt of the election from the employer, the MA organization must submit a disenrollment notice to CMS within timeframes specified by CMS.

■ 22. Amend § 422.68 by revising paragraph (b) to read as follows:

§ 422.68 Effective dates of coverage and change of coverage.

* * * * *

(b) *Annual coordinated election periods.* For an election or change of election made during the annual coordinated election period as described in § 422.62(a)(2)(i), coverage is effective as of the first day of the following calendar year except that for the annual coordinated election period described in § 422.62(a)(2)(ii), elections made after December 31, 2005 through May 15, 2006 are effective as of the first day of the first calendar month following the month in which the election is made.

* * * * *

■ 23. Amend § 422.74 by-

A. Revising the section heading.

B. Revising paragraph (b)(1)(ii).

C. Adding paragraph (b)(2)(iv).

D. Revising paragraph (c)(1).

E. Revising paragraph (d)(1).

F. Revising paragraph (d)(2).

■ The revisions and addition read as follows:

§ 422.74 Disenrollment by the MA Organization.

* * * * *

(b) * * *

(1) * * *

(ii) The individual has engaged in disruptive behavior specified at paragraph (d)(2) of this section.

* * * * *

(2) * * *

(iv) Individuals enrolled in a specialized MA plan for special needs individuals that exclusively serves and enrolls special needs individuals who no longer meet the special needs status of that plan (or deemed continued eligibility, if applicable).

(c) * * *

(1) Be provided to the individual before submission of the disenrollment to CMS; and

* * * * *

(d) *Process for disenrollment*—(1) *Monthly basic and supplementary premiums are not paid timely.* An MA organization may disenroll an individual from the MA plan for failure to pay basic and supplementary premiums under the following circumstances:

(i) The MA organization can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount, including:

(A) Alerting the individual that the premiums are delinquent;

(B) Providing the individual with a grace period, that is, an opportunity to pay past due premiums in full. The length of the grace period will be, at minimum, one month and will begin on the first day of the month for which the premium is unpaid.

(C) Advising the individual that failure to pay the premiums by the end of the grace period will result in termination of MA coverage.

(ii) The MA organization provides the enrollee with notice of disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) If the enrollee fails to pay the premium for optional supplemental benefits but pays the basic premium and any mandatory supplemental premium, the MA organization has the option to discontinue the optional supplemental benefits and retain the individual as an MA enrollee.

(2) Disruptive Behavior. (i) *Definition of disruptive behavior.* An MA plan enrollee is disruptive if his or her behavior substantially impairs the plan's ability to arrange for or provide services to the individual or other plan members. An individual cannot be considered disruptive if such behavior is related to the use of medical services or compliance (or noncompliance) with medical advice or treatment.

(ii) *Basis of disenrollment for disruptive behavior.* An organization may disenroll an individual whose behavior is disruptive as defined in 422.74(d)(2)(i) only after it meets the requirements described in this section and CMS has reviewed and approved the request.

(iii) *Effort to resolve the problem.* The MA organization must make a serious effort to resolve the problems presented by the individual, including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness and developmental disabilities. In addition, the MA organization must inform the individual of the right to use the organization's grievance procedures. The beneficiary has a right to submit any information or explanation that he or she may wish to the MA organization.

(iv) *Documentation.* The MA organization must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraph (iii), and any extenuating circumstances. The MA organization may request from CMS the ability to decline future enrollment by the individual. The MA organization must submit this information and any documentation received by the beneficiary to CMS.

(v) *CMS review of the proposed disenrollment.* CMS will review the information submitted by the MA organization and any information submitted by the beneficiary (which the MA organization must forward to CMS) to determine if the MA organization has fulfilled the requirements to request disenrollment for disruptive behavior. If the organization has fulfilled the necessary requirements, CMS will review the information and make a decision to approve or deny the request for disenrollment, including conditions on future enrollment, within 20 working days. During the review, CMS will ensure that staff with appropriate clinical or medical expertise review the case before making the final decision. The MA organization will be required to provide a reasonable accommodation, as determined by CMS, for the individual in such exceptional circumstances that CMS deems necessary. CMS will notify the MA organization within 5 working days after making its decision.

(vi) *Effective date of disenrollment.* If CMS permits an MA organization to disenroll an individual for disruptive behavior, the termination is effective the first day of the calendar month after the month in which the MA organization gives the individual notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section, unless otherwise determined by CMS.

* * * * *

■ 24. Amend § 422.80 by-

A. Revising paragraph (a).

B. Revising paragraph (e)(1)(ii).

C. Revising paragraph (e)(1)(iii).

D. Revising paragraph (e)(1)(iv).

E. Revising paragraph (e)(1)(v).

F. Adding paragraph (e)(1)(ix).

■ The revisions and additions read as follows:

§ 422.80 Approval of marketing materials and election forms.

(a) *CMS review of marketing materials.* (1) Except as provided in paragraph (a)(2) of this section, an MA organization may not distribute any marketing materials (as defined in paragraph (b) of this section), or election forms, or make such materials or forms available to individuals eligible to elect an MA organization unless—

(i) At least 45 days (or 10 days if using marketing materials that use, without modification, proposed model language as specified by CMS) before the date of distribution the MA organization has submitted the material or form to CMS for review under the guidelines in paragraph (c); and

(ii) CMS does not disapprove the distribution of new material or form.

(2) The MA organization may distribute the marketing materials 5 days following their submission to CMS if—

(i)The MA organization is deemed by CMS to meet certain performance requirements established by CMS; or

(ii)The MA organization certifies that in the case of certain marketing materials designated by CMS, it followed all applicable marketing guidelines or used model language specified by CMS without modification.

* * * * *

(e) * * *

(1) * * *

(ii) Engage in any discriminatory activity, including targeted marketing to Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(iii) Solicit Medicare beneficiaries door-to-door.

(iv) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the MA organization. The MA organization may not claim it is recommended or endorsed by CMS or Medicare or the Department of Health and Human Services or that CMS or Medicare or the Department of Health and Human Services recommends that the beneficiary enroll in the MA plan. It may, however, explain that the organization is approved for participation in Medicare.

(v) Distribute marketing materials for which, before expiration of the 45-day period (or 10 days as provided in paragraph (a)(1) of this section), the MA organization receives from CMS written notice of disapproval because it is inaccurate or misleading, or misrepresents the MA organization, its marketing representatives, or CMS.

* * * * *

(ix) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

* * * * *

Subpart C—Benefits and Beneficiary Protections

§ 422.100 [Amended]

■ 25. Amend § 422.100 by-

A. Revising paragraph (b)(2).

B. Revising paragraph (c)(1).

C. Removing paragraph (e).

D. Redesignating paragraph (f) as paragraph (e).

E. Redesignating paragraph (g) as paragraph (f).

F. Redesignating paragraph (h) as paragraph (g).

G. Redesignating paragraph (i) as paragraph (h).

H. Redesignating paragraph (j) as paragraph (i).

I. Revising newly redesignated paragraph (f) introductory text.

J. Revising newly redesignated paragraph (f)(2).

■ The revisions read as follows:

Subpart C—Benefits and Beneficiary Protections

§ 422.100 General requirements.

* * * * *

(b) * * *

(2) An MA plan (and an MA MSA plan, after the annual deductible in § 422.103(d) has been met) offered by an MA organization satisfies paragraph (a) of this section with respect to benefits for services furnished by a noncontracting provider if that MA plan provides payment in an amount the provider would have received under original Medicare (including balance billing permitted under Medicare Part A and Part B).

(c) ***

(1) Basic benefits are all Medicare-covered services, except hospice services.

* * * * *

(f) *CMS review and approval of MA benefits*. CMS reviews and approves MA benefits using written policy guidelines and requirements in this part and other CMS instructions to ensure that—

* * * * *

(2) MA organizations are not designing benefits to discriminate against beneficiaries, promote discrimination, discourage enrollment or encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services; and

* * * * *

■ 26. Amend § 422.101 by-

A. Revising paragraph (b)(2).

B. Revising paragraph (b)(3) introductory text.

C. Adding paragraph (b)(4).

D. Adding paragraph (b)(5).

E. Adding paragraph (d).

F. Adding paragraph (e).

■ The revision and additions read as follows:

§ 422.101 Requirements relating to basic benefits.

* * * * *

(b) * * *

(2) General coverage guidelines included in original Medicare manuals and instructions unless superseded by regulations in this part or related instructions; and

(3) Written coverage decisions of local Medicare contractors with jurisdiction for claims in the geographic area in which services are covered under the MA plan. If an MA plan covers geographic areas encompassing more than one local coverage policy area, the MA organization offering such an MA plan may elect to apply to plan enrollees in all areas uniformly the coverage policy that is the most beneficial to MA enrollees. MA organizations that elect this option must notify CMS before selecting the area that has local coverage policies that are most beneficial to enrollees as follows:

* * * * *

(4) Instead of applying rules in paragraph (b)(3) of this section, and to the extent it exercises this option, an organization offering an MA regional plan in an MA region that covers more than one local coverage policy area must uniformly apply all of the local coverage policy determinations that apply in the selected local coverage policy area in that MA region to all parts of that same MA region. The selection of the single local coverage policy area's local coverage policy determinations to apply throughout the MA region is at the discretion of the MA regional plan and is not subject to CMS pre-approval.

(5) If an MA organization offering an MA local plan elects to exercise the option in paragraph (b)(3) of this section related to a local MA plan, or if an MA organization offering an MA regional plan elects to exercise the option in paragraph (b)(4) of this section related to an MA regional plan, then the MA organization must make information on the selected local coverage policy readily available, including through the Internet, to enrollees and health care providers.

* * * * *

(d) *Special cost-sharing rules for MA regional plans*. In addition to the requirements in paragraph (a) through paragraph (c) of this section, MA regional plans must provide for the following:

(1) *Single deductible*. MA regional plans, to the extent they apply a deductible, are only permitted to have only a single deductible related to combined Medicare Part A and Part B services (to the extent they have a deductible). Applicability of the single deductible may be differential for specific in-network services and may also be waived for preventative services or other items and services.

(2) *Catastrophic limit*. MA regional plans are required to provide for a catastrophic limit on beneficiary out-of-pocket expenditures for in-network benefits under the original Medicare fee-for-service program (Part A and Part B benefits).

(3) *Total catastrophic limit*. MA regional plans are required to provide a total catastrophic limit on beneficiary out-of-pocket expenditures for in-network and out-of-network benefits under the original Medicare fee-for-service program. This total out-of-pocket catastrophic limit, which would apply to both in-network and out-of-network benefits under original Medicare, may be higher than the in-network catastrophic limit in paragraph (d)(2) of this section, but may not increase the limit described in paragraph (d)(2) of this section.

(4) *Tracking of deductible and catastrophic limits and notification*. MA regional plans are required to track the deductible (if any) and catastrophic limits in paragraphs (d)(1) through (d)(3) of this section based on incurred out-of-pocket beneficiary costs for original Medicare covered services, and are also required to notify members and health care providers when the deductible (if any) or a limit has been reached.

(e) *Other rules for MA regional plans*. (1) MA regional plans are required to provide reimbursement for all covered benefits, regardless of whether those benefits are provided within or outside of the network of contracted providers.

(2) In applying the actuarially equivalent level of cost-sharing with respect to MA bids related to benefits under the original Medicare program option as set forth at § 422.256(b)(3), only the catastrophic limit on out-of-pocket expenses for in-network benefits in paragraph (d)(2) of this section will be taken into account.

■ 27. Amend § 422.102 by-

A. Revising paragraph (a)(1).

B. Revising paragraph (a)(3).

C. Adding paragraph (a)(4).

■ The revisions and addition read as follows:

§ 422.102 Supplemental benefits.

(a) * * *

(1) Subject to CMS approval, an MA organization may require Medicare enrollees of an MA plan (other than an MSA plan) to accept or pay for services in addition to Medicare-covered services described in § 422.101.

* * * * *

(3) CMS approves mandatory supplemental benefits if the benefits are designed in accordance with CMS' guidelines and requirements as stated in this part and other written instructions.

(4) Beginning in 2006, an MA plan may reduce cost sharing below the actuarial value specified in section 1854(e)(4)(A) of the Act only as a mandatory supplemental benefit.

* * * * *

■ 28. Amend § 422.103 by—

A. Revising the section heading.

B. Revising paragraph (a).

■ The revisions read as follows:

§ 422.103 Benefits under an MA MSA plan.

(a) General rule. An MA organization offering an MA MSA plan must make available to an enrollee, or provide reimbursement for, at least the services described in § 422.101 after the enrollee incurs countable expenses equal to the amount of the plan's annual deductible.

* * * * *

■ 29. Amend § 422.105 by-

A. Revising the section heading.

B. Revising paragraph (a).

C. Revising paragraph (b).

■ The revisions read as follows:

§ 422.105 Special rules for self-referral and point of service option.

(a) *Self-referral.* When an MA plan member receives an item or service of the plan that is covered upon referral or pre-authorization from a contracted provider of that plan, the member cannot be financially liable for more than the normal in-plan cost sharing, if the member correctly identified himself or herself as a member of that plan to the contracted provider before receiving the covered item or service, unless the contracted provider can show that the enrollee was notified prior to receiving the item or service that the item or service is covered only if further action is taken by the enrollee.

(b) *Point of service option.* As a general rule, a POS benefit is an option that an MA organization may offer in an MA coordinated care plan to provide enrollees with additional choice in obtaining specified health care services. The organization may offer A POS option—

(1) Before January 1, 2006, under a coordinated care plan as an additional benefit as described in section 1854(f)(1)(A) of the Act;

(2) Under a coordinated care plan as a mandatory supplemental benefit as described in § 422.102(a); or

(3) Under a coordinated care plan as an optional supplemental benefit as described in § 422.102(b).

(4) An MA regional plan or local MA PPO is permitted to offer a POS–LIKE benefit as described in paragraphs (b)(2) or (b)(3) of this section as a supplemental benefit. An MA regional plan or local MA PPO may offer a POS–LIKE option as a supplemental benefit where cost sharing for out-of-network services is reduced, in a limited manner, for services obtained from out-of-network providers. Offering a POS–LIKE supplemental benefit does not affect the MA regional plan's or local MA PPO's responsibility to provide reimbursement for all covered benefits, regardless of whether those benefits are provided within the network of contracted providers.

* * * * *

■ 30. Amend § 422.106 by-

A. Revising the paragraph (c) heading.

B. Revising paragraph (c)(2).

C. Adding paragraph (d).

■ The revisions and addition read as follows:

§ 422.106 Coordination of benefits with employer or union group health plans and Medicaid.

* * * * *

(c) *Waiver or modification of contracts with MA organizations.*

* * * * *

(2) Approved waivers or modifications under this paragraph granted to any MA organization may be used by any other similarly situated MA organization in developing its bid.

(d) *Employer sponsored MA plans for plan years beginning on or after January 1, 2006.* (1) CMS may waive or modify any requirement in this part or Part D that hinders the design of, the offering of, or the enrollment in, an MA plan (including an MA-PD plan) offered by one or more employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof), or that is offered, sponsored or administered by an entity on behalf of one or more employers or labor organizations, to furnish benefits to the employers' employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations. Any entity seeking to offer, sponsor, or administer such an MA plan described in this paragraph may request, in writing, from CMS, a waiver or modification of requirements in this part that hinder the design of, the offering of, or the enrollment in, such MA plan.

(2) An MA plan described in this paragraph may restrict the enrollment of individuals in that plan to individuals who are beneficiaries and participants in that plan.

(3) Approved waivers or modifications under this paragraph granted to any MA plan may be used by any other similarly situated MA plan in developing its bid.

■ 31. Amend § 422.108 by revising paragraph (f) to read as follows:

§ 422.108 Medicare secondary payer (MSP) procedures.

* * * * *

(f) *MSP rules and State laws.* Consistent with § 422.402 concerning the Federal preemption of State law, the rules established under this section supersede any State laws, regulations, contract requirements, or other standards that would otherwise apply to MA plans. A State cannot take away an MA organization's right under Federal law and the MSP regulations to bill, or to authorize providers and suppliers to bill, for services for which Medicare is not the primary payer. The MA organization will exercise the same rights to recover from a primary plan, entity, or individual that the Secretary exercises under the MSP regulations in subparts B through D of part 411 of this chapter.

■ 32. Amend § 422.109 by-

A. Revising paragraph (a)(2).

B. Revising paragraph (c)(2)(iv).

C. Revising paragraph (c)(3).

■ The revisions read as follows:

§ 422.109 Effect of national coverage determinations (NCDs) and legislative changes in benefits.

(a) * * *

(2) The estimated cost of Medicare services furnished as a result of a particular NCD or legislative change in benefits represents at least 0.1 percent of the national average per capita costs.

* * * * *

(c) * * *

(2) * * *

(iv) Any services, including the costs of the NCD service or legislative change in benefits, to the extent the MA organization is already obligated to cover it as a supplemental benefit under § 422.102.

(3) Costs for significant cost NCD services or legislative changes in benefits for which CMS fiscal intermediaries and carriers will make payment are those Medicare costs not listed in paragraphs (c)(2)(i) through (c)(2)(iv) of this section.

* * * * *

■ 33. Amend § 422.110 by-

A. Revising paragraph (b).

B. Removing paragraph (c).

■ The revision reads as follows:

§ 422.110 Discrimination against beneficiaries prohibited.

* * * * *

(b) *Exception.* An MA organization may not enroll an individual who has been medically determined to have end-stage renal disease. However, an enrollee who develops end-stage renal disease while enrolled in a particular MA organization may not be disenrolled for that reason. An individual who is an enrollee of a particular MA organization, and who resides in the MA plan service area at the time he or she first becomes MA eligible, or, an individual enrolled by an MA organization that allows those who reside outside its MA service area to enroll in an MA plan as set forth at § 422.50(a)(3)(ii), then that individual is considered to be ''enrolled'' in the MA organization for purposes of the preceding sentence.

§ 422.111 [Amended]

■ 34. Amend § 422.111 by-

A. Revising paragraph (b)(2) introductory text.

B. Redesignating paragraph (b)(3) introductory text as paragraph (b)(3)(i) and revising it.

C. Adding new paragraph (b)(3)(ii).

D. Revising paragraph (b)(9).

E. Adding paragraph (b)(11).

F. Revising paragraph (c)(1).

G. Revising paragraph (d)(2).

H. Revising paragraph (e).

I. Removing paragraph (f)(4).

J. Removing paragraph (f)(6).

K. Redesignating paragraph (f)(5) as paragraph (f)(4).

L. Redesignating paragraph (f)(7) as paragraph (f)(5).

M. Redesignating paragraph (f)(8) as paragraph (f)(6).

N. Redesignating paragraph (f)(9) as paragraph (f)(7).

O. Redesignating paragraph (f)(10) as paragraph (f)(8).

P. Redesignating paragraph (f)(11) as paragraph (f)(9).

Q. Revising newly redesignated paragraph (f)(5)(iv).

R. Removing newly redesignated paragraph (f)(5)(v).

S. Redesignating paragraph (f)(5)(vi) as paragraph (f)(5)(v).

T. Redesignating paragraph (f)(5)(vii) as paragraph (f)(5)(vi).

U. Redesignating paragraph (f)(5)(viii) as paragraph (f)(5)(vii).

V. Revising newly redesignated paragraph (f)(9).

W. Adding new paragraph (f)(10).

X. Adding new paragraph (f)(11)

Y. Adding new paragraph (f)(12)

■ The revisions and addition read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(b) * * *

(2) *Benefits*. The benefits offered under a plan, including applicable conditions and limitations, premiums and cost-sharing (such as copayments, deductibles, and coinsurance) and any other conditions associated with receipt or use of benefits; and to the extent it offers Part D as an MD-PD plan, the information in § 423.128 of this chapter; and for purposes of comparison-

* * * * *

(3) *Access*. (i) The number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services; any out-of network coverage; any point-of-service option, including the supplemental premium for that option; and how the MA organization meets the requirements of § 422.112 and § 422.114 for access to services offered under the plan.

(ii) The process MA regional plan enrollees should follow to secure in-network cost sharing when covered services are not readily available from contracted network providers.

* * * * *

(9) *Quality improvement program*. A description of the quality improvement program required under § 422.152.

* * * * *

(11) *Catastrophic caps and single deductible*. MA organizations sponsoring MA regional plans are required to provide enrollees a description of the catastrophic stop-loss coverage and single deductible (if any) applicable under the plan.

(c) * * *

(1) The information required in paragraph (f) of this section.

* * * * *

(d) * * *

(2) For changes that take effect on January 1, notify all enrollees at least 15 days before the beginning of the Annual Coordinated Election Period defined in section 1851(e)(3)(B) of the Act.

* * * * *

(e) *Changes to provider network*. The MA organization must make a good faith effort to provide written notice of a termination of a contracted provider at least 30 calendar days before the termination effective date to all enrollees who are patients seen on a regular basis by the provider whose contract is terminating, irrespective of whether the termination was for cause or without cause. When a contract termination involves a primary care professional, all enrollees who are patients of that primary care professional must be notified.

(f) * * *

(5) * * *

(iv) In the case of an MA MSA plan, the amount of the annual MSA deposit.

* * * * *

(9) *Supplemental benefits*. Whether the plan offers mandatory and optional supplemental benefits, including any reductions in cost sharing offered as a mandatory supplemental benefit as permitted under section 1852(a)(3) of the Act (and implementing regulations at § 422.102) and the terms, conditions, and premiums for those benefits.

(10) The names, addresses, and phone numbers of contracted providers from whom the enrollee may obtain in-network coverage in other parts of the service area.

(11) If an MA organization exercises the option in § 422.101(b)(3) or (b)(4) related to an MA plan, then it must make the local coverage determination that applies to members of that plan readily available to providers, including through a web site on the Internet.

(12) To the extent an MA organization has a web site or provides MA plan information through the Internet, then it must also post copies of its Evidence of Coverage, Summary of Benefits and information (names, addresses, phone numbers, specialty) on the network of contracted providers on an Internet web site. Such posting does not relieve the MA organization of its responsibility under § 422.111(a) to provide hard copies to enrollees.

§ 422.112 [Amended]

■ 35. Amend § 422.112 by-

A. Revising the heading of paragraph (a) and paragraph (a) introductory text.

B. Revising paragraph (a)(1).

C. Removing paragraph (a)(4).

D. Redesignating paragraph (a)(5) as paragraph (a)(4).

E. Redesignating paragraph (a)(6) as paragraph (a)(5).

F. Redesignating paragraph (a)(7) as paragraph (a)(6).

G. Redesignating paragraph (a)(8) as paragraph (a)(7).

H. Redesignating paragraph (a)(9) as paragraph (a)(8).

I. Redesignating paragraph (a)(10) as paragraph (a)(9).

J. Revising the heading of paragraph (b) and paragraph (b) introductory text.

K. Adding paragraph (c).

■ The revisions and addition read as follows:

§ 422.112 Access to services.

(a) *Rules for coordinated care plans*. An MA organization that offers an MA coordinated care plan may specify the networks of providers from whom enrollees may obtain services if the MA organization ensures that all covered services, including supplemental services contracted for by (or on behalf of) the Medicare enrollee, are available and accessible under the plan. To accomplish this, the MA organization must meet the following requirements:

(1) *Provider network*. (i) Maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served. These providers are typically used in the network as primary care providers (PCPs), specialists, hospitals, skilled nursing facilities, home health agencies, ambulatory clinics, and other providers.

(ii) *Exception*: MA regional plans, upon CMS pre-approval, can use methods other than written agreements to establish that access requirements are met.

* * * * *

(b) *Continuity of care*. MA organizations offering coordinated care plans must ensure continuity of care and integration of services through

arrangements with contracted providers that include-

* * * * *

(c) *Essential hospital.* An MA regional plan may seek, upon application to CMS, to designate a noncontracting hospital as an essential hospital as defined in section 1858(h) of the Act under the following conditions:

(1) The hospital that the MA regional plan seeks to designate as essential is a general acute care hospital identified as a ''subsection(d)'' hospital as defined in section 1886(d)(1)(B) of the Act.

(2) The MA regional plan provides convincing evidence to CMS that the MA regional plan needs to contract with the hospital as a condition of meeting access requirements under this section.

(3) The MA regional plan must establish that it made a ''good faith'' effort to contract with the hospital to be designated as an essential hospital and that the hospital refused to contract with it despite its ''good faith'' effort. A ''good faith'' effort to contract will be established to the extent that the MA regional plan can show it has offered the hospital a contract providing for the payment of rates in an amount no less than the amount the hospital would have received had payment been made under section 1886(d) of the Act.

(4) The MA regional plan must establish that there are no competing Medicare participating hospitals in the area to which MA regional plan enrollees could reasonably be referred for inpatient hospital services.

(5) The hospital that is to be designated as an essential hospital provides convincing evidence to CMS that the amounts normally payable under section 1886 of the Act (and which the MA regional plan has agreed to pay) will be less than the hospital's actual costs of providing care to the MA regional plan's enrollee.

(6) If CMS determines the requirements in paragraphs (c)(1) through (c)(5) of this section have been met, it will make payment to the essential hospital in accordance with section 1858(h)(2) of the Act based on the order in which claims are received, as limited by the amounts specified in section 1858(h)(3) of the Act.

(7) If CMS determines the requirements in paragraphs (c)(1) through (c)(4) of this section have been met, (and if they continue to be met upon annual renewal of the CMS contract with the MA organization offering the MA regional plan), then the hospital designated by the MA regional plan in paragraph (c)(1) of this section shall be ''deemed'' to be a network hospital to that MA regional plan based on the exception in paragraph (a)(1)(ii) of this section and normal in-network inpatient hospital cost sharing levels (including the catastrophic limit described in § 422.101(d)(2)) shall apply to all plan members accessing covered inpatient hospital services in that hospital.

■ 36. Amend § 422.113 by-

A. Revising paragraph (b)(2)(v).

B. Revising paragraph (c)(2)(iv).

■ The revisions read as follows:

§ 422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services.

* * * * *

(b) * * *

(2) * * *

(v) With a limit on charges to enrollees for emergency department services of $50 or what it would charge the enrollee if he or she obtained the services through the MA organization, whichever is less.

* * * * *

(c) * * *

(2) * * *

(iv) Must limit charges to enrollees for post-stabilization care services to an amount no greater than what the organization would charge the enrollee if he or she had obtained the services through the MA organization. For purposes of cost sharing, post-stabilization care services begin upon inpatient admission.

* * * * *

■ 37. Amend § 422.114 by—

A. Revising the section heading to read as set forth below.

B. Adding paragraph (c) to read as follows:

§ 422.114 Access to services under an MA private fee-for-service plan.

* * * * *

(c) *Contracted network.* Private fee-for-service plans that meet network adequacy requirements for a category of health care professional or provider by meeting the requirements in paragraph (a)(2)(ii) of this section may provide for a higher beneficiary copayment in the case of health care professionals or providers of that same category who do not have contracts or agreements to provide covered services under the terms of the plan.

■ 38. Amend § 422.133 by adding paragraph (b)(4) to read as follows:

§ 422.133 Return to home skilled nursing facility.

* * * * *

(b) * * *

(4) If an MA organization elects to furnish SNF care in the absence of a prior qualifying hospital stay under § 422.101(c), then that SNF care is also subject to the home skilled nursing facility rules in this section. In applying the provisions of this section to coverage under this paragraph, references to a hospitalization, or discharge from a hospital, are deemed to refer to wherever the enrollee resides immediately before admission for extended care services.

* * * * *

Subpart D—Quality Improvement

■ 39. In subpart D, remove ''quality assurance'' wherever it appears and add in its place ''quality improvement.''

■ 40. Revise § 422.152 to read as follows:

§ 422.152 Quality improvement program.

(a) *General rule.* Each MA organization (other than MA private-fee-for-service and MSA plans) that offers one or more MA plans must have, for each of those plans, an ongoing quality improvement program that meets the applicable requirements of this section for the services it furnishes to its MA enrollees. As part of its ongoing quality improvement program, a plan must—

(1) Have a chronic care improvement program that meets the requirements of paragraph (c) of this section concerning elements of a chronic care program;

(2) Conduct quality improvement projects that can be expected to have a favorable effect on health outcomes and enrollee satisfaction, and meet the requirements of paragraph (d) of this section; and

(3) Encourage its providers to participate in CMS and HHS quality improvement initiatives.

(b) *Requirements for MA coordinated care plans (except for regional MA plans) and including local PPO plans that are offered by organizations that are licensed or organized under State law as HMOs.* An MA coordinated care plan's (except for regional PPO plans and local PPO plans as defined in paragraph (e) of this section) quality improvement program must—

(1) In processing requests for initial or continued authorization of services, follow written policies and procedures that reflect current standards of medical practice.

(2) Have in effect mechanisms to detect both underutilization and overutilization of services.

(3) Measure and report performance. The organization offering the plan must do the following:

(i) Measure performance under the plan, using the measurement tools required by CMS, and report its performance to CMS. The standard

measures may be specified in uniform data collection and reporting instruments required by CMS.

(ii) Make available to CMS information on quality and outcomes measures that will enable beneficiaries to compare health coverage options and select among them, as provided in § 422.64(c)(10).

(4) Special rule for MA local PPO-type plans that are offered by an organization that is licensed or organized under State law as a health maintenance organization must meet the requirements specified in paragraphs (b)(1) through (b)(3) of this section.

(c) *Chronic care improvement program requirements*. Develop criteria for a chronic care improvement program. These criteria must include—

(1) Methods for identifying MA enrollees with multiple or sufficiently severe chronic conditions that would benefit from participating in a chronic care improvement program; and

(2) Mechanisms for monitoring MA enrollees that are participating in the chronic care improvement program.

(d) *Quality improvement projects*. (1) Quality improvement projects are an organization's initiatives that focus on specified clinical and nonclinical areas and that involve the following:

(i) Measurement of performance.

(ii) System interventions, including the establishment or alteration of practice guidelines.

(iii) Improving performance.

(iv) Systematic and periodic follow-up on the effect of the interventions.

(2) For each project, the organization must assess performance under the plan using quality indicators that are—

(i) Objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research; and

(ii) Capable of measuring outcomes such as changes in health status, functional status and enrollee satisfaction, or valid proxies of those outcomes.

(3) Performance assessment on the selected indicators must be based on systematic ongoing collection and analysis of valid and reliable data.

(4) Interventions must achieve demonstrable improvement.

(5) The organization must report the status and results of each project to CMS as requested.

(e) *Requirements for MA regional plans and MA local plans that are PPO plans as defined in this section*—(1) *Definition of local preferred provider organization plan*. For purposes of this section, the term local preferred provider organization (PPO) plan means an MA plan that—

(i) Has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;

(ii) Provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; and

(iii) Is offered by an organization that is not licensed or organized under State law as a health maintenance organization.

(2) MA organizations offering an MA regional plan or local PPO plan as defined in this section must:

(i) Measure performance under the plan using standard measures required by CMS and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS.

(ii) Evaluate the continuity and coordination of care furnished to enrollees.

(iii) If the organization uses written protocols for utilization review, the organization must—

(A) Base those protocols on current standards of medical practice; and

(B) Have mechanisms to evaluate utilization of services and to inform enrollees and providers of services of the results of the evaluation.

(f) *Requirements for all types of plans*—(1) *Health information*. For all types of plans that it offers, an organization must—

(i) Maintain a health information system that collects, analyzes, and integrates the data necessary to implement its quality improvement program;

(ii) Ensure that the information it receives from providers of services is reliable and complete; and

(iii) Make all collected information available to CMS.

(2) *Program review*. For each plan, there must be in effect a process for formal evaluation, at least annually, of the impact and effectiveness of its quality improvement program.

(3) *Remedial action*. For each plan, the organization must correct all problems that come to its attention through internal surveillance, complaints, or other mechanisms.

§ 422.154 [Removed]

■ 41. Remove § 422.154.

■ 42. Amend § 422.156 by-

A. Revising paragraph (b)(1).

B. Adding paragraph (b)(7).

■ The revision and addition read as follows:

§ 422.156 Compliance deemed on the basis of accreditation.

* * * * *

(b) * * *

(1) Quality improvement.

* * * * *

(7) Part D prescription drug benefit programs that are offered by MA programs.

* * * * *

Subpart E—Relationships With Providers

§ 422.202 [Amended]

■ 43. In § 422.202, amend paragraph (b) introductory text by removing ''quality assurance'' and adding ''quality improvement'' in its place.

§ 422.204 [Amended]

■ 44. In § 422.204, amend paragraph (b)(2)(ii) by removing ''quality assurance'' and adding ''quality improvement'' in its place.

■ 45. In § 422.208, the following changes are made:

A. Paragraph (c)(2) is revised.

B. Paragraph (h) is removed.

C. Paragraph (i) is redesignated as paragraph (h).

■ The revision reads as follows:

§ 422.208 Physician incentive plans: Requirements and limitations.

* * * * *

(c) * * *

(2) If the physician incentive plan places a physician or physician group at substantial financial risk (as determined under paragraph (d) of this section) for services that the physician or physician group does not furnish itself, the MA organization must assure that all physicians and physician groups at substantial financial risk have either aggregate or per-patient stop-loss protection in accordance with paragraph (f) of this section and conduct periodic surveys in accordance with paragraph (h) of this section.

* * * * *

■ 46. Section 422.210 is revised to read as follows:

§ 422.210 Assurances to CMS.

Each organization will provide assurance satisfactory to the Secretary that the requirements of § 422.208 are met.

■ 47. In 422.214, the following changes are made:

A. Paragraph (a)(1) is revised.

B. Paragraph (b) is revised.

■ The revisions read as follows:

§ 422.214 Special rules for services furnished by noncontract providers.

(a) * * *

(1) Any provider (other than a provider of services as defined in section 1861(u) of the Act) that does not

have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an MA coordinated care plan, an MSA plan, or an MA private fee-for-service plan must accept, as payment in full, the amounts that the provider could collect if the beneficiary were enrolled in original Medicare.

* * * * *

(b) Services furnished by section 1861(u) providers of service. Any provider of services as defined in section 1861(u) of the Act that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an MA coordinated care plan, an MSA plan, or an MA private fee-for-service plan must accept, as payment in full, the amounts (less any payments under § 412.105(g) and § 413.86(d) of this chapter) that it could collect if the beneficiary were enrolled in original Medicare. (Section 412.105(g) concerns indirect medical education payment to hospitals for managed care enrollees. Section 413.86(d) concerns calculating payment for direct medical education costs.)

■ 48—49. Subpart F is revised to read as follows:

Subpart F—Submission of Bids, Premiums, and Related Information and Plan Approval

Secs.
422.250 Basis and scope.
422.252 Terminology.
422.254 Submission of bids.
422.256 Review, negotiation, and approval of bids.
422.258 Calculation of benchmarks.
422.262 Beneficiary premiums.
422.264 Calculation of savings.
422.266 Beneficiary rebates.
422.270 Incorrect collections of premiums and cost sharing.

Subpart F-Submission of Bids, Premiums, and Related Information and Plan Approval

§ 422.250 Basis and scope.

This subpart is based largely on section 1854 of the Act, but also includes provisions from section 1853 and section 1858 of the Act. It sets forth the requirements for the Medicare Advantage bidding payment methodology, including CMS' calculation of benchmarks, submission of plan bids by Medicare Advantage (MA) organizations, establishment of beneficiary premiums and rebates through comparison of plan bids and benchmarks, and negotiation and approval of bids by CMS.

§ 422.252 Terminology.

Annual MA capitation rate means a county payment rate for an MA local area (county) for a calendar year. The terms ''per capita rate'' and ''capitation rate'' are used interchangeably to refer to the annual MA capitation rate.

MA local area means a payment area consisting of county or equivalent area specified by CMS.

MA monthly basic beneficiary premium means the premium amount an MA plan (except an MSA plan) charges an enrollee for benefits under the original Medicare fee-for-service program option (if any), and is calculated as described at § 422.262.

MA monthly MSA premium means the amount of the plan premium for coverage of benefits under the original Medicare program through an MSA plan, as set forth at § 422.254(e).

MA monthly prescription drug beneficiary premium is the MA-PD plan base beneficiary premium, defined at section 1860D–13(a)(2) of the Act, as adjusted to reflect the difference between the plan's bid and the national average bid (as described in § 422.256(c)) less the amount of rebate the MA-PD plan elects to apply, as described at § 422.266(b)(2).

MA monthly supplemental beneficiary premium is the portion of the plan bid attributable to mandatory and/or optional supplemental health care benefits described under § 422.102, less the amount of beneficiary rebate the plan elects to apply to a mandatory supplemental benefit, as described at § 422.266(b)(2)(i).

MA-PD plan means an MA local or regional plan that provides prescription drug coverage under Part D of Title XVIII of the Social Security Act.

Monthly aggregate bid amount means the total monthly plan bid amount for coverage of an MA eligible beneficiary with a nationally average risk profile for the factors described in § 422.308(c), and this amount is comprised of the following:

(1) The unadjusted MA statutory non-drug monthly bid amount for coverage of original Medicare benefits;

(2) The amount for coverage of basic prescription drug benefits under Part D (if any); and

(3) The amount for provision of supplemental health care benefits (if any).

Plan basic cost sharing means cost sharing that would be charged by a plan for benefits under the original Medicare FFS program option before any reductions resulting from mandatory supplemental benefits.

Unadjusted MA area-specific non-drug monthly benchmark amount means, for local MA plans serving one county, the county capitation rate CMS publishes annually, and for local MA plans serving multiple counties it is the weighted average of county rates in a plan's service area, weighted by the plan's projected enrollment per county.

Unadjusted MA region-specific non-drug monthly benchmark amount means, for MA regional plans, the amount described at § 422.258(b).

Unadjusted MA statutory non-drug monthly bid amount means a plan's estimate of its average monthly required revenue to provide coverage of original Medicare benefits to an MA eligible beneficiary with a nationally average risk profile for the risk factors CMS applies to payment calculations as set forth at § 422.308(c).

§ 422.254 Submission of bids.

(a) *General rules.* (1) Not later than the first Monday in June, each MA organization must submit to CMS an aggregate monthly bid amount for each MA plan (other than an MSA plan) the organization intends to offer in the upcoming year in the service area (or segment of such an area if permitted under § 422.262(c)(2)) that meets the requirements in paragraph (b) of this section. With each bid submitted, the MA organization must provide the information required in paragraph (c) of this section and, for plans with rebates as described at § 422.266(a), the MA organization must provide the information required in paragraph (d) of this section.

(2) CMS has the authority to determine whether and when it is appropriate to apply the bidding methodology described in this section to ESRD MA enrollees.

(3) If the bid submission described in paragraphs (a)(1) and (2) of this section is not complete, timely, or accurate, CMS has the authority to impose sanctions under subpart O of this part or may choose not to renew the contract.

(b) *Bid requirements.* (1) The monthly aggregate bid amount submitted by an MA organization for each plan is the organization's estimate of the revenue required for the following categories for providing coverage to an MA eligible beneficiary with a national average risk profile for the factors described in § 422.308(c):

(i) The statutory non-drug bid amount, which is the MA plan's estimated average monthly required revenue for providing benefits under the original Medicare fee-for-service program option (as defined in § 422.252).

(ii) The amount to provide basic prescription drug coverage, if any (defined at section 1860D–2(a)(3) of the Act).

(iii) The amount to provide supplemental health care benefits, if any.

(2) Each bid is for a uniform benefit package for the service area.

(3) Each bid submission must contain all estimated revenue required by the plan, including administrative costs and return on investment.

(4) The bid amount is for plan payments only but must be based on plan assumptions about the amount of revenue required from enrollee cost-sharing. The estimate of plan cost-sharing for the unadjusted MA statutory non-drug monthly bid amount for coverage of original Medicare benefits must reflect the requirement that the level of cost sharing MA plans charge to enrollees must be actuarially equivalent to the level of cost sharing (deductible, copayments, or coinsurance) charged to beneficiaries under the original Medicare program option. The actuarially equivalent level of cost sharing reflected in a regional plan's unadjusted MA statutory non-drug monthly bid amount does not include cost sharing for out-of-network Medicare benefits, as described at § 422.101(d).

(c) *Information required for coordinated care plans and MA private fee-for-service plans.* MA organizations' submission of bids for coordinated care plans, including regional MA plans and specialized MA plans for special needs beneficiaries (described at § 422.4(a)(1)(iv)), and for MA private fee-for-service plans must include the following information:

(1) The plan type for each plan.

(2) The monthly aggregate bid amount for the provision of all items and services under the plan, as defined in § 422.252 and discussed in paragraph (a) of this section.

(3) The proportions of the bid amount attributable to-

(i) The provision of benefits under the original Medicare fee-for-service program option (as defined at § 422.100(c));

(ii) The provision of basic prescription drug coverage (as defined at section 1860D–2(a)(3) of the Act; and

(iii) The provision of supplemental health care benefits (as defined § 422.102).

(4) The projected number of enrollees in each MA local area used in calculation of the bid amount, and the enrollment capacity, if any, for the plan.

(5) The actuarial basis for determining the amount under paragraph (c)(2) of this section, the proportions under paragraph (c)(3) of this section, the amount under paragraph (b)(4) of this section, and additional information as CMS may require to verify actuarial bases and the projected number of enrollees.

(6) A description of deductibles, coinsurance, and copayments applicable under the plan and the actuarial value of the deductibles, coinsurance, and copayments.

(7) For qualified prescription drug coverage, the information required under section 1860D–11(b) of the Act with respect to coverage.

(8) For the purposes of calculation of risk corridors under § 422.458, MA organizations offering regional MA plans in 2006 and/or 2007 must submit the following information developed using the appropriate actuarial bases.

(i) Projected allowable costs (defined in § 422.458(a)).

(ii) The portion of projected allowable costs attributable to administrative expenses incurred in providing these benefits.

(iii) The total projected costs for providing rebatable integrated benefits (as defined in § 422.458(a)) and the portion of costs that is attributable to administrative expenses.

(9) For regional plans, as determined by CMS, the relative cost factors for the counties in a plan's service area, for the purposes of adjusting payment under § 422.308(d) for intra-area variations in an MA organization's local payment rates.

(d) *Beneficiary rebate information.* In the case of a plan required to provide a monthly rebate under § 422.266 for a year, the MA organization offering the plan must inform CMS how the plan will distribute the beneficiary rebate among the options described at § 422.266(b).

(e) *Information required for MSA plans.* MA organizations intending to offer MA MSA plans must submit—

(1) The enrollment capacity (if any) for the plan;

(2) The amount of the MSA monthly premium for basic benefits under the original Medicare fee-for-service program option;

(3) The amount of the plan deductible; and

(4) The amount of the beneficiary supplemental premium, if any.

(f) Separate bids must be submitted for Part A and Part B enrollees and Part B-only enrollees for each MA plan offered.

§ 422.256 Review, negotiation, and approval of bids.

(a) *Authority.* Subject to paragraphs (a)(2), (d), and (e) of this section, CMS has the authority to review the aggregate bid amounts submitted under § 422.252 and conduct negotiations with MA organizations regarding these bids (including the supplemental benefits) and the proportions of the aggregate bid attributable to basic benefits, supplemental benefits, and prescription drug benefits.

(1) When negotiating bid amounts and proportions, CMS has authority similar to that provided the Director of the Office of Personnel Management for negotiating health benefits plans under 5 U.S.C. chapter 89.

(2) *Noninterference.* (i) In carrying out Parts C and D under this title, CMS may not require any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services.

(ii) CMS may not require a particular price structure for payment under such a contract, with the exception of payments to Federally qualified health centers as set forth at § 422.316.

(b) *Standards of bid review.* Subject to paragraphs (d) and (e) of this section, CMS can only accept bid amounts or proportions described in paragraph (a) of this section if CMS determines the following standards have been met:

(1) The bid amount and proportions are supported by the actuarial bases provided by MA organizations under § 422.254.

(2) The bid amount and proportions reasonably and equitably reflects the plan's estimated revenue requirements for providing the benefits under that plan, as the term revenue requirements is used for purposes of section 1302(8) of the Public Health Service Act.

(3) *Limitation on enrollee cost sharing.* For coordinated care plans (including regional MA plans and specialized MA plans) and private fee-for-service plans (other than MSA plans):

(i) The actuarial value of plan basic cost sharing, reduced by any supplemental benefits, may not exceed—

(ii) The actuarial value of deductibles, coinsurance, and copayments that would be applicable for the benefits to individuals entitled to benefits under Part A and enrolled under Part B in the plan's service area with a national average risk profile for the factors described in § 422.308(c) if they were not members of an MA organization for the year, except that cost sharing for non-network Medicare services in a regional MA plan is not counted under the amount described in paragraph (b)(2)(i) of this section.

(c) *Negotiation process.* The negotiation process may include the resubmission of information to allow MA organizations to modify their initial bid submissions to account for the

outcome of CMS' regional benchmark calculations required under § 422.258(b) and the outcome of CMS' calculation of the national average monthly bid amount required under section 1860D–13(a)(4) of the Act.

(d) *Exception for private fee-for-service plans.* For private fee-for-service plans defined at § 422.4(a)(3), CMS will not review, negotiate, or approve the bid amount, proportions of the bid, or the amounts of the basic beneficiary premium and supplemental premium.

(e) *Exception for MSA plans.* CMS does not review, negotiate, or approve amounts submitted with respect to MA MSA plans, except to determine that the deductible does not exceed the statutory maximum, defined at § 422.103(d).

§ 422.258 Calculation of benchmarks.

(a) The term ''MA area-specific non-drug monthly benchmark amount'' means, for a month in a year:

(1) *For MA local plans with service areas entirely within a single MA local area,* 1/12th of the annual MA capitation rate (described at § 422.306) for the area, adjusted as appropriate for the purpose of risk adjustment.

(2) *For MA local plans with service areas including more than one MA local area*, an amount equal to the weighted average of annual capitation rates for each local area (county) in the plan's service area, using as weights the projected number of enrollees in each MA local area that the plan used to calculate the bid amount, and adjusted as appropriate for the purpose of risk adjustment.

(b) For MA regional plans, the term ''MA region-specific non-drug monthly benchmark amount'' is:

(1) The sum of two components: the statutory component (based on a weighted average of local benchmarks in the region, as described in paragraph (c)(3) of this section; and the plan bid component (based on a weighted average of regional plan bids in the region as described in paragraph (c)(4) of this section).

(2) Announced before November 15 of each year, but after CMS has received the plan bids.

(c) *Calculation of MA regional non-drug benchmark amount.* CMS calculates the monthly regional non-drug benchmark amount for each MA region as follows:

(1) *Reference month.* For all calculations that follow, CMS will determine the number of MA eligible individuals in each local area, in each region, and nationally as of the reference month, which is a month in the previous calendar year CMS identifies.

(2) *Statutory market share.* CMS will determine the statutory national market share percentage as the proportion of the MA eligible individuals nationally who were not enrolled in an MA plan.

(3) *Statutory component of the region-specific benchmark.* (i) CMS calculates the unadjusted region-specific non-drug amount by multiplying the county capitation rate by the county's share of the MA eligible individuals residing in the region (the number of MA eligible individuals in the county divided by the number of MA eligible individuals in the region), and then adding all the enrollment-weighted county rates to a sum for the region.

(ii) CMS then multiplies the unadjusted region-specific non-drug amount from paragraph (c)(3)(i) of this section by the statutory market share to determine the statutory component of the regional benchmark.

(4) *Plan-bid component of the region-specific benchmark.* For each regional plan offered in a region, CMS will multiply the plan's unadjusted region-specific non-drug bid amount by the plan's share of enrollment (as determined under paragraph (c)(5) of this section) and then sum these products across all plans offered in the region. CMS then multiples this by 1 minus the statutory market share to determine the plan-bid component of the regional benchmark.

(5) *Plan's share of enrollment.* CMS will calculate the plan's share of MA enrollment in the region as follows:

(i) In the first year that any MA regional plan is being offered in an MA region, and more than one MA regional plan is being offered, CMS will determine each regional plan's share of enrollment based on one of two possible approaches. CMS may base this factor on equal division among plans, so that each plan's share will be 1 divided by the number of plans offered. Alternatively, CMS may base this factor on each regional plan's estimate of projected enrollment. Plan enrollment projections are subject to review and adjustment by CMS to assure reasonableness.

(ii) If two or more regional plans are offered in a region and were offered in the reference month: The plan's share of enrollment will be the number of MA eligible individuals enrolled in the plan divided by the number of MA eligible individuals enrolled in all of the plans in the region, as of the reference month.

(iii) If a single regional plan is being offered in the region: The plan's share of enrollment is equal to 1.

§ 422.262 Beneficiary premiums.

(a) Determination of MA monthly basic beneficiary premium. (1) For an MA plan with an unadjusted statutory non-drug bid amount that is less than the relevant unadjusted non-drug benchmark amount, the basic beneficiary premium is zero.

(2) For an MA plan with an unadjusted statutory non-drug bid amount that is equal to or greater than the relevant unadjusted non-drug benchmark amount, the basic beneficiary premium is the amount by which (if any) the bid amount exceeds the benchmark amount. All approved basic premiums must be charged; they cannot be waived.

(b) Consolidated monthly premiums. Except as specified in paragraph (b)(2) of this section, MA organizations must charge enrollees a consolidated monthly MA premium.

(1) The consolidated monthly premium for an MA plan (other than a MSA plan) is the sum of the MA monthly basic beneficiary premium (if any), the MA monthly supplementary beneficiary premium (if any), and the MA monthly prescription drug beneficiary premium (if any).

(2) *Special rule for MSA plans.* For an individual enrolled in an MSA plan offered by an MA organization, the monthly beneficiary premium is the supplemental premium (if any).

(c) *Uniformity of premiums*—(1) *General rule.* Except as permitted for supplemental premiums pursuant to § 422.106(d), for MA contracts with employers and labor organizations, the MA monthly bid amount submitted under § 422.254, the MA monthly basic beneficiary premium, the MA monthly supplemental beneficiary premium, the MA monthly prescription drug premium, and the monthly MSA premium of an MA organization may not vary among individuals enrolled in an MA plan (or segment of the plan as provided for local MA plans under paragraph (c)(2) of this section). In addition, the MA organization cannot vary the level of cost-sharing charged for basic benefits or supplemental benefits (if any) among individuals enrolled in an MA plan (or segment of the plan).

(2) *Segmented service area option.* An MA organization may apply the uniformity requirements in paragraph (c)(1) of this section to segments of an MA local plan service area (rather than to the entire service area) as long as such a segment is composed of one or more MA payment areas. The information specified under § 422.254 is submitted separately for each segment. This provision does not apply to MA regional plans.

(d) *Monetary inducement prohibited.* An MA organization may not provide for cash or other monetary rebates as an inducement for enrollment or for any other reason or purpose.

(e) *Timing of payments.* The MA organization must permit payments of MA monthly basic and supplemental beneficiary premiums and monthly prescription drug beneficiary premiums on a monthly basis and may not terminate coverage for failure to make timely payments except as provided in § 422.74(b).

(f) *Beneficiary payment options.* An MA organization must permit each enrollee, at the enrollee's option, to make payment of premiums (if any) under this part to the organization through-

(1) Withholding from the enrollee's Social Security benefit payments, or benefit payments by the Railroad Retirement Board or the Office of Personnel Management, in the manner that the Part B premium is withheld;

(2) An electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account);

(3) According to other means that CMS may specify, including payment by an employer or under employment-based retiree health coverage on behalf of an employee, former employee (or dependent), or by other third parties such as a State.

(i) Regarding the option in paragraph (f)(1) of this section, MA organizations may not impose a charge on beneficiaries for the election of this option.

(ii) An enrollee may opt to make a direct payment of premium to the plan.

§ 422.264 Calculation of savings.

(a) *Computation of risk adjusted bids and benchmarks.*

(1) *The risk adjusted MA statutory non-drug monthly bid amount* is the unadjusted plan bid amount for coverage of original Medicare benefits (defined at § 422.254), adjusted using the factors described in paragraph (c) of this section for local plans and paragraph (e) of this section for regional plans.

(2) The *risk adjusted MA area-specific non-drug monthly benchmark amount* is the unadjusted benchmark amount for coverage of original Medicare benefits by a local MA plan (defined at § 422.258), adjusted using the factors described in paragraph (c) of this section.

(3) The *risk adjusted MA region-specific non-drug monthly benchmark amount* is the unadjusted benchmark for coverage of original Medicare benefits amount by a regional MA plan (defined at § 422.258) adjusted using the factors described in paragraph (e) of this section.

(b) *Computation of savings for MA local plans.* The average per capita monthly savings for an MA local plan is 100 percent of the difference between the plan's risk-adjusted statutory non-drug monthly bid amount (described in paragraph (a)(1) of this section) and the plan's risk-adjusted area-specific non-drug monthly benchmark amount (described in paragraph (a)(2) of this section). Plans with bids equal to or greater than plan benchmarks will have zero savings.

(c) *Risk adjustment factors for determination of savings for local plans.* CMS will publish the first Monday in April before the upcoming calendar year the risk adjustment factors described in paragraph (c)(1) or (c)(2) of this section determined for the purpose of calculating savings amounts for MA local plans.

(1) For the purpose of calculating savings for MA local plans CMS has the authority to apply risk adjustment factors that are plan-specific average risk adjustment factors, Statewide average risk adjustment factors, or factors determined on a basis other than plan-specific factors or Statewide average factors.

(2) In the event that CMS applies Statewide average risk adjustment factors, the statewide factor for each State is the average of the risk factors calculated under § 422.308(c), based on all enrollees in MA local plans in that State in the previous year. In the case of a State in which no local MA plan was offered in the previous year, CMS will estimate an average and may base this average on average risk adjustment factors applied to comparable States or applied on a national basis.

(d) *Computation of savings for MA regional plans.* The average per capita monthly savings for an MA regional plan and year is 100 percent of the difference between the plan's risk-adjusted statutory non-drug monthly bid amount (described in paragraph (a)(1) of this section) and the plan's risk-adjusted region-specific non-drug monthly benchmark amount (described in paragraph (a)(3) of this section), using the risk adjustment factors described in paragraph (e) of this section. Plans with bids equal to or greater than plan benchmarks will have zero savings.

(e) *Risk adjustment factors for determination of savings for regional plans.* CMS will publish the first Monday in April before the upcoming calendar year the risk adjustment factors described in paragraph (e)(1)and (e)(2) of this section determined for the purpose of calculating savings amounts for MA regional plans.

(1) For the purpose of calculating savings for MA regional plans, CMS has the authority to apply risk adjustment factors that are plan-specific average risk adjustment factors, Region-wide average risk adjustment factors, or factors determined on a basis other than MA regions.

(2) In the event that CMS applies region-wide average risk adjustment factors, the region-wide factor for each MA region is the average of the risk factors calculated under § 422.308(c), based on all enrollees in MA regional plans in that region in the previous year. In the case of a region in which no regional plan was offered in the previous year, CMS will estimate an average and may base this average on average risk adjustment factors applied to comparable regions or applied on a national basis.

§ 422.266 Beneficiary rebates.

(a) *General rule.* An MA organization must provide to the enrollee a monthly rebate equal to 75 percent of the average per capita savings (if any) described in § 422.264(b) for MA local plans and § 422.264(d) for MA regional plans.

(b) *Form of rebate.* The rebate required under this paragraph must be provided by crediting the rebate amount to one or more of the following:

(1) *Supplemental health care benefits.* MA organizations may apply all or some portion of the rebate for a plan toward payment for non-drug supplemental health care benefits for enrollees as described in § 422.102, which may include the reduction of cost sharing for benefits under original Medicare and additional health care benefits that are not benefits under original Medicare. MA organizations also may apply all or some portion of the rebate for a plan toward payment for supplemental drug coverage described at § 423.104(f)(1)(ii), which may include reduction in cost sharing and coverage of drugs not covered under Part D. The rebate, or portion of rebate, applied toward supplemental benefits may only be applied to a mandatory supplemental benefit, and cannot be used to fund an optional supplemental benefit.

(2) *Payment of premium for prescription drug coverage.* MA organizations that offer a prescription drug benefit may credit some or all of the rebate toward reduction of the MA monthly prescription drug beneficiary premium.

(3) *Payment toward Part B premium.* MA organizations may credit some or all of the rebate toward reduction of the

Medicare Part B premium (determined without regard to the application of subsections (b), (h), and (i) of section 1839 of the Act).

(c) *Disclosure relating to rebates.* MA organizations must disclose to CMS information on the amount of the rebate provided, as required at § 422.254(d). MA organizations must distinguish, for each MA plan, the amount of rebate applied to enhance original Medicare benefits from the amount of rebate applied to enhance Part D benefits.

§ 422.270 Incorrect collections of premiums and cost-sharing.

(a) *Definitions.* As used in this section-

(1) Amounts incorrectly collected-

(i) Means amounts that-

(A) Exceed the limits approved under § 422.262;

(B) In the case of an MA private fee-for-service plan, exceed the MA monthly basic beneficiary premium or the MA monthly supplemental premium submitted under § 422.262; and

(C) In the case of an MA MSA plan, exceed the MA monthly beneficiary supplemental premium submitted under § 422.262, or exceed permissible cost sharing amounts after the deductible has been met per § 422.103; and

(ii) Includes amounts collected from an enrollee who was believed to be entitled to Medicare benefits but was later found not to be entitled.

(2) *Other amounts due* are amounts due for services that were—

(i) Emergency, urgently needed services, or other services obtained outside the MA plan; or

(ii) Initially denied but, upon appeal, found to be services the enrollee was entitled to have furnished by the MA organization.

(b) *Basic commitments.* An MA organization must agree to refund all amounts incorrectly collected from its Medicare enrollees, or from others on behalf of the enrollees, and to pay any other amounts due the enrollees or others on their behalf.

(c) *Refund methods*—(1) *Lump-sum payment.* The MA organization must use lump-sum payments for the following:

(i) Amounts incorrectly collected that were not collected as premiums.

(ii) Other amounts due.

(iii) All amounts due if the MA organization is going out of business or terminating its MA contract for an MA plan(s).

(2) *Premium adjustment or lump-sum payment, or both.* If the amounts incorrectly collected were in the form of premiums, or included premiums as well as other charges, the MA organization may refund by adjustment of future premiums or by a combination of premium adjustment and lump-sum payments.

(3) *Refund when enrollee has died or cannot be located.* If an enrollee has died or cannot be located after reasonable effort, the MA organization must make the refund in accordance with State law.

(d) *Reduction by CMS.* If the MA organization does not make the refund required under this section by the end of the contract period following the contract period during which an amount was determined to be due to an enrollee, CMS will reduce the premium the MA organization is allowed to charge an MA plan enrollee by the amounts incorrectly collected or otherwise due. In addition, the MA organization would be subject to sanction under subpart O of this part for failure to refund amounts incorrectly collected from MA plan enrollees.

■ 50–51. Subpart G is revised to read as follows:

Subpart G—Payments to Medicare Advantage Organizations

Sec.
422.300 Basis and scope.
422.304 Monthly payments.
422.306 Annual MA capitation rates.
422.308 Adjustments to capitation rates, benchmarks, bids, and payments.
422.310 Risk adjustment data.
422.311 Announcement of annual capitation rate, benchmarks, and methodology changes.
422.314 Special rules for beneficiaries enrolled in MA MSA plans.
422.316 Special rules for payments to Federally qualified health centers.
422.318 Special rules for coverage that begins or ends during an inpatient hospital stay.
422.320 Special rules for hospice care.
422.322 Source of payment and effect of MA plan election on payment.
422.324 Payments to MA organizations for graduate medical education costs.

Subpart G—Payments to Medicare Advantage Organizations

§ 422.300 Basis and scope.

This subpart is based on sections 1853, 1854, and 1858 of the Act. It sets forth the rules for making payments to Medicare Advantage (MA) organizations offering local and regional MA plans, including calculation of MA capitation rates and benchmarks, conditions under which payment is based on plan bids, adjustments to capitation rates (including risk adjustment), and other payment rules.

See § 422.458 in subpart J for rules on risk sharing payments to MA regional organizations.

§ 422.304 Monthly payments.

(a) *General rules.* Except as provided in paragraph (b) of this section, CMS makes advance monthly payments of the amounts determined under paragraphs (a)(1) and (a)(2) of this section for coverage of original fee-for-service benefits for an individual in an MA payment area for a month.

(1) *Payment of bid for plans with bids below benchmark.* For MA plans that have average per capita monthly savings (as described at § 422.264(b) for local plans and § 422.264(d) for regional plans), CMS pays:

(i) The unadjusted MA statutory non-drug monthly bid amount defined in § 422.252, risk-adjusted as described at § 422.308(c) and adjusted (if applicable) for variations in rates within the plan's service area (described at § 422.258(a)(2)) and for the effects of risk adjustment on beneficiary premiums under § 422.262; and

(ii) The amount (if any) of the rebate described in paragraph (a)(3) of this section.

(2) *Payment of benchmark for plans with bids at or above benchmark.* For MA plans that do not have average per capita monthly savings (as described at § 422.264(b) for local plans and § 422.264(d) for regional plans), CMS pays the unadjusted MA area-specific non-drug monthly benchmark amount specified at § 422.258, risk-adjusted as described at § 422.308(c) and adjusted (if applicable) for variations in rates within the plan's service area (described at § 422.258(a)(2)) and for the effects of risk adjustment on beneficiary premiums under § 422.262.

(3) *Payment of rebate for plans with bids below benchmarks.* The rebate amount under paragraph (a)(1)(ii) of this section is the amount of the monthly rebate computed under § 422.266(a) for that plan, less the amount (if any) applied to reduce the Part B premium, as provided under § 422.266(b)(3)).

(b) *Separate payment for Federal drug subsidies.* In the case of an enrollee in an MA-PD plan, defined at § 422.252, the MA organization offering such a plan also receives-

(1) Direct and reinsurance subsidy payments for qualified prescription drug coverage, described at section 1860D–15(a) and (b) of the Act (other than payments for fallback prescription drug plans described at section 1860D–11(g)(5) of the Act); and

(2) Reimbursement for premium and cost sharing reductions for low-income individuals, described at section 1860D–14 of the Act.

(c) *Special rules*—(1) *Enrollees with end-stage renal disease.* (i) For enrollees determined to have end-stage renal

disease (ESRD), CMS establishes special rates that are actuarially equivalent to rates in effect before the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(ii) CMS publishes annual changes in these capitation rates no later than the first Monday in April each year, as provided in § 422.312.

(iii) CMS applies appropriate adjustments when establishing the rates, including risk adjustment factors.

(iv) CMS reduces the payment rate for each renal dialysis treatment by the same amount that CMS is authorized to reduce the amount of each composite rate payment for each treatment as set forth in section 1881(b)(7) of the Act. These funds are to be used to help pay for the ESRD network program in the same manner as similar reductions are used in original Medicare.

(2) *MSA enrollees*. In the case of an MSA plan, CMS pays the unadjusted MA area-specific non-drug monthly benchmark amount for the service area, determined in accordance with § 422.314(c) and subject to risk adjustment as set forth at § 422.308(c), less 1/12 of the annual lump sum amount (if any) CMS deposits to the enrollee's MA MSA.

(3) *RFB plan enrollees*. For RFB plan enrollees, CMS adjusts the capitation payments otherwise determined under this subpart to ensure that the payment level is appropriate for the actuarial characteristics and experience of these enrollees. That adjustment can be made on an individual or organization basis.

(d) *Payment areas*—(1) *General rule*. Except as provided in paragraph (e) of this section—

(i) An MA payment area for an MA local plan is an MA local area defined at § 422.252.

(ii) An MA payment area for an MA regional plan is an MA region, defined at § 422.455(b)(1).

(2) *Special rule for ESRD enrollees*. For ESRD enrollees, the MA payment area is a State or other geographic area specified by CMS.

(e) *Geographic adjustment of payment areas for MA local plans*—(1) *Terminology*. ''Metropolitan Statistical Area'' and ''Metropolitan Division'' mean any areas so designated by the Office of Management and Budget in the Executive Office of the President.

(2) *State request*. A State's chief executive may request, no later than February 1 of any year, a geographic adjustment of the State's payment areas for MA local plans for the following calendar year. The chief executive may request any of the following adjustments to the payment area specified in paragraph (c)(1)(i) of this section:

(i) A single statewide MA payment area.

(ii) A metropolitan-based system in which all non-metropolitan areas within the State constitute a single payment area and any of the following constitutes a separate MA payment area:

(A) All portions of each single Metropolitan Statistical Area within the State.

(B) All portions of each Metropolitan Statistical Area within each Metropolitan Division within the State.

(iii) A consolidation of noncontiguous counties.

(3) *CMS response*. In response to the request, CMS makes the payment adjustment requested by the chief executive. This adjustment cannot be requested or made for payments to regional MA plans.

(4) *Budget neutrality adjustment for geographically adjusted payment areas*. If CMS adjusts a State's payment areas in accordance with paragraph (d)(2) of this section, CMS at that time, and each year thereafter, adjusts the capitation rates so that the aggregate Medicare payments do not exceed the aggregate Medicare payments that would have been made to all the State's payments areas, absent the geographic adjustment.

§ 422.306 Annual MA capitation rates.

Subject to adjustments at § 422.308(b) and § 422.308(g), the annual capitation rate for each MA local area is determined under paragraph (a) of this section for 2005 and each succeeding year, except for years when CMS announces under § 422.312(b) that the annual capitation rates will be determined under paragraph (b) of this section.

(a) *Minimum percentage increase rate*. The annual capitation rate for each MA local area is equal to the minimum percentage increase rate, which is the greater of—

(1) 102 percent of the annual capitation rate for the preceding year; or

(2) The annual capitation rate for the area for the preceding year increased by the national per capita MA growth percentage (defined at § 422.308(a)) for the year, but not taking into account any adjustment under § 422.308(b) for a year before 2004.

(b) *Greater of the minimum percentage increase rate or local area fee-for-service costs*. The annual capitation rate for each MA local area is the greater of—

(1) The minimum percentage increase rate under paragraph (a) of this section; or

(2) The amount determined, no less frequently than every 3 years, to be the adjusted average per capita cost for the MA local area, as determined under section 1876(a)(4) of the Act, based on 100 percent of fee-for-service costs for individuals who are not enrolled in an MA plan for the year, with the following adjustments:

(i) Adjusted as appropriate for the purpose of risk adjustment;

(ii) Adjusted to exclude costs attributable to payments under section 1886(h) of the Act for the costs of direct graduate medical education; and

(iii) Adjusted to include CMS' estimate of the amount of additional per capita payments that would have been made in the MA local area if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense or the Department of Veterans Affairs.

§ 422.308 Adjustments to capitation rates, benchmarks, bids, and payments.

CMS performs the following calculations and adjustments to determine rates and payments:

(a) *National per capita growth percentage*. The national per capita growth percentage for a year, applied under § 422.306, is CMS' estimate of the rate of growth in per capita expenditures under this title for an individual entitled to benefits under Part A and enrolled under Part B. CMS may make separate estimates for aged enrollees, disabled enrollees, and enrollees who have ESRD.

(b) *Adjustment for over or under projection of national per capita growth percentages*. CMS will adjust the minimum percentage increase rate at § 422.306(a)(2) and the adjusted average per capita cost rate at § 422.306(b)(2) for the previous year to reflect any differences between the projected national per capita growth percentages for that year and previous years, and the current estimates of those percentages for those years. CMS will not make this adjustment for years before 2004.

(c) *Risk adjustment*—(1) *General rule*. CMS will adjust the payment amounts under § 422.304(a)(1), (a)(2), and (a)(3) for age, gender, disability status, institutional status, and other factors CMS determines to be appropriate, including health status, in order to ensure actuarial equivalence. CMS may add to, modify, or substitute for risk adjustment factors if those changes will improve the determination of actuarial equivalence.

(2) *Risk adjustment: Health status*—(i) *Data collection*. To adjust for health status, CMS applies a risk factor based on data obtained in accordance with § 422.310.

(ii) *Implementation*. CMS applies a risk factor that incorporates inpatient hospital and ambulatory risk adjustment data. This factor is phased as follows:

(A) 100 percent of payments for ESRD MA enrollees in 2005 and succeeding years.

(B) 75 percent of payments for aged and disabled enrollees in 2006.

(C) 100 percent of payments for aged and disabled enrollees in 2007 and succeeding years.

(3) *Uniform application*. Except as provided for MA RFB plans under § 422.304(c)(3), CMS applies this adjustment factor to all types of plans.

(d) *Adjustment for intra-area variations*. CMS makes the following adjustments to payments.

(1) *Intra-regional variations*. For payments for an MA regional plan for an MA region, CMS will adjust the payment amount specified at § 422.304(a)(1) and (a)(2) to take into account variations in local payment rates among the different MA local areas included in the region.

(2) *Intra-service area variations*. For payments to an MA local plan with a service area covering more than one MA local area (county), CMS will adjust the payment amount specified in § 422.304(a)(1) and (a)(2) to take into account variations in local payment rates among the different MA local areas included in the plan's service area.

(e) *Adjustment relating to risk adjustment: the government premium adjustment*. CMS will adjust payments to an MA plan as necessary to ensure that the sum of CMS' monthly payment made under § 422.304(a) and the plan's monthly basic beneficiary premium equals the unadjusted MA statutory non-drug bid amount, adjusted for risk and for intra-area or intra-regional payment variation.

(f) *Adjustment of payments to reflect number of Medicare enrollees*—(1) *General rule*. CMS adjusts payments retroactively to take into account any difference between the actual number of Medicare enrollees and the number on which it based an advance monthly payment.

(2) *Special rules for certain enrollees*. (i) Subject to paragraph (f)(2)(ii) of this section, CMS may make adjustments, for a period (not to exceed 90 days) that begins when a beneficiary elects a group health plan (as defined in § 411.1010) offered by an MA organization, and ends when the beneficiary is enrolled in an MA plan offered by the MA organization.

(ii) CMS does not make an adjustment unless the beneficiary certifies that, at the time of enrollment under the MA plan, he or she received from the organization the disclosure statement specified in § 422.111.

(g) *Adjustment for national coverage determination (NCD) services and legislative changes in benefits*. If CMS determines that the cost of furnishing an NCD service or legislative change in benefits is significant, as defined in § 422.109, CMS will adjust capitation rates, or make other payment adjustments, to account for the cost of the service or legislative change in benefits. Until the new capitation rates are in effect, the MA organization will be paid for the significant cost NCD service or legislative change in benefits on a fee-for-service basis as provided under § 422.109(b).

(h) *Adjustments to payments to regional MA plans for purposes of risk corridor payments*. For the purpose of calculation of risk corridors under § 422.458, MA organizations offering regional MA plans in 2006 and/or 2007 must submit, after the end of a contract year and before a date CMS specifies, the following information:

(1) Actual allowable costs (defined in § 422.458(a)) for the previous contract year.

(2) The portion of the costs attributable to administrative expenses incurred in providing these benefits.

(3) The total costs for providing rebatable integrated benefits (as defined in § 422.458(a)) and the portion of the costs that is attributable to administrative expenses in addition to the administrative expenses described in paragraph (h)(2) of this section.

§ 422.310 Risk adjustment data.

(a) *Definition of risk adjustment data*. Risk adjustment data are all data that are used in the application of a risk adjustment payment model.

(b) *Data collection: Basic rule*. Each MA organization must submit to CMS (in accordance with CMS instructions) the data necessary to characterize the context and purposes of each service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner. CMS may also collect data necessary to characterize the functional limitations of enrollees of each MA organization.

(c) *Sources and extent of data*. (1) To the extent required by CMS, risk adjustment data must account for the following:

(i) Services covered under the original Medicare program.

(ii) Medicare covered services for which Medicare is not the primary payer.

(iii) Other additional or supplemental benefits that the MA organization may provide.

(2) The data must account separately for each provider, supplier, physician, or other practitioner that would be permitted to bill separately under the original Medicare program, even if they participate jointly in the same service.

(d) *Other data requirements*. (1) MA organizations must submit data that conform to the requirements for equivalent data for Medicare fee-for-service when appropriate, and to all relevant national standards. Alternatively, MA organizations may submit data according to an abbreviated format, as specified by CMS.

(2) The data must be submitted electronically to the appropriate CMS contractor.

(3) MA organizations must obtain the risk adjustment data required by CMS from the provider, supplier, physician, or other practitioner that furnished the services.

(4) MA organizations may include in their contracts with providers, suppliers, physicians, and other practitioners, provisions that require submission of complete and accurate risk adjustment data as required by CMS. These provisions may include financial penalties for failure to submit complete data.

(e) *Validation of risk adjustment data*. MA organizations and their providers and practitioners will be required to submit a sample of medical records for the validation of risk adjustment data, as required by CMS. There may be penalties for submission of false data.

(f) *Use of data*. CMS uses the data obtained under this section to determine the risk adjustment factor used to adjust payments, as required under § 422.304(a)(1), (a)(2), and (a)(3). CMS may also use the data for other purposes except for medical records data.

(g) *Deadlines for submission of risk adjustment data*. Risk adjustment factors for each payment year are based on risk adjustment data submitted for services furnished during the 12-month period before the payment year that is specified by CMS. As determined by CMS, this 12-month period may include a 6-month data lag that may be changed or eliminated as appropriate.

(1) The annual deadline for risk adjustment data submission is the first Friday in September for risk adjustment data reflecting services furnished during the 12-month period ending the prior June 30, and the first Friday in March for data reflecting services furnished during the 12-month period ending the prior December 31.

(2) CMS allows a reconciliation process to account for late data submissions. CMS continues to accept risk adjustment data submitted after the

March deadline until December 31 of the payment year. After the payment year is completed, CMS recalculates the risk factors for affected individuals to determine if adjustments to payments are necessary. Risk adjustment data that are received after the annual December 31 late data submission deadline will not be accepted for the purposes of reconciliation.

§ 422.312 Announcement of annual capitation rate, benchmarks, and methodology changes.

(a) *Capitation rates*—(1) *Initial announcement*. Not later than the first Monday in April each year, CMS announces to MA organizations and other interested parties the following information for each MA payment area for the following calendar year:

(i) The annual MA capitation rate.

(ii) The risk and other factors to be used in adjusting those rates under § 422.308 for payments for months in that year.

(2) CMS includes in the announcement an explanation of assumptions used and a description of the risk and other factors.

(3) *Regional benchmark announcement*. Before the beginning of each annual, coordinated election period under § 422.62(a)(2), CMS will announce to MA organizations and other interested parties the MA region-specific non-drug monthly benchmark amount for the year involved for each MA region and each MA regional plan for which a bid was submitted under § 422.256.

(b) *Advance notice of changes in methodology*. (1) No later than 45 days before making the announcement under paragraph (a)(1) of this section, CMS notifies MA organizations of changes it proposes to make in the factors and the methodology it used in the previous determination of capitation rates.

(2) The MA organizations have 15 days to comment on the proposed changes.

§ 422.314 Special rules for beneficiaries enrolled in MA MSA plans.

(a) *Establishment and designation of medical savings account (MSA)*. A beneficiary who elects coverage under an MA MSA plan—

(1) Must establish an MA MSA with a trustee that meets the requirements of paragraph (b) of this section; and

(2) If he or she has more than one MA MSA, designate the particular account to which payments under the MA MSA plan are to be made.

(b) *Requirements for MSA trustees*. An entity that acts as a trustee for an MA MSA must—

(1) Register with CMS;

(2) Certify that it is a licensed bank, insurance company, or other entity qualified, under sections 408(a)(2) or 408(h) of the Internal Revenue Code of 1986, to act as a trustee of individual retirement accounts;

(3) Agree to comply with the MA MSA provisions of section 138 of the Internal Revenue Code of 1986; and

(4) Provide any other information that CMS may require.

(c) *Deposit in the MA MSA*. (1) The payment is calculated as follows:

(i) The monthly MA MSA premium is compared with 1/12 of the annual capitation rate applied under this section for the area determined under § 422.306.

(ii) If the monthly MA MSA premium is less than 1/12 of the annual capitation rate applied under this section for the area, the difference is the amount to be deposited in the MA MSA for each month for which the beneficiary is enrolled in the MSA plan.

(2) CMS deposits the full amount to which a beneficiary is entitled under paragraph (c)(1)(ii) of this section for the calendar year, beginning with the month in which MA MSA coverage begins.

(3) If the beneficiary's coverage under the MA MSA plan ends before the end of the calendar year, CMS recovers the amount that corresponds to the remaining months of that year.

§ 422.316 Special rules for payments to Federally qualified health centers.

If an enrollee in an MA plan receives a service from a Federally qualified health center (FQHC) that has a written agreement with the MA organization offering the plan concerning the provision of this service (including the agreement required under section 1857(e)(3) of the Act and as codified in § 422.527)—

(a) CMS will pay the amount determined under section 1833(a)(3)(B) of the Act directly to the FQHC at a minimum on a quarterly basis, less the amount the FQHC would receive for the MA enrollee from the MA organization and taking into account the cost sharing amount paid by the enrollee; and

(b) CMS will not reduce the amount of the monthly payments under this section as a result of the application of paragraph (a) of this section.

§ 422.318 Special rules for coverage that begins or ends during an inpatient hospital stay.

(a) *Applicability*. This section applies to inpatient services in a ''subsection (d) hospital'' as defined in section 1886(d)(1)(B) of the Act, a psychiatric hospital described in section 1886(d)(1)(B)(i) of the act, a rehabilitation hospital described in section 1886(d)(1)(B)(ii) of the Act, a distinct part rehabilitation unit described in the matter following clause (v) of section 1886(d)(1)(B) of the Act, or a long-term care hospital (described in section 1886(d)(1)(B)(iv)).

(b) *Coverage that begins during an inpatient stay*. If coverage under an MA plan offered by an MA organization begins while the beneficiary is an inpatient in one of the facilities described in paragraph (a) of this section—

(1) Payment for inpatient services until the date of the beneficiary's discharge is made by the previous MA organization or original Medicare, as appropriate;

(2) The MA organization offering the newly-elected MA plan is not responsible for the inpatient services until the date after the beneficiary's discharge; and

(3) The MA organization offering the newly-elected MA plan is paid the full amount otherwise payable under this subpart.

(c) *Coverage that ends during an inpatient stay*. If coverage under an MA plan offered by an MA organization ends while the beneficiary is an inpatient in one of the facilities described in paragraph (a) of this section—

(1) The MA organization is responsible for the inpatient services until the date of the beneficiary's discharge;

(2) Payment for those services during the remainder of the stay is not made by original Medicare or by any succeeding MA organization offering a newly-elected MA plan; and

(3) The MA organization that no longer provides coverage receives no payment for the beneficiary for the period after coverage ends.

§ 422.320 Special rules for hospice care.

(a) *Information*. An MA organization that has a contract under subpart K of this part must inform each Medicare enrollee eligible to select hospice care under § 418.24 of this chapter about the availability of hospice care (in a manner that objectively presents all available hospice providers, including a statement of any ownership interest in a hospice held by the MA organization or a related entity) if—

(1) A Medicare hospice program is located within the plan's service area; or

(2) It is common practice to refer patients to hospice programs outside that area.

(b) *Enrollment status*. Unless the enrollee disenrolls from the MA plan, a

beneficiary electing hospice continues his or her enrollment in the MA plan and is entitled to receive, through the MA plan, any benefits other than those that are the responsibility of the Medicare hospice.

(c) *Payment.* (1) No payment is made to an MA organization on behalf of a Medicare enrollee who has elected hospice care under § 418.24 of this chapter, except for the portion of the payment attributable to the beneficiary rebate for the MA plan, described in § 422.266(b)(1) plus the amount of the monthly prescription drug beneficiary premium (described at § 422.252). This no-payment rule is effective from the first day of the month following the month of election to receive hospice care, until the first day of the month following the month in which the election is terminated.

(2) During the time the hospice election is in effect, CMS' monthly capitation payment to the MA organization is reduced to the sum of—

(i) An amount equal to the beneficiary rebate for the MA plan, as described in § 422.304(a)(3) or to zero for plans with no beneficiary rebate, described at § 422.304(a)(2); and

(ii) The amount of the monthly prescription drug beneficiary premium (if any).

(3) In addition, CMS pays through the original Medicare program (subject to the usual rules of payment)—

(i) The hospice program for hospice care furnished to the Medicare enrollee; and

(ii) The MA organization, provider, or supplier for other Medicare-covered services to the enrollee.

§ 422.322 Source of payment and effect of MA plan election on payment.

(a) *Source of payments.* (1) Payments under this subpart for original fee-for-service benefits to MA organizations or MA MSAs are made from the Federal Hospital Insurance Trust Fund or the Supplementary Medical Insurance Trust Fund. CMS determines the proportions to reflect the relative weight that benefits under Part A, and benefits under Part B represents of the actuarial value of the total benefits under title XVIII of the Act.

(2) Payments to MA-PD organizations for statutory drug benefits provided under this title are made from the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

(b) *Payments to the MA organization.* Subject to § 412.105(g) and § 413.86(d) of this chapter and § 422.109, § 422.264, and § 422.266, CMS' payments under a contract with an MA organization (described in § 422.304) with respect to an individual electing an MA plan offered by the organization are instead of the amounts which (in the absence of the contract) would otherwise be payable under original Medicare for items and services furnished to the individual.

(c) *Only the MA organization entitled to payment.* Subject to § 422.314, § 422.318, § 422.320, and § 422.520 and sections 1886(d)(11) and 1886(h)(3)(D) of the Act, only the MA organization is entitled to receive payment from CMS under title XVIII of the Act for items and services furnished to the individual.

§ 422.324 Payments to MA organizations for graduate medical education costs.

(a) MA organizations may receive direct graduate medical education payments for the time that residents spend in non-hospital provider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs.

(b) MA organizations may receive direct graduate medical education payments if all of the following conditions are met:

(1) The resident spends his or her time assigned to patient care activities.

(2) The MA organization incurs ''all or substantially all'' of the costs for the training program in the non-hospital setting as defined in § 413.86(b) of this chapter.

(3) There is a written agreement between the MA organization and the non-hospital site that indicates the MA organization will incur the costs of the resident's salary and fringe benefits and provide reasonable compensation to the non-hospital site for teaching activities.

(c) An MA organization's allowable direct graduate medical education costs, subject to the redistribution and community support principles specified in § 413.85(c) of this chapter, consist of—

(1) Residents' salaries and fringe benefits (including travel and lodging where applicable); and

(2) Reasonable compensation to the non-hospital site for teaching activities related to the training of medical residents.

(d) The direct graduate medical education payment is equal to the product of—

(1) The lower of—

(i) The MA organization's allowable costs per resident as defined in paragraph (c) of this section; or

(ii) The national average per resident amount; and

(2) Medicare's share, which is equal to the ratio of the number of Medicare beneficiaries enrolled to the total number of individuals enrolled in the MA organization.

(e) Direct graduate medical education payments made to MA organizations under this section are made from the Federal Supplementary Medical Insurance Trust Fund.

Subpart I—Organization Compliance With State Law and Preemption by Federal Law

■ 52. Section 422.402 is revised to read as follows:

§ 422.402 Federal preemption of State law.

The standards established under this part supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to the MA plans that are offered by MA organizations.

■ 53. Amend § 422.404 by revising paragraph (a) to read as follows:

§ 422.404 State premium taxes prohibited.

(a) *Basic rule.* No premium tax, fee, or other similar assessment may be imposed by any State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa, or any of their political subdivisions or other governmental authorities with respect to any payment CMS makes on behalf of MA enrollees under subpart G of this part, or with respect to any payment made to MA plans by beneficiaries, or payment to MA plans by a third party on a beneficiary's behalf.

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■ 54. A new subpart J is added to read as follows:

Subpart J—Special Rules for MA Regional Plans

Sec.
422.451 Moratorium on new local preferred provider organization plans.
422.455 Special rules for MA Regional plans.
422.458 Risk sharing with regional MA organizations for 2006 and 2007.

Subpart J—Special Rules for MA Regional Plans

§ 422.451 Moratorium on new local preferred provider organization plans.

CMS will not approve the offering of a local preferred provider organization plan during 2006 or 2007 in a service area unless the MA organization seeking to offer the plan was offering a local preferred provider organization plan in the service area before December 31, 2005.

§ 422.455 Special rules for MA Regional Plans.

(a) *Coverage of entire MA region.* The service area for an MA regional plan

will consist of an entire MA region established under paragraph (b) of this section, and an MA region may not be segmented as described in § 422.262(c)(2).

(b) *Establishment of MA regions*—(1) *MA region*. The term ''MA region'' means a region within the 50 States and the District of Columbia as established by CMS under this section.

(2) *Establishment*—(i) *Initial establishment*. By January 1, 2005, CMS will establish and publish the MA regions.

(ii) *Periodic review and revision of service areas*. CMS may periodically review MA regions and may revise the regions if it determines the revision to be appropriate.

(3) *Requirements for MA regions*. CMS will establish, and may revise, MA regions in a manner consistent with the following:

(i) *Number of regions*. There will be no fewer than 10 regions, and no more than 50 regions.

(ii) *Maximizing availability of plans*. The main purpose of the regions is to maximize the availability of MA regional plans to all MA eligible individuals without regard to health status, or geographic location, especially those residing in rural areas.

(4) *Market survey and analysis*. Before establishing MA regions, CMS will conduct a market survey and analysis, including an examination of current insurance markets, to assist CMS in determining how the regions should be established.

(c) *National plan*. An MA regional plan can be offered in more than one MA region (including all regions).

§ 422.458 Risk sharing with regional MA organizations for 2006 and 2007.

(a) *Terminology*. For purposes of this section—

Allowable costs means, with respect to an MA regional plan offered by an organization for a year, the total amount of costs that the organization incurred in providing benefits covered under the original Medicare fee-for-service program option for all enrollees under the plan in the region in the year and in providing rebatable integrated benefits, as defined in this paragraph, reduced by the portion of those costs attributable to administrative expenses incurred in providing these benefits.

Rebatable integrated benefits means those non-drug supplemental benefits that are funded through beneficiary rebates (described at § 422.266(b)(1)) and that CMS determines are additional health benefits not covered under the original Medicare program option and that require expenditures by the plan. For purposes of the calculation of risk corridors, these are the only supplemental benefits that count toward allowable costs.

Target amount means, with respect to an MA regional plan offered by an organization in a year, the total amount of payments made to the organization for enrollees in the plan for the year (which includes payments attributable to benefits under the original Medicare fee-for-service program option as defined in § 422.100(c)(1), the total of the MA monthly basic beneficiary premium collectable for those enrollees for the year, and the total amount of rebatable integrated benefits), reduced by the amount of administrative expenses assumed in the portion of the bid attributable to benefits under original Medicare fee-for-service program option or to rebatable integrated benefits.

(b) *Application of risk corridors for benefits covered under original fee-for-service Medicare*—(1) *General rule*. This section will only apply to MA regional plans offered during 2006 or 2007.

(2) *Notification of allowable costs under the plan*. In the case of an MA organization that offers an MA regional plan in an MA region in 2006 or 2007, the organization must notify CMS, before that date in the succeeding year as CMS specifies, of—

(i) Its total amount of costs that the organization

incurred in providing benefits covered under the original Medicare fee-for-service program option for all enrollees under the plan (as described in paragraph (a) of this section).

(ii) Its total amount of costs that the organization incurred in providing rebatable integrated benefits for all enrollees under the plan (as described in paragraph (a) of this section), and, with respect to those benefits, the portion of those costs that is attributable to administrative expenses that is in addition to the administrative expense incurred in provision of benefits under the original Medicare fee-for-service program option.

(c) *Adjustment of payment*—(1) *No adjustment if allowable costs within 3 percent of target amount*. If the allowable costs for the plan for the year are at least 97 percent, but do not exceed 103 percent, of the target amount for the plan and year, there will be no payment adjustment under this section for the plan and year.

(2) *Increase in payment if allowable costs above 103 percent of target amount*—(i) *Costs between 103 and 108 percent of target amount*. If the allowable costs for the plan for the year are greater than 103 percent, but not greater than 108 percent, of the target amount for the plan and year, CMS will increase the total of the monthly payments made to the organization offering the plan for the year under § 422.302(a) (section 1853(a) of the Act) by an amount equal to 50 percent of the difference between those allowable costs and 103 percent of that target amount.

(ii) *Costs above 108 percent of target amount*. If the allowable costs for the plan for the year are greater than 108 percent of the target amount for the plan and year, CMS will increase the total of the monthly payments made to the organization offering the plan for the year under section 1853(a) of the Act by an amount equal to the sum of—

(A) 2.5 percent of that target amount; and

(B) 80 percent of the difference between those allowable costs and 108 percent of that target amount.

(3) *Reduction in payment if allowable costs below 97 percent of target amount*—(i) *Costs between 92 and 97 percent of target amount*. If the allowable costs for the plan for the year are less than 97 percent, but greater than or equal to 92 percent, of the target amount for the plan and year, CMS will reduce the total of the monthly payments made to the organization offering the plan for the year under § 422.302(a) (section 1853(a) of the Act) by an amount (or otherwise recover from the plan an amount) equal to 50 percent of the difference between 97 percent of the target amount and those allowable costs.

(ii) *Costs below 92 percent of target amount*. If the allowable costs for the plan for the year are less than 92 percent of the target amount for the plan and year, CMS will reduce the total of the monthly payments made to the organization offering the plan for the year under § 422.302(a) (section 1853(a)of the Act) by an amount (or otherwise recover from the plan an amount) equal to the sum of-

(A) 2.5 percent of that target amount; and

(B) 80 percent of the difference between 92 percent of that target amount and those allowable costs.

(d) *Disclosure of information*—(1) *General rule*. Each MA organization offering an MA regional plan must provide CMS with information as CMS determines is necessary to implement this section; and

(2) According to existing § 422.502(d)(1)(iii) (section 1857(d)(2)(B) of the Act), CMS has the right to inspect and audit any books and records of the organization that pertain to the information regarding costs

provided to CMS under paragraph (b)(2) of this section.

(3) *Restriction on use of information.* Information disclosed or obtained for the purposes of this section may be used by officers, employees, and contractors of DHHS only for the purposes of, and to the extent necessary in, implementing this section.

(e) *Organizational and financial requirements*—(1) *General rule.* Regional MA plans offered by MA organizations must be licensed under State law, or otherwise authorized under State law, as a risk-bearing entity (as defined in § 422.2) eligible to offer health insurance or health benefits coverage in each State in which it offers one or more plans. However, as provided for under this section, MA organizations offering MA regional plans may obtain a temporary waiver of State licensure. In the case of an MA organization that is offering an MA regional plan in an MA region, and is not licensed in each State in which it offers such an MA regional plan, the following rules apply:

(i) The MA organization must be licensed to bear risk in at least one State of the region.

(ii) For the other States in a region in which the organization is not licensed to bear risk, if it demonstrates to CMS that it has filed the necessary application to meet those requirements, CMS may temporarily waive the licensing requirement with respect to each State for a period of time as CMS determines appropriate for the timely processing of the application by the State or States.

(iii) If the State licensing application or applications are denied, CMS may extend the licensing waiver through the end of the plan year or as CMS determines appropriate to provide for a transition.

(2) *Selection of appropriate State.* In the case of an MA organization to which CMS grants a waiver and that is licensed in more than one State in a region, the MA organization will select one of the States, the rules of which shall apply in States where the organization is not licensed for the period of the waiver.

(f) *Regional stabilization fund*—(1) *Establishment.* The MA Regional Plan Stabilization Fund (referred to in this paragraph (f) as the ''Fund'') is available beginning in 2007 for two purposes:

(i) *Plan entry.* To provide incentives to have MA regional plans offered in each MA region under paragraph (f)(4) of this section.

(ii) *Plan retention.* To provide incentives to retain MA regional plans in certain MA regions with below-national-average MA market penetration under paragraph (f)(5) of this section.

(2) *Availability of funding from savings.* Funds made available under section 1853(f) of the Act are transferred into a special account in the Treasury from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in the proportion specified in section 1853(f) of the Act, ''payments From Trust Funds,'' on a monthly basis.

(3) *Funding limitation*—(i) *General rule.* The total amount expended from the Fund as a result of the application of this section through the end of a calendar year may not exceed the amount available to the Fund as of the first day of that year. For purposes of this section, amounts that are expended under this title insofar as those amounts would not have been expended but for the application of this section will be counted as amounts expended as a result of that application.

(ii) *Application of limitation.* CMS will obligate funds from the Fund for a year only if the Chief Actuary of CMS and the appropriate budget officer certify that there are available in the Fund at the beginning of the year sufficient amounts to cover all of those obligations incurred during the year consistent with paragraph (f)(3)(i) of this section. CMS will take those steps, in connection with computing additional payment amounts under paragraphs (f)(4) and (f)(5) of this section and including limitations on enrollment in MA regional plans receiving those payments or computing lower payment amounts, to ensure that sufficient funds are available to make those payments for the entire year.

(4) *Plan entry funding*—(i) *General rule.* Funding is available under this paragraph for a year in the following situations:

(A) *National plan.* For a national bonus payment described in paragraph (f)(4)(ii) of this section, when a single MA organization offers an MA regional plan in each MA region in the year, but only if there was not a national plan offered in each region in the previous year. Funding under this paragraph is only available with respect to any individual MA organization for a single year, but may be made available to more than one such organization in the same year.

(B) *MA Regional Plans.* Subject to paragraph (f)(4)(i)(C) of this section, for an increased amount under paragraph (f)(4)(iv) of this section for an MA regional plan offered in an MA region that did not have any MA regional plan offered in the prior year.

(C) *Limitation on MA regional plan funding in case of national plan.* There will be no payment adjustment under paragraph (f)(4)(iii) of this section for a year for which a national bonus payment is made under paragraph (f)(4)(ii) of this section.

(ii) *National bonus payment.* The national bonus payment under this paragraph will—

(A) Be available to an MA organization only if the organization offers MA regional plans in every MA region;

(B) Be available for all MA regional plans of the organization regardless of whether any other MA regional plan is offered in any region; and

(C) Be subject to amounts available under paragraph (f)(3) of this section for a year and be equal to 3 percent of the benchmark amount otherwise applicable for each MA regional plan offered by the organization.

(iii) *Regional payment adjustment*—(A) *General rule.* The increased amount under this paragraph for an MA regional plan in an MA region for a year must be an amount, determined by CMS, based on the bid submitted for that plan (or plans) and will be available to all MA regional plans offered in that region and year. That amount may be based on the mean, mode, or median or other measure of those bids and may vary from region to region. CMS will not limit the number of plans or bids in a region.

(B) *Multi-year funding.* Subject to amounts available under paragraph (f)(3) of this section, funding will be available for a period determined by CMS.

(C) *Application to all plans in a region.* Funding under this paragraph for an MA region will be made available for all MA regional plans offered in the region.

(D) *Limitation on availability of plan retention funding in next year.* If plans receive plan entry funding in a year, plans in that region are prohibited from receiving plan retention funding in the following year.

(iv) *Application.* Any additional payment under this section provided for an MA regional plan for a year will be treated as if it were an addition to the benchmark amount otherwise applicable to that plan and year, but will not be taken into account in the computation of any benchmark amount for any subsequent year.

(5) *Plan retention funding*—(i) *General rule.* Funding is available under this paragraph for a year with respect to MA regional plans offered in an MA region for the increased amount specified in paragraph (f)(5)(ii) of this

section but only if the region meets the requirements of paragraphs (f)(5)(iii)(A), (f)(5)(iii)(B), (f)(5)(iii)(C) and (f)(5)(iii)(E) of this section.

(ii) *Payment increase*. The increased amount under this paragraph for an MA regional plan in an MA region for a year will be an amount, determined by CMS, that does not exceed the greater of—

(A) 3 percent of the benchmark amount applicable in the region; or

(B) The amount as (when added to the benchmark amount applicable to the region) will result in the ratio of-

(*1*) That additional amount plus the benchmark amount computed under section 1854(b)(4)(B)(i)of the Act, ''the risk-adjusted benchmark amount'' for the region and year, to the adjusted average per capita cost for the region and year, as estimated by CMS under section 1876(a)(4) of the Act and adjusted as appropriate for the purpose of risk adjustment; being equal to—

(*2*) The weighted average of those benchmark amounts for all the regions and that year, to the average per capita cost for the United States and that year, as estimated by CMS under section 1876(a)(4)of the Act and adjusted as appropriate for the purpose of risk adjustment.

(iii) *Regional requirements*. The requirements of this paragraph for an MA region for a year are as follows:

(A) *Notification of plan exit*. CMS has received notice (as specified by CMS), before a new contract year, that one or more MA regional plans that were offered in the region in the previous year will not be offered in the succeeding year.

(B) *Regional plans available from fewer than two MA organizations in the region*. CMS determines that if the plans referred to in paragraph (f)(5)(iii)(A) of this section are not offered in the year, fewer than two MA organizations will be offering MA regional plans in the region in the year involved.

(C) *Percentage enrollment in MA regional plans below national average*. For the previous year, CMS determines that the average percentage of MA eligible individuals residing in the region who are enrolled in MA regional plans is less than the average percentage of those individuals in the United States enrolled in those plans.

(D) *Application*. Any additional payment under this paragraph provided for an MA regional plan for a year will be treated as if it were an addition to the benchmark amount otherwise applicable to that plan and year, but will not be taken into account in the computation of any benchmark amount for any subsequent year.

(E) *2–consecutive-year limitation*. In no case will plan retention funding be available under this paragraph in an MA region for more than 2 consecutive years.

Subpart K-Application Procedures and Contracts for Medicare Advantage Organizations

■ 55. Amend § 422.500 by-

A. Revising the section heading.

B. Designating the undesignated introductory text as paragraph (b) and adding the heading ''Definitions.≥

C. Adding new paragraph (a).

■ The revisions and addition read as follows:

§ 422.500 Scope and definitions.

(a) *Scope*. This subpart sets forth application requirements for entities seeking a contract as a Medicare organization offering an MA plan. MA organizations offering prescription drug plans must, in addition to the requirements of this part, follow the requirements of part 423 of this chapter specifically related to the prescription drug benefit.

(b) *Definitions*. For purposes of this subpart, the following definitions apply:

* * * * *

§ 422.501, § 422.502, and § 422.504 [Redesignated]

■ 56. Redesignate § 422.501, § 422.502, and § 422.504 as § 422.503, § 422.504, and § 422.505, respectively.

■ 57. Add new § 422.501 to read as follows:

§ 422.501 Application requirements.

(a) *Scope*. This section sets forth application requirements for entities that seek a contract as an MA organization offering an MA plan.

(b) *Completion of an application*. (1) In order to obtain a determination on whether it meets the requirements to become an MA organization and is qualified to provide a particular type of MA plan, an entity, or an individual authorized to act for the entity (the applicant) must complete a certified application, in the form and manner required by CMS, including the following:

(i) Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards applicable to MA plans, and is authorized by the State to accept prepaid capitation for providing, arranging, or paying for the comprehensive health care services to be offered under the MA contract; or

(ii) For regional plans, documentation of application for State licensure in any State in the region that the organization is not already licensed.

(2) The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, the requirements described in this part.

(c) *Responsibility for making determinations*. (1) CMS is responsible for determining whether an entity qualifies as an MA organization and whether proposed MA plans meet the requirements of this part.

(2) A CMS determination that an entity is qualified to act as an MA organization is distinct from the bid negotiation that occurs under subpart F of this part and such negotiation is not subject to the appeals provisions included in subpart N of this part.

(d) *Resubmittal of application*. An application that has been denied by CMS may not be resubmitted for 4 months after the date of the notice from CMS denying the application.

(e) *Disclosure of application information under the Freedom of Information Act*. An applicant submitting material that he or she believes is protected from disclosure under 5 U.S.C. 552, the Freedom of Information Act, or because of exemptions provided in 45 CFR part 5 (the Department's regulations providing exceptions to disclosure), must label the material ''privileged'' and include an explanation of the applicability of an exception described in 45 CFR part 5. Any final decisions as to whether material is privileged is the final decision of the Secretary.

■ 58. Add new § 422.502 to read as follows:

§ 422.502 Evaluation and determination procedures.

(a) *Basis for evaluation and determination*. (1) CMS evaluates an application for an MA contract on the basis of information contained in the application itself and any additional information that CMS obtains through other means such as on-site visits, public hearings, and any other appropriate procedures.

(2) After evaluating all relevant information, CMS determines whether the applicant's application meets the applicable requirements of § 422.501.

(b) *Use of information from a prior contracting period*. If an MA organization has failed to comply with the terms of a previous contract with CMS under title XVIII of the Act, or has failed to complete a corrective action plan during the term of the contract, CMS may deny an application based on the applicant's failure to comply with that prior contract with CMS even if the

contract applicant meets all of the current requirements.

(c) *Notice of determination*. Within timeframes determined by CMS, it notifies each applicant that applies for an MA contract under this part of its determination and the basis for the determination. The determination is one of the following:

(1) *Approval of application*. If CMS approves the application, it gives written notice to the applicant, indicating that it qualifies to contract as an MA organization.

(2) *Intent to deny*. (i)If CMS finds that the applicant does not appear to be able to meet the requirements for an MA organization and/or has not provided enough information to evaluate the application, CMS gives the contract applicant notice of intent to deny the application for an MA contract and a summary of the basis for this preliminary finding.

(ii) Within 10 days from the date of the intent to deny notice, the contract applicant must respond in writing to the issues or other matters that were the basis for CMS' preliminary finding and must revise its application to remedy any defects CMS identified.

(3) *Denial of application*. If CMS denies the application, it gives written notice to the contract applicant indicating —

(i) That the applicant is not qualified to contract as an MA organization under Part C of title XVIII of the Act;

(ii) The reasons why the applicant is not qualified; and

(iii) The applicant's right to request reconsideration in accordance with the procedures specified in subpart N of this part.

(d) *Oversight of continuing compliance*. (1) CMS oversees an MA organization's continued compliance with the requirements for an MA organization.

(2) If an MA organization no longer meets those requirements, CMS terminates the contract in accordance with § 422.510.

§ 422.503 [Amended]

■ 59. Amend newly redesignated § 422.503 by-

A. Redesignating paragraphs (b)(1) through (b)(5) as paragraphs (b)(2) through (b)(6) respectively.

B. Adding new paragraph (b)(1).

C. Revising newly redesignated paragraph (b)(4)(ii).

D. Revising newly redesignated paragraph (b)(4)(vi)(F).

E. Adding new paragraphs (b)(4)(vi)(G)(*1*), and (*2*).

F. Adding new paragraph (b)(4)(vi)(H).

G. Revising newly redesignated paragraph (b)(6) introductory text.

H. Revising newly redesignated paragraph (b)(6)(i).

■ The revisions read as follows:

§ 422.503 General provisions.

* * * * *

(b) * * *

(1) Complete an application as described in § 422.501.

* * * * *

(4) * * *

(ii) To operate a quality improvement program and have an agreement for external quality review as required under this part.

* * * * *

(vi) * * *

(F) Procedures for internal monitoring and auditing.

(G) * * *

(*1*) If the MA organization discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.

(*2*) The MA organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation referenced in paragraph (b)(4)(vi)(G)(1) of this section.

(H) For MA-PDPs, A comprehensive fraud and abuse plan to detect and prevent fraud, waste, and abuse as specified at § 423.504(b)(4)(vi)(H) of this chapter.

* * * * *

(6) The MA organization's contract must not have been non-renewed under § 422.506 within the past 2 years unless—

(i) During the 6-month period beginning on the date the organization notified CMS of the intention to non-renew the most recent previous contract, there was a change in the statute or regulations that had the effect of increasing MA payments in the payment area or areas at issue; or

* * * * *

■ 60. Amend newly redesignated § 422.504 by-

A. Revising paragraph (e)(4) introductory text.

B. Revising paragraph (e)(4)(ii)

C. Revising paragraph (e)(4)(iii).

D. Removing paragraph (f)(2)(vii).

E. Redesignating paragraph (f)(2)(viii) as paragraph (f)(2)(vii).

F. Revising paragraph (h).

G. Revising paragraph (i)(3)(ii).

■ The revisions read as follows:

§ 422.504 Contract provisions.

* * * * *

(e) * * *

(4) HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 10 years from the end of the final contract period or completion of audit, whichever is later unless-

* * * * *

(ii) There has been a termination, dispute, or allegation of fraud or similar fault by the MA organization, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, fraud, or similar fault; or

(iii) CMS determines that there is a reasonable possibility of fraud or similar fault, in which case CMS may inspect, evaluate, and audit the MA organization at any time.

* * * * *

(h) *Requirements of other laws and regulations*. The MA organization agrees to comply with-

(1) Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (32 U.S.C. 3729 et. seq.), and the anti-kickback statute (section 1128B(b)) of the Act); and

(2) HIPAA administrative simplification rules at 45 CFR parts 160, 162, and 164.

(i) * * *

(3) * * *

(ii) Accountability provisions that indicate that the MA organization may only delegate activities or functions to a provider, related entity, contractor, or subcontractor in a manner consistent with the requirements set forth at paragraph (i)(4)of this section.

* * * * *

■ 61. Amend newly redesignated § 422.505 by adding paragraph (d).

§ 422.505 Effective date and term of contract.

* * * * *

(d) *Renewal of contract contingent on reaching agreement on the bid*. Although an MA organization may be determined qualified to renew its contract under this section, if the organization and CMS cannot reach agreement on the bid under subpart F of this part, no renewal will take place, and the failure to reach an agreement is not subject to the appeals provisions in subpart N of this part.

■ 62. Amend § 422.506 by-

A. Revising paragraph (a)(2)(i).

B. Revising paragraph (a)(2)(ii).

C. Revising paragraph (a)(3) introductory text.

■ The revisions read as follows:

§ 422.506 Nonrenewal of contract.

(a) * * *

(2) * * *

(i) CMS in writing, by the first Monday in June of the year in which the contract would end;

(ii) Each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective. This notice must include a written description of alternatives available for obtaining Medicare services within the service area, including alternative MA plans, Medigap options, and original Medicare and must receive CMS approval prior to issuance.

* * * * *

(3) CMS may accept a nonrenewal notice submitted after the first Monday in June if-

* * * * *

■ 63. Amend § 422.510 by revising paragraph (a)(4) to read as follows:

§ 422.510 Termination of Contract by CMS.

(a) * * *

(4) There is credible evidence that the PDP sponsor committed or participated in false, fraudulent, or abusive activities affecting the Medicare program, including submission of false or fraudulent data.

* * * * *

■ 64. Amend § 422.520 by-

A. Revising the section heading.

B. Revising paragraph (a)(3).

C. Redesignating paragraph (b) introductory text as paragraph (b)(1).

D. Adding new paragraph (b)(2).

E. Adding new paragraph (d).

■ The revisions and additions read as follows:

§ 422.520 Prompt payment by MA organization.

(a) * * *

(3) All other claims from non-contracted providers must be paid or denied within 60 calendar days from the date of the request.

(b) * * *

(2) The MA organization is obligated to pay contracted providers under the terms of the contract between the MA organization and the provider.

* * * * *

(d) A CMS decision to not conduct a hearing under paragraph (c) of this section does not disturb any potential remedy under State law for 1866(a)(1)(O) of the Act.

■ 65. Add new § 422.527 at the end of subpart K to read as follows:

§ 422.527 Agreements with Federally qualified health centers.

The contract between the MA organization and CMS must specify that—

(a) The MA organization must pay a Federally qualified health center (FQHC) a similar amount to what it pays other providers for similar services.

(b) Under such a contract, the FQHC must accept this payment as payment in full, except for allowable cost sharing which it may collect.

(c) Financial incentives, such as risk pool payments or bonuses, and financial withholdings are not considered in determining the payments made by CMS under § 422.316(a).

Subpart L-Effect of Change of Ownership or Leasing of Facilities During Term of Contract

■ 66. Amend § 422.550 by revising paragraph (a)(2) to read as follows:

§ 422.550 General provisions.

(a) * * *

(2) *Asset transfer*. Transfer of title and property to another party constitutes change of ownership.

* * * * *

Subpart M—Grievances, Organization Determinations and Appeals

■ 67. Amend § 422.560 by-

A. Adding paragraph (a)(3).

B. Adding paragraph (c).

■ The additions read as follows:

§ 422.560 Basis and scope.

(a) * * *

(3) Section 1869 of the Act specifies the amount in controversy needed to pursue a hearing and judicial review and authorizes representatives to act on behalf of individuals that seek appeals. These provisions are incorporated for MA appeals by section 1852(g)(5) of the Act and part 405 of this chapter.

* * * * *

(c) *Relation to ERISA requirements*. Consistent with section 1857(i)(2) of the Act, provisions of this subpart may, to the extent applicable under regulations adopted by the Secretary of Labor, apply to claims for benefits under group health plans subject to the Employee Retirement Income Security Act.

■ 68. Amend § 422.561 by-

A. Removing the definition of ''authorized representative''.

B. Revising the definition of ''Enrollee''.

C. Adding the definition of ''Representative''.

■ The revisions and addition read as follows:

§ 422.561 Definitions.

* * * * *

Enrollee means an MA eligible individual who has elected an MA plan offered by an MA organization.

* * * * *

Representative means an individual appointed by an enrollee or other party, or authorized under State or other applicable law, to act on behalf of an enrollee or other party involved in the appeal. Unless otherwise stated in this subpart, the representative will have all of the rights and responsibilities of an enrollee or party in obtaining an organization determination or in dealing with any of the levels of the appeals process, subject to the applicable rules described in part 405 of this chapter.

■ 68a. Amend § 422.562 by—

A. Revising paragraph (b)(4)(iv).

B. Revising paragraph (b)(4)(vi).

C. Revising paragraph (c)(1)(ii).

D. Revising paragraph (d).

■ The revisions read as follows:

§ 422.562 General provisions.

* * * * *

(b) * * *

(4) * * *

(iv) The right to an ALJ hearing if the amount in controversy is met, as provided in § 422.600.

* * * * *

(vi) The right to judicial review of the hearing decision if the amount in controversy is met, as provided in § 422.612.

(c) * * *

(1) * * *

(ii) The QIO review decision is subject only to the appeal procedures set forth in part 478 of this chapter.

* * * * *

(d) *When other regulations apply*. Unless this subpart provides otherwise, the regulations in part 405 of this chapter (concerning the administrative review and hearing processes and representation of parties under titles II and XVIII of the Act), apply under this subpart to the extent they are appropriate.

■ 69. Amend § 422.564 by—

A. Redesignating paragraphs (d) and (e) as paragraphs (f) and (g).

B. Adding a new paragraph (d).

C. Adding a new paragraph (e).

■ The additions read as follows:

§ 422.564 Grievance procedures.

* * * * *

(d) *Method for filing a grievance*. (1) An enrollee may file a grievance with the MA organization either orally or in writing.

(2) An enrollee must file a grievance no later than 60 days after the event or incident that precipitates the grievance.

(e) *Grievance disposition and notification*. (1) The MA organization must notify the enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 days

after the date the organization receives the oral or written grievance.

(2) The MA organization may extend the 30-day timeframe by up to 14 days if the enrollee requests the extension or if the organization justifies a need for additional information and documents how the delay is in the interest of the enrollee. When the MA organization extends the deadline, it must immediately notify the enrollee in writing of the reasons for the delay.

(3) The MA organization must inform the enrollee of the disposition of the grievance in accordance with the following procedures:

(i) All grievances submitted in writing must be responded to in writing.

(ii) Grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.

(iii) All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO. For any complaint submitted to a QIO, the MA organization must cooperate with the QIO in resolving the complaint.

* * * * *

■ 70. Amend § 422.566 by revising paragraph (b)(4) to read as follows:

§ 422.566 Organization determinations.

* * * * *

(b) * * *

(4) Discontinuation or reduction of a service if the enrollee believes that continuation of the services is medically necessary.

* * * * *

■ 71. Amend § 422.568 by-

A. Revising paragraph (a).

B. Revising paragraph (c).

■ The revisions read as follows:

§ 422.568 Standard timeframes and notice requirements for organization determinations.

(a) *Timeframe for requests for service.* When a party has made a request for a service, the MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination. The MA organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an MA organization's decision to deny). When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension.

* * * * *

(c) *Written notice for MA organization denials.* If an MA organization decides to deny service or payment in whole or in part, or if an enrollee disagrees with an MA organization's decision to discontinue or reduce the level of care for an ongoing course of treatment, the organization must give the enrollee written notice of the determination.

* * * * *

■ 72. Amend § 422.570 by revising paragraph (d)(2)(ii) to read as follows:

§ 422.570 Expediting certain organization determinations.

* * * * *

(d) * * *

(2) * * *

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision not to expedite; and

* * * * *

■ 73. Amend § 422.572 by —

A. Revising paragraph (b).

B. Revising paragraph (c).

■ The revisions read as follows:

§ 422.572 Timeframes and notice requirements for expedited organization determinations.

* * * * *

(b) *Extensions.* The MA organization may extend the 72–hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an MA organization's decision to deny). When the MA organization extends the deadline, it must notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(c) *Confirmation of oral notice.* If the MA organization first notifies an enrollee of an adverse expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

* * * * *

■ 74. Amend § 422.582 by-

A. Revising paragraph (a).

B. Revising paragraph (b).

C. Revising paragraph (c)(2) introductory text.

■ The revisions read as follows:

§ 422.582 Request for a standard reconsideration.

(a) *Method and place for filing a request.* A party to an organization determination must ask for a reconsideration of the determination by making a written request to the MA organization that made the organization determination. The MA organization may adopt a policy for accepting oral requests.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, a party must file a request for reconsideration within 60 calendar days from the date of the notice of the organization determination.

(c) * * *

(2) *How to request an extension of timeframe.* If the 60-day period in which to file a request for reconsideration has expired, a party to the organization determination may file a request for reconsideration with the MA organization. The request for reconsideration and to extend the timeframe must—

* * * * *

■ 75. Amend § 422.584 by revising paragraph (e) to read as follows:

§ 422.584 Expediting certain reconsiderations.

* * * * *

(e) *Action following acceptance of a request.* If an MA organization grants a request for expedited reconsideration, it must conduct the reconsideration and give notice in accordance with § 422.590.

* * * * *

■ 76. Amend § 422.590 by —

A. Revising paragraph (a)(1).

B. Revising paragraph (d)(2).

■ The revisions read as follows:

§ 422.590 Timeframes and responsibility for reconsiderations.

(a) *Standard reconsideration: Request for services.* (1) If the MA organization makes a reconsidered determination that is completely favorable to the enrollee, the MA organization must issue the determination (and effectuate it in accordance with § 422.618(a)) as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard

reconsideration. The MA organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an MA organization's decision to deny). When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. For extensions, the MA organization must issue and effectuate its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

* * * * *

(d) * * *

(2) *Extensions*. The MA organization may extend the 72–hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an MA organization's decision to deny). When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension.

* * * * *

■ 77. Amend § 422.600 by-

A. Revising paragraph (a).

B. Revising paragraph (b).

■ The revisions read as follows:

§ 422.600 Right to a hearing.

(a) If the amount remaining in controversy after reconsideration meets the threshold requirement established annually by the Secretary, any party to the reconsideration (except the MA organization) who is dissatisfied with the reconsidered determination has a right to a hearing before an ALJ.

(b) The amount remaining in controversy, which can include any combination of Part A and Part B services, is computed in accordance with part 405 of this chapter.

* * * * *

■ 78. Amend § 422.602 by—

A. Revising paragraph (a).

B. Revising paragraph (b).

C. Revising paragraph (d).

■ The revisions read as follows:

§ 422.602 Request for an ALJ hearing.

(a) *How and where to file a request*. A party must file a written request for a hearing with the entity specified in the IRE's reconsideration notice.

(b) *When to file a request*. Except when an ALJ extends the time frame as provided in part 405 of this chapter, a party must file a request for a hearing within 60 days of the date of the notice of a reconsidered determination. The time and place for a hearing before an ALJ will be set in accordance with § 405.1020.

* * * * *

(d) *Insufficient amount in controversy*. (1) If a request for a hearing clearly shows that the amount in controversy is less than that required under § 422.600, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than the amount required under § 422.600, the ALJ discontinues the hearing and does not rule on the substantive issues raised in the appeal.

■ 79. Revise § 422.608 to read as follows:

§ 422.608 Medicare Appeals Council (MAC) review.

Any party to the hearing, including the MA organization, who is dissatisfied with the ALJ hearing decision, may request that the MAC review the ALJ's decision or dismissal. The regulations under part 405 of this chapter regarding MAC review apply to matters addressed by this subpart to the extent that they are appropriate.

■ 80. Amend § 422.612 by—

A. Revising paragraph (a)(2).

B. Revising paragraph (b).

C. Revising paragraph (c).

■ The revisions read as follows:

§ 422.612 Judicial review.

(a) * * *

(2) The amount in controversy meets the threshold requirement established annually by the Secretary.

(b) *Review of MAC decision*. Any party, including the MA organization, may request judicial review (upon notifying the other parties) of the MAC decision if it is the final decision of CMS and the amount in controversy meets the threshold established in paragraph (a)(2) of this section.

(c) *How to request judicial review*. In order to request judicial review, a party must file a civil action in a district court of the United States in accordance with section 205(g) of the Act. See part 405 of this chapter for a description of the procedures to follow in requesting judicial review.

■ 81. Amend § 422.616 by revising paragraph (a) to read as follows:

§ 422.616 Reopening and revising determinations and decisions.

(a) An organization or reconsidered determination made by an MA organization, a reconsidered determination made by the independent entity described in § 422.592, or the decision of an ALJ or the MAC that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, under the rules in part 405 of this chapter.

* * * * *

■ 82. Amend § 422.620 by—

A. Revising the section heading.

B. Revising paragraph (b).

C. Revising paragraph (c).

■ The revisions read as follows:

§ 422.620 How enrollees of MA organizations must be notified of noncovered inpatient hospital care.

* * * * *

(b) *Physician concurrence required*. Before discharging an individual or changing the level of care in an inpatient hospital setting, the MA organization must obtain the concurrence of the physician who is responsible for the enrollee's inpatient care.

(c) *Notice to the enrollee*. When applicable, the written notice of non-coverage must be issued no later than the day before hospital coverage ends. The written notice must include the following elements:

(1) The reason why inpatient hospital care is no longer needed or covered;

(2) The effective date and time of the enrollee's liability for continued inpatient care;

(3) The enrollee's appeal rights;

(4) If applicable, the new lower level of care being covered in the hospital setting; and

(5) Any additional information specified by CMS.

■ 83. Amend § 422.622 by revising paragraph (b)(1)(i) to read as follows:

§ 422.622 Requesting immediate QIO review of noncoverage of inpatient hospital care.

* * * * *

(b) * * *

(1) * * *

(i) To the QIO that has an agreement with the hospital under part 475, subpart C of this chapter;

* * * * *

Subpart N-Medicare Contract Determinations and Appeals

■ 84. Amend § 422.648 by adding paragraph (c) to read as follows:

§ 422.648 Reconsideration: Applicability.

* * * * *

(c) Notice of any redetermination favorable to the MA organization applicant, including those resulting from a hearing or Administrator review conducted under this subpart, must be issued by July 15 for the contract in question to be effective on January 1 of the following year.

Subpart O-Intermediate Sanctions

■ 85. Amend § 422.752 by—

A. Revising paragraph (a) introductory text.

B. Revising paragraph (a)(8) introductory text.

C. Revising paragraph (b)

■ The revisions read as follows:

§ 422.752 Basis for imposing sanctions.

(a) *All intermediate sanctions*. For the violations listed in this paragraph (a), we may impose one, or more, of the sanctions specified in § 422.750(a)(2), (a)(3), or (a)(4) on any MA organization that has a contract in effect. The MA organization may also be subject to other applicable remedies available under law.

* * * * *

(8) Employs or contracts with an individual or entity who is excluded from participation in Medicare under section 1128 or 1128A of the Act (or with an entity that employs or contracts with such an excluded individual or entity) for the provision of any of the following:

* * * * *

(b) *Suspension of enrollment and marketing*. If CMS makes a determination under § 422.510(a), CMS may impose the intermediate sanctions in § 422.750(a)(2) and (a)(4).

■ 86. Amend § 422.756 by-

A. Revising paragraph (f)(2).

B. Revising paragraph (f)(3).

■ The revisions read as follows:

§ 422.756 Procedures for imposing sanctions.

* * * * *

(f) * * *

(2) In the case of a violation described in paragraph (a) of § 422.752, or a determination under paragraph (b) of § 422.752 based upon a violation under § 422.510(a)(4) (involving fraudulent or abusive activities), in accordance with the provisions of part 1003 of this chapter, the OIG may impose civil money penalties on the MA organization in accordance with part 1003 of this chapter in addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

(3) In the case of a determination under § 422.752(b) other than a determination based upon a violation under § 422.510(a)(4), CMS may impose civil money penalties on the MA organization in the amounts specified in § 422.758 in addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

■ 87. Amend § 422.758 by-

A. Revising the introductory text.

B. Revising paragraph (c).

■ The revisions read as follows:

§ 422.758 Maximum amount of civil money penalties imposed by CMS.

If CMS makes a determination under § 422.510(a), as described in § 422.752(b) excepting those determinations under § 422.510(a)(4), CMS may impose civil money penalties in addition to, or in place of, the sanctions that CMS may impose under § 422.756(c) in the following amounts:

* * * * *

(c) If CMS makes a determination that a MA organization has terminated its contract other than in a manner described under § 422.512 and that the MA organization has therefore failed to substantially carry out the terms of the contract—$250 per Medicare enrollee from the terminated MA plan or plans at the time the MA organization terminated its contract, or $100, 000, whichever is greater.

Nomenclature Changes

■ 88. In part 422, remove ''Departmental Appeals Board'' wherever it appears and add in its place ''Medicare Appeals Council''.

■ 89. In part 422, remove ''DAB'' wherever it appears and add in its place ''MAC''.

■ 90. In part 422, remove ''Medicare+Choice'' wherever it appears and add in its place ''Medicare Advantage''.

■ 91. In part 422, remove ''M+C'' wherever it appears and add in its place ''MA''.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare Supplementary Medical Insurance Program)

Dated: January 10, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Dated: January 14, 2005.

Tommy G. Thompson,

Secretary of Health and Human Services.

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The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6064**
Public Laws Update Service (numbers, dates, etc.)	**741–6043**
TTY for the deaf-and-hard-of-hearing	**741–6086**

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FEDERAL REGISTER PAGES AND DATE, JANUARY

1–248 3
249–660 4
661–1160 5
1161–1324 6
1325–1654 7
1655–1788 10
1789–1994 11
1995–2324 12
2325–2560 13
2561–2796 14
2797–2926 18
2927–3138 19
3139–3278 21
3279–3472 24
3473–3590 25
3591–3850 26
3851–4002 27
4003–4742 28

CFR PARTS AFFECTED DURING JANUARY

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
7859 1159
7860 2321
7861 2797
7862 3271
7863 3273
7864 3275

Executive Orders:
13332 (Superseded by EO 13368) 1147
13368 1147
13369 2323
13370 3137
12947 (See Notice of January 17, 2005) 3277
13099 (See Notice of January 17, 2005) 3277

Administrative Orders:
Notices:
Notice of January 17, 2005 3277
Presidential Determinations:
No. 2004-48 of September 20, 2004 1783
No. 2005-12 of December 10, 2004 1785
No. 2005-13 of December 14, 2004 1
No. 2005-16 of January 4, 2005 1787
No. 2005-17 of January 7, 2005 3851
No. 2005-18 of January 13, 2005 3853

5 CFR

550 3855
576 3858

Proposed Rules:
213 1833
315 1833
353 1068
530 1068
531 1068
550 1068
575 1068
610 1068
630 1068

7 CFR

301 ..... 249, 4003
900 2744
926 1995
983 ..... 661, 4193
1150 2744
1160 2744
1205 2744
1206 2744
1207 2744
1209 2744
1210 2744
1215 2744
1216 2744
1218 2744
1219 2744
1220 2744
1230 2744
1240 2744
1250 2744
1260 2744
1280 2744
1434 3139
1466 1789
1486 253
1924 1325
2902 1792
3565 2927

Proposed Rules:
97 1835
360 2573
916 4041
917 4041
923 2573
925 1837
927 2520
945 3313
982 1839
985 2027
987 3315
1160 2032
1205 2034
1530 3150

8 CFR

241 661
1240 661
1241 661

Proposed Rules:
214 3984

9 CFR

93 460
94 460
95 460
96 460

Proposed Rules:
Ch. III 4047

10 CFR

30 2001
50 3591
824 3599

Proposed Rules:
20 ..... 2577, 3898
40 2053
71 312
709 1383
710 1383
851 3812

11 CFR

111 3

12 CFR

701 3861
708a 4005
708b 3279
Proposed Rules:
611 2963
612 2963
614 2963
615 2963
618 2963
619 2963
620 2963
630 2963

13 CFR

125 1655
Proposed Rules:
121 2976

14 CFR

13 ....1812, 2925
21 2325
23 ....1326, 2561
25 ....675, 1161, 1163, 2009, 2325, 3140
29 2011
39 ....7, 10, 261, 265, 677, 679, 680, 684, 685, 687, 690, 1169, 1172, 1176, 1178, 1180, 1182, 1184, 1328, 1329, 1332, 1335, 1336, 1338, 1340, 1655, 1815, 2330, 2333, 2336, 2339, 2934, 2937, 2941, 2944, 2946, 3296, 3299, 3473, 3614, 3863, 3867, 3871, 4191
47 240
49 240
65 1634
71 ....1342, 1343, 2342, 2343, 2344, 2345, 2346, 2347, 2348, 2948, 3614, 3615, 3616, 4191
73 2564
97 ....691, 1186, 4010
Proposed Rules:
23 2977
39 ....51, 317, 725, 727, 729, 731, 733, 735, 737, 1211, 1215, 2057, 2060, 2062, 2064, 2066, 2067, 2070, 2370, 2826, 2980, 2982, 2985, 2987, 3318, 3320, 4048, 4050, 4052, 4055
71 ....1396, 1397, 1399, 2989, 2991, 3155, 3156, 3656
212 3158
257 2372
382 4058

15 CFR

742 2348
774 2348
996 693
Proposed Rules:
30 2072
710 1216
711 1216
712 1216
713 1216
714 1216
715 1216
716 1216
717 1216
718 1216
719 1216
720 1216
721 1216
722 1216
723 1216
724 1216
725 1216
726 1216
727 1216
728 1216
729 1216
904 740

16 CFR

305 3874
316 3110
Proposed Rules:
Ch. 1 2074
312 2580
1633 2470
1634 2514

17 CFR

140 2565
171 2350
210 ....1506, 3108
228 ....1506, 3108
229 ....1506, 3108
230 ....1506, 3108
232 1506
239 ....1506, 3108
240 ....1506, 3108
242 ....1506, 3108
245 ....1506, 3108
249 ....1506, 3108
275 2712
Proposed Rules:
200 1503
201 1503
230 1503
240 ....1503, 2829
242 ....1503, 2829
249 ....1503, 2829
270 1503
275 2716

18 CFR

35 265
358 284
Proposed Rules:
284 319

20 CFR

404 11
408 11
416 11
Proposed Rules:
655 3993

21 CFR

20 2799
510 2352
520 ....1817, 1818, 2352
558 ....2566, 2567
1304 291
1306 291
1310 ....291, 294
Proposed Rules:
357 741

24 CFR

203 3838
1000 4000
Proposed Rules:
81 1774
200 1750
203 3266
242 1750

25 CFR

Proposed Rules:
542 1840

26 CFR

1 ....704, 2012, 3475, 4012, 4013
20 295
301 ....295, 704, 2012
602 ....704, 4013
Proposed Rules:
1 ....746, 749, 1400, 2075, 4058
31 767
301 ....2075, 2076

27 CFR

4 2799
7 194
9 2801
24 2799
25 194
Proposed Rules:
9 ....3322, 3328, 3333

28 CFR

570 1659
Proposed Rules:
35 2992
36 2992

29 CFR

101 3477
102 3477
1910 1112
1915 1112
1926 1112
4022 2568
4044 2568
Proposed Rules:
4000 2080
4010 2080

30 CFR

Proposed Rules:
701 3840
774 3840

31 CFR

1 2805
285 ....3142, 3616
Proposed Rules:
50 2830
92 2081

32 CFR

Proposed Rules:
202 4061

33 CFR

27 17
100 3879
110 ....2353, 3617
117 ....1187, 1343, 2355, 2570, 4013, 4014, 4016, 4019
165 ....20, 1187, 1345, 2017, 2019, 2355, 2357, 2806, 2950, 3145, 3299, 3617, 3623, 3625, 3627
Proposed Rules:
117 ....773, 3168, 4074, 4077
151 1400
165 1400
401 3495

34 CFR

Proposed Rules:
230 2582
300 1673
303 1673

36 CFR

219 ....1022, 1023
Proposed Rules:
242 1216

37 CFR

1 ....1818, 3880
2 2952
3 1818
41 3880
Proposed Rules:
258 3656
404 1403

38 CFR

36 3892
Proposed Rules:
17 1841

39 CFR

111 ....1346, 2953
501 ....705, 1348

40 CFR

30 3629
31 3629
52 ....22, 1663, 1664, 1824, 2358, 2954, 3479, 3632, 4019, 4023
62 1668
63 1670
81 ....944, 1664, 4023
82 1972
180 ....706, 708, 1349, 1357, 3634, 3642, 3649, 4026, 4032
228 2808
271 ....1825, 3902
Proposed Rules:
51 ....1314, 1640
52 ....53, 1640, 1673, 2085, 2992, 3335, 3658, 4079
62 1674,
80 ....640, 646
81 ....1673, 3170, 3174
93 323
122 2832
194 2101
262 3501
271 ....1842, 3894
372 1674
710 3658

41 CFR

101–11 3132
102–42 2318
102–95 3132

42 CFR

70 3490
400 4194
403 4194
411 4194

417.....4194, 4588
422.....4588
423.....4194
Proposed Rules:
9.....1843
63a.....4080

44 CFR

64.....2817
65.....2959

45 CFR

Proposed Rules:
1801.....3178

47 CFR

1.....556
15.....1360
27.....1189
64.....720, 2360
73.....25, 723, 724, 2571, 2572, 3654, 3655, 4037, 4038
76.....25
Proposed Rules:
64.....60, 61, 62
73.....63, 775, 3666, 3667
76.....63

48 CFR

206.....2361
225.....2361
252.....2361
Ch. 3.....38
401.....41
403.....41
404.....41
405.....41
406.....41
407.....41
408.....41
410.....41
411.....41
413.....41
414.....41
415.....41
416.....41
419.....41
422.....41
423.....41
424.....41
425.....41
426.....41
428.....41
432.....41
433.....41
434.....41
436.....41
439.....41
445.....41
450.....41
452.....41
453.....41
533.....298
552.....298
1835.....2022
1852.....2022

49 CFR

1.....2819
15.....1379
24.....590
171.....2367, 3302
172.....2367
173.....2367, 3302
174.....3302
175.....2367
176.....3302
177.....3302
192.....3147
199.....50
224.....144
579.....2022
571.....299
1520.....1379
1572.....2542
Proposed Rules:
171.....3179
172.....3179
173.....3179
175.....3179
229.....2105
238.....2105
385.....3339
390.....3339
395.....3339
571.....2105
572.....2105
598.....2105
605.....4081

50 CFR

17.....426, 1190, 1286, 1940, 3438, 3493
222.....1830
224.....1830
226.....1830
229.....2367
622.....300, 4039
635.....302
648.....303, 1686, 2023, 2820, 2821
679.....3310, 3311, 3896, 4039
Proposed Rules:
17.....1858, 2244, 3504
20.....3180
100.....1216
226.....325
229.....776
648.....68, 2108, 2586
660.....3668

REMINDERS

The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

RULES GOING INTO EFFECT JANUARY 28, 2005

ENVIRONMENTAL PROTECTION AGENCY

Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:
- Bifenazate; published 1-28-05
- Quinoxyfen; published 1-28-05

FEDERAL COMMUNICATIONS COMMISSION

Common carrier services:
- Interconnection—
  - Incumbent local exchange carriers unbounding obligations; local competition provisions; wireline services offering advanced telecommunications capability; published 12-29-04

Radio services, special:
- Advanced wireless services; published 12-29-04

Television broadcasting:
- Digital television conversion—
  - Digital low power television, television translator stations, and digital television booster stations and related issues; published 11-29-04

Television stations; table of assignments:
- Florida; published 12-29-04

HEALTH AND HUMAN SERVICES DEPARTMENT

Food and Drug Administration

Medical devices:
- Cardiovascular and neurological devices—
  - Embolization devices; reclassification; published 12-29-04

NATIONAL CREDIT UNION ADMINISTRATION

Credit unions:
- Conversion of insured credit unions to mutual savings banks; information disclosure; published 1-28-05

PERSONNEL MANAGEMENT OFFICE

Pay administration:
- Compensatory time off for travel; published 1-27-05

TRANSPORTATION DEPARTMENT

Federal Aviation Administration

Airworthiness directives:
- Boeing; published 1-13-05
- Great Lakes Aircraft Co., LLC; published 12-16-04
- Letecke Zavody; published 12-16-04
- Rolls-Royce plc; published 1-13-05

Standard instrument approach procedures; published 1-28-05

RULES GOING INTO EFFECT JANUARY 29, 2005

HOMELAND SECURITY DEPARTMENT

Coast Guard

Regattas and marine parades:
- Annual Gasparilla Marine Parade; published 1-27-05

RULES GOING INTO EFFECT JANUARY 30, 2005

HOMELAND SECURITY DEPARTMENT

Coast Guard

Drawbridge operations:
- Florida; published 1-28-05

COMMENTS DUE NEXT WEEK

AGENCY FOR INTERNATIONAL DEVELOPMENT

Assistance awards to U.S. non-Governmental organizations; marking requirements; comments due by 2-3-05; published 12-20-04 [FR 04-27791]

AGRICULTURE DEPARTMENT

Agricultural Marketing Service

Cotton classing, testing and standards:
- Classification services to growers; 2004 user fees; Open for comments until further notice; published 5-28-04 [FR 04-12138]

Dates (domestic) produce or packed in—
- California; comments due by 2-3-05; published 1-24-05 [FR 05-01179]

Fish and shellfish; mandatory country of origin labeling; comments due by 2-2-05; published 12-28-04 [FR 04-28349]

AGRICULTURE DEPARTMENT

Food Safety and Inspection Service

Meat and poultry inspection:
- Food labeling—
  - Ready-to-eat meat and poultry products; listeria monocytogenes workshops for small and very small plants; comments due by 1-31-05; published 12-2-04 [FR 04-26516]
- Listeria monocytogenes interim final rule; effectiveness assessment; report availability; comments due by 1-31-05; published 12-2-04 [FR 04-26515]

AGRICULTURE DEPARTMENT

Acquisition regulations:
- Miscellaneous amendments; comments due by 2-2-05; published 1-3-05 [FR 04-28439]

COMMERCE DEPARTMENT

National Oceanic and Atmospheric Administration

Civil procedures; comments due by 1-31-05; published 1-5-05 [FR 04-28751]

COURT SERVICES AND OFFENDER SUPERVISION AGENCY FOR THE DISTRICT OF COLUMBIA

Semi-annual agenda; Open for comments until further notice; published 12-22-03 [FR 03-25121]

DEFENSE DEPARTMENT

Acquisition regulations:
- Pilot Mentor-Protege Program; Open for comments until further notice; published 12-15-04 [FR 04-27351]

DEFENSE DEPARTMENT

Engineers Corps

Nationwide permit program; miscellaneous amendments; comments due by 1-31-05; published 11-30-04 [FR 04-26263]

ENERGY DEPARTMENT

Meetings:
- Environmental Management Site-Specific Advisory Board—
  - Oak Ridge Reservation, TN; Open for comments until further notice; published 11-19-04 [FR 04-25693]

ENERGY DEPARTMENT

Energy Efficiency and Renewable Energy Office

Commercial and industrial equipment; energy efficiency program:
- Test procedures and efficiency standards—
  - Commercial packaged boilers; Open for comments until further notice; published 10-21-04 [FR 04-17730]

ENERGY DEPARTMENT

Federal Energy Regulatory Commission

Electric rate and corporate regulation filings:
- Virginia Electric & Power Co. et al.; Open for comments until further notice; published 10-1-03 [FR 03-24818]

Natural Gas Policy Act:
- Natural gas pipeline companies; selective discounting policy; comments due by 1-31-05; published 12-2-04 [FR 04-26535]

ENVIRONMENTAL PROTECTION AGENCY

Air programs:
- Fuels and fuel additives—
  - Gasoline produced or imported for use in Hawaii, Alaska, Puerto Rico, and Virgin Islands; antidumping baselines; comments due by 2-3-05; published 1-4-05 [FR 05-00043]
  - Hazardous air pollutants from mobile sources; emissions control; default baseline values; comments due by 2-3-05; published 1-4-05 [FR 05-00042]

Air quality implementation plans; approval and promulgation; various States:
- Kentucky; comments due by 2-2-05; published 1-3-05 [FR 04-28702]
- New Mexico; comments due by 1-31-05; published 12-30-04 [FR 04-28501]
- Texas; comments due by 2-2-05; published 1-3-05 [FR 04-28700]

Environmental statements; availability, etc.:
- Coastal nonpoint pollution control program—
  - Minnesota and Texas; Open for comments until further notice; published 10-16-03 [FR 03-26087]

Toxic substances:
Enzymes and proteins; nomenclature inventory; comments due by 1-30-05; published 12-17-04 [FR 04-27642]
Significant new uses—
Polybrominated diphenylethers; comments due by 2-4-05; published 12-6-04 [FR 04-26731]
Water pollution control:
National Pollutant Discharge Elimination System—
Concentrated animal feeding operations in New Mexico and Oklahoma; general permit for discharges; Open for comments until further notice; published 12-7-04 [FR 04-26817]
Water pollution; effluent guidelines for point source categories:
Meat and poultry products processing facilities; Open for comments until further notice; published 9-8-04 [FR 04-12017]

FEDERAL COMMUNICATIONS COMMISSION

Common carrier services:
Interconnection—
Incumbent local exchange carriers unbounding obligations; local competition provisions; wireline services offering advanced telecommunications capability; Open for comments until further notice; published 12-29-04 [FR 04-28531]
Telephone Consumer Protection Act; implementation—
Interstate telephone calls; Florida statute and telemarketing law; declaratory ruling petition; comments due by 2-2-05; published 1-3-05 [FR 04-28419]
Interstate telephone calls; Indiana revised statutes and administrative code; declaratory ruling petition; comments due by 2-2-05; published 1-3-05 [FR 04-28417]
Interstate telephone calls; Wisconsin statutes and administrative code; declaratory ruling petition; comments due by 2-2-05; published 1-3-05 [FR 04-28418]
Radio stations; table of assignments:
Arkansas; comments due by 1-31-05; published 12-29-04 [FR 04-28424]
Minnesota; comments due by 1-31-05; published 12-29-04 [FR 04-28422]
North Carolina; comments due by 1-31-05; published 12-29-04 [FR 04-28416]
Texas; comments due by 1-31-05; published 12-29-04 [FR 04-28423]

HEALTH AND HUMAN SERVICES DEPARTMENT

Food and Drug Administration

Food additives:
Secondary direct food additives—
Acidified sodium clorite solutions; comments due by 1-31-05; published 12-30-04 [FR 04-28577]
Food for human consumption:
Beverages—
Bottled water; comments due by 1-31-05; published 12-2-04 [FR 04-26531]
Human drugs:
Nasal decongestant drug products (OTC); final monograph amendment; comments due by 1-31-05; published 11-2-04 [FR 04-24423]
Reports and guidance documents; availability, etc.:
Evaluating safety of antimicrobial new animal drugs with regard to their microbiological effects on bacteria of human health concern; Open for comments until further notice; published 10-27-03 [FR 03-27113]
Medical devices—
Dental noble metal alloys and base metal alloys; Class II special controls; Open for comments until further notice; published 8-23-04 [FR 04-19179]

HEALTH AND HUMAN SERVICES DEPARTMENT

Acquisition regulations:
Technical amendments; comments due by 2-2-05; published 1-3-05 [FR 04-27697]

HOMELAND SECURITY DEPARTMENT

Coast Guard

Anchorage regulations:
Maryland; Open for comments until further notice; published 1-14-04 [FR 04-00749]
Drawbridge operations:
Georgia; comments due by 2-1-05; published 12-3-04 [FR 04-26587]
Pollution:
Marine liquefied natural gas spills; thermal and vapor dispersion exclusion zones; rulemaking petition; comments due by 2-1-05; published 11-3-04 [FR 04-24454]

HOMELAND SECURITY DEPARTMENT

U.S. Citizenship and Immigration Services

Immigration:
Evidence processing request; standardized timeframe; removal; comments due by 1-31-05; published 11-30-04 [FR 04-26371]

HOUSING AND URBAN DEVELOPMENT DEPARTMENT

Community planning and development programs; consolidated submissions:
Consolidated plan; revisions and updates; comments due by 1-31-05; published 12-30-04 [FR 04-28430]
Manufactured home construction and safety standards:
Manufacturing Housing Consensus Committee recommendations; comments due by 1-31-05; published 12-1-04 [FR 04-26381]
Mortgage and loan insurance programs:
Home equity conversion mortgages; long term care insurance; mortgagor's single up-front mortgage premium; waiver; comments due by 2-1-05; published 12-3-04 [FR 04-26591]

INTERIOR DEPARTMENT

Fish and Wildlife Service

Endangered and threatened species permit applications
Recovery plans—
Paiute cutthroat trout; Open for comments until further notice; published 9-10-04 [FR 04-20517]
Endangered and threatened species:
Florida manatee; protection areas—
Additions; comments due by 2-2-05; published 12-6-04 [FR 04-26709]

NUCLEAR REGULATORY COMMISSION

Environmental statements; availability, etc.:
Fort Wayne State Developmental Center; Open for comments until further notice; published 5-10-04 [FR 04-10516]

SECURITIES AND EXCHANGE COMMISSION

Securities:
Securities offerings reform; registration, communications, and offering processes; modification; comments due by 1-31-05; published 11-17-04 [FR 04-24910]

SMALL BUSINESS ADMINISTRATION

Disaster loan areas:
Maine; Open for comments until further notice; published 2-17-04 [FR 04-03374]
Small business size standards:
Size standards restructuring and Small Business Innovation Research Program eligibility; comments due by 2-1-05; published 12-3-04 [FR 04-26609]

SOCIAL SECURITY ADMINISTRATION

Social security benefits, special veterans benefits, and supplemental security income:
Federal old age, survivors, and disability insurance, and aged, blind, and disabled—
Cross-program recovery of benefit overpayments; expanded authority; comments due by 2-2-05; published 1-3-05 [FR 04-28693]

OFFICE OF UNITED STATES TRADE REPRESENTATIVE

Trade Representative, Office of United States

Generalized System of Preferences:
2003 Annual Product Review, 2002 Annual Country Practices Review, and previously deferred product decisions; petitions disposition; Open for comments until further notice; published 7-6-04 [FR 04-15361]

TRANSPORTATION DEPARTMENT

Air travel; nondiscrimination on basis of disability:
Regulation update, reorganization, and clarification; statutory requirement to cover foreign air carriers; comments due by 2-2-05;

published 11-4-04 [FR 04-24371]

TRANSPORTATION DEPARTMENT

Federal Aviation Administration

Airworthiness directives:

Airbus; comments due by 1-31-05; published 12-16-04 [FR 04-27505]

Bell Helicopter Textron Canada; comments due by 1-31-05; published 12-1-04 [FR 04-26425]

Boeing; comments due by 1-31-05; published 12-16-04 [FR 04-27503]

McDonnell Douglas; comments due by 1-31-05; published 12-16-04 [FR 04-27512]

Airworthiness standards:

Special conditions—

Dessault Aviation Model Falcon Fan Jet, Falcon Fan Jet series D, E, and F, and Mystere-Falcon Models 20-C5, 20-D5, 20-E5, 20-F5, and 200 series airplanes; comments due by 1-31-05; published 12-30-04 [FR 04-28556]

Class E airspace; comments due by 1-31-05; published 12-17-04 [FR 04-27687]

TRANSPORTATION DEPARTMENT

Federal Highway Administration

Enginneering and traffic operations:

Uniform Traffic Control Devices Manual—

Traffic sign retroreflectivity; comments due by 2-1-05; published 10-22-04 [FR 04-23674]

TRANSPORTATION DEPARTMENT

Federal Railroad Administration

Railroad safety:

Locomotive crashworthiness; comments due by 2-3-05; published 1-12-05 [FR 05-00570]

TRANSPORTATION DEPARTMENT

National Highway Traffic Safety Administration

Motor vehicle safety standards:

Brake hoses; comments due by 2-3-05; published 12-20-04 [FR 04-27088]

Hydraulic and electric brake systems; comments due by 1-31-05; published 12-17-04 [FR 04-27595]

TRANSPORTATION DEPARTMENT

Research and Special Programs Administration

Hazardous materials:

Transportation—

Aircraft carriage; requirement revisions; comments due by 1-31-05; published 11-10-04 [FR 04-24376]

TREASURY DEPARTMENT

Alcohol and Tobacco Tax and Trade Bureau

Alcohol; viticultural area designations:

Texoma area; Montague County, et al., TX; comments due by 1-31-05; published 11-30-04 [FR 04-26329]

LIST OF PUBLIC LAWS

This is the first in a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "P L U S" (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal_register/public_laws/public_laws.html*.

A cumulative List of Public Laws for the second session of the 108th Congress will appear in the issue of January 31, 2005.

The text of laws is not published in the **Federal Register** but may be ordered in "slip law" (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at *http://www.gpoaccess.gov/plaws/index.html*. Some laws may not yet be available.

H.R. 241/P.L. 109-1

To accelerate the income tax benefits for charitable cash contributions for the relief of victims of the Indian Ocean tsunami. (Jan. 7, 2005; 119 Stat. 3)

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