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42 CFR Parts 417, 422 and 423
Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, and 423

[CMS–4144–F]

RIN 0938–AQ00

Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule makes revisions to the Medicare Advantage (MA) program (Part C) and Prescription Drug Benefit Program (Part D) to implement provisions specified in the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively referred to as the Affordable Care Act) (ACA) and make other changes to the regulations based on our experience in the administration of the Part C and Part D programs. These latter revisions clarify various program participation requirements; make changes to strengthen beneficiary protections; strengthen our ability to identify strong applicants for Part C and Part D program participation and remove consistently poor performers; and make other clarifications and technical changes.

DATES: *Effective Dates:* These regulations are effective on June 6, 2011, unless otherwise specified in this final rule. Amendments to 42 CFR 422.564, 422.624, and 422.626 published April 4, 2003 at 68 FR 16652 are effective June 6, 2011.

Applicability Date: In section II.A. of the preamble of this final rule, we provide a table (Table 1) which lists key changes in this final rule that have an applicability date other than the effective 60 days after the date of display of this final rule.

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Regulations Text

Acronyms

ACA The Affordable Care Act of 2010 (which is the collective term for the Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act (Pub. L. 111–152))
AO Accrediting Organization
ADS Automatic Dispensing System
AEP Annual Enrollment Period
AHFS American Hospital Formulary Service
AHFS–DI American Hospital Formulary Service-Drug Information
AHRQ Agency for Health Care Research and Quality
ALJ Administrative Law Judge
ANOC Annual Notice of Change
BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
BIPA Medicare, Medicaid, and SCHIP Benefits Improvement Protection Act of 2000 (Pub. L. 106–554)
CAHPS Consumer Assessment Health Providers Survey
CAP Corrective Action Plan
CCIP Chronic Care Improvement Program
CCS Certified Coding Specialist
CHIP Children's Health Insurance Programs
CMP Civil Money Penalties or Competitive Medical Plan
CMR Comprehensive Medical Review
CMS Centers for Medicare & Medicaid Services
CMS–HCC CMS Hierarchal Condition Category
CTM Complaints Tracking Module
COB Coordination of Benefits
CORF Comprehensive Outpatient Rehabilitation Facility
CPC Certified Professional Coder
CY Calendar year
DOL U.S. Department of Labor
DRA Deficit Reduction Act of 2005 (Pub. L. 109–171)
DUM Drug Utilization Management
EGWP Employer Group/Union-Sponsored Waiver Plan
EOB Explanation of Benefits
EOC Evidence of Coverage
ESRD End-Stage Renal Disease
FACA Federal Advisory Committee Act
FDA Food and Drug Administration (HHS)
FEHBP Federal Employees Health Benefits Plan
FFS Fee-For-Service
FY Fiscal year
GAO Government Accountability Office
HCPP Health Care Prepayment Plans
HEDIS HealthCare Effectiveness Data and Information Set
HHS [U.S. Department of] Health and Human Services
HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191)
HMO Health Maintenance Organization
HOS Health Outcome Survey
HPMS Health Plan Management System

ICD–9–CM Internal Classification of Disease, 9th, Clinical Modification Guidelines
ICEP Initial Coverage Enrollment Period
ICL Initial Coverage Limit
ICR Information Collection Requirement
IRMAA Income-Related Monthly Adjustment Amount
IVC Initial Validation Contractor
LEP Late Enrollment Penalty
LIS Low Income Subsidy
LTC Long Term Care
MA Medicare Advantage
MAAA Member of the American Academy of Actuaries
MA–PD Medicare Advantage—Prescription Drug Plans
M+C Medicare +Choice program
MOC Medicare Options Compare
MPDPF Medicare Prescription Drug Plan Finder
MIPPA Medicare Improvements for Patients and Providers Act of 2008
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)
MSA Metropolitan Statistical Area
MSAs Medical Savings Accounts
MSP Medicare Secondary Payer
MTM Medication Therapy Management
MTMP Medication Therapy Management Program
NAIC National Association Insurance Commissioners
NCPDP National Council for Prescription Drug Programs
NCQA National Committee for Quality Assurance
NGC National Guideline Clearinghouse
NIH National Institutes of Health
NOMNC Notice of Medicare Non-coverage
OEP Open Enrollment Period
OIG Office of Inspector General
OMB Office of Management and Budget
OPM Office of Personnel Management
OTC Over the Counter
PART C Medicare Advantage
PART D Medicare Prescription Drug Benefit Programs
PBM Pharmacy Benefit Manager
PDE Prescription Drug Event
PDP Prescription Drug Plan
PFFS Private Fee For Service Plan
POS Point of service
PPO Preferred Provider Organization
PPS Prospective Payment System
P&T Pharmacy & Therapeutics
QIO Quality Improvement Organization
QRS Quality Review Study
PACE Programs of All Inclusive Care for the Elderly
RADV Risk Adjustment Data Validation
RAPS Risk Adjustment Payment System
RHIA Registered Health Information Administrator
RHIT Registered Health Information Technician
SEP Special Enrollment Periods
SHIP State Health Insurance Assistance Programs
SNF Skilled Nursing Facility
SNP Special Needs Plan
SPAP State Pharmaceutical Assistance Programs
SSA Social Security Administration
SSI Supplemental Security Income
TMR Targeted Medication Review
TrOOP True Out-Of-Pocket
U&C Usual and Customary
USP U.S. Pharmacopoeia

I. Background

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) established a new "Part C" in the Medicare statute (sections 1851 through 1859 of the Social Security Act (the Act) which established the current MA program (known as Medicare+Choice under the BBA). The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) established the Part D program and made significant revisions to Part C provisions governing the Medicare Advantage (MA) program. The MMA directed that important aspects of the Part D program be similar to, and coordinated with, regulations for the MA program. Generally, the provisions enacted in the MMA took effect January 1, 2006. The final rules implementing the MMA for the MA and Part D prescription drug programs appeared in the **Federal Register** on January 28, 2005 (70 FR 4588 through 4741 and 70 FR 4194 through 4585, respectively).

As we have gained experience with the MA program and the prescription drug benefit program, we periodically have revised the Part C and Part D regulations to continue to improve or clarify existing policies and/or codify current guidance for both programs. In December 2007, we published a final rule with comment on contract determinations involving Medicare Advantage (MA) organizations and Medicare Part D prescription drug plan sponsors (72 FR 68700). In April 2008, we published a final rule to address policy and technical changes to the Part D program (73 FR 20486). In September 2008 and January 2009, we finalized revisions to both the Medicare Advantage and Medicare prescription drug benefit programs (73 FR 54226 and 74 FR 1494, respectively) to implement provisions in the Medicare Improvement for Patients and Providers Act (MIPPA) (Pub. L. 110–275), which contained provisions affecting both the Medicare Part C and Part D programs, and to make other policy changes and clarifications based on experience with both programs (73 FR 54208, 73 FR 54226, and 74 FR 2881). We also clarified the MIPPA marketing provisions in a November 2008 interim final rule (73 FR 67407).

Proposed and final rules addressing additional policy clarifications under the Part C and Part D programs appeared in the October 22, 2009 (74 FR 54634) and April 15, 2010 **Federal Register** (75 FR 19678 through 19826), respectively. (These rules are hereinafter referred to as the October 2009 proposed rule and the April 2010 final rule, respectively.) As noted when issuing these rules, we believed that additional programmatic and operational changes were needed in order to further improve our oversight and management of the Part C and Part D programs, and to further improve a beneficiary's experience under MA or Part D plans.

Indeed, one of the primary reasons set forth in support of issuing our April 2010 final rule was to address beneficiary concerns associated with the annual task of selecting a Part C or Part D plan from so many options. We noted that while it was clear that the Medicare Part C and Part D programs have been successful in providing additional health care options for beneficiaries, a significant number of beneficiaries have been confused by the array of choices provided and have found it difficult to make enrollment decisions that are best for them. Moreover, experience had shown that organizations submitting multiple bids under Part C and Part D had not consistently submitted benefit designs significantly different from each other, which we believed added to beneficiary confusion. For this reason, the April 2010 rule required that multiple plan submissions in the same area have significant differences from each other. Other changes set forth in the April 2010 final rule were aimed at strengthening existing beneficiary protections, improving payment rules and processes, enhancing our ability to pursue data collection for oversight and quality assessment, strengthening formulary policy, and finalizing a number of clarifications and technical corrections to existing policy.

On November 22, 2010, a proposed rule (hereinafter referred to as the November 2010 proposed rule) appeared in the **Federal Register** (75 FR 224), in which we proposed to continue our process of implementing improvements in policy consistent with those included in the April 2010 final rule, while also implementing changes to the Part C and Part D programs made by recent legislative changes. The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010, as passed by the Senate on December 24, 2009, and the House on March 21, 2010. The Health Care and Education Reconciliation Act (Pub. L. 111–152), which was enacted on March 30, 2010, modified a number of Medicare provisions in Pub. L. 111–148 and added several new provisions. The Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health

Care and Education Reconciliation Act (Pub. L. 111–152) are collectively referred to as the Affordable Care Act (ACA). The ACA includes significant reforms to both the private health insurance industry and the Medicare and Medicaid programs. Provisions in the ACA concerning the Part C and Part D programs largely focus on beneficiary protections, MA payments, and simplification of MA and Part D program processes. These provisions affect the way we implement our policies concerning beneficiary cost-sharing, assessing bids for meaningful differences, and ensuring that cost-sharing structures in a plan are transparent to beneficiaries and not excessive. Some of the other provisions for which we proposed revisions to the MA and Part D programs, based on the ACA and our experiences in administering the MA and Part D programs, concern MA and Part D marketing, including agent/broker training; payments to MA organizations based on quality ratings; standards for determining if organizations are fiscally sound; low income subsidy policy under the Part D program; payment rules for non-contract health care providers; extending current network adequacy standards to Medicare medical savings account (MSA) plans that employ a network of providers; establishing limits on out-of-pocket expenses for MA enrollees; and several revisions to the special needs plan requirements, including changes concerning SNP approvals and deeming. In general, the proposed rule was intended to strengthen the way we administer the Part C and Part D programs, and to aid beneficiaries in making the best plan choices for their health care needs.

II. Provisions of the Final Regulations and Analysis of and Responses to Public Comments

A. Overview of the Final Changes and Public Comments Received

1. Overview of the Final Changes

In the sections that follow, we discuss the changes made in the final rule to regulations in 42 CFR parts 417, 422, and 423 governing the MA and prescription drug benefit programs. To better frame the discussion of the specific regulatory provisions, we have structured the preamble narrative by topic area rather than in subpart order. Accordingly, we address the following five specific goals:

- Implementing the provisions of the ACA.
- Clarifying various program participation requirements.
- Strengthening beneficiary protections.
- Strengthening our ability to distinguish stronger applicants for Part C and Part D program participation and to remove consistently poor performers.
- Implementing other clarifications and technical changes.

A number of the revisions and clarifications in this final rule affect both the MA and prescription drug programs, and some affect section 1876 cost contracts. Within each section, we have provided a chart listing all subject areas containing provisions affecting the Part C, Part D, and section 1876 cost contract programs, and the associated regulatory citations that are being revised.

We note that these regulations are effective 60 days after the date of display of the final rule. Table 1 lists key changes that have an applicability date other than 60 days after the date of display of this final rule. The applicability dates are discussed in the preamble for each of these items.

We are implementing several changes to the regulations to reflect provisions in the ACA which are already in effect. Table 2 lists the key changes. While these ACA provisions became effective on the statutory effective date, the regulations implementing these provisions will be effective 60 days after the date of display of the final rule.

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Table 1: Applicability Date of Key Provisions Other than 60 Days after the Date of Display of the Final Rule

Preamble Section	Section Title	Applicability Date
II.B.10	Elimination of Medicare Part D Cost-Sharing for Individuals Receiving Home and Community-Based Services	01/01/2012
II.B.11	Appropriate Dispensing of Prescription Drugs in Long-term Care Facilities Under PDPs and MA-PD Plans	01/01/2013
II.B.12	Complaint System for Medicare Advantage Organizations and PDPs	01/01/2012
II.B.13	Uniform Exceptions and Appeals Process for Prescription Drug Plans and MA-PD Plans	01/01/2012
II.B.17	Improvements to Medication Therapy Management Programs	01/01/2013
II.B.20.a through d	Medicare Advantage Benchmark, Quality Bonus Payments, and Rebate	01/01/2012
II.E.4	Required Use of Electronic Transaction Standards for Multi-Ingredient Drug Compounds; Payment for Multi-Ingredient Drug Compounds	01/01/2012
II.F.4	Part D Transition Requirements	01/01/2012

Table 2: Key Statutory Provisions with Statutory Effective Dates Earlier than 60 Days after the Date of Display of the Final Rule

Preamble Section	Section Title	Effective Date of Statutory Requirement As Specified in the ACA
II.B.2	Simplification of Beneficiary Election Periods	01/01/2011
II.B.3.b	Extending SNP Authority	Upon enactment of the ACA
II.B.3.c	Dual Eligible SNP Contracts with State Medicaid Agencies	Upon enactment of the ACA
II.B.4	Section 1876 Cost Contract Plan Competition Requirements	Upon enactment of the ACA
II.B.5	Making Senior Housing Facility Demonstration Plans Permanent	01/01/2010
II.B.6	Authority to Deny Bids	01/01/2011
II.B.7	Determination of Part D Low-Income Benchmark Premium	01/01/2011
II.B.8.a through c	Voluntary De Minimis Policy for Subsidy Eligible Individuals	Plan year 2011
II.B.9.a through c	Increase In Part D Premiums Due to the Income Related Monthly Adjustment Amount (D-IRMAA)	01/01/2011
II.B.14	Including Costs Incurred by AIDS Drug Assistance Programs and the Indian Health Service Toward the Annual Part D Out-of-Pocket Threshold	01/01/2011
II.B.18	Changes to Close the Part D Coverage Gap	01/01/2011
II.B.19.a	Authority to Apply Frailty Adjustment under PACE payment rules for Certain Specialized MA Plans for Special Needs Individuals	01/01/2011
II.B.19.b	Application of Coding Adjustment	01/01/2006
II.B.19.c	Improvements to Risk Adjustment for Special Needs Individuals with Chronic Health Conditions	01/01/2011

2. Public Comments Received on the Proposed Rule

We received approximately 261 timely public comments on the November 2010 proposed rule. These public comments addressed issues on multiple topics. Commenters included health and drug plan organizations, insurance industry trade groups, pharmacy associations, pharmaceutical benefit manager (PBM) organizations, provider associations, representatives of hospital and long term care institutions, drug manufacturers, mental health and disease specific advocacy groups, beneficiary advocacy groups, researchers, and others.

In this final rule, we address all comments and concerns on the policies included in the proposed rule. We also reference comments that were outside the scope of the proposals set forth in the proposed rule, in the comment and response sections of this final rule.

We present a summary of the public comments and our responses to them in the applicable subject-matter sections of this final rule.

Comment: A commenter stated that CMS revised the date for the closing of the comment period from January 21, 2011 to January 11, 2011 and requested that CMS provide a rationale for shortening the comment period for the proposed rule.

Response: Our proposed rule was placed on display at the Office of the Federal Register and made available on the CMS Web site on November 10, 2010. Section 1871(b)(1) of the Act requires "notice" of the proposed rule, and a period of 60 days for public comment thereon. Because notice of the provisions of the proposed rule was provided on November 10, 2010 the comment period closed on January 11, 2011, which is 60 days after the date of display of the proposed rule at the Office of the Federal Register and on the CMS Web site.

B. Changes To Implement the Provisions of the Affordable Care Act

The ACA includes significant reforms of both the private health insurance industry and the Medicare and Medicaid programs. Provisions in the ACA that concern the Part C and Part D programs largely focus on beneficiary protections, MA payments, and simplification of MA and Part D program processes. The changes based on provisions in the ACA are detailed in Table 3.

TABLE 3—Changes to Implement the Provisions of the Affordable Care Act

PROVISION	PART 417/422		PART 423	
	Subpart	Section	Subpart	Section
Cost Sharing for Specified Services at Original Medicare Levels	Subpart B Subpart C	§417.454 §422.100	N/A	N/A
Simplification of Beneficiary Election Periods	Subpart B	§422.62 §422.68	Subpart B	§423.38 §423.40
Special Needs Plan (SNP) Provisions	Subpart A Subpart C Subpart D	§422.2 §422.4 §422.101,§422.107 §422.152	N/A	N/A
Section 1876 Cost Contractor Competition Requirements	Subpart J	§417.402	N/A	N/A
Making Senior Housing Facility Demonstration Plans Permanent	Subpart A Subpart B	§422.2 §422.53	N/A	N/A
Authority to Deny Bids	Subpart F	§422.254,§422.256	Subpart F	§423.265 §423.272
Determination of Part D Low-Income Benchmark Premium	N/A	N/A	Subpart P	§423.780
Voluntary De Minimis Policy for Subsidy Eligible Individuals	N/A	N/A	Subpart B Subpart P	§423.34 §423.780
Increase In Part D Premiums Due to the Income Related Monthly Adjustment Amount (D-IRMAA)	N/A	N/A	Subpart B Subpart F	§423.44 §423.286 §423.293
Elimination of Medicare Part D Cost-Sharing for Individuals Receiving Home and Community-Based Services	N/A	N/A	Subpart P	§423.772 §423.782
Appropriate Dispensing of Prescription Drugs in Long-Term Care Facilities Under PDPs and MA-PD Plans	N/A	N/A	Subpart D	§423.154
Complaint System for Medicare Advantage Organizations and PDPs	Subpart K	§422.504	Subpart K	§423.505

PROVISION	PART 417/422		PART 423	
	Subpart	Section	Subpart	Section
Uniform Exceptions and Appeals Process for Prescription Drug Plans and MA-PD Plans	N/A	N/A	Subpart C Subpart M	§423.128 §423.562
Including Costs Incurred by AIDS Drug Assistance Programs and the Indian Health Service Toward the Annual Part D Out-of-Pocket Threshold	N/A	N/A	Subpart C Subpart J	§423.100 §423.464
Cost Sharing for Medicare-Covered Preventive Services	Subpart B Subpart C	§417.454 §422.100	N/A	N/A
Elimination of the Stabilization Fund	Subpart J	§422.458	N/A	N/A
Improvements to Medication Therapy Management Programs	N/A	N/A	Subpart D	§423.153
Changes to Close the Part D Coverage Gap	N/A	N/A	Subpart C Subpart R	§423.104 §423.884
Payments to Medicare Advantage Organizations	Subpart G	§422.308	N/A	N/A
Medicare Advantage Benchmark, Quality Bonus Payments, and Rebate	Subpart F	§422.252,§422.258 §422.266	N/A	N/A
Quality Bonus Payment and Rebate Retention Appeals	Subpart F	§422.260	N/A	N/A

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1. Cost Sharing for Specified Services at Original Medicare Levels (§ 417.454 and § 422.100)

Section 3202 of the ACA amended section 1852 of the Act to establish new standards for MA plans' cost sharing. Specifically, section 1852(a)(1)(B) of the Act was amended by the addition of a new clause (iii) that limits cost sharing under MA plans so that it cannot exceed the cost sharing imposed under Original Medicare for specific services identified in a new clause (iv). New section 1852(a)(1)(B)(iv) of the Act lists the three service categories for which cost sharing in MA plans may not exceed that required in Original Medicare (chemotherapy administration services, renal dialysis services, skilled nursing care) and section 1852(a)(1)(B)(iv)(IV) of the Act specifies that this limit on cost sharing also applies to such other services that the Secretary determines appropriate, including services that the Secretary determines require a high level of predictability and transparency for beneficiaries. The limits on cost sharing in clause (iii) are "subject to" an exception in clause (v) which provides that, "[i]n the case of services described in clause (iv) for which there is no cost sharing required under Parts A and B, cost sharing may be required for those services" under the clause (i) standard in place prior to the amendments made by section 3202 of the ACA. This section requires that overall cost sharing for Medicare Part A and B services be actuarially equivalent to that imposed under Original Medicare. As noted in the April 2010 final rule (75 FR 19712) and clarified in our April 16, 2010 policy guidance, the provisions of section 3202 of the ACA apply to MA plans offered in CY 2011. To codify these provisions, we proposed to amend § 422.100 by adding new paragraph (j). In addition, under our authority in section 1876(i)(3)(D) of the Act to impose "other terms and conditions" deemed "necessary and appropriate," we proposed to add new paragraph (e) in § 417.101 to extend the requirements in section 3202 of the ACA to section 1876 cost contracts. In this rule we explain that our proposed addition to § 417.101 was technically incorrect and have corrected the regulation citation so that our proposed addition is new paragraph (e) to § 417.454 to extend the requirements in section 3202 of the ACA to section 1876 cost contracts. We believe that this extension is necessary in order to ensure that all Medicare beneficiaries have the benefit of the cost sharing protections enacted in the ACA, regardless of whether they receive their Part A and B benefits through Original Medicare, an MA plan, or under a section 1876 cost contract.

In our April 16, 2010 guidance issued via the Health Plan Management System (HPMS) ("Benefits Policy and Operations Guidance Regarding Bid Submissions; Duplicative and Low

Enrollment Plans; Cost Sharing Standards; General Benefits Policy Issues; and Plan Benefits Package (PBP) Reminders for Contract Year (CY) 2011"), we included clarifying information related to implementation of the required cost sharing for chemotherapy administration services, renal dialysis services, and skilled nursing care for CY 2011 and we defined chemotherapy administration services to include chemotherapy drugs, radiation therapy services and other related chemotherapeutic agents, as well as administration, and skilled nursing care to mean skilled nursing facility services. We also clarified that, since there is no cost sharing under Original Medicare for the first 20 days of skilled nursing services, under section 1852(a)(1)(B)(v) of the Act, the new restrictions in section 3202 of the ACA do not apply to such services during this period.

In our proposed additions to § 417.454 and § 422.100, we proposed to incorporate these definitions for the two service categories. We welcomed comments on these proposed cost sharing standards.

We also proposed to limit cost sharing for home health services under MA plans to that charged under Original Medicare and noted that, although we can generally rely on our authority at 1852(a)(1)(B)(iv)(IV) of the Act to apply Original Medicare cost sharing limits to other services that the Secretary determines appropriate, because there is no cost sharing under Original Medicare for home health services, as in the case of the first 20 days of skilled nursing facility services, the exception in clause (v) of section 1852(a)(1)(B) of the Act would apply, and the limit on cost sharing under section 1852(a)(1)(B)(iii) of the Act would not apply. Thus, in proposing to apply Original Medicare cost sharing amounts to home health services or any other service with zero cost sharing, we instead indicated that we would rely on our authority in section 1856(b)(1) of the Act to establish MA standards by regulation, and in section 1857(e)(1) of the Act to impose additional "terms and conditions" found "necessary and appropriate" to require that cost sharing for these services under MA plans conform to that under Original Medicare, meaning that no cost sharing could be imposed for these services.

We solicited public comment on our proposal to limit cost sharing for home health services to that charged for those services under Original Medicare.

Comment: There were many commenters who opposed our proposal to limit cost sharing for home health services under MA and cost plans at Original Medicare levels. The commenters expressed concern that limiting cost sharing for home health decreases their flexibility in their plan design and limits the plans' tools to ensure appropriate utilization of home health care.

MedPAC strongly opposed our proposal to limit home health cost sharing to $0 for several reasons including: Home health is a less well-defined benefit in Medicare and its appropriate use is more difficult to monitor and the proposed prohibition on cost sharing for home health is unduly restrictive. They also argued that CMS' proposal is based on weak rationale. The comment included a statement of MedPAC's belief that cost sharing should be one of the tools that plans can use at their discretion as a means of ensuring appropriate utilization. The comment informed us that MedPAC was currently considering these kinds of issues as a part of their deliberations on whether or not to recommend that traditional FFS Medicare should have cost sharing for home health services, along with the level of such cost sharing and the circumstances in which the cost sharing would apply.

Response: We find MedPAC's concerns about our proposal, in addition to those expressed by many other commenters to be persuasive and believe we should not finalize, at this time, our proposal to prohibit cost sharing for in-network home health services. MedPAC has recommended to Congress that it should direct the Secretary to establish a per episode copayment for home health episodes of care that are not preceded by a hospitalization or post-acute care use. We believe it is reasonable for us to take time to perform additional analyses of home health service utilization by beneficiaries enrolled in MA plans.

Comment: We received several comments that supported our proposal to limit cost sharing for home health services at Original Medicare levels. Those commenters believe that it will provide beneficiaries with a benefit package that is transparent and easily predictable for out-of-pocket expenses.

Response: We thank the commenters for their support but, as previously discussed at length, we believe that it would be more appropriate not to finalize our proposal. We will continue to evaluate the effectiveness of our current policies to protect beneficiaries from unfair or discriminatory cost sharing, confusing plan choices, and unaffordable care before implementing any additional policy change. Furthermore, under current policy only plans that provide extra beneficiary protection from high cost sharing by adopting a voluntary MOOP are permitted to charge cost sharing for home health services. We will continue to find the most appropriate balance between protecting beneficiaries from excessive out-of-pocket cost sharing and ensuring the financial viability of the MA program.

Comment: One commenter stated that prohibiting cost sharing for home health could lead to further pricing challenges and another stated there are a number of provisions in the ACA that limit a plan's ability to charge cost sharing for specified services and that these provisions are being implemented at the same time that CMS is implementing payment cuts and medical costs are continuing to increase. The commenter stated all plans would be in jeopardy of financial insolvency if they are prohibited from balancing costs, benefits, and payment cuts.

Response: As stated in our proposed rule, we estimated that the cost to the Medicare program of our proposal would not be significant. We also stated that we did not expect a significant financial impact on the relatively few plans that charge cost sharing for home health services. However, given our decision not to move forward with this proposal for other reasons, this issue is moot.

Comment: We received one comment that expressed concern that our proposed codification section 3202 of the ACA could be interpreted and implemented in a manner so as to mandate the cost sharing obligation to be charged, rather than permitting plans to set cost sharing levels at or below that cost sharing limit amount.

Response: We thank the commenter for sharing this concern. We thought we were clear in our proposal that plans would be able to set cost sharing levels at or below those charged under Original Medicare but will make every effort to be clear and consistent in our guidance related to these limits.

Comment: We received two comments that requested that we add Durable Medical Equipment (DME) to the list of service categories for which cost sharing may not exceed the levels required under Original Medicare.

Response: We thank the commenters for their suggestion and we will consider proposing that addition in future rulemaking.

Comment: We received several comments that challenged CMS' decision to allow plans to charge cost sharing during the first 20 days of skilled nursing care. One commenter

stated that charging cost sharing in the first part of the SNF stay makes sense for the plans but does not make sense for the beneficiaries. They stated that they understand CMS' actuarial equivalency rationale and that the law allows MA cost sharing for the services, but believe CMS' policy is contrary to the intent of health care reform. Another commenter stated that prohibiting cost sharing for the first 20 days of skilled nursing care would increase transparency for beneficiaries and could offer better opportunities for frail beneficiaries.

Response: Prior to the ACA, we allowed plans to charge cost sharing during the first 20 days of skilled nursing care so long as the plan's SNF benefit satisfied the actuarial equivalence test. In subregulatory guidance subsequent to enactment of the ACA, we clarified that because there is not cost sharing under Original Medicare for the first 20 days of SNF care, under section 1852(a)(1)(B)(v) of the Act, the new restrictions in section 3202 of the ACA do not apply to such services during this period and that we would continue our policy to allow cost sharing during the first 20 days of SNF care. We do not believe that enrolled beneficiaries are disadvantaged by this policy for at least two reasons. First, plans' cost sharing for SNF care is transparent to beneficiaries as it is reflected in the Summary of Benefits and the Medicare Plan Finder and second, because of the beneficiary protections from unexpected, unmanageable out-of-pocket costs that Medicare requires all MA plans to provide.

CMS limits the cost sharing that may be charged for SNF care so that it does not exceed what the beneficiary would pay under Original Medicare, including the minimal cost sharing we allow during the first 20 days in a covered SNF stay. We believe that minimal cost sharing is more than offset by other savings and protections offered under plans' benefit packages. One very important protection that all plans are required to offer is the maximum out-of-pocket (MOOP) limit on enrolled beneficiaries' out-of-pocket costs for covered in-network services. The maximum amount an enrolled beneficiary can be required to pay for those services is $6,700. In addition, most plans that charge cost sharing in the first 20 days of SNF care, waive the Original Medicare requirement for a 3-day qualifying inpatient hospital stay which saves beneficiaries enrolled in those plans from having to pay the costs for an inpatient stay.

Comment: One commenter requested that CMS establish an employer group waiver excepting MA plans offered through employer/union group health plans from the proposed cost sharing standards.

Response: We thank the commenter for this suggestion but we believe that employer group plans must be subject to the same cost sharing as other MA plans in order to provide the beneficiaries enrolled in those plans the same protections as beneficiaries enrolled in other MA and cost plans.

Comment: Several commenters supported our proposed codification of section 3202 of the ACA to limit cost sharing for chemotherapy administration services, renal dialysis services, skilled nursing care, and such other services as the Secretary determines appropriate to levels not to exceed that charged under Original Medicare and stated that it was welcome news for beneficiaries. One commenter specifically expressed support for the extension of the cost sharing limits to section 1876 cost contracts. Some of the commenters also requested that CMS provide greater clarity that the limits on cost sharing apply only to in-network services.

Response: We thank the commenters for their support and in response to the these comments we will revise our proposed regulation text to clarify in § 422.100 that the cost sharing charged for chemotherapy administration services, renal dialysis services and skilled nursing care provided in-network may not exceed the amount of cost sharing required for those services under Original Medicare. Thus, in part, the final regulation text will be revised to read: "On an annual basis, CMS would evaluate whether there are service categories for which MA plans' *in-network* cost sharing may not exceed that required under Original Medicare and specify in regulation which services are subject to that cost sharing limit."

Comment: A few commenters objected to our codification in the proposed rule of our proposal to extend the cost sharing limits of section 3202 of the ACA to section 1876 cost plans because we proposed to set forth this requirement in a new paragraph (g) to § 417.101, which otherwise does not govern cost plans. The commenters suggested that we instead add a new paragraph to § 417.454, Charges to Medicare enrollees. One commenter also recommended that we change our reference to "MA plans" in the proposed regulation language to "HMO" or "CMP" to be consistent with the standard terminology used in the regulations to refer to the section 1876 contracting entity.

Response: We thank the commenters for their suggestions. Accordingly, in this final rule, we will not include the cost-sharing requirements in § 417.101, but will instead add new paragraph (e) to § 417.454 to require cost sharing charged by section 1876 cost plans for chemotherapy, renal dialysis and skilled nursing care to be limited to that charged under Original Medicare. We also will remove reference to "MA plans" in the new regulatory text language and replace it with "HMO or CMP."

We have considered all of the comments on this proposal and will finalize, as revised, the addition of a new paragraph and (j) to § 422.100 to implement section 3202 of the ACA requiring that MA plans' in-network cost sharing charges for chemotherapy, SNF care and dialysis will be no greater than that charged under Original Medicare, and a new paragraph (e) to § 417.454 to extend these protections to section 1876 cost contracts. However, we will not finalize our proposal to add new paragraph (4) to § 417.454(e) or new paragraph (4) to § 422.100(j) to prohibit plans from charging cost sharing for home health services.

2. Simplification of Beneficiary Election Periods (§ 422.62, § 422.68, § 423.38, and § 423.40)

Section 3204 of the ACA modified section 1851(e)(3)(B) of the Act such that, beginning with plan year 2012, the annual coordinated election period (AEP) under Parts C and D will be held from October 15 to December 7. We proposed to amend 0§ 422.62(a)(2) and § 423.38(b) to codify this change.

Section 3204 of the ACA also revised section 1851(e)(2)(C) of the Act to establish, beginning in 2011, a 45-day period at the beginning of the year (January 1 through February 14) that allows beneficiaries enrolled in MA plans the opportunity to disenroll and join Original Medicare, with the option to enroll in a Medicare prescription drug plan. This 45-day period, also referred to as the Medicare Advantage Disenrollment Period (MADP), replaces the open enrollment period (OEP) that previously occurred annually from January 1st through March 31st. To codify this provision, we proposed the following changes:

- § 422.62(a) was amended to provide for this new disenrollment opportunity and clarify that the OEP ended after 2010;
- § 422.68(f) was amended to specify the effective date for disenrollment

requests submitted during the new 45-day disenrollment period;

• § 423.38(d) was amended to allow individuals who disenrolled from an MA plan between January 1 through February 14th to enroll in a standalone PDP; and

• § 423.40(d) was amended to specify the enrollment effective dates for individuals who enroll in a standalone Medicare prescription drug plan after disenrolling from MA during the 45-day period.

Comment: Commenters requested that CMS conduct beneficiary education on the new AEP timeframe.

Response: We are strongly committed to using all available means for ensuring that beneficiaries are made aware of the new AEP timeframes. Thus, we expect to conduct specific outreach and education on this topic and highlight the change in Medicare & You 2012 which will be mailed to all beneficiaries.

Comment: Commenters recommended that CMS adjust the timing of plan bids and make other important information, such as model notices, available earlier for plan preparation of the AEP. In addition, commenters requested that plan marketing be allowed to start earlier than October 1 for the AEP.

Response: We are considering the timing of our processes and will be making appropriate adjustments as we prepare for a successful implementation of the new AEP timeframe, but we do not plan to change the bid submission or plan marketing dates. The plan bid submission date is set by statute and remains the first week in June, leaving only a narrow timeframe for review and approval of bids and benefits and to ensure that marketing materials align with approved benefits. Accurate marketing materials are key to enabling beneficiaries to make appropriate determinations regarding their health care and prescription drug coverage. Also, we do not believe it is appropriate or necessary to allow plans to market earlier than October 1 given that a beneficiary may not enroll in a plan until October 15th.

Comment: Commenters recommended that CMS create an open enrollment period that would allow beneficiaries to enroll in Medigap products without regard to health status or pre-existing conditions. Another commenter recommended that CMS clarify that beneficiaries who disenroll from an MA plan using the 45-day disenrollment period do not have guaranteed issue rights to prevent underwriting the plan premium if they choose to purchase a Medigap policy.

Response: Section 1882 of the Act does not provide for a Federal annual open enrollment period for Medigap. Further the commenter is correct that using the MADP does not give the beneficiary guaranteed issue rights under Federal law to prevent health-based underwriting of the Medigap policy premium. In some cases, State Medigap laws may offer additional guaranteed issue rights to beneficiaries who are affected by the MADP.

Comment: Some commenters recommended that CMS establish a special election period (SEP) for the first year of the new AEP timeframe to allow individuals to make plan elections through December 31. Additionally, one commenter suggesting allowing plan sponsors to accept and process enrollment requests received from December 8 through December 31.

Response: Again, we will take a number of steps to ensure that beneficiaries are made aware of the new AEP timeframes, and that they have the tools they need to make informed decisions during the new AEP timeframe. We believe that through planned outreach and education efforts directly to beneficiaries and with stakeholders and plans, beneficiaries will have sufficient notification to make their health plan elections by December 7. We believe that the establishment of the suggested SEP would directly conflict with the clear intent of the statute.

Comment: A commenter recommended that individuals using the opportunity afforded by the MADP be allowed to enroll in an MA plan offered by the same parent organization instead of defaulting to Original Medicare. Another commenter recommended CMS find a less expensive alternative to the MADP such as reinstating the open enrollment period or eliminating lock-in.

Response: Again, the new 45-day disenrollment period, as established in the ACA, is clearly designed to permit only moves from MA to Original Medicare. Eliminating or broadening the scope of this election period would contradict the intent of the statute. Similarly, "lock-in" is mandated by the statute and cannot be eliminated by CMS.

Comment: A commenter addressed CMS' plans to establish an SEP to allow beneficiaries in an MA plan with less than five stars to enroll in a plan with five stars outside of the normal enrollment periods. The commenter recommended that, in regions where there are no plans with five stars, individuals be allowed to enroll in plans with 4.5 stars outside of the normal enrollment periods.

Response: We appreciate the suggestion; however the SEP for individuals to enroll in 5-star plans is outside the scope of this regulation. We will consider this suggestion as we finalize guidance concerning the scope of the SEP associated with Plan Ratings later this year. We appreciate the comments that were submitted and will be finalizing these proposals without modification.

3. Special Needs Plan (SNP) Provisions (§ 422.2, § 422.4, § 422.101, § 422.107, and § 422.152)

In our proposed rule, we defined a fully integrated dual eligible special needs plan (SNP) as specified by the ACA, and set forth proposed regulations implementing changes made by the ACA. These changes would extend the authority to offer SNPs, extend provisions permitting existing D–SNPs that are not expanding their service areas to continue operating without contracts with State Medicaid agencies through 2012, and establish a required NCQA quality approval process for SNPs.

a. Adding a Definition of Fully Integrated Dual Eligible SNP (§ 422.2)

Section 3205 of the ACA revised section 1853(a)(1)(B) of the Act to provide authority to apply a frailty payment under PACE payment rules for certain individuals enrolled in fully integrated dual eligible special needs plans described in section 3205(b) of the ACA. In order to implement this provision, we proposed a definition of fully integrated dual eligible special needs plan to § 422.2 that will apply for these purposes. Under our proposed definition, the D–SNP must meet the following criteria in order to be considered a fully integrated dual eligible special needs plan:

• Enroll special needs individuals entitled to medical assistance under a Medicaid State plan, as defined in section 1859(b)(6)(B)(ii) of the Act and § 422.2.

• Provide dual eligible beneficiaries access to Medicare and Medicaid benefits under a single managed care organization (MCO).

• Have a capitated contract with a State Medicaid agency that includes coverage of specified primary, acute and long-term care benefits and services, consistent with State policy.

• Coordinate the delivery of covered Medicare and Medicaid health and long-term care services, using aligned care management and specialty care network methods for high-risk beneficiaries.

• Employ policies and procedures approved by CMS and the State to coordinate or integrate member materials, including enrollment, communications, grievance and appeals, and quality assurance.

In this final rule, we adopt our proposed definition of a fully integrated dual eligible special needs plan with some modification. For reasons discussed below, we have in this final rule revised the definition by removing the word "including" and have replaced the word "assurance" with "improvement."

Comment: The majority of commenters supported our proposed definition of a fully integrated dual eligible special needs plan. However, three commenters raised concerns about two potential ambiguities in the part of the proposed definition which requires that a fully integrated dual eligible special needs plan "[e]mploy policies and procedures approved by CMS and the State to coordinate or integrate member materials, including enrollment, communications, grievance and appeals, and quality assurance." Specifically, these commenters recommended that we eliminate the word "including" after member materials, because the functions that follow the word "including" in the proposed definition are not all related to member materials. Further, these same commenters suggested that we use the terms "performance measurement" in place of "quality assurance" in the proposed definition, because, as suggested by the commenters, the term "performance measurement" is more consistent with current regulatory language.

Response: We appreciate the commenters' support for the definition we proposed for a fully integrated dual eligible special needs plan. We agree with the commenters that, as written, the final prong of the proposed definition is not sufficiently clear about what policies and procedures must be approved by CMS and the State to ensure integration and coordination. Accordingly, in response to these comments, we have revised this part of the proposed definition in § 422.2 of the MA program regulations by eliminating the word "including" after member materials because, as the commenters suggest, the functions that follow the word "including" are not all related to member materials. We believe this word deletion makes this prong of the definition more clear, and also more accurately reflects our intention that a fully integrated dual eligible special needs plan coordinate or integrate Medicaid and Medicare member materials, enrollment, communications, grievance and appeals, and quality improvement. In addition, we revised this part of the proposed definition by substituting the terms "quality improvement" for "quality assurance" (or "performance measurement" as suggested by three commenters). "Quality improvement" is most consistent with existing MA terminology. We believe the term "performance measurement" does not sufficiently specify our intention to ensure that this portion of the definition requires coordinated or integrated policies regarding quality. Further, the use of the term "quality improvement" intentionally demonstrates our intention that a fully integrated dual eligible special needs plan integrate or coordinate the full spectrum of programs and tools utilized to ensure quality.

Comment: Several commenters suggested that we broadly or flexibly interpret the definition of a fully integrated dual eligible special needs plan to allow for the broad variety of dual eligible special needs plan contracting arrangements in place in different States. Additionally, one commenter that submitted a comment with this suggestion also requested that under the third prong of the definition, we allow for some combination of specified primary, acute and long-term care benefits and services because States need flexibility to design the details of their programs in response to their stakeholders' needs and concerns. In contrast, another commenter urged us to use caution when approving plans as fully integrated dual eligible special needs plans, and recommended that we specify that any fully integrated dual eligible special needs plan purporting to offer long-term supports and services must offer the full range available in a given State.

Response: We believe that there is a great deal of flexibility in our proposed definition of a fully integrated dual eligible special needs plan, as written in the proposed rule and this final rule, to account for the variability in State integration efforts. For example, the terms "consistent with State policy" in the definition recognizes the variability in the degree and extent to which Medicaid services are covered from one State to the next. Additionally, as highlighted by another commenter, use of the word "specified" in the definition ("coverage of *specified* primary, acute, and long term care benefits and services, consistent with State policy") also acknowledges that States vary in the degree to which Medicaid services are covered by the State by only requiring the plan to cover those services specified by the State Medicaid Agency. Moreover, fully integrated dual eligible special needs plans and States have the flexibility to choose to contract to serve certain subsets of the sState's overall dual eligible population, provided that the MIPPA compliant State contract between the State and the fully integrated dual eligible special needs plan supports this arrangement. Therefore, in order to meet this definition a plan will be required to provide all covered Medicaid primary, acute and long-term care services and benefits to beneficiaries, and not some combination thereof.

Comment: One commenter recommended that we include in the definition of a fully integrated dual eligible special needs plan the reference to PACE frailty levels from the statutory definition of a fully integrated dual eligible special needs plan found in section 3205 of the ACA. This commenter suggested that this reference to PACE frailty levels should be included in the definition of a fully integrated dual eligible special needs plan, as well as where it now appears in § 422.308.

Response: While section 3205 of the ACA provides us with the authority to apply a frailty adjustment payment to a fully integrated dual eligible special needs plan with a similar average level of frailty as the PACE program, the statute does not limit our ability to use the definition of a fully integrated dual eligible special needs plan for only this purpose. Therefore, we will not include this requested reference in the final definition so we are able use this definition for other purposes in the future.

Comment: One commenter asked us to clarify what is meant by "aligned care management and specialty care network methods for high-risk beneficiaries," and also provided brief recommendations on how to implement this requirement. Further, the commenter recommended that any clarification on the "aligned care management" requirement specify that a fully integrated dual eligible special needs plan is responsible for managing care that is covered by Medicare or Medicaid in such a way that the individual beneficiary gets full access to all services covered by both programs.

Response: Section 164(d) of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) requires that special needs plans "have in place an evidenced-based model of care with appropriate networks of providers and specialists * * * and use[s] an interdisciplinary team in the

management of care." The terms "aligned care management and specialty care network methods for high-risk beneficiaries" derive from this requirement in MIPPA. In the September 18, 2008 **Federal Register**, we issued an interim final rule with comment on this MIPPA provision. We have received several comments on this provision and will finalize the provision later this year. As such, the final rule will provide additional clarification on what is required to "coordinates the delivery of covered Medicare and Medicaid health and long-term care services, using aligned care management and specialty care network methods for high-risk beneficiaries" as required by the definition for a fully integrated dual eligible special needs plan.

Comment: One commenter asked us to clarify the requirement that a plan designated as a fully integrated dual eligible special needs plan must provide notices specific to the dual-eligible population it is serving as opposed to generic notices designed for non-dual beneficiaries that do not correctly identify their rights and obligations.

Response: We appreciate this concern and currently require certain communications be developed specific to a beneficiary's eligibility. For example, we have created an Annual Notice of Change/Evidence of Coverage standard template specifically for dual eligible special needs plans for use starting with contract year 2012. The template was developed through several rounds of consumer testing and listening sessions with SNP representatives and consumer advocates. Other CMS models may be customized to meet the needs of dual eligible members. Furthermore, fully integrated and dual eligible special needs plans are required to coordinate and integrate member materials to contain information specific to both the Medicare and Medicaid benefits. We are committed to ensuring beneficiaries receive appropriate and helpful marketing materials and will continue to explore opportunities to improve beneficiary experience in this regard.

Comment: One commenter recommends that we approve and allow both fully integrated dual eligible special needs plans and non-fully integrated dual eligible special needs plans to operate so that a larger population of duals may be served by these plans.

Response: We agree with this commenter's recommendation. We will continue to approve and allow both fully integrated dual eligible special needs plans and non-fully integrated dual eligible special needs plan to operate so a larger population of duals may be served by these plans.

Comment: One commenter seeks clarification in the requirement that a fully integrated dual eligible special needs plan have a "capitated" contract with the State Medicaid agency.

Response: In response to this comment to clarify the meaning of the term "capitated" in the third prong of the definition, a capitated contract is a contract that provides for a fixed payment from the State Medicaid Agency to the fully integrated dual eligible special needs plan that does not vary based on services provided in exchange for the plan's provision of the covered Medicaid benefits to the beneficiaries.

b. Extending SNP Authority

Based on section 3205(a) of the ACA, which revised section 1859(f)(1) of the Act, we proposed in our November 2010 proposed rule (75 FR 71198) to extend the authority for SNPs to restrict enrollment to special needs individuals, thereby permitting SNPs to continue to limit enrollment to special needs individuals through the 2013 contract year. This extension applies to all SNP categories defined at § 422.2, with the exception of dual eligible SNPs (D–SNPs) that do not have a contract with the State in which they operate in contract year 2013, as described in section II.B.3.c of this final rule.

This provision was effective upon enactment of the ACA. However, we proposed that the regulations implementing this provision would be effective 60 days after the publication of this final rule.

After considering comments, we are finalizing this provision without modification.

Comment: Several commenters believed that delaying the proposed provision's effective date until 60 days after publication of the final rule was unnecessary.

Response: We disagree with the commenters' claim that it is unnecessary to delay implementation of this provision until 60-days following publication of this final rule. While section 3205(a) of the ACA was effective upon enactment, the regulations codifying this provision can be effective no earlier than 60 days following publication of this final rule, as provided under the Administrative Procedure Act for economically significant regulations.

Comment: One commenter suggested that extending the SNP program for longer than 1 year would provide SNPs with more operational certainty.

Response: Our proposed provision extended all SNPs, with the exception of D–SNPs that do not have a State contract in the State in which they operate, until contract year 2013, consistent with the statutory language at section 1859(f)(1) of the Act. We do not have the statutory authority to extend the SNP authority beyond the length of time Congress specified in the ACA. Therefore, we are finalizing this provision without modification.

c. Dual-Eligible SNP Contracts With State Medicaid Agencies (§ 422.107)

Section 164(c)(2) of MIPPA required all new D–SNPs and all existing D–SNPs that are seeking to expand their service areas to have contracts with the State Medicaid agencies in the States in which they operate. The provision allowed existing D–SNPs that were not seeking to expand their service areas to continue to operate without a State contract through the 2010 contract year as long as they met all other statutory requirements. Section 3205 of the ACA, which revised section 164(c)(2) of MIPPA, extends the date that D–SNPs not seeking to expand their service areas can continue to operate without a State contract to December 31, 2012. In order to implement this provision, we proposed to revise § 422.107(d)(ii) to specify the new deadline.

This provision was effective upon enactment of the ACA. However, we proposed that the regulations implementing this provision would be effective 60 days after the publication of the final rule.

Comment: Many commenters supported this proposed provision. However, the majority of the comments we received on this provision centered on the operational issues related to the State contracting requirement. Several commenters indicated that variation in State contracting and procurement processes has caused some D–SNPs to experience delays in obtaining contracts with State Medicaid agencies and they requested that CMS give D–SNPs additional flexibility to meet these contracting deadlines. A few commenters suggested that CMS incentivize States to engage with D–SNPs that are seeking to contract with the State(s) in their service areas, while another commenter proposed that CMS hold plans harmless if States either refuse to contract with them or require them to meet contract requirements that are beyond the minimum CMS-required contract elements. Other commenters recommended that CMS provide further regulatory and operational guidance on the State contracting process. Several commenters expressed concern that

States were receiving conflicting information from CMS central and regional offices (ROs), and asked CMS to develop a model State contract for dissemination to D–SNPs, States, and the CMS ROs. Some commenters recommended that CMS establish a system of review and oversight of D–SNP State contracts through rulemaking.

Response: The proposed rule neither codified the D–SNP State contracting requirement nor specified specific contract requirements; it only amended § 422.107 to conform to the statutory extension of the State contracting deadline for existing, non-expanding D–SNPs. Comments about operationalizing the State contracting requirement were not strictly within the scope of this rule. We note that, although we are not addressing these specific operational concerns in this final rule, we intend to provide additional operational guidance on the D–SNP State contracting requirements in future operational guidance well in advance of the State contracting deadline of December 31, 2012.

d. Approval of Special Needs Plans by the National Committee for Quality Assurance (§ 422.4, § 422.101, and § 422.152)

The ACA amended section 1859(f) of the Act to require that all SNPs, existing, new, and those wishing to expand their service areas, be approved by the National Committee for Quality Assurance (NCQA) effective January 1, 2012 and subsequent years. Section 1859(f) of the Act further specified that the NCQA approval process shall be based on the standards established by the Secretary.

In our November 2010 proposed rule (75 FR 71199), we stated that both the quality improvement (QI) program plan description and the model of care (MOC) are critical clinical elements that represent the potential for the SNP to provide integrated care for Medicare enrollees. We proposed that NCQA review both the QI program plan description and the MOC submitted during the application process for all SNPs using standards developed by CMS. Specifically, we proposed to add a new paragraph (iv) to § 422.4(a) to require MA plans wishing to offer a SNP, whether new or current, to be approved by NCQA, effective January 1, 2012, by submitting their quality QI program plan and MOC to CMS for NCQA evaluation and approval, per CMS guidance. We also proposed to codify the new requirement at § 422.101(f), which specifies MOC requirements, by adding a new paragraph (vi). Finally, we proposed to codify the new requirement by revising § 422.152(g), which specifies QI program requirements.

In the proposed rule, we also clarified that CMS would not participate in the scoring and review of the MOC and QI program plans. We also stated in our proposed rule that we would release specific instructions and guidance to organizations, including the specific criteria that NCQA would use to evaluate the QI program plan description and MOC, information about technical assistance training that would be available to the SNPs as they prepared their QI program plan and MOC submissions, as well as details on the frequency of the SNP approval process. We also expressed concern that an annual approval process could be burdensome for plans and solicited comments on how to determine the appropriate frequency for the SNP approval process.

Based on the comments we received on the proposed rule, we are modifying § 422.4(a)(iv), § 422.101(f), and § 422.152(g), as described below.

Comment: Several commenters expressed concern with our proposed SNP approval process and the components that comprise that process. Specifically, these commenters noted that both the 2012 application cycle and the 2011 SNP structure and process measure submissions were due in February 2011. The commenters requested that CMS clarify any relationship between the two processes. Other commenters requested that CMS link the SNP approval process to the work NCQA currently performs around QI, MOC and HEDIS® requirements.

Response: In our proposed rule, we proposed that NCQA would review the QI program plan and MOC submitted by all SNPs during the application cycle using standards developed by CMS. Our basis for this proposal was that the description of the plan's QI program plan and the MOC contained critical elements representing the potential for a SNP to provide integrated care for Medicare enrollees. Some commenters appear to have confused our proposed requirements for the SNP approval process with other quality requirements, such as, the quality improvement projects (QIPs), chronic care improvement programs (CCIPs) and the NCQA structure and process measures. As a result of this confusion, the majority of these comments did not support using evaluation of either the QI program plan or MOC as part of this process. Other commenters recommended that CMS ensure that there is consistency between the requirements for the SNP approval process and those of the other, unrelated NCQA quality assessment process.

Response: We agree with commenters that the QI program plan may not be the most appropriate basis for approval of SNPs. Therefore, we have modified our original proposal by removing evaluation of the QI program plan from the NCQA SNP approval process described in § 422.4(a)(iv), § 422.101(f), and § 422.152(g). As a result, the SNP approval process will be based only on evaluation of the MOC, which will allow the NCQA to focus purely on a component of quality that is primarily clinical in nature and is also unique to SNPs. Removing evaluation of the QI program plan from the SNP approval process may also help reduce the confusion and concern plans expressed about alignment of the SNP approval process with other QI assessment measures and activities. All MA plans will still be required to submit their QI program plan; however, we will retain responsibility for review and assessment of this component as part of our larger QI efforts.

Comment: Several commenters urged CMS to ensure that there is consistency between the QI program and MOC documents submitted during the application process and NCQA structure and process measures submissions.

Response: The submission of structure and process measures is an ongoing annual QI assessment activity for all SNPs. The SNP approval process is a separate process for ensuring that SNPs comprehend the unique requirements of the SNP program and are capable of implementing these requirements. We believe commenters may be confusing submission of structure and process measures and the SNP approval process given NCQA's involvement in both processes, even though there is no relationship between the two. Therefore, we clarify that there is no relationship between the documents required to be submitted during the application process and the information required for the structure and process measures submissions.

Comment: Two commenters requested that CMS address the relationship between the requirements for D–SNPs to contract with States, the SNP application, and the new SNP approval process. They further requested that CMS clarify that if a D–SNP were approved by NCQA for longer than one year but lost its State contract, CMS would not approve the D–SNP and would terminate the plan.

Response: The D–SNP State contracting requirement is separate from the SNP approval and SNP application

processes and is described elsewhere in this final rule.

Comment: Several commenters recommended that CMS consider incorporating the SNP approval process into the existing NCQA accreditation process. One of the commenters requested that CMS replace specific Medicare requirements, such as QI program requirements that may be part of the NCQA accreditation process, in lieu of more appropriate and relevant MOC and SNP-specific measures.

Response: Section 1859(f) of the Act specifies that the SNP approval process "shall be based on the standards established by the Secretary." While CMS has broad discretion regarding the development of the SNP approval process, our goal is to develop a process that is equitable for all SNPs. We do not believe that substituting NCQA accreditation for explicit SNP approval is appropriate because accreditation is voluntary, and not all plans are accredited, nor is NCQA the only accreditation organization recognized by CMS. CMS also has agreements with URAC (formerly the Utilization Review Accreditation Committee) and the Accreditation Association for Ambulatory Healthcare (AAAHC) to be deeming accreditation organizations. Each accreditation organization defines its fully accredited status level differently.

Comment: Several commenters supported our proposal to consider implementing a multi-year approval period for high scoring plans. These commenters recommended a 3-to-5-year approval cycle to limit the administrative burden on plans that demonstrate their ability to meet the needs of special needs populations. These commenters stated that implementing an extended approval cycle would also allow CMS the opportunity to provide additional oversight of low performing plans. Two commenters recommended that CMS structure the approval process in a manner similar to that of the NCQA structure and process measures review cycle.

Response: We agree with the commenters' position that a multi-year approval period would limit MA organizations' administrative burden. To that end, we intend to implement a multi-year approval process that will allow plans that receive a higher score on NCQA's evaluation of their MOC to be granted a longer approval period, meaning they would not be required to be reapproved for 1 or more years, unlike plans that score at the lower end of the scoring spectrum and which will be granted a shorter approval period. Specific guidance regarding the standards for multiyear approvals will be provided in separate guidance such as HPMS memoranda and annual call letters.

Comment: One commenter supported a multi-year approval cycle but recommended that, rather than develop new measures, CMS should use QI measures that SNPs currently collect, such as annual QI audit results.

Response: We are conducting a review of the MOCs from a sample of the SNPs. While data are not yet available from these audits, we expect that the audits will be completed by the end of calendar year 2011. We will use these data to revise and improve the MOC requirements in the future, as well as to refine the required evaluation criteria for the SNP approval process over time. We will also continue to research additional and appropriate QI measures to use as part of this process.

Comment: To avoid introducing additional complexity into the transition to NCQA approval of SNPs, one commenter recommended that CMS not introduce new criteria for evaluation of SNPs at this time. This commenter also recommended that, once our approval standards are finalized, CMS leave them intact for several years in order to give NCQA and plans time to assess operational impacts and to fine-tune their systems.

Response: We intend to continue using criteria for evaluation of SNPs that are familiar to plans. However, we will continue researching the feasibility of revising the criteria for future approval cycles. We will communicate changes to these criteria and provide opportunities for public review and comment.

Comment: Several commenters expressed concern that CMS is proposing to delegate full authority of the SNP approval process to NCQA. These commenters did not favor giving so much authority to a private entity whose processes and activities are not subject to public scrutiny. These commenters recommended that CMS periodically audit NCQA's work to ensure that the work it is tasked with performing is serving the best interests of the beneficiaries.

Response: Section 1859(f) of the Act requires that NCQA approve SNPs based on standards established by the Secretary. We will maintain oversight of this process via its contract with NCQA, as well as by establishing appropriate standards for NCQA approval, as described elsewhere in this preamble.

Comment: One commenter requested that CMS clarify that it will continue its own review of SNP applications rather than allow NCQA approvals of two documents to serve as deemed compliance with all regulatory requirements.

Response: We confirm that we will retain responsibility of the MA and SNP application review process, and the SNP approval process is one component of this process. We believe this commenter may have confused the NCQA approval process with the annual application process, since both have the same timeline.

Comment: Several commenters recommended that CMS remove the SNP approval process from the annual SNP application timeframe.

Response: We disagree with these commenters' recommendation. While we proposed to link the SNP approval process to the MA application process, the SNP approval process is only one component of the overall process for determining whether a SNP may operate in contract year 2012. SNPs must still complete other components of the SNP proposal and other CMS requirements to be fully operational in contract year 2012. We believe we are minimizing MA organizations' administrative burden by linking the SNP approval process to the annual application cycle. Synchronizing the timelines for these two processes will allow SNPs to follow timelines and procedures with which they are familiar and allow for SNP approvals to be completed prior to the bid submission deadline.

Comment: One commenter recommended that CMS work with SNPs to identify a list of SNP-specific clinical and non-clinical QIP topics that are relevant to target populations served by SNPs, as well as a list of topics for dual-eligible SNPs (D–SNPs) that could be coordinated with State Medicaid agencies so that they can meet both Federal and State requirements.

Response: A major element in the design of the QIPs and CCIPs continues to be that they must address a target population that is appropriate for that plan. We intend to review the non-clinical and clinical QIPs and CCIPs that MA organizations have submitted to identify gaps in topics that plans should be addressing. We intend to issue further guidance on the submission of QIPs and CCIPs, through HPMS memoranda or the annual call letter process.

Comment: Several commenters requested the opportunity to review and comment on the new QI program plan and MOC instructional guidance.

Response: We are currently in the process of conducting a review of MOCs from a sample of SNPs. Information received from the review will be used to assist us in revising and improving the

MOC. In addition, we intend to use the information to modify and refine the required evaluation criteria over time to improve the QI program and the MOC. Updates or changes to the QI program plan and MOC instructional guidance will be made available in advance for public review and comment.

Comment: One commenter recommended that the CMS Federal Coordinated Health Care Office work with NCQA and States to align MOC and QI program requirements established by CMS for the SNP approval process for D–SNPs.

Response: We appreciate the recommendation and note that we are already working closely with the Federal Coordinated Health Care Office on a myriad of SNP issues.

Comment: One commenter believed it was not clear when plans that are not requesting a service area expansion (SAE) would be evaluated. This commenter also requested that CMS clarify whether the January 1, 2012 effective date means that the approval process begins in 2012 or that the approvals must be completed for all existing SNPs prior to January 1, 2012 (thus beginning in 2011).

Response: We approve potential applicants for contract the year prior to the date the contract becomes operational. Therefore, any requirements that must be in effect as of January 1, 2012 will be addressed as part of the 2012 SNP application cycle for contract year 2012. The deadline for submitting applications for consideration during the 2012 application cycle was February 24, 2011.

4. Section 1876 Cost Contractor Competition Requirements (§ 417.402)

In accordance with section 3206 of the ACA, which revised section 1876(h)(5)(C) of the Act, we proposed in our November 2010 proposed rule (FR 75 71199) to extend implementation of the section 1876 cost contract competition provisions until January 1, 2013. Previously, MIPPA had specified that section 1876 cost contractors operating in service areas or portions of service areas with two or more local or two or more regional Medicare coordinated care plans meeting minimum enrollment requirements (5,000 enrollees for urban areas and 1,500 enrollees for non urban areas) would be non-renewed beginning in 2010.

In implementing the new contract non-renewal date, we specified in our November 2010 proposed rule that we would evaluate enrollment of competing MA coordinated care plans beginning in 2012, send out non-renewal notices to affected section 1876 cost contracts in 2013, and that affected section 1876 cost contractors would first be unable to offer a plan beginning contract year 2014. We proposed to codify the statutory change in § 417.402(c).

We received no comments on this provision and are finalizing the provision as proposed.

5. Making Senior Housing Facility Demonstration Plans Permanent (§ 422.2 and § 422.53)

Section 3208 of the ACA established (at section 1859(g) of the Act) that as of January 1, 2010, senior housing facility plans participating as of December 31, 2009 "in a demonstration project established by the Secretary under which such a plan was offered for not less than 1 year" may continue participation as Medicare Advantage senior housing facility plans. In implementing this provision of the ACA, we proposed in our November 2010 proposed rule (75 FR 71199 and 71200) to amend the definitions at § 422.2 to include "senior housing facility plan" as a new coordinated care plan type. Our proposed definition of the term was consistent with the statutory requirements for such plans at section 1859(g) of the Act: that such a plan restrict enrollment to individuals who reside in a continuing care retirement community as defined in § 422.133(b)(2); provide primary care services onsite and have a ratio of accessible physicians to beneficiaries that we determine is adequate consistent with prevailing patterns of community health care as provided under § 422.112(a)(10); provide transportation services for beneficiaries to specialty providers outside of the facility; and was participating as of December 31, 2009 in a demonstration established by us for not less than 1 year. We also noted that a senior housing facility plan must otherwise meet all requirements applicable to MA organizations under this part.

In addition, we proposed to add a new § 422.53 to subpart B of Part 422 to address the eligibility and enrollment policies applicable to senior housing facility plans. We proposed specifying at § 422.53 that MA senior housing facility plans must restrict enrollment in these plans to residents of continuing care retirement communities, and that individuals enrolled in such plans must meet all other MA eligibility requirements in order to be eligible to enroll. In addition, we proposed specifying at § 422.53(c) that an MA senior housing facility plan must verify the eligibility of each individual enrolling in its plan using a CMS-approved process. We proposed that the regulations implementing this provision would be effective 60 days after the publication of the final rule.

We are finalizing our proposed provisions regarding senior housing facility plans without modification.

Comment: One commenter requested that our regulations make clear that, if a beneficiary who is enrolled in a senior housing facility plan moves out of the senior housing facility, he/she would be eligible for a special election period and, therefore, able to enroll in another MA plan or PDP outside of the annual election period.

Response: We agree with this commenter that a special election period should apply in this situation; however, it is not necessary to codify a new special election period for this situation. Current guidance in Chapter 2 of the Medicare Managed Care Manual *http://www.cms.gov/MedicareMangCareEligEnrol/Downloads/FINALMAEnrollmentandDisenrollmentGuidanceUpdateforCY2011.pdf,* entitled "Medicare Advantage Enrollment and Disenrollment," provides that an MA enrollee is eligible for the SEP for changes in residence if he/she moves out of the plan's service area. Since a senior housing facility plan's service area is comprised of only the senior housing facility, an enrollee who moves out of the senior housing facility may use this existing SEP to enroll in any MA or Part D plan for which he/she is eligible in his/her new place of residence and is eligible for Medigap guaranteed issue rights if he/she disenrolls to Original Medicare.

6. Authority to Deny Bids (§ 422.254, § 422.256, § 423.265, and § 423.272)

Section 3209 of the ACA amends section 1854(a)(5) of the Act by adding subsection (C) (ii) to stipulate and expressly provide that the Secretary may deny a bid submitted by an MA organization for an MA plan if it proposes significant increases in cost sharing or decreases in benefits offered under the plan. Section 3209 of the ACA also extends this provision to apply to the review of bids from Part D sponsors by amending section 1860D–11(d) of the Act to add a new paragraph (3). This statutory authority applies to bids submitted for contract years beginning on or after January 1, 2011. However, as indicated in section II.A. of this final rule, the regulations codifying this provision will be effective 60 days after the date of display of the final rule.

In the proposed rule, we stated that we believe these amendments clarify the Secretary's authority to deny bids

submitted by MA organizations and PDP sponsors and provide support for our current policies as specified in our final rule, "Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" (75 FR 19678 through 19826). These policies include imposing limits on cost sharing and denying bids submitted by plans with sustained low enrollment or bids for multiple plans offered by the same MA organization or PDP sponsors in a service area that are not meaningfully different with respect to benefits or costs. These policies were further discussed in a memorandum sent on April 16, 2010 via the Health Plan Management System (HPMS) titled "Benefits Policy and Operations Guidance Regarding Bid Submissions; Duplicative and Low Enrollment Plans; Cost Sharing Standards; General Benefits Policy Issues; and Plan Benefits Package (PBP) Reminders for Contract Year (CY) 2011."

Because these policies have been implemented so recently, we concluded that it was premature to propose additional regulatory restrictions limiting MA organizations' or PDP sponsors' flexibility in developing plan bids until we are able to evaluate the effectiveness and impact on the market of those current policies. However, in the preamble to the proposed rule, we requested comments on the criteria outlined in our April 16, 2010 guidance issued via HPMS and whether we should establish additional requirements to limit plan offerings in a service area and whether there are other measures we should consider as part of future rulemaking that may help us in our efforts to protect beneficiaries and promote the provision of high quality, affordable health plans. We also invited comments on whether we should adopt other substantive criteria for exercising our authority under 3209 of the ACA by implementing caps or limits on the number of plans offered in a region, or on the number of sponsors participating in the program. Finally, we solicited comments on the best way to ensure fair notice and equal treatment for all plan bids in the absence of specific non-acceptance and denial policies. While we indicated that we would not propose additional specific regulatory criteria for CY 2012, we noted that our decision should not be interpreted as an indication that we would not adopt specific policies in future rulemaking. We will consider the suggestions and comments we received from the public on the proposed rule to guide our future policy.

We proposed to codify the amendments made to sections 1854(a)(5) and 1860D–11(d) of the Act by adding paragraph (a)(5) to § 422.254, revising § 422.256(a), adding paragraph (b)(3) to § 423.265 and by adding paragraph (b)(4) to § 423.272.

Comment: We received several recommendations in response to our request for comments on our current meaningful differences policies. Commenters recommended that CMS issue clear and comprehensive guidance containing the CMS criteria for evaluating and accepting or denying MA and Part D plan bids well in advance of the bid deadline. Moreover, commenters recommended that CMS provide specific information to MA organizations and Part D sponsors that is sufficiently detailed to allow sponsors the ability to replicate the methodologies applied in the tools that CMS uses in its bid evaluations. This information should be sufficient for plan actuaries to test their assumptions against CMS assumptions prior to their bid submission.

Response: We appreciate your comments regarding our current meaningful differences policies. We have released, via the Final Rate Announcement and Call Letter for CY 2012 released on April 4, 2011, a detailed discussion of the methods and tools that CMS intends to use to evaluate bids and ensure beneficiaries enjoy meaningful choices among MA and Part D plans. Specifically, in the final CY 2012 Call Letter, we announce that we will make an out-of-pocket cost (OOPC) model available that will allow plans to calculate OOPC estimates for each of their benefit offerings to prepare for negotiations with us. Standalone PDPs, MA, and MA–PD sponsors and organizations are encouraged to run their plan benefit structures through the OOPC model to ensure meaningful differences between their plan offerings as required by CMS regulations (see § 423.272(b)(3)(i) and § 423.265(b)(2)). Plans will be asked to complete this analysis prior to submitting their bids for the CY 2012.

A detailed discussion regarding the thresholds that CMS will be using for CY 2012 meaningful differences policies are included in the Final Rate Announcement and Call Letter for CY 2012.

Comment: We received several comments regarding the bid evaluation tools used by CMS and as specified in the April 16, 2010 guidance. Specifically, commenters indicated that if the total beneficiary cost (TBC) metric is used in future bidding cycles, CMS will need to take into account plan-specific variations such as plan consolidation, new plan service areas, pairing of plans to meet target margins and other payment policy issues such as the lagged sustainable growth rate (SGR) fix.

A few commenters indicated that CMS did not provide sufficiently detailed information as to how plan benefits as part of the OOPC calculation were projected and estimated for 2011. A number of sponsors discovered during bid negotiations that estimates they had produced to guide their benefit designs were significantly different than CMS recommendations. Commenters recommended CMS reevaluate use of the tool to analyze plan bids and engage in detailed discussion with MA and Part D plan sponsors to identify alternatives.

One commenter believes the OOPC tool, which is used by CMS to provide out-of-pocket costs information through the *http://www.Medicare.gov* Web site, is inappropriate and the estimates produced by the tool are not linked to the projections of MA and Part D plan-specific enrollee utilization of healthcare services and the revenue needed to fund them that are at the core of plan bids. Instead, these estimates reflect utilization under the Medicare fee-for-service program for a sample of beneficiaries that is somewhat out of date.

Response: We appreciate the commenters' suggestions and critique of our current bid evaluation tools. Based on the comments we have received in response to this rule and from the industry following bid negotiations for CY 2011, we have committed to providing additional information regarding the OOPC calculation and an OOPC tool to address the industry's specific concerns and to support their development of plan bids for CY 2012. We have also provided additional guidance and proposed policies for bid review in the Final Rate Announcement and Call Letter for CY 2012.

Comment: A few commenters recommend that star quality ratings either should, or should not, be used when evaluating plan bids. One commenter indicated that quality ratings, such as low star ratings, should be used as bid evaluation criteria since lower star ratings would result in decreased enrollment causing the plan to eventually fail meeting our low-enrollment thresholds. Other commenters support the use of star ratings and recommended that CMS only reassign beneficiaries to plans with a star rating of four stars or higher ensuring beneficiaries are offered plans that have a track record of quality service. One commenter indicated that they support the use of the star rating system; however, CMS would need to

consider the different changes faced by plans in geographic areas.

Response: We appreciate the comments we received regarding the potential use of quality ratings in determining whether to deny or decline bids under our new authority. While we will not be codifying specific criteria under this rule at this time, in the future we may explore the use of our authority to deny bids based on quality ratings, such as the star ratings.

Comment: Several commenters indicate that CMS should not impose limits on the number of plans in a service area, nor limit the number of MA organizations or Part D sponsors participating in the program, as this would be inconsistent with the competitive framework of the MA and Part D programs. One commenter indicated that limiting the number of plans in a specific service area would limit competition and potentially lead to higher prices and program costs in the long run. Another commenter suggests that CMS defer further consideration of initiatives to limit the number of plans offered until the impact of existing policies and statutory program changes can be fully evaluated.

Response: We appreciate the comments we received regarding limiting the number of plans in a service area and limiting the organizations that participate in the program using the new authority to not accept bids. We will not be codifying such limits under this rule. We will consider these comments if we propose additional rulemaking limiting plans in a service area, or, limiting organizations participating in the program.

Comment: One commenter requests that we continue the waiver of our meaningful differences policy for employer group waiver plans (EGWPs).

Response: We announced in the Final Rate Announcement and Call Letter for CY 2012, released on April 4, 2011, that this waiver will continue to apply to EGWPs for CY 2012 and future contract years.

Comment: Many commenters indicated either their support for, or opposition to, a premium increase threshold when determining whether to deny or decline bids under our new authority. In particular, one commenter indicated that CMS be permitted to deny a bid if such premium increases or benefit changes are unsubstantiated. An exception to an unsubstantiated change would be if actuarially the benefit design requires that benefits be decreased if premiums increased. Another commenter indicated that denying bids based upon changes to premiums assumes all sponsors have gravitated to the same level of maturity and that individual plan differences should be accounted for when applying a cap on premium increases.

Response: We appreciate the comments we received regarding the use of strict limits on premium increases or benefit decreases when evaluating bids. While we will not be codifying into regulation strict limitations on premium increases or benefit decreases as part of this final rule, we will take these comments into consideration as our policies regarding our authority to deny bids evolve.

Comment: One commenter urged that CMS consider a plan's proposed profit margin in order to assure consistent and fair treatment across health plans. This commenter believed that plans with higher profit margins have a greater capacity to implement member cost reductions requested by CMS, and plans that have losses, or very small profit margins, should be allowed to increase their profit to allow for risk reserves.

Response: We appreciate the recommendation provided by this commenter. As our meaningful differences policies and the impact of such policies on plan bids evolve, we will consider the possibility of examining plan profit margins as part of our bid evaluation criteria.

Comment: A few commenters believed it was important for us to develop an appeals process for plans that face bid denials and that such processes should allow for the timely reconsideration of our decision.

Response: We will not be adopting specific bid denial criteria or processes in this final rule. We will continue to work with plans prior to, and during, the bidding process to ensure the meaningful differences policies and bid evaluation criteria, as set forth in our CY 2012 Final Rate Announcement and Call Letter, take into account the individual plan's population, service area, and level of maturity. We will ensure this information is provided in a timely manner so that plans will know, prospectively, our expectations regarding the plans that will be made available to our Medicare population.

Comment: We received many comments requesting that CMS disclose, prior to bid development, all criteria that will be used to review bids each contract year. The commenters asserted that without definitions of what CMS identifies as "significant increases" in cost sharing or "decreases in benefits" offered and all other criteria by which plan bids will be evaluated and possibly denied, MAOs and Part D sponsors could be subject to inconsistent and potentially unfair bid denials. Commenters overwhelmingly requested that CMS make available in this final rule, its annual Call Letter or other appropriate published guidance, no later than mid-April, the specific standards plan bids will be required to meet as well as, the tools and methodologies that would be necessary for plans to replicate CMS' bid review results. They asserted that if plans are provided the appropriate tools and information they will be able to develop and submit initial plan bids that meet all CMS requirements.

Response: We agree with commenters that plan bids based on guidance we provide prior to or during bid development are more likely to satisfy our requirements. The final CY 2012 Call Letter, released on April 4, 2011, provides the tools and information necessary for sponsors to develop and submit complete initial bids that will meet our requirements.

Comment: Some of the comments we received requested that CMS not deny bids based on increases in beneficiary costs or on decreases in benefits offered because plans may need to increase costs or decrease benefit offerings to cover the growing gap between costs for providing services and revenue. Commenters expressed concern that continued application of the Total Beneficiary Cost (TBC) review criterion that CMS used for review of CY 2011 bids has the potential to undermine the financial integrity of plan bids and to adversely affect enrolled beneficiaries. Some stated their beliefs that the constraint on increases in plans' revenue required to meet the TBC measure is likely below a reasonable cost trend and could result in negative margins for some plan bids, putting them in conflict with other CMS bid guidance. Finally, commenters asserted that CMS criteria that limit premium and other beneficiary cost increases or decreases in benefits offered are not consistent with competitive bidding, the fundamental principal that bids should satisfy actuarial soundness requirements that anticipated revenue is sufficient to cover plan costs, or the requirement that bids be certified by actuaries.

Response: We understand that MAOs and Part D plan sponsors may be facing a number of challenges as they develop plan bids for CY 2012, including those related to meeting our standards for meaningfully different plan offerings, out-of-pocket maximums and cost sharing standards. We develop bid requirements with input from our Office of the Actuary (OACT), which takes into consideration the potential impact of its own guidance regarding negative margins. Together, we have developed a

TBC requirement that will not restrict a plan's ability to meet any additional bid guidance (for example, OACT's negative margin requirement) and considers environmental changes, as well as changes in Medicare payment and their impact on plan bids. In our final CY 2012 Call Letter, we describe the methodology we will use to limit significant increases in TBC to ensure that plans offered for CY 2012 are affordable and offer good value for enrollees. As described previously, we have provided a detailed discussion of the methods and tools we intend to use to evaluate plan bids in our CY 2012 Call Letter. We evaluate this guidance annually, and make refinements as necessary, taking into consideration comments we receive from industry following the end of bid review season. For CY 2012, we also are providing additional information about the OOPC calculation and will make an OOPC model available so that plans will be able to calculate OOPC estimates for their target benefit offerings in advance of submitting their bids to CMS. We believe that this increased transparency will support plans in their work to develop their benefit designs.

Comment: Many commenters indicated that if CMS does maintain its policy to approve only plan bids that do not propose significant increases in beneficiary costs or decreases in benefits offered using the TBC measure then the measure will need to take into account the large effects of CMS payment changes, plan-specific variations such as plan consolidation, new plan service areas, whether the plan is a SNP, pairing of plans to meet target margin and other payment policy issues. One commenter urged that MAOs be able to adjust for mistakes made in prior years' bids, such as to revise benefit amounts to curb demonstrated adverse selection into the plan.

Response: We thank the commenters for their suggestions for enhancing the development of the TBC criterion. We have considered these issues and worked with OACT to incorporate several of these factors, to the extent possible, into the TBC measure for CY 2012. However, we wish to point out that CMS does not support the notion that a plan should be able to adjust their pricing year to year to account for "mistakes" in a prior year's bid. Plans are responsible for submitting bids that reflect accurate and actuarially reasonable bid projections and assumptions for the coming year, which should not include amounts attributable to making up for errors in a past year. Therefore, our TBC measure will not account for errors in a plan's previous year's bid. To the extent practicable, we will consider relevant and appropriate factors and circumstances in order to develop and publish in a timely manner measures that we will use to evaluate bids consistently across plans.

Comment: Commenters expressed their concern that any single threshold established by CMS for review of significant increases in beneficiary costs or decreases in benefits offered would fail to address the many circumstances that vary across plans such as, geographic location, plan size, plan experience, plan type, and their belief that CMS must ensure that plans have some "due process" rights related to the upcoming contract year bid review. In addition to receiving full and timely disclosure of the criteria to be used for evaluating plan bids, commenters would like an opportunity to question, or comment on, CMS' methodologies prior to their implementation, and request assurance from CMS that bids will be reviewed using only published criteria. The commenters believe that CMS owes them a meaningful opportunity to challenge the application of CMS' criteria to their bids, using actuarial analysis, and to modify a bid that does not satisfy the criteria or where CMS choose not to accept the organization's rationale for the bid. As another example, commenters requested that CMS permit bid approvals in cases in which the plan can demonstrate actuarial justification for decreases in benefits offered and/or increases in beneficiary costs that exceed CMS' threshold.

Response: We thank the commenters for sharing these concerns. As in past years, our goal is to ensure that the MA and Part D programs remain healthy and that there are meaningful, high value choices available to beneficiaries We note that during CY 2011 bid reviews, the vast majority of outlier plans came into compliance with CMS guidance or submitted acceptable justifications to CMS for their plan bid. In an effort to reduce confusion, and the need for resubmissions, CMS is providing comprehensive guidance and tools in advance of the bid submission deadline so that organizations can develop initial submissions that meet all bid requirements. Organizations had an opportunity to comment on our guidance and methodology through the draft CY 2012 Call Letter and we considered such comments in preparing the final CY 2012 Call Letter, released on April 4, 201l.

Comment: One commenter recommended that CMS, as it implements its authority deny bids, continue to examine the impact of cost sharing for specialty tier drugs in a plan's formulary which may reduce patient access to needed medications.

Response: This comment is not relevant to the discussion in the proposed rule concerning our authority to deny bids; rather, it is a comment on CMS' formulary review process. We have in place a rigorous formulary review process that ensures cost-sharing imposed by plans on drugs found on specialty tiers will not impede a beneficiary's access to medications.

7. Determination of Part D Low-Income Benchmark Premium (§ 423.780)

The ACA amends the statute governing the calculation of the LIS benchmark premium amount (see section 3302 of the ACA, as amended by section 1102 of HCERA). As amended, section 1860D–14(b)(3)(B)(iii) of the Act requires us to calculate the LIS benchmarks using MA–PD basic Part D premiums before the application of Part C rebates each year, beginning with 2011. We proposed to update the regulations at § 423.780(b)(2)(ii)(C) to incorporate this change. We also proposed that the regulations implementing this provision would be effective 60 days after the publication of the final rule.

Comment: We received several comments in support of the proposed change.

Response: We agree that LIS benchmarks should be calculated using basic Part D premiums before the application of Part C rebates and we are finalizing this provision without modification.

8. Voluntary De Minimis Policy for Subsidy Eligible Individuals (§ 423.34 and § 423.780)

Section 3303(a) of the ACA modifies section 1860D–14(a) of the Act by creating a new subsection (5) that permits PDPs and MA–PD plans to waive a *de minimis* monthly beneficiary premium for low income subsidy (LIS) eligible individuals who are enrolled in the plan. The provision also prohibits the Secretary from reassigning LIS individuals enrolled in a plan with a premium greater than the LIS benchmark premium amount, so long as the amount of the premium that exceeds the LIS benchmark is *de minimis* and the plan volunteers to waive that *de minimis* amount.

Section 3303(b) of the ACA modifies section 1860D–1(b)(1) of the Act by inserting new language in subparagraph (C) and adding a new subparagraph (D) that permits the Secretary to include PDPs and MA–PD plans that waive the *de minimis* amount in the auto-

enrollment process that we use to enroll those LIS-Eligible individuals who fail to enroll in a Part D plan. If these plans are included in the process, and more than one such plan exists within the respective PDP region, the statute requires that enrollees be randomly assigned among all such plans in the PDP region. We proposed to amend § 423.34 and § 423.780(f) to codify the new statutory requirements. The statutory provision is effective January 1, 2011; however, as indicated in section II.A. of this final rule, the regulations implementing these provisions are effective 60 days after the date of display of this final rule.

a. Reassigning LIS Individuals (§ 423.34)

Section 423.34(c) specifies that CMS may reassign certain LIS-eligible individuals if CMS determines that further enrollment is warranted. We have used this authority to reassign LIS-eligible individuals annually when a PDP's monthly beneficiary premium amount will exceed the low income benchmark, as calculated in § 423.780(b)(2). As noted previously, the ACA prohibits the Secretary from reassigning a plan's LIS eligible enrollees based on the fact that the plan's monthly beneficiary premium exceeds the LIS benchmark premium amount, so long as the amount of premium that exceeds the LIS benchmark is *de minimis* and the plan volunteers to waive that *de minimis* amount. Thus, plans that would otherwise have lost enrollees because of a *de minimis* monthly beneficiary premium can retain such membership. We proposed to amend § 423.34(c) regarding reassignment of LIS beneficiaries to reflect section 1860D–14(a)(5) of the Act.

Comment: All commenters supported our proposal to amend section § 423.34(c) to reflect newly added section 1860–14(a)(5) of the Act. These commenters noted that the primary benefits of such a *de minimis* policy are to minimize the need for reassignments, and the associated disruptions of an individual's continuity of care. One commenter recommended that we provide additional language in § 423.34(c)(1) to describe the circumstances under which reassignment occurs and the individuals affected by reassignment, in order to provide meaningful context for the exception described in § 423.34(c)(2).

Response: We agree with commenters that the *de minimis* policy supports the desirable goal of minimizing disruptions of an individual's continuity of care potentially associated with reassignment, while simultaneously ensuring a zero-premium Part D benefit to certain LIS-eligible individuals unlikely to have the financial means to pay the *de minimis* amount. Also, we appreciate the suggestion that additional context be added in § 423.34(c)(1) to describe the circumstances under which reassignment occurs and the individuals affected by reassignment. However, we believe that it is more appropriate to provide the level of detail the commenters request through subregulatory guidance. Therefore, we are finalizing our proposal to amend § 423.34(c) without modification. We will update Chapter 3 of the Medicare Prescription Drug Benefit Manual, ("Eligibility, Enrollment, and Disenrollment"—available at the following link: *http://www.cms.gov/MedicarePresDrugEligEnrol*) to provide the additional context requested by commenters.

b. Enrollment of LIS-Eligible Individuals (§ 423.34)

Section 423.34(d) specifies that CMS will automatically enroll LIS-eligible individuals who fail to enroll in a PDP. The pool of PDPs into which we auto-enroll these individuals includes those plans with monthly beneficiary premiums for LIS-eligible individuals that do not exceed the low income benchmark as calculated in § 423.780(b)(2). We proposed to amend § 423.34(d) regarding auto-enrollment of LIS-eligible individuals to be consistent with section 1860D–1(b)(1) of the Act, as modified by section 3303(b) of the ACA, which expands the Secretary's discretionary authority to include PDPs or MA–PD plans that voluntarily waive the de minimis amount in the pool of Part D plans qualified to receive auto-enrollees and reassignees, if the Secretary determines that such inclusion is warranted.

Comment: The majority of commenters supported our proposal to amend § 423.34(d) to be consistent with section 1860D–1(b)(1) of the Act, as modified by section 3303(b) of the ACA. However, a few commenters urged that CMS not codify such discretionary authority with respect to including MA–PD plans that voluntarily waive the *de minimis* amount in the pool of qualified plans to receive auto-enrollees and reassignees. Among the reasons they cited for not including the provisions concerning MA–PD plans in the regulations were that: (1) Random auto-enrollment and reassignment of such beneficiaries into MA–PD plans could have deleterious consequences on an individual's access to his or her Part A and Part B benefits; and (2) the public policy goal of eliminating premium cost-sharing for such LIS-eligible beneficiaries would not be accomplished for those individuals enrolled into an MA–PD plan with a Part D beneficiary premium within the *de minimis* amount but a Part C beneficiary premium of an amount for which the LIS recipient would incur liability.

Response: We agree with the concerns raised by these commenters, particularly with respect to the potential disruption of an individual's access to his or her Part A and Part B benefits (for example, by imposing network restrictions) by including MA–PD plans that voluntarily waive the *de minimis* amount in the pool of Part D plans qualified to receive auto-enrollees and reassignees. Since the inception of the auto-enrollment and reassignment processes, this concern has served as an underlying basis for inclusion of only PDPs in the pool of Part D plans that receive auto-enrollees and reassignees. We also agree that auto-enrollment and reassignment of such LIS-eligible individuals into MA–PD plans, in some cases, would fall short of our public policy goal of ensuring zero premium cost-sharing for these beneficiaries to access their Part D benefit.

For the reasons stated previously, we are amending § 423.34(d) to codify the Secretary's authority only with respect to including PDPs that voluntarily waive the *de minimis* amount in the pool of plans qualified to receive auto-enrollees and reassignees. At this time, we do not intend to exercise such authority to auto-enroll or reassign LIS-eligible beneficiaries into PDPs that voluntarily waive the *de minimis,* except under limited instances, such as to allow beneficiaries to remain within the same parent organization or to ensure that LIS-eligible beneficiaries in all PDP regions have access to a plan with zero beneficiary premium liability. However, the regulations will retain the flexibility to permit future reassignments to PDPs above the LIS benchmark that waive the *de minimis amount,* should the Secretary determine such reassignments to be warranted.

Comment: One commenter suggested that CMS examine the impact on enrollment stability if the Agency were to apply the *de minimis* policy to partial premium subsidy recipients.

Response: The underlying goal of the *de minimis* policy is to minimize unexpected disruptions of care that may result from reassignment. The proposed application of the *de minimis* policy to full-benefit subsidy beneficiaries supports this policy goal, as we do not reassign partial premium subsidy recipients enrolled in a Part D plan with

a beneficiary premium amount that exceeds the LIS benchmark amount. Since partial premium subsidy recipients pay a partial premium, they are more likely to be accustomed to proactively selecting a plan with a premium amount within their financial means to avoid disruption of care. Finally, application of the *de minimis* policy to partial premium subsidy recipients would partially undermine the downward pressure on Part D bids by decreasing the incentive for plans to bid lower in order to retain such beneficiaries. Therefore, we are making no modifications to our *de minimis* proposal with respect to its application to only full-benefit subsidy recipients.

Comment: One commenter urged CMS to permit plan sponsors to reassign LIS beneficiaries enrolled in its "enhanced plan" into the plan sponsor's "basic plan." The commenter noted that such a change would minimize disruption of care as the beneficiary would remain within the same parent organization, which typically has the same formularies and many similar benefits and services across plans. The commenter further noted that such a policy would prevent potential future terminations of members due to non-payment of premium, since their premium in the new plan should be much less than in the enhanced plan.

Response: In accordance with our long-standing public policy of honoring a beneficiary's plan choice by excluding from the reassignment process those beneficiaries who have proactively enrolled in a plan, we will continue our like-minded policy that prohibits plans from passively and selectively reassigning LIS-eligible beneficiaries who have proactively enrolled in the sponsor's enhanced plan. In the rare instance of plan consolidations, such reassignments may be permitted at our discretion, as they would not dishonor the beneficiary's plan choice, since the chosen plan no longer exists under such circumstances. Such situations would generally involve the elimination of the enhanced plan for all enrollees, and thus would not result in the selective reassignment of LIS-eligible beneficiaries.

c. Premium Subsidy (§ 423.780)

We also proposed to amend § 423.780(f) to reflect section 1860D–14(a)(5) of the Act, permitting a Part D plan to waive a *de minimis* amount that is above the monthly beneficiary premium defined in § 423.780(b)(2)(ii)(A) or (B) for full subsidy individuals as defined in § 423.780(a) or § 423.780(d)(1), provided waiving the *de minimis* amount results in a monthly beneficiary premium that is equal to the established low income benchmark as defined in § 423.780(b)(2). In addition, because section 1860D–14(a)(5) of the Act refers to waivers of *de minimis* premium that exceeds the low-income benchmark, which accounts only for the basic benefit, we limit the waiver of the *de minimis* amount to the premium applicable to the basic benefit.

Comment: We received one comment strongly encouraging CMS to increase the *de minimis* amount beyond $2.00 for full-benefit dual-eligible beneficiaries enrolled in special needs plans to help meet the needs of this more vulnerable population.

Response: We determine the *de minimis* amount based on the outcome of the plan bidding process. We consider the impacts of setting the *de minimis* amount at varying levels each year, including the impact on the number of zero premium plans and the number of reassignments. At this time, however, we do not believe that it is necessary to apply different *de minimis* amounts for various plan types, because we believe that a uniform *de minimis* amount ensures that impacted beneficiaries are treated equitably in terms of their premium assistance regardless of plan type. Thus, we plan to continue establishing a uniform *de minimis* amount applicable to all plan types each year.

Comment: Some commenters recommended that CMS release the LIS benchmarks and the *de minimis* amount earlier than August to allow adequate time for Part D sponsors to modify systems and member communications given the statutory change to the AEP.

Response: While we appreciate concerns about providing sufficient time for Part D sponsors to modify their systems and member communications, we cannot determine the regional LIS benchmarks until August when the Part D bids have been received and reviewed. In order for Part D sponsors to modify systems and member communications, they would need both the regional LIS benchmarks and the *de minimis* amount. Additionally, we release the *de minimis* amount in August to ensure that it does not influence bid submissions inappropriately. Therefore, we will not be modifying the release date of the regional LIS benchmarks or *de minimis* amount and are finalizing our proposal without modification.

9. Increase In Part D Premiums Due to the Income Related Monthly Adjustment Amount (D—IRMAA) (§ 423.44, § 423.286, and § 423.293)

Section 3308 of the ACA amended section 1860D–13(a) of the Act by establishing an income related monthly adjustment amount (hereafter referred to as Part D—IRMAA) that is added to the monthly Part D premium for individuals whose modified adjusted gross income exceeds the same income threshold amounts established under section 1839(i) of the Act with respect to the Medicare Part B income related monthly adjustment amount (Part B—IRMAA).

In CY 2007, the income ranges set forth in section 1839(i) of the Act required that individual and joint tax filers enrolled in Part B whose modified adjusted gross income exceeded $80,000 and $160,000, respectively, would be assessed the Part B—IRMAA on a sliding scale. As specified in section 1839(i)(5) of the Act, since the implementation of the Part B—IRMAA, each dollar amount within the income threshold tiers has been adjusted annually based on the Consumer Price Index. As a result of the annual adjustment, for calendar year 2010, the income threshold amounts were increased to reflect the four income threshold amount tiers shown below:

Individual tax filers with income:	Joint tax filers with income:	Premium Percentage
Equal to or less than $85,000	Equal to or less than $170,000	0—No IRMAA
Greater than $85,000 and less than or equal to 107,000	Greater than $170,000 and less than or equal to $214,000	35 percent
Greater than $107,000 and less than or equal to $160,000	Greater than $214,000 and less than or equal to $320,000	50 percent
Greater than $160,000 and less than or equal to $214,000	Greater than $320,000 and less than or equal to $428,000	65 percent
Greater than $214,000	Greater than $428,000	80 percent

We note that section 3402 of the ACA freezes the income thresholds at the above 2010 levels through 2019.

In accordance with section 3308 of the ACA, effective January 1, 2011, any individual enrolled in the Medicare prescription drug program whose modified adjusted gross income exceeds the same income threshold amount tiers established under Part B will have an income related increase to his/her Part D monthly premium. Section 3308 of the ACA provides that the Part D—IRMAA will be calculated using the Part D national base beneficiary premium and the premium percentages in the above chart as follows: BBP × [(P percent − 25.5 percent)/25.5 percent]. The BBP is the base beneficiary premium and P is the applicable premium percentage (35 percent, 50 percent, 65 percent, or 80 percent). The premium percentage used in the calculation will depend on the level of the Part D enrollee's modified adjusted gross income.

Section 3308 of the ACA requires CMS to provide the Social Security Administration (SSA) with the national base beneficiary premium amount used to calculate the Part D—IRMAA no later than September 15 of every year, beginning in 2010. Beginning in 2010, we must also provide SSA, no later than October 15 of each year, with: (1) The modified adjusted gross income threshold ranges; (2) the applicable percentages established for Part D—IRMAA in accordance with section 1839(i) of the Act; (3) the corresponding monthly adjustment amounts; and (4) any other information SSA deems necessary to carry out the Part D—IRMAA. With respect to the final item, we previously provided SSA with an initial list of all individuals enrolled in the Part D program.

In accordance with section 3308 of the ACA and the interim final rule with request for comments entitled "Regulations Regarding Income-Related Monthly Adjustment Amounts to Medicare Beneficiaries' Prescription Drug Coverage Premiums" (75 FR 75884), SSA used this initial list of Part D enrollees to request beneficiary-specific tax payer information from the Internal Revenue Service in order to determine: (1) Which Part D enrollees exceed the income threshold amounts established under section 1839(i) of the Act; and (2) the income related monthly adjustment amount that these enrollees must pay. This exchange of information between CMS and SSA occurred in 2010 so that individuals identified were billed the correct Part D—IRMAA beginning January 1, 2011. Following this initial data exchange with SSA, CMS will routinely provide SSA with the names of all individuals newly enrolling in the Part D program so that SSA can repeat the process of identifying individuals who must pay the Part D—IRMAA and the specific income-related amount. We will also routinely provide the names of individuals who have disenrolled from the Part D program so that such individuals will no longer be assessed the Part D—IRMAA. In cases where an individual disagrees with a determination that he/she is subject to the Part D—IRMAA, such individual may appeal as provided in the SSA regulations under 20 CFR part 418.

Section 3308 of the ACA also stipulates that the Part D—IRMAA must be withheld from benefit payments in accordance with section 1840 of the Act. Therefore, in cases where an individual is receiving benefit payments from SSA, the Railroad Retirement Board (RRB), or the Office of Personnel Management (OPM), the Part D—IRMAA must be withheld from such benefit payments. However, if the benefit payment is insufficient to allow the Part D—IRMAA withholding, or an individual is not receiving benefit payments as described in section 1840 of the Act, section 3308 of the ACA requires SSA to enter into agreements with CMS, RRB, and OPM, as necessary, in order to allow the Part D—IRMAA to be collected directly from these beneficiaries.

To implement section 3308 of the ACA, we proposed to revise § 423.286 (rules regarding premiums), § 423.293 (collection of monthly beneficiary premium), and § 423.44 (involuntary disenrollment by PDP).

a. Rules Regarding Premiums (§ 423.286)

Currently, § 423.286(a) provides that 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 with the exception of employer group waivers, the assessment of the Part D late enrollment penalty, or an enrollee receiving low-income assistance. We proposed to revise the following:

- Section 423.286(a) to include the assessment of the income related monthly adjustment amount as another exception to the requirement for a uniform monthly beneficiary premium for a Part D plan in a PDP region;
- Section 423.286(d)(4) to define the increase for the income related monthly adjustment amount for Part D;
- Section 423.286(d)(4)(i) to specify that SSA would determine the individuals that are subject to the Part D—IRMAA and the amount of the adjustment;
- Section 423.286(d)(4)(ii) to provide the formula used to calculate the monthly adjustment amount; and
- Section 423.286(d)(4) to provide appeals rights to individuals who disagree with SSA's determination that they are subject to the Part D—IRMAA or the threshold amount of the adjustment they must pay.

Comment: Commenters wanted to know if there was any plan responsibility in tracking or collecting the Part D—IRMAA. One commenter believed the Part D—IRMAA would

cause beneficiary confusion and that plans would have little recourse to address beneficiary concerns. A few commenters requested that CMS provide information to plans, including copies of communications released to the IRMAA population and individuals' Part D—IRMAA billing information, potentially through the Medicare Advantage Prescription Drug (MARx) System via a transaction reply response (TRR). This information would enable plans to address both general and specific beneficiary concerns and provide proactive communications to improve the beneficiary experience. Lastly, a commenter encouraged CMS to provide plans with guidance regarding how plans' customer service agents can best handle beneficiary inquiries regarding income related adjustments to their premium.

Response: Part D plan sponsors do not have responsibility for tracking or collecting the Part D—IRMAA. Section 3308 of the ACA clearly states that the additional amount is to be withheld from a beneficiary's Social Security benefit check. In cases where the benefit check is not sufficient to allow the withholding, the beneficiary will be directly billed the amount by CMS. However, as discussed below, Part D plan sponsors will be responsible for providing beneficiaries with the disenrollment notice after we notify plans that the beneficiary's Part D coverage has been terminated for failure to pay his/her Part D—IRMAA.

On December 10, 2010, we released to Part D plan sponsors a memorandum entitled, "Part D—Income Related Monthly Adjustment Amount—Frequently Asked Questions & Answers," which included plain-language, beneficiary-friendly questions and answers specifically addressing inquiries plans may receive from beneficiaries. These FAQs include information such as how the Part D—IRMAA is collected, the responsible entity for determining who should be assessed the amount, as well as the appropriate government agency a beneficiary should contact with additional questions.

We have provided clear instructions to plans regarding the appropriate referral agency for specific questions regarding an individual's Part D—IRMAA determination and billing. We will continue to work with Part D plan sponsors to determine what specific additional guidance they need in answering beneficiary inquiries related to the Part D—IRMAA.

Comment: A commenter asserted that there will be an increase in premium-related complaints submitted to 1–800–MEDICARE due to the Part D—IRMAA noting that plans are unable to influence or control members' experiences related to the premium increase and should not be penalized for these complaints. The commenter requested that CMS exclude complaints specific to the Part D—IRMAA premiums in plan quality metrics.

Response: While there may be an increase in the number of beneficiary complaints related to the Part D—IRMAA, we believe our developed scripts and FAQs will address most concerns. We agree beneficiary complaints related to these types of issues should not be part of Medicare Part D plan sponsors' quality metrics.

Comment: Commenters requested that we clarify how a Part D sponsor would operationalize the Part D—IRMAA and whether the Part D—IRMAA affects the Part D bid or the base beneficiary premium.

Response: Currently, Part D sponsors are not expected to implement any operational changes with regards to the collection of the Part D—IRMAA. Unlike the normal Part D plan premiums, applicable beneficiaries will not pay the Part D—IRMAA to Part D sponsors. Instead, as noted previously, the Part D—IRMAA will be collected by the Federal government via a withholding from beneficiaries' SSA, RRB, or OPM benefit payments or collected by us directly. As stated previously, though, Part D plan sponsors will be responsible for providing beneficiaries with the disenrollment notice if we involuntarily disenroll an individual for failure to pay his/her Part D—IRMAA, just as they would for any other disenrollment action initiated via a CMS transaction file, such as those disenrollments that result from choosing another plan.

Consistent with section 1860D–15(a)(1) of the Act, we will not apply Part D—IRMAA to the base beneficiary premium used to calculate the Part D direct subsidy payments. In addition, no other Part D—IRMAA related adjustments will be made to the Part D payments received by Part D sponsors. As a result, the Part D—IRMAA is expected to have no impact on the Part D bids or Federal payments received by Part D sponsors.

Comment: One commenter conveyed that it did not support the imposition of the Part D—IRMAA because of the "potentially adverse effect" of this provision, referencing our estimate that approximately 220,000 beneficiaries may disenroll from the Part D program as a result of the Part D—IRMAA (see 75 FR 71256). Another commenter suggested that CMS monitor the impact of this policy on enrollment in Part D plans and the potential for adverse selection. More specifically, this commenter was concerned that the most healthy, affluent seniors may elect to delay enrollment in a Part D plan as it may be financially advantageous to pay the late enrollment penalty for delaying enrollment rather than paying the Part D—IRMAA for many years when expected drug expenditures are minimal. Despite one of the commenters' dislike for this statutory requirement, the commenter applauded CMS for developing timely regulations to implement this new requirement.

Response: We have no discretionary authority to waive the Part D—IRMAA, which is clearly required by the ACA. We are dedicated to ensuring a timely and thorough implementation and appreciate acknowledgement of our efforts to develop regulations to implement this new requirement. We will monitor all aspects of Part D—IRMAA implementation, including the impact of this policy has on future Part D disenrollments and enrollments.

Comment: One commenter asserted that the introduction of the IRMAA for Part B and Part D premiums through Social Security deductions is not understood by many beneficiaries. Consequently, the commenter encouraged consideration of some notification from SSA or CMS of each individual's premiums under each Part prior to the upcoming year.

Response: Each year, SSA will determine who will be assessed an IRMAA in both the Part B and Part D programs. In November, SSA will send the beneficiary an annual letter that indicates the amount of any IRMAA the individual may owe. Further, CMS and SSA developed beneficiary-friendly publications and FAQs to assist beneficiaries and our partners with understanding this new requirement. We believe that more outreach and education will assist beneficiaries in understanding the IRMAA and which government Agency (CMS or SSA) should be contacted with further questions. Plans may refer beneficiaries to SSA with questions regarding the content of their annual letter from SSA regarding the IRMAA.

We would also like to note that in the preamble of the proposed rule we inadvertently referenced the wrong citation in describing our proposal to add provisions regarding a beneficiary's right to file an appeal of SSA's Part D—IRMAA determination. We referenced § 423.286(d)(4)(iii) and (iv), but should have referred to § 423.286(d)(4)(i) which is where these provisions were

proposed and where they are being finalized in this rule.

b. Collection of Monthly Beneficiary Premium (§ 423.293)

We proposed establishing a new § 423.293(d)(1) to describe how the Part D—IRMAA would be collected. First, we addressed the process for collecting the Part D—IRMAA from SSA, RRB, or OPM benefit payments. In cases where SSA determines that a Part D enrollee must pay a Part D—IRMAA, such amount must be paid through withholding from the enrollee's Social Security benefit payments, or benefit payments by the RRB or OPM in the manner that the Part B premium is withheld. Additionally, we proposed at § 423.293(d)(2) that in cases where premium withholding is not possible because the monthly benefit check is insufficient to allow the withholding, or the enrollee is not receiving any monthly benefit payment, the individual must be directly billed for the Part D—IRMAA through an electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account) or according to other means that we may specify.

Section 3308 of the ACA provides that the Part D—IRMAA is an increase to the monthly beneficiary premium for certain individuals. Section 1851(g)(B)(i) of the Act, as incorporated by section 1860D–1(b)(5) of the Act, establishes that a beneficiary may be terminated for failing to pay his/her Part D premiums. At § 423.293(d)(3), we proposed that CMS will terminate Part D coverage for any individual who fails to pay the income related monthly adjustment amount in accordance with proposed § 423.44 (see discussion below).

Comment: Several commenters conveyed that they understood that implementation of the Part D—IRMAA requires coordination among CMS, Part D plan sponsors, and SSA, with SSA having primary responsibility for an individual's IRMAA determination. They suggested that the final regulations address the need for the timely exchange of beneficiary information and any updates in order to facilitate coordination amongst these entities. As an example, commenters contended that in cases where a higher income beneficiary is no longer enrolled in a Part D plan, the Part D sponsor should send this information immediately to CMS and SSA so that the Part D—IRMAA is no longer deducted from the beneficiary's benefit check or billed to the beneficiary.

Response: We appreciate the recommendation that CMS and SSA maintain close and timely coordination related to Part D enrollment and the Part D—IRMAA. As noted in the proposed rule "* * * CMS will routinely provide SSA with the names of all individuals newly enrolling in the Part D program * * * and will also routinely provide the names of individuals who have disenrolled from the Part D program so that such individuals will no longer be assessed the Part D—IRMAA." Furthermore, as stated in § 423.36 and in our guidance, Part D plan sponsors must submit the disenrollment transactions to CMS within 7 calendar days of receipt of the beneficiary's completed disenrollment request in order to ensure the correct effective date. (See Chapter 3, § 50.4.1 "Voluntary Disenrollments" of the *Medicare Prescription Drug Benefit Manual* published August 17, 2010). We believe that through this existing process, all involved entities will receive timely notification to address changes to either Part D enrollment or Part D—IRMAA.

Comment: One commenter asserted that they foresaw enrollment "glitches" similar to those of LIS-eligible beneficiaries who were inadvertently dropped from one plan but not correctly auto-enrolled in the next. This commenter further stated that, undoubtedly, some high-income beneficiaries would face disenrollment because of miscommunications that result because prescription drug plan premiums are paid to their chosen plan and the Part D—IRMAA is paid to CMS. Based on this assertion, the commenter encouraged CMS to develop an expeditious, straight-forward process for resolving such problems and to publicize that process on Medicare.gov.

Response: We appreciate the commenter's concern about possible problems or beneficiary confusion regarding payments for the Part D—IRMAA to the Federal government and plan premiums. The vast majority of individuals required to pay the Part D—IRMAA will have the IRMAA amount deducted from their monthly benefit check, which will eliminate the possibility of involuntary disenrollment for failure to pay the Part D—IRMAA. For those individuals who will be billed by CMS directly, we will notify them via monthly billing notices. Further, we have developed FAQs for use by plans, partners, and 1–800–MEDICARE to educate beneficiaries on the proper means to make payments for their Part D—IRMAA. However, we will consider outlining the process for Part D—IRMAA payment and possible disenrollment on Medicare.gov to assist in beneficiary understanding.

c. Involuntary Disenrollment by CMS (§ 423.44)

Section 3308 of the ACA provides that the Part D—IRMAA increases the monthly beneficiary premium for individuals who are subject to the assessment. Therefore, we proposed to apply provisions similar to the existing Part D premium rules to terminate Part D coverage (provided for by Section 1860D–13(c) of the Act) for any individual who fails to pay the Part D—IRMAA. Specifically, we proposed the following:

- Section 423.44(e)(1) provides that CMS will disenroll individuals who do not pay their Part D—IRMAA.
- Section 423.44(e)(2) provides individuals a 3-month grace period to pay outstanding Part D—IRMAA amounts before they are involuntarily disenrolled.
- Section 423.44(e)(3) provides an opportunity for a disenrolled beneficiary to establish "good cause" for failure to pay their Part D—IRMAA and have their plan enrollment reinstated if Part D—IRMAA arrearages are paid.
- Section 423.44(e)(4) requires PDPs, after notification by CMS, to notify enrollees of the termination of their enrollment in the Part D plan in a form and manner determined by CMS.
- Section 423.44(e)(5) establishes that the effective date of disenrollment is the first day following the initial grace period.
- Finally, we proposed modifying the title of § 423.44 from "Involuntary Disenrollment by the PDP" to "Involuntary Disenrollment from Part D Coverage."

Comment: We received several comments on the length of the proposed grace period applicable to Part D—IRMAA premiums. While several commenters commended CMS for proposing a longer grace period to pay the Part D—IRMAA, other commenters suggested that CMS synchronize the 3-month grace period for payment of the Part D—IRMAA with the plans' minimum 2-month grace period already established by CMS regulations and guidance. Commenters asserted that having different grace periods could cause potential conflict and confusion if the enrollee failed to pay both the Part D premium and the Part D—IRMAA and was provided a grace period by both the PDP and CMS, but on differing timelines (for example, a 2-month grace period under the PDP and a 3-month grace period under CMS).

Commenters also requested that we take into consideration the potential

overlap, conflicts, and/or confusion that could occur for beneficiaries receiving notices for non-payment of their plan premium and non-payment of the Part D—IRMAA and any conflicting grace periods. The commenter requested that CMS revise the approach to better coordinate the timing of the plan beneficiary disenrollment notices with the plan and the Part D—IRMAA grace periods and that we should do our best to prevent the potential problems. Another commenter asked us to clarify that a Part D beneficiary could be disenrolled from a Part D plan for failure to pay the plan premium after the plan's two-month grace period regardless of whether the enrollee has paid their Part D—IRMAA or has not exhausted the 3-month grace period for the D—IRMAA.

In addition, one commenter recommended that CMS delay implementation of the grace period specific to the Part D—IRMAA in light of the other CMS provisions that require process and system changes. According to this commenter, CMS should consider this recommendation since the Part D—IRMAA affects only a small percentage of the total Part D population.

Response: Under the Original Medicare program, beneficiaries assessed the Part B–IRMAA are afforded an initial 3-month grace period to pay their Part B premiums before they are terminated. As individuals may be subject to both the Part B and the Part D—IRMAA, we believe that the grace period for both programs should be consistent.

With respect to synchronizing the Part D—IRMAA with plan premium grace periods, our regulations at § 423.44(d)(1)(iii) stipulate that plans choosing to implement a policy of involuntary disenrollment for failure to pay the Part D plan premium must provide a minimum 2-month grace period. A Part D plan sponsor with an established 2-month minimum grace period may disenroll a beneficiary for failing to pay the plan's premium, if such grace period ends prior to the 3-month grace period allotted for payment of the Part D—IRMAA. Current guidance (Medicare Prescription Drug Benefit Manual, Chapter 3, § 50.3.1) allows plans to implement a longer grace period or forgo involuntary disenrollments for failure to pay premiums entirely. Therefore, plans already have the ability to modify their respective grace periods and are encouraged to do so if they believe the existence of two different grace periods will create conflict or confusion.

As noted previously, the vast majority of individuals subject to the Part D—IRMAA are paying the income-based amount through a deduction from their Social Security checks, and thus the grace period associated specifically with payment of the Part D—IRMAA is not a factor. However, to the extent that individuals fail to pay only the Part D—IRMAA, we believe it is appropriate to use the same procedures and time frames that apply to the Part B–IRMAA. Note that individuals who fail to pay the Part D premium that is owed to a plan may be disenrolled by the plan after the expiration of the 2-month grace period, regardless of the payment status of their Part D—IRMAA.

If a plan chooses to retain a grace period that is shorter than the one specific to the Part D—IRMAA, once the beneficiary is disenrolled from the plan, the assessment of the Part D—IRMAA will cease. Therefore, the beneficiary will receive the disenrollment notice as a result of not paying the plan's premium and there will be no need to issue the involuntary notice for failing to pay the Part D—IRMAA. For example, if the beneficiary fails to pay the plan premium within the plan's grace period but the grace period specific to the Part D—IRMAA has not lapsed, the Part D plan sponsor will, in accordance with CMS rules, send us a plan transaction to disenroll the beneficiary. Following confirmation from us that the disenrollment transaction has been accepted, the Part D plan sponsor must send the beneficiary the disenrollment notice no later than 3 business days following the last day of the grace period. (See Chapter 3, Section 50.3.1 of the Medicare Prescription Drug Benefit Manual.) Once the beneficiary has been disenrolled from the plan, the withholding and/or billing of the Part D—IRMAA will cease. Lastly, in those cases where the Part D—IRMAA and the plan premium grace periods are different, but end on the same date, the beneficiary will receive two disenrollment notifications—Notice of Failure to Pay Plan Premiums and the Notification of Involuntary Disenrollment by the Centers for Medicare and Medicaid Services for Failure to Pay the Part D—IRMAA since the former conveys information about requesting the plan to reconsider its decision and the latter provides information about requesting a "good cause" determination.

For these reasons, we are finalizing the regulatory provisions as proposed. However, we will carefully consider these comments and potential system impacts as it develops its program instructions to plans regarding the procedures for disenrolling beneficiaries who fail to pay their Part D—IRMAA and the timing of when plans will convey the notice. In addition, we will closely monitor the disenrollment process and make adjustments to the process to ensure optimum coordination between the timing of the grace period and the issuance of the beneficiary disenrollment notice.

Comment: One commenter recommended that CMS make attempts to collect the Part D—IRMAA before terminating the enrollee, and encourages CMS to publish, with opportunity for public comment, the proposed process for doing so.

Response: As explained previously, for individuals that do not have their Part D—IRMAA deducted from their Social Security checks, we are following the same process we use in collecting the Part B–IRMAA. This process involves repeated monthly statements (initial bill, second notice and a delinquent notice) to the beneficiary to solicit the payment and to notify the individual of the potential consequences of failure to make a payment prior to disenrollment at the end of the initial 3-month grace period. In addition, if payment is not made, the beneficiary will have an additional 3 months to establish "good cause" for failure to pay their Part D—IRMAA and remit payment for any arrearages to be reinstated into their Part D plan. We believe this process provides sufficient notification to the beneficiary and opportunity to pay their Part D—IRMAA prior to disenrollment for failure to pay.

Comment: Several commenters expressed concern with the proposed requirement that plans issue the disenrollment notice to enrollees involuntarily disenrolled for failure to pay their Part D—IRMAA. Commenters believed that CMS was in the best position to send these notices in a timely manner since we, not the plan, are aware of the member's Part D—IRMAA amount and any possible arrearages. Commenters were concerned that if plans served as an intermediary in this process, they would inevitably be contacted with complaints or subject to grievances. It was suggested that a CMS-generated notice would reduce the burden on plans and would more clearly communicate to enrollees that CMS should be contacted regarding questions on the Part D—IRMAA.

Response: As described previously, individuals who are subject to disenrollment based on their failure to pay the Part D—IRMAA will have first received a series of monthly billing statements from CMS informing them of

their obligation to pay the Part D—IRMAA, and the consequences of their failure to do so. If and when disenrollments do become necessary, we believe affected individuals should be afforded the same notices that other individuals would receive from their plans. Thus, we disagree that plans should not be responsible for sending a disenrollment notice. Such notices are part of a plan's daily business operations. This process is consistent with existing requirements for disenrollment of a beneficiary who is no longer eligible to remain in a Medicare prescription drug plan due to loss of Medicare Part A and/or B. In this situation, we involuntarily disenroll the beneficiary, and the beneficiary's Part D plan sponsor is required to provide the individual with the Disenrollment Due to Loss of Medicare Part A and/or Part B Notice (See Chapter 3, Section 50.2.2 of the Medicare Prescription Drug Benefit Manual).

We recognize that Part D plan sponsors may receive questions from their members regarding the disenrollment. As such, the notification used by Part D plan sponsors will explicitly state that the disenrollment is being effectuated by the plan at CMS' direction. This notice further instructs the beneficiary to contact us, not the plan, about questions pertaining to the notice. As noted previously, the December 10, 2010 CMS memorandum mentioned previously provides plans with language they can use in responding to members' Part D—IRMAA inquiries. We will continually develop and release information to Part D plan sponsors, partners, and beneficiaries via the CMS information channels (1–800–MEDICARE, *http://www.medicare.gov*) that will assist beneficiaries with questions about their Part D—IRMAA and direct them to the appropriate entity for assistance. Thus, we will retain the proposed provision that Part D plan sponsors will provide a beneficiary with the notice when he/she is disenrolled for failing to pay the Part D—IRMAA.

Comment: A commenter contended that it was not clear from our proposal if CMS intended to tell Part D plan sponsors to disenroll the non-paying member before or after the end of the grace period. The commenter concluded that if timing for notification is the latter, this could result in a retroactive disenrollment from the plan, with possible complications in terms of bills for non-covered services and medications retroactive to the effective date of the disenrollment.

Response: We recognize this concern and will keep this issue in mind as we develop operational guidance on the disenrollment process.

Comment: Two commenters disagreed with the proposed policy of an additional 3-month grace period for individuals to establish "good cause" after the disenrollment date, allowing for no disruption in coverage if reinstated. Another commenter suggested that plans be informed if a disenrolled member requests a "good cause" determination for failure to pay their Part D—IRMAA.

Response: We believe that beneficiaries should be afforded the opportunity to establish "good cause" for not paying the Part D—IRMAA amount and the ability to be reinstated in their Part D coverage without interruption. We appreciate the comment regarding plan notification of requests for good cause and will take this into consideration as we develop the process for good cause" determinations. (See section II.C.8 of this preamble for a further discussion of this issue.)

Comment: A few commenters expressed concern about what would happen to individuals involuntarily disenrolled from their plan for failure to pay their Part D—IRMAA. Some commenters requested that we clarify that a disenrollment for failure to pay the Part D—IRMAA would result in a loss of health coverage if the individual is enrolled in an MA plan, cost plan, or employer group health plan with prescription drug coverage. Another commenter asked whether a beneficiary who is disenrolled for failure to pay the Part D—IRMAA would be subject to the Part D late enrollment penalty (LEP) upon reenrollment in a Part D plan. In addition, commenters made the following suggestions:

- Establish a special enrollment period (SEP) for disenrolled individuals to re-enroll into another MA-only (or a cost plan).
- Allow for passive enrollment into an MA-only plan within the same organization if an individual is disenrolled from their MA–PD plan for failure to pay Part D—IRMAA.
- Grant employer group waiver plans a waiver from the disenrollment process.

Response: An individual in an MA–PD who fails to pay the Part D—IRMAA within the 3-month grace period will be disenrolled to Original Medicare. Because this policy ensures that beneficiaries will not lose health care coverage, we believe an SEP is unwarranted and unnecessary. Furthermore, a beneficiary's Part D coverage may be reinstated without interruption if within 3 months after disenrollment, the enrollee demonstrates "good cause" for failure to pay the Part D—IRMAA and pays all Part D—IRMAA and plan premium arrearages. The SEP policy at § 423.38(c)(8)(ii) permits CMS to address exceptional enrollment cases for individuals on a case-by-case basis. To the extent that individuals believe they have exceptional situations that warrant consideration to enroll in a MA-only (or other plan that does not offer Part D coverage), they should call 1–800–MEDICARE and ask to be put in touch with a CMS regional caseworker. In addition, the policies for the Part D LEP remain unchanged by the implementation of Part D—IRMAA. An individual who is disenrolled for failure to pay the Part D—IRMAA may be subject to the Part D LEP if he or she goes without creditable prescription drug coverage for 63 days or more. If an individual would like to restart prescription drug coverage, he or she would have to pay any arrearages and make an election during a valid enrollment period.

Individuals in employer group waiver plans and employer group health plans will also be disenrolled for failure to pay Part D—IRMAA. Employer groups that want to assure that their members retain coverage are not prohibited from informing their retirees that they will be reimbursed by their employer group for any Part D—IRMAA they are required to pay.

We appreciate the comments on our proposals and, for the reasons contained in the discussion previously, are finalizing these provisions as proposed. We have, however, made technical revisions to § 423.286(d)(4) and§ 423.293(d) to incorporate references to the new SSA regulations regarding the Part D IRMAA, which were published after the issuance of our proposed rule.

10. Elimination of Medicare Part D Cost-Sharing for Individuals Receiving Home and Community-Based Services (§ 423.772 and § 423.782)

The MMA, as reflected in § 423.782, established that full-benefit dual eligible institutionalized individuals have no cost-sharing for covered Part D drugs under their PDP or MA–PD plan. Section 3309 of the ACA eliminates cost-sharing for full-benefit dual eligible individuals who are receiving home and community-based services (HCBS) under a home and community-based waiver authorized for a State under section 1115 or subsection (c) or (d) of section 1915 of the Act, or under a State Plan Amendment under section 1915(i) of the Act, or if such services are

provided through enrollment in a Medicaid managed care organization with a contract under section 1903(m) or 1932 of the Act. These services are targeted to frail, elderly individuals who, without the delivery in their home of services such as personal care services, would be at risk of institutionalization. We proposed to amend § 423.772 to establish the definition of "individual receiving home and community-based services" and § 423.782(a)(2)(ii) to reflect that these individuals will have no cost-sharing. The Best Available Evidence (BAE) policy set forth in § 423.800—which requires plans to charge a lower copayment if certain evidence is provided—is written broadly enough that it will apply to this new copayment category; therefore, we proposed to make no regulatory changes to § 423.800. We proposed to update our guidance to plans to provide additional detail on how the BAE rules apply to this population.

Section 3309 of the ACA provides the Secretary with discretion regarding the effective date of this provision, with the stipulation that it shall be effective no earlier than January 1, 2012. We proposed that this provision would take effect on January 1, 2012, because we believed it was important to provide this benefit at the earliest possible date to an estimated 600,000 beneficiaries a year.

Comment: Commenters supported our proposal to amend § 423.772 to establish the definition of an "individual receiving home and community-based services" and § 423.782(a)(2)(ii) to reflect that these individuals will have no cost-sharing. One commenter urged the inclusion of individuals residing in assisted living facilities in the definition of an "individual receiving home and community-based services" in § 423.772.

Response: The commenter that urged the inclusion of individuals residing in assisted living facilities in the definition of an "individual receiving home and community-based services" raises an important distinction warranting the following clarification in our guidance to plans and States. Individuals residing in an assisted living facility will be included in the definition of an "individual receiving home and community-based services" only to the extent that they satisfy the inclusion criteria set forth in section 3309 of the ACA. Specifically, the assisted living facility resident must be a full-benefit dual eligible individual receiving HCBS under a home and community-based waiver authorized for a State under section 1115 or subsection (c) or (d) of section 1915 of the Act, or under a State Plan Amendment under section 1915(i) of the Act, or if such services are provided through enrollment in a Medicaid managed care organization with a contract under section 1903(m) or 1932 of the Act.

We appreciate the strong support we received from commenters for our proposal to amend § 423.772 to establish the definition of an "individual receiving home and community-based services" and § 423.782(a)(2)(ii) to reflect that these individuals will have no cost-sharing. We are finalizing these regulations as proposed.

Comment: Many commenters urged us to provide explicit guidance on the types of BAE that would be deemed acceptable to establish HCBS status, along with clear reporting requirements for plans receiving such evidence to report it to us. Several of these commenters recommended that we categorize these individuals on the Transaction Reply Report (TRR) as low-income subsidy level 3 (institutionalized—$0 cost share), as opposed to developing a new low-income subsidy level for the HCBS status. One commenter requested guidance on whether the PDE value will be unique for these individuals.

Response: We agree with commenters that successful implementation of this provision will require us to update its guidance to plans to provide additional detail on how BAE rules apply to this population. In such guidance, we intend to address key concerns raised by commenters, including at a minimum how such beneficiaries will appear on the TRR, their low-income subsidy level, and the correct PDE value to be reported.

Comment: Several commenters urged CMS to provide explicit guidance to State Medicaid Agencies regarding the new zero copayment group, and develop data transfer protocols to ensure that States accurately identify HCBS eligible individuals and transmit such data to CMS in a timely fashion.

Response: We look forward to partnering closely with States to facilitate the identification of all such HCBS eligible individuals and to ensure timely and accurate transmission of the necessary data to CMS. We will provide customized guidance to states to ensure that they have a clear understanding of this new category of individuals qualified for the zero copayment status. We will require State Medicaid Agencies to submit data at least monthly identifying these individuals by leveraging the existing data exchange currently used by States to identify their dual eligible individuals to CMS. We will add a new value for the existing institutional status field, which will prompt CMS to set a zero copayment liability for full-benefit dual eligible beneficiaries who qualify for HCBS zero cost-sharing, as set forth under section 3309 of the ACA.

Comment: One commenter recommended that CMS provide model notifications to Part D plans to send to affected beneficiaries to ensure that such beneficiaries are provided maximal opportunities to understand their new zero copayment Part D status. Another commenter suggested that CMS develop a form for Medicaid Managed Care plans to provide to beneficiaries, attesting to their use of HCBS services.

Response: We thank the commenters for these suggestions. We will determine later in 2011 whether the existing Part D model notifications that provide such beneficiaries with their copayment status are adequate or whether a new Part D model notice customized to this population might be beneficial. We will also consider the latter suggested notice as we update our BAE guidance to plans to ensure the most efficient procedures for accurately identifying this population.

Comment: Two commenters noted that individuals who receive HCBS under a home and community-based waiver under section 1115 and State plan participants under section 1915 of the Act generally receive letters informing them that they have qualified. These commenters described such letters as varying significantly among States and programs, and urged that CMS work with plans to help them identify such letters to serve as BAE.

Response: We will work with States to identify the most common forms of such letters provided to participants, and we intend to share best practices with plans to more effectively identify full-benefit subsidy eligible individuals who qualify for zero cost-sharing under this HCBS provision.

Comment: One commenter urged CMS to clarify that an effective date of January 1, 2012, for the HBCS provision does not permit retroactive application of the zero cost-sharing benefit to extend prior to January 1, 2012, notwithstanding that the effective date of LIS eligibility in many cases is retroactive and extends prior to January 1, 2012.

Response: In accordance with section 3309 of the ACA, the Secretary's discretionary authority to establish the effective date of the HCBS provision is limited by the stipulation that the effective date shall be no earlier than January 1, 2012. This effective date does not allow for retroactive application of

the zero cost-sharing benefit to extend prior to January 1, 2012, even for beneficiaries whose effective date of LIS eligibility extends prior to January 1, 2012. We appreciate the commenter bringing to our attention the need for such clarification and we will provide such clarification in our guidance to plans.

Comment: A commenter urged that CMS require Part D sponsors to appropriately reimburse long term care (LTC) pharmacies for the additional value that those pharmacies must provide to beneficiaries receiving pharmacy services in assisted living facilities, such as special unit dose medication packaging, medication delivery, and medication reviews by pharmacists.

Response: Any such reimbursements are a matter of negotiation between the plan sponsor and the LTC pharmacy.

Comment: Two commenters recommended that CMS adopt the same procedural approach for determining the deeming period for HCBS eligibility that CMS uses for individuals who qualify for the full-benefit subsidy based on Medicaid enrollment. Specifically, if an individual appears on State files as eligible for HCBS at any point during the year, that individual would qualify for the HCBS zero cost-sharing for the remainder of the year. If an individual shows as eligible in the month of July or any later month in the year, the HCBS zero cost-sharing would continue through the next plan year.

Response: We thank the commenters for raising this issue, as it warrants the following noteworthy clarification in our guidance to plans and States. To ensure procedural consistency and operational efficiency, we will apply the same procedural approach for determining the deeming period for HCBS eligibility that we apply for individuals who qualify for the full benefit subsidy based on Medicaid enrollment, as set forth under § 423.773(c)(2), to the extent that an individual's HCBS deemed period does not exceed the individual's full-benefit dual deemed period. Specifically, if an individual is deemed eligible for HCBS zero cost-sharing at any point during the year, that individual will qualify for HCBS zero cost-sharing for the remainder of the year. If an individual is deemed eligible for HCBS zero cost-sharing in the month of July or any later month in the year, the individual's HCBS zero cost-sharing will continue through the next plan year so long as the individual was also deemed in the month of July or any later month in the year for the full-benefit subsidy based on Medicaid enrollment. In other words, an individual's ongoing HCBS deemed status is dependent on concurrent deemed full-benefit dual eligibility. We believe that this policy will promote effective administration of the HCBS cost-sharing benefit and decrease the administrative burden on CMS and State Medicaid Agencies, as well as on HCBS eligible individuals. We note that it also is consistent with how we determine the deeming period for institutionalized full benefit dual eligible individuals.

We appreciate the comments that were submitted on these provisions and will be finalizing these proposals.

11. Appropriate Dispensing of Prescription Drugs in Long-Term Care Facilities Under PDPs and MA–PD Plans (§ 423.154)

In our proposed rule, we proposed to implement section 3310 of the ACA by adding a new regulation at § 423.154 to govern how plan sponsors (all organizations and sponsors offering Part D including stand-alone Part D plans, MA organizations, EGWP contracts, and PACE plans) direct network pharmacy dispensing of covered Part D drugs in LTC facilities. Under § 423.154 (a)(1)(i) of the proposed rule, we require all sponsors to contract with network pharmacies servicing LTC facilities, as defined in § 423.100, to dispense brand medications, as defined in § 423.4, to enrollees in such facilities in no greater than 7-day increments at a time. In an effort to target the drugs resulting in the most financial waste and to lessen the burden for facilities transitioning from 30-day supplies to 7-day-or-less supplies, we proposed initially limiting the requirement for 7-day-or-less dispensing to brand drugs as defined in § 423.4. We noted in the proposed rule that as a result of consultation with industry representatives, a transitional approach would ease the initial burden on nursing and pharmacist staff by reducing the number of products for which a pharmacy would have to transition from dispensing one 30-day supply per month to dispensing at least four 7-day supplies per month. We also acknowledged that we are not aware of any objective data that demonstrate the cost effectiveness of full versus partial implementation, but welcomed comments from the public presenting such data and also solicited comments on how soon the industry can transition to include generic drugs in the 7-day-or-less requirement.

Under § 423.154(a)(1)(ii) of the proposed rule, we require Part D sponsors to permit the use of uniform dispensing techniques defined by each of the LTC facilities being serviced. We proposed to define uniform techniques to mean that dispensing methodologies will be uniform with respect to the type of packaging used to dispense Part D drugs within a LTC facility, but may vary by the quantity of medication (days' supply) dispensed at a time. We explained that it is the LTC facilities that are in the best position to identify uniform dispensing techniques to be used throughout their LTC facility. Therefore, we proposed that Part D sponsors must permit their contracted pharmacies to implement the uniform dispensing techniques selected by each LTC facility, and may not require the use of a different packaging system or technology than that selected by the facility through its contracted LTC pharmacy.

We noted in the proposed rule that we do not expect pharmacy delivery schedules to change as a result of the 7-day-or-less dispensing requirement since deliveries are generally made daily to accommodate new admissions and first doses. We do recognize, however, that there may be changes in the way some pharmacies make deliveries. We stated in the preamble of the proposed rule that, subject to State restrictions, pharmacies, and LTC facilities may agree to use a common carrier for some deliveries to LTC facilities. We would not consider a contractual agreement for a pharmacy to deliver a portion of Part D drugs to Part D enrollees residing in LTC facilities via common carrier as causing the pharmacy to be considered a mail order pharmacy. We solicited comments on our interpretation.

We proposed to exclude from the requirements of § 423.154(a), those drugs that are difficult to dispense in a 7-day-or-less supply and those drugs that are dispensed for acute illnesses. We expressed our belief that requiring these types of drugs to be dispensed in 7-day-or-less increments could result in safety or efficacy concerns or could have the counterproductive effect of increasing drug waste. For medications that we proposed to exclude from the requirement, we encouraged use of smaller size containers, when available, to reduce the potential for waste. We proposed to codify these exclusions at § 423.154(b) and solicited comments on the types of dosage forms and drugs that should be excluded from the requirements under § 423.154(a).

We explained that we considered "return for credit and reuse" as a possible solution to reduce waste in LTC facilities. Although "return for credit and reuse" is not prohibited by CMS, we recognized limitations to this approach since "return for credit and

reuse" is not permitted in all states, often excludes lower cost generic drugs, is frequently limited to a subset of drugs in unused or specially approved packaging, does not address issues regarding diversion, and is subject to Drug Enforcement Agency (DEA) limitations with respect to controlled substances. Upon consideration of these facts, we decided that "return for credit and reuse" would not be the optimal solution to address the issue of unused drugs in LTC facilities under Part D.

Although we did not propose "return for credit and reuse" as an alternative to 7-day-or-less dispensing, we understand that it may be a supplement to reduce the minimal pharmaceutical waste associated with 7-day-or-less dispensing, particularly in circumstances where a Part D drug can be safely returned to stock for reuse. We proposed to explicitly allow "return for credit and reuse" in LTC pharmacies, when "return for credit and reuse" is permitted under the State law and is explicitly allowed under the contract between the Part D sponsor and the pharmacy. In addition, when permitted or required contractually, we noted that pharmacy dispensing fees paid to pharmacies may take into account restocking fees consistent with the modification to dispensing fees under § 423.100, "Dispensing Fees" discussed in section II. F. of this final rule (Other Clarifications and Technical Changes).

We explained in our proposed rule that only when data has been systematically collected will the extent of waste of Part D drugs be quantifiable on other than an anecdotal basis. Therefore, we proposed to add a provision at § 423.154(f) to require that Part D sponsors include terms in their LTC pharmacy contracts that require any unused drugs originally dispensed to the Part D sponsor's enrollees to be returned to the pharmacy (not necessarily for reuse) and reported to the sponsor. Such contracts would also address contractual obligations for disposal in accordance with Federal and State regulations. We solicited comments on whether there are DEA or state technical issues that may be barriers to the implementation of this provision.

We noted that options for billing to accommodate 7-day-or-less dispensing are being discussed in a National Council for Prescription Drug Programs (NCPDP) workgroup, and unless the industry voluntarily adopts a single billing standard, we believe that Part D sponsors should generally allow pharmacies to use be currently accepted transactions to minimize burden in transitioning to more frequent dispensing of smaller amounts.

Pursuant to our authority under section 1860D–12(b)(3)(D) of the Act, which incorporates by reference section 1857(e)(1) of the Act, we proposed a new requirement under § 423.154(a)(2) in which Part D sponsors must collect and report to CMS the dispensing methodology used for each dispensing event described by § 423.154(a)(1)(i) and (ii) and on the nature and quantity of unused drugs returned to the pharmacy. This data collection would be done in an effort to help us estimate the relative efficiencies of dispensing methodologies and determine the residual waste to estimate additional savings.

We stated in the proposed rule that this provision would likely lead to a change in copayment methodology. We noted that we anticipate the implementation of particular copayment methodologies will be dependent on the billing and dispensing methodologies used, and as a result, we acknowledged that copayment methodologies within the same plan may vary depending on the LTC facility where the beneficiary resides. Copayment may be collected at the first dispensing event in a month, the last dispensing event in a month, or prorated based on the number of days a Part D drug was dispensed in a month. However, due to the relatively small copayments for low-income subsidy (LIS) beneficiaries, copayments for LIS beneficiaries should be billed with the first or last dispensing event of the month.

Under § 423.154(c) of the proposed rule, we would waive the requirements under paragraph (a) for pharmacies when they dispense brand Part D drugs to Part D enrollees residing in intermediate care facilities for the mentally retarded (ICFMR) and institutes for mental disease (IMDs) due to specific problems with medication delivery and dispensing to closed (and often locked) facilities. We explained that waiving the requirements in this instance would be consistent with the statute when done on a uniform basis (that is, all similarly situated LTC facilities) and when there is a demonstration that applying the dispensing requirements to pharmacies servicing enrollees residing in that type of LTC facility would not serve to reduce waste. We solicited comments on whether other types of facilities (such as LTC facilities utilizing Indian Health Service (IHS) facilities to provide Part D drugs or utilizing Tribal facilities providing pharmacy services for the IHS under Pub. L. 93–638 compacts or contracts) should also be waived from the requirement and on the specific reasons as to why those facilities should be waived from the requirement. In addition, we solicited specific comments on the waiver criteria for LTC pharmacies.

Under § 423.154(d) of the proposed rule and pursuant to section 3310 of the ACA, the requirements of this section would be effective January 1, 2012. However, under § 423.154(e) of the proposed rule, we proposed to allow an independent community pharmacy (such as, not a closed door pharmacy dedicated to servicing LTC facilities only) that is the primary provider of the Part D drugs to a small LTC facility (less than 80 beds) located in a rural community (as defined by the Bureau of the Census) to dispense no more than a 14-day supply through December 31, 2012, assuming that the pharmacy is not already dispensing a 7-day supply to any patient population in the LTC facility. We explained that we expected that Part D sponsors contracting with these pharmacies would find solutions to their significant challenges and work toward full compliance with § 423.154(a) during this extension. Under the proposed rule, these pharmacies would be required to come into full compliance with § 423.154(a) by January 1, 2013. We solicited comments on this matter.

Based on the preceding, we proposed revising § 423.150 by renumbering paragraphs (b) through (g) as paragraphs (c) through (h) and adding a new paragraph (b) to address appropriate dispensing of covered Part D drugs to enrollees in LTC facilities. We proposed adding new requirements, as discussed previously, at § 423.154 to require Part D sponsors to ensure that all pharmacies servicing LTC facilities dispense no more than a 7-day supply of brand medications and use uniform dispensing methodologies as defined by each of the LTC facilities being serviced. In addition, under § 423.154(a)(2), we proposed requiring Part D sponsors to collect and report, as CMS specifies, the dispensing methodology used for each dispensing event described by paragraphs (a)(1)(i) and (ii) of § 423.154. We proposed identifying exceptions to this requirement at § 423.154(b)(1) and (2) relative to specific drugs and waivers of this requirement for specific pharmacies under § 423.154(c). Pursuant to section 3310 of the ACA, we proposed an effective date of January 1, 2012 for these requirements at § 423.154(d), with a limited extension through December 31, 2012 for pharmacies meeting the requirements under § 423.154(e). We also proposed that Part D sponsors require any unused Part D drugs originally dispensed to

their enrollees to be returned to the pharmacy and reported to the sponsor and address whether "return for credit and reuse" is permitted under their contracts with pharmacies servicing LTC facilities at § 423.154(f).

Comment: We received several comments regarding the term "waste." Commenters requested that we clarify the term. Some commenters recommended that we not use the term "waste" but rather "unused drugs" because the "waste" description in the proposed rule does not harmonize with definitions of waste in other State and Federal regulations applicable to unused pharmaceuticals.

Response: We agree with the commenters that the use of the term "waste" may cause confusion because "waste" as discussed in the proposed rule may not be consistent with other agencies' definitions. Further, we believe that in using the term "waste" in section 3310 of the ACA, Congress intended to refer to unused drugs. Therefore, in this final rule we will use the term "unused drugs" instead of "waste."

Comment: A few commenters requested that we allow for 14-day-or-less dispensing instead of 7-day-or-less dispensing. Commenters stated that a 14-day dispensing cycle would balance CMS's goal of reducing drug waste with the administrative, technological, and financial burdens placed on Part D sponsors, pharmacies, and beneficiaries. Commenters urged CMS to consider implementing a 14-day-or-less dispensing cycle because it is a more reasonable and realistic goal that will minimize the burden on pharmacies, beneficiaries, and plans. Some commenters stated that the statute does not mandate 7-day dispensing and that the dispensing techniques may (but need not) include weekly dispensing.

Response: We initially proposed limiting these techniques to 7-days-or-less methodologies. We continue to believe that 7-day-or-less dispensing more effectively minimizes the volume of unused drugs and the resulting financial waste paid for under the Part D program. However, the majority of comments we received in response to our request for information on the impact of our proposed provision suggested that costs might increase significantly. While this point of view conflicts with other opinions we heard during the consultation period with the industry, we did not receive detailed comments that supported more moderate cost increases. We also received little additional information during the comment period on the amount of unused drugs in LTC facilities paid for under the Part D program, and none that could be considered as thorough, unbiased, or authoritative. As a result, the information we have to work with in projecting potential savings reflects widely divergent estimates. The variation in savings estimates range from as low as approximately 3 percent to as high as 17 percent for 7-day supplies, and as high as 20 to 25 percent for automated dose dispensing. Given the divergence in estimates and the uncertainty in the rate of conversion to the more efficient methodologies, we have elected to be conservative in estimating savings and costs in order to finalize a policy we estimate will result in savings. Therefore, we are finalizing the requirement to dispense in 14-day-or-less increments. Nothing about this change, however, precludes facilities and pharmacies from selecting 7-day-or-less methodologies or Part D sponsors from incentivizing the adoption of more efficient dispensing techniques.

We agree with the commenters that the statute does not mandate 7-day-or-less dispensing. Section 3310 of ACA, which is implemented by § 423.154, states "[t]he Secretary shall require PDP sponsors of prescription drug plans to utilize specific uniform dispensing techniques, as determined by the Secretary, in consultation with relevant stakeholders, * * * such as weekly, daily, or automated dose dispensing * * *" Because the dispensing frequencies are illustrative examples (as indicated by the use of the phrase "such as"), we interpret this language as an indicator of Congress' preference to give the Secretary flexibility in determining the dispensing increments based on information received from the relevant stakeholders. Based on comments, we believe that 14-day-or-less dispensing is a more prudent approach to initially implementing section 3310 of ACA. A 14-day-or-less dispensing requirement will place less of a burden on pharmacies and LTC facilities than a 7-day-or-less dispensing requirement while allowing CMS to collect data to determine the impact of 14-day-or-less dispensing on unused drugs in LTC facilities.

For purposes of scoring this final rule, we project that the current aggregate level of dispensing fees will double. Obviously, the negotiations between LTC pharmacies and Part D sponsors or PBMs that would determine any changes in dispensing fees have not yet taken place and the actual level of dispensing fees is not knowable. Historically, we believe dispensing fees on LTC claims have been relatively low and not directly related to pharmacy costs, reflecting the economies of scale and dominant competitive strategy of long-term care pharmacies in a highly concentrated industry and the negotiating leverage of large PBMs. Therefore, pharmacy costs have not been recovered solely through dispensing fees, but also through other revenue sources, such as mark-up of negotiated prices for drug sales over acquisition costs and receipt of rebates from drug manufacturers. Since these other revenue sources are expected to remain, it is not at all clear that negotiated dispensing fees must or will increase directly in proportion to the number of dispensing events per month as some, but not all, commenters assert. Although the way we are finalizing this rule will result in only minimal additional costs (for example, only one additional dispensing event per month with 14-day dispensing and a substantial reduction in burden associated with the reporting requirements as compared to the proposed rule), we believe that there will be some upward pressure on dispensing fees to incentivize the use of more efficient and cost effective systems in some pharmacies. Therefore, in order to be as conservative as possible in projecting cost increases, we have assumed a doubling of the current aggregate level of dispensing fees.

The comments that follow refer to the 7-day-or-less dispensing requirement reflecting our requirement in the proposed rule. We believe that the comments also apply to 14-day-or-less dispensing, as it is a shorter dispensing increment than traditional 30-day dispensing used in LTC facilities today. Although all of the comments apply to 14-day-or-less dispensing, we believe that some of the burden and costs described in the comments are decreased as a result of less frequent dispensing events per month associated with 14-day-dispensing versus 7-day-dispensing.

Comment: We received few comments related to concerns about patient care. Some commenters believe that that the confusion resulting from two different dispensing methodologies will lead to medication errors and patient safety issues. Another commenter was concerned about delays in treatment, in particular related to protected class drugs, resulting from, for example, delivery delays due to bad weather. Another commenter recommended that we implement 7-day-or-less dispensing only when the requirement is not likely to interfere with patient care.

Response: Based on our conversations with the industry, we know that most facilities have experience utilizing

multiple dispensing methodologies today. For example, most pharmacies dispense using one technique for their Part D patients and another for their Part A patients. We understand that many pharmacies already dispense in less-than-30-day increments for their Part A patients because it is more efficient for the LTC facilities to do so. This is because the LTC facilities must pay for Part A drugs out of their per diem payments. These LTC facilities already require their LTC pharmacists to employ 7- or 14-day dispensing methodologies to limit exposure to unnecessary costs associated with unused drugs when they are the payor. Thus, it is clear that LTC facilities and their contracted pharmacies have been able to manage dispensing to patients using multiple dispensing methodologies. Consequently, we do not see any evidence that multiple dispensing methodologies per se in a LTC facility necessarily results in medication errors, and we received no comment that provided any specific information to support this assertion.

In fact, we believe that the original 7-day-or-less dispensing requirement, and to a somewhat lesser extent, the new 14-day-or-less dispensing requirement, incentivizes the use of the most effective and efficient dispensing technologies, such as automated dose dispensing, which we believe based on conversations with LTC facility and pharmacy staff who have implemented such systems, will actually result in fewer medication errors. We learned from multiple industry representatives that automated dose dispensing systems reduce medication errors by ensuring the accuracy of the medication dispensed to the patient by eliminating many manual steps involved in removing doses from multiple blister packs and collecting them in paper cups prior to the medication pass. In addition, these systems free up nursing time allowing nursing staff to focus more on patient care.

We believe that facilities and pharmacies evaluating the optimal systems to employ in meeting the required change from 30-day dispensing will seriously consider all alternatives, and many will find that the confluence of improvements in dispensing equipment technology and developments in health information technology standards, combined with changes in dispensing fees represent an excellent opportunity to upgrade their dispensing systems to the most efficient methodologies to further both cost-effective operations and competitive advantage.

As stated in the proposed rule, we have learned from many industry representatives that delivery schedules will not be expected to change significantly to accommodate 14-day-or-less dispensing. We received a few comments on the proposed rule asserting that there might be delays in therapy as a result of changes to delivery schedules to accommodate shorter dispensing increments. However, no commenters provided details that contradict what we heard from most industry representatives during consultation. In most LTC facilities deliveries are already made on a daily basis to accommodate new admissions and first doses. We did not receive any comments with substantiating detail that lead us to believe delivery schedules will have to significantly change as a result of this requirement. Nor do we believe that bad weather will impact deliveries to any greater extent than it does today. We did, however, state in the proposed rule that the way in which some deliveries are made may have to change. We stated that, when allowed by State law, common carriers may be used to make some deliveries from the pharmacy to the LTC facility. So in rare circumstances when a delivery cannot be made by the pharmacy, deliveries by common carrier may supplement the delivery schedule. In summary, the comments we received did not persuade us that the information we received during our pre-rulemaking consultation with the industry was incorrect or insufficient, and for this reason, we continue to believe that the parties are capable of handling various dispensing methodologies and frequent deliveries, and thus the 14-day-or-less dispensing requirement will not interfere with patient care.

Comment: Several commenters supported the proposal that a pharmacy should not be considered a mail order pharmacy because the pharmacy delivers some of the drugs using a common carrier.

Response: We received only supportive comments on this issue, and we intend to issue guidance in manual chapters to document this policy.

Comment: We received a couple of comments regarding the identification of brand name versus generic drugs. A commenter questioned whether the brand name status would be based on the NDA/ANDA status.

Response: As indicated in the proposed rule, "brand name drug" is defined at § 423.4. "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 U.S.C. 355(c)), including an application referred to in section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(b)(2)). Thus, the definition specifically refers to a drug approved under an NDA. In response to this comment, however, and to avoid confusion, we are making a technical change to the regulation to refer to "brand name drug" instead of "brand name medication."

Comment: We received many comments in support of our proposal to limit the 7-day-or-less dispensing requirement to brand name drugs only to minimize any transition issues. Commenters agreed that the majority of the financial waste is associated with brand name drugs. Commenters also stated that limiting the requirement to brand name drugs was a practical approach. We also received a smaller number of comments from certain pharmacies and from environmental groups that did not support our proposal to limit the requirements to brand name drugs. Environmental groups urged us to include generics in the requirement because generic drugs account for majority of the unused drugs (in terms of quantity).

Response: We proposed to limit the requirement to brand name drugs because, after consultation with the industry, we were persuaded by its arguments that by targeting brand name drugs, we would target a majority of the financial waste but minimize the initial burden on LTC facilities and pharmacies converting from a 30-day dispensing increment to a shorter dispensing increment. Once we are able to collect data on unused drugs and negotiated prices in the Part D market, we will be in a better position to evaluate the implications of extending the requirement to generics. As we stated in our proposed rule, however, nothing in the requirement prevents LTC facilities and pharmacies from extending the practice to generic drugs, and we encourage Part D sponsors to facilitate that practice. Given that pharmacies and facilities have that flexibility, we continue to believe that imposing this requirement initially only for brand name drugs is the appropriate policy.

We agree with the environmental groups that extending the requirement to generic drugs would result in fewer unused drugs. However, we must weigh the effect of our proposal against the costs to the Part D program that may arise and the burden on LTC pharmacies and facilities. As such, we believe that the phased-in approach—which focuses first on reducing the amount of unused

drugs in terms of monetary waste—is appropriate.

Comment: Some commenters requested that we conduct a pilot program or conduct studies prior to implementing the 7-day-or-less dispensing requirement. We received some comments recommending that we limit the 7-day-or-less requirement to the most expensive brand name drugs and add drugs to the requirement after studying the impact of the 7-day-or-less requirement. Some commenters urged us to conduct studies prior to extending the 7-day-dispensng requirement beyond brand name drugs and, in particular, measure the increase in dispensing fees relative to the average cost of generic drugs not wasted, to determine whether the requirement should be extended beyond brand-name drugs.

Response: We disagree with the commenters that believe studies or pilots must be conducted prior to any 14-day-or-less requirements. First, section 3310 of the ACA does not contemplate that we conduct a study prior to implementing the provision. Second, we do not believe a pilot program is necessary. Shorter dispensing cycles have already been successfully implemented in many LTC facilities and thus, are not a new approach that warrants a pilot program. Moreover, as noted previously, we already are proceeding with implementation on an incremental basis by applying the requirement only to brand name drugs and taking other steps to facilitate information gathering. In this way, we already are further mitigating any burden associated with this transition by initially focusing on only a portion (20 percent of the drugs dispensed) of drugs dispensed. As discussed elsewhere in this final rule, we will be requiring pharmacies to report dispensing methodologies and report unused drugs to Part D sponsors. Our reporting requirements will provide us with data we can use to evaluate the implications of extending the requirement to generic drugs. Finally, we decline to limit the 14-day-or-less dispensing requirement to the most expensive brand name drugs. Pharmacy reimbursement varies from pharmacy to pharmacy and plan to plan, and therefore the most expensive brand name drugs similarly may vary. We do not believe it would be useful or prudent for us to attempt to identify and maintain a list of such drugs, particularly given that we are prohibited from interfering with price negotiations.

Comment: We received a number of comments in support of our acknowledgment that it is not possible or practical for CMS or Part D sponsors to identify the uniform dispensing techniques that must be used in all pharmacies. We also received comments asking us to clarify "dispensing methodology." Commenters wanted us to clarify whether "dispensing methodology" refers to only the technique used or also the number of days. We received one comment that CMS should require all plan sponsors utilize "7-day" dispensing rather than "7-day-or-less" dispensing. The commenter argues: (1) "7-day-or-less" dispensing is neither uniform nor specific as mandated by the statute; (2) less than 7-days will increase dispensing fee-related costs; and (3) it is impractical because each LTC facility and LTC pharmacy would have to ascertain the requirements imposed by each resident's plan and then manage those requirements.

Response: For the purposes of this provision, the term "dispensing methodology" refers to both the packaging system (for example, single or multidose packing systems such as punch cards, envelopes, or strip packaging) and the dispensing increment (such as 14-day, 7-day, "2–2–3" day, "4–3" day, daily, or automated dose dispensing). "Uniform dispensing techniques" refers to the dispensing methodology or methodologies used in a particular LTC facility. As stated in the proposed rule, the days' supply dispensed to enrollees may vary depending on the drug. Under this provision, it is the LTC facilities that select the dispensing methodology or methodologies used in the LTC facility, obviously in concert with their contracted LTC pharmacy. We disagree with the commenter that our requirements are neither uniform nor specific. We also disagree with the commenter's third point and believe it indicates a misunderstanding of our proposal. The dispensing methodology (or methodologies) will be uniform with respect to each LTC facility, and these uniform requirements will apply to all Part D sponsors and pharmacies dispensing to enrollees in that facility. Thus, a LTC facility may choose to have one dispensing methodology for brand name Part D drugs, and another for generic Part D drugs, and a third for drugs dispensed to non-Part D enrollees. As long as the facility, not the Part D sponsor, chooses the methodologies, such methodologies will be uniform throughout that facility. Conversations with the industry lead us to believe that the facilities will elect to standardize around the 14-day-or-less dispensing methodologies because these methodologies will minimize waste-related costs across the board. Further, the LTC facility will identify the specific type (or types) of packaging to be used to dispense Part D drugs within the LTC facility. Although the days' supply dispensed at a time may vary (up to 14 days' worth), we believe the 14-day maximum is sufficiently uniform, particularly given that LTC facilities may vary widely in terms of their resources, physical plant, and enrollee population. Given these disparities, we continue to believe that it is the LTC facilities that are in the best position to identify the uniform dispensing technique or techniques to be used throughout the facility. That is, we look to the facility to define the technique or combination of techniques that meet the facilities' business needs in concert with their contracted LTC pharmacies and require that the Part D sponsors defer to that decision rather than impose their own requirements. Therefore, the LTC facility will not need to ascertain Part D sponsors' requirements for the LTC facility's residents—indeed, our requirement is precisely the opposite.

However, we agree with the commenter that dispensing fees will likely increase with 14-day-or-less dispensing. Although we are prohibited from intervening between negotiations between Part D plans and pharmacies, we do expect that dispensing fees will increase with the increased number of dispensing events in a billing cycle up to a point. Consistent with feedback from the LTC industry and comments on the proposed rule, we believe that drugs dispensed in shorter dispensing increments will result in fewer unused drugs. We also believe that appropriate dispensing fees that differentiate among the various dispensing methodologies could incentivize more rapid adoption of the most cost-effective technologies and effectively align facility, plan sponsor, and public interest in minimizing costs associated with unused drugs.

Comment: Several commenters asserted that leaving uniform dispensing techniques to the discretion of the LTC facility would lead to undue expense upon pharmacies. One commenter stated that the proposal would lead to more concentration in the LTC pharmacy business which would potentially increase costs.

Response: We believe this comment is based on a misunderstanding of what is meant by "uniform." The commenter may believe that we intended to impose a requirement for a single dispensing methodology throughout each LTC facility and that such regimentation would present a barrier to entry in the

market to pharmacies that specialize in innovative systems. Decreased competition could be expected to result in higher prices. However, as explained previously, we define "uniform" by the dispensing methodologies chosen by the facility because the facility will choose the set of dispensing methodologies that best suits its needs and effectively minimize costs. We expect pharmacies will work with the LTC facilities they contract with to determine the 14-day-or-less dispensing methodology or methodologies that will work best for the LTC facility, taking into account not only physical plant and labor considerations, but also the overall cost effectiveness and waste reduction potential. Again, we have no intent to limit the range of methodologies selected by the LTC facilities to meet the facilities' needs; rather we mean to prohibit Part D sponsors requirements from imposing different requirements than those selected by the facility.

Comment: We received comments stating that CMS should be indifferent to dispensing, shipping and other operational methods employed by a pharmacy as long the billing for the medication is not in excess of 7-days of usage.

Response: We disagree. Section 3310 of the Act directs us to impose requirements aimed at reducing the amount of unused drugs in LTC facilities. For that reason, we do not believe it is enough for us to merely limit billing to no greater than 14-day increments. If we were to focus only on billing, nothing would preclude a pharmacy from dispensing a full 30-day supply of drugs and bill for all of them in 14-day increments regardless of whether they had been used. Such a practice would not prevent the accumulation of unused drugs in LTC facilities and certainly would not reduce financial waste associated with unused drugs. Thus, the commenter's suggested approach would, in our view, run counter to the purpose of the statute.

Comment: Some commenters supported CMS' decision not to require the use of automated dose dispensing. The commenters agreed that such systems are not practical for all facilities. We also received many comments that generally supported the use of automated dose dispensing systems. Commenters believe that these systems are the most efficient and cost effective way to reduce the volume of unused drugs and increase patient safety. We received comments that CMS should promote the rapid adoption of this technology by ensuring appropriate dispensing fees, providing incentive programs similar to the electronic prescribing incentive program, and establishing a Federal program that makes capital more readily available to LTC pharmacies and facilities that are investing in technologies aimed at reducing waste.

Response: We agree that automated dose dispensing systems appear to be the most efficient and effective way to reduce waste. However, as stated in the proposed rule, we recognize there are significant limitations to the rapid industry-wide adoption of automated dose dispensing systems, including capital acquisition costs, state pharmacy board restrictions, lack of final automated medical record to pharmacy system interface standards, and inventory considerations. Additionally, automated dose dispensing may not be considered practical by some LTC facilities due to physical size and plant limitations. However, given our proposed changes to the definition of "dispensing fee" in § 423.100 and the prohibition on our ability to interfere with negotiations between pharmacies and Part D sponsors, we do not believe it is necessary or appropriate for us to provide financial incentives or support of the type the commenters suggest. With respect to incentive programs, we understand the value of the incentive programs; however, we do not believe that the implementation of section 3310 of ACA is predicated on those programs.

Comment: We received comments in support of our proposal to limit the 7-day-or-less dispensing requirement to LTC facilities as defined in § 423.100. This definition excludes assisted living facilities. We also received several comments requesting that we extend the requirements to include assisted living facilities. One commenter stated that including assisted living facilities in the requirements would reduce the pharmacy burden of having to manage multiple dispensing systems. Another commenter suggested that including assisted living facilities in the requirements would be the only way to ensure the Part D sponsors would reimburse pharmacies for services provided.

Response: We decline to revise the regulation to include assisted living facilities. Section 3310 of the ACA refers to LTC facilities, which we believe indicates Congress's intent that the requirements apply to LTC facilities as defined in our regulations that predate the ACA. Therefore, terms and conditions pertaining to services to residents in assisted living facilities, including any differential in dispensing fees is a matter of negotiation between the parties. Moreover, we are aware that the medication packaging requirements needed for beneficiaries residing in assisted living facilities may be different from the medication packaging needs of beneficiaries residing in LTC facilities due to the different levels of independence of the residents of the facilities. Therefore, extending the requirements to assisted living facilities may not reduce the burden associated with multiple systems. However, nothing in the provision precludes pharmacies from extending 14-day-or-less dispensing to assisted living facilities if the assisted living facilities and pharmacies decide that is the best option for their operations. Pharmacies and facilities believing that it is a burden to manage multiple dispensing systems may want to consider extending 14-day-or-less dispensing to assisted living facilities. Pharmacies choosing to extend 14-day-or-less dispensing to assisted living facilities are free to negotiate dispensing fees to reflect that service. However, dispensing fees for those services remain a matter of contract negotiations between the pharmacy and the Part D sponsor.

Comment: We received support for our proposal that the requirements would apply to all pharmacies, including closed-door LTC pharmacies, retail pharmacies, and mail order pharmacies that dispense to Part D enrollees residing in LTC facilities. We received a couple of comments requesting that we limit the requirements to those pharmacies contracted to the LTC pharmacy network, in part, because most retail and mail order pharmacies have no means to identify enrollees residing in LTC facilities.

Response: We disagree that the requirements should be limited to pharmacies dedicated to dispensing medications to patients residing in LTC facilities because we do not believe section 3310 of the ACA is intended to apply only to those pharmacies. We further believe that to accomplish that the purpose of section 3310 of the ACA, which is to reduce the amount of unused drugs in LTC facilities, it is necessary for all pharmacies that dispense Part D drugs to enrollees in LTC facilities to dispense brand name drugs in no greater than 14-day increments. We note that Part D sponsors receive a long-term care institutionalized resident report twice a year from CMS. This report provides information to Part D sponsors on which of their enrollees are institutionalized, as well as the names and addresses of the particular LTC facilities in which those beneficiaries reside. Therefore, Part D sponsors' pharmacies providing services to LTC facilities do have a way

to identify enrollees residing in LTC facilities. Moreover, sponsors generally become aware of their enrollees' institutionalized status much sooner when they get a claim from the LTC pharmacy including the "place of service" code. Upon receipt of that claim, the Part D sponsor is required to contract with that LTC pharmacy. Part D sponsors manage the care of their enrollees, not merely process claims for prescription drugs. Part D sponsors' LTC pharmacies must be capable of meeting certain performance and service criteria, as specified under 50.5.2 of Chapter 5 of the Medicare Prescription Drug Benefit Manual. These performance criteria must be incorporated into an addendum to a Part D sponsor's standard network contract for those pharmacies that would like to be designated as a network long-term care pharmacy. In order to comply with these criteria, sponsors must be able to identify beneficiaries residing in LTC facilities. For these reasons, we believe sponsors will have sufficient information to determine to which enrollees these dispensing requirements apply and can therefore appropriately monitor pharmacy compliance with these requirements.

Comment: We received many comments requesting that we extend the 7-day-or-less dispensing requirement to pharmacies other than those that dispense to LTC facilities. Many commenters requested that we investigate the potential to reduce the volume of unused drugs in other non-institutionalized settings including retail pharmacy and mail order pharmacy.

Response: We appreciate these comments and will consider them as appropriate for future rulemaking; however, we decline to extend these requirements at this time—our proposal was intended to implement section 3310 of the ACA, which is specific to reducing unused Part D drugs in LTC facilities. However, we again reiterate that pharmacies, facilities and Part D sponsors are free to implement measures intended to reduce the amount of unused drugs dispensed, and we believe our revised definition of "dispensing fees" in § 423.100 makes it clear that costs associated with such measures can appropriately be included in pharmacy dispensing fees.

Comment: Many commenters supported our proposal to exclude certain drugs from the 7-day-or-less dispensing requirement. In addition to the list of excluded drugs suggested in the proposed rule, some organizations specifically recommended that we exclude all antibiotics, insulin and diabetic supplies, all controlled substances, contraceptives, liquids, patches, limited distribution drugs, kits, Boniva monthly, vaginal rings, Prephase and Prempro, steroid bursts, weekly medications, Fosamax, powdered medications, total parenteral nutrition (TPNs), and compounded medications. Many commenters requested that we exclude liquids from the 7-day-or-less requirement for practical and patient-safety-related reasons. Some commenters thought it may be difficult to interpret and operationalize the "drugs difficult to dispense in supply increments of 7-day-or-less" exclusion. We also received comments requesting that we clarify the definition of "acute illness." Finally, many commenters requested that CMS should maintain a list of excluded drugs to promote consistency across the industry.

Response: We agree with the commenters who believe the "drugs difficult to dispense" standard may be difficult to interpret and operationalize and, as a result, we are modifying this standard. We will require 14-day-or-less dispensing specifically for solid oral doses of brand name drugs. We also will eliminate the reference to "acute illnesses" and "drugs difficult to dispense." Based on the comments, we will specifically exclude antibiotics and drugs that must be dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information and drugs that are customarily dispensed in their original packaging to assist patients with compliance (for example, oral contraceptives). We believe that with this simplification of the rule, a list of Part D drugs by NDC is not necessary; therefore, we decline to maintain such a list.

We disagree with commenters that requested that we exclude controlled drugs. As stated in the proposed rule, the Drug Enforcement Agency rules do not preclude dispensing controlled drugs in 14-day-or-less increments. Further, we believe that 14-day-or-less dispensing of controlled drugs will result in less unused controlled drugs in the LTC facilities, and therefore, will be less of a disposal burden on LTC facilities or a diversion risk. But unlike antibiotics and drugs that must be dispensed in their original packaging, we do not find a similar basis for excluding controlled substances from the dispensing requirements (unless they are excluded for another reason) because there is no clinical or patient safety reason to do so.

Comment: We received some comments requesting an exemption from the dispensing requirement in cases where a prescriber determines that it is medically necessary for the enrollee to receive more than a 7-day supply at a time and in cases where patients are stabilized on a medication. One commenter stated that some drugs and biologicals may require a longer time period in order to gauge tolerance or efficacy, and in those circumstances a partial fill may not be medically appropriate.

Response: We disagree with these comments. First, we believe an exclusion from the dispensing requirements for "medical necessity" is unnecessary. As we stated in the proposed rule, the dispensing requirements have no bearing on the quantity prescribed. A prescriber is free to prescribe any quantity of medication that he or she believes is medically appropriate for the patient. Our requirements merely would govern the increment in which such medication is dispensed to the facility at a time. Further, we are not persuaded that there should be an exception for patients who are stabilized on a medication—we believe it would be more burdensome for pharmacies, Part D sponsors, and LTC facilities to apply beneficiary-specific, drug-specific dispensing requirements without any benefit in the form of reduced financial waste associated with unused drugs. In fact, such an approach could both increase the amount of unused drugs and increase costs. Moreover, while we agree that some drugs and biologicals require a longer time to gauge tolerance or efficacy, we disagree that the answer is to exempt these drugs from the dispensing requirements. To the contrary, it makes more sense to dispense those drugs in 14-day-or-less increments. If the patient does not tolerate the drug or the drug is ineffective and has to be discontinued, fewer unused drugs will result when a 14-or-less day's supply, as opposed to a 30-day supply, is discontinued.

Comment: Some commenters agreed that return and reuse was not an optimal method to reduce the amount of unused drugs in LTC facilities. Others commented that we should allow either return and reuse or a 7-day-or-less dispensing requirement, but not both. Others commented that we should prohibit "return for credit and reuse" for Part D drugs that are subject to the 7-day-or-less dispensing requirement. Some commenters requested that we exempt from the requirement those pharmacies that already utilize low-waste practices or "return for credit and reuse".

Response: As stated in the proposed rule, we considered "return for credit

and reuse" as a way to reduce waste in LTC facilities. We explained that there are limitations to this approach, especially that fact that not all states allow "return for credit and reuse," and reuse of controlled substances is limited by the DEA. Because of these limitations, we believe financial waste will be more effectively reduced by preventing the accumulation of unused drugs in the first place rather than addressing handling of unused drugs after they have accumulated in the LTC facilities. That said, we do not prohibit the "return for credit and reuse" of drugs, and under this provision require Part D sponsors' pharmacy contracts to explicitly address whether return and reuse is authorized where permitted by State law. As stated in the proposed rule, we recognize that "return for credit and reuse" can be effective in certain situations (for example, where there is an onsite pharmacy at the LTC facility); however, we believe that "return for credit and reuse," where allowed by State law, should be used in conjunction with 14-day-or-less dispensing to further reduce the volume of unused drugs over and above that of 14-day-or-less dispensing. We decline to provide an exception from the requirements for those pharmacies already practicing techniques that limit the volume of unused Part D drugs. Part D sponsors' pharmacies that already utilize 14-day-or-less dispensing will be compliant with the requirements. Therefore, pharmacies utilizing "other low waste practices" will not be exempt from the 14-day-or-less dispensing requirements.

Comment: A few organizations commented that the dispensing methodology would not be apparent from the claim making it difficult to comply with the proposed reporting requirement that the Part D sponsor collect and report information on the dispensing methodology used for each dispensing event. We also received comments requesting that we not apply the reporting requirement absent compelling justification of how we will use the information to evaluate efficiencies. Some commenters questioned our authority to collect data on dispensing methodologies and unused Part D drugs. We received a comment that the National Council for Prescription Drug Programs (NCPDP) has developed codes for dispensing methodology that are compatible with the HIPAA billing transactions and that will facilitate CMS's and Part D sponsors' ability to track the dispensing.

Response: We will collect the data from sponsors through Part D reporting requirements. Under section 1860D–12(b)(3)(D) of the Act, which incorporates section 1857(e)(1) of the Act, we are authorized to require Part D sponsors to provide such information as we find necessary or appropriate. We are concurrently issuing further guidance on this reporting requirement in a revision to the Part D Reporting Requirements (currently approved under OMB Control No. 0938–0992). We intend to use this data to determine the extent to which the dispensing requirements reduce the amount of unused drugs and determine the cost effectiveness of expanding the requirement beyond brand name drugs. We note that billing transactions are handled through regulatory processes associated with HIPAA transactions. We appreciate the comment from NCPDP that they have developed codes for dispensing methodologies that will facilitate CMS's and Part D sponsors' ability to track the dispensing using information available on version D.0 claim transactions.

Comment: Some commenters supported our proposal to have unused drugs returned to the pharmacy and also supported data collection of the quantity and types of drugs that go unused in LTC facilities. We also received several comments from organizations requesting that CMS delay the requirement that unused drugs be returned to the pharmacy and reported to the Part D sponsor until such time when NCPDP has developed an electronic transaction to capture the nature and quantity of unused drugs. Commenters stated that manual reporting of unused drugs would create a burden on the pharmacy and sponsor and require additional staffing to accommodate the increased workload. Some organizations recommended that we require all solid oral doses (brand and generic drugs) to be dispensed in 7-day-or-less increments and eliminate the "return and report" requirement at least until an NCPDP transaction is developed. Some commenters wanted us to clarify the "return and report" provision. Commenters requested that we clarify whether the provision applies to Part D drugs dispensed prior to the implementation date of the requirement and whether drugs to which the requirements do not apply were exempt from the "return and report" requirement. Many commenters believed that the Controlled Substance Act, hazardous waste laws, and State laws would be a barrier to LTC facilities returning unused drugs to pharmacies. One commenter requested that we add an option for the LTC facilities to report the unused drugs. Another commented that since Part D sponsors do not directly contract with LTC facilities, the Part D sponsors will not have the authority to require LTC facilities to return unused medications to LTC pharmacies. Some commenters stated that there may be more effective ways to gather data than to require all unused drugs be returned to the pharmacies.

Response: As a result of comments, we better understand the existing State and Federal requirements on LTC facilities to manage waste. In response to the comments, we will eliminate the requirement that unused drugs be transferred to the pharmacy and instead retain only the requirement that Part D sponsors collect information from the network LTC pharmacies to determine the amount of unused brand and generic drugs, as defined in § 423.4. We understand that pharmacies routinely receive a date of discontinuation or other information that can be used to calculate such a date (for example, the start date of the new "substitute" prescription may be used as the discontinuation date of the previous prescription) from the LTC facility whenever a medication is discontinued for any reason. Therefore, we believe pharmacies have the data in their own systems to calculate the difference between the quantity dispensed and the quantity consumed, which can be used to calculate the amount of unused medication and which plan sponsors can audit and validate reported amounts. We are revising the PRA package for the Part D Reporting Requirements (currently approved under OMB Control No. 0938–0992) to reflect this approach and will be able to confirm our understanding in the next comment period for the Reporting Requirements.

However, for pharmacies that voluntarily adopt 7-day-or-less dispensing for all solid oral doses (that is, both brand name drugs and generic drugs), we will waive the requirement that Part D sponsors report on the unused drugs. All other pharmacies must report on the amount of unused brand and generic drugs as of implementation of this provision, January 1, 2013. We continue to believe that reporting is essential in order to acquire data from which to evaluate the potential savings from extending the dispensing requirement to generic drugs. Only when data has been systematically collected will the extent of the volume of unused Part D drugs be quantifiable. However, we will eliminate the reporting requirement for those pharmacies that immediately adopt 7-day-or-less dispensing for *both* brand name and generic drugs given

that doing so will almost eliminate unused drugs.

Comment: We received a comment requesting that CMS prohibit plan sponsors from seeking credits for unused drugs that are returned to LTC pharmacies but not reused. We also received a comment requesting that CMS ensure that the final regulations expressly state that beneficiaries are to share in any refund resulting from the return in proportion to the amount of the total cost for the returned drugs covered by their cost sharing contribution.

Response: We believe that the commenter is concerned that sponsors will demand credit for unused drugs associated with the reporting requirement. We stress that this is not the requirement under the rule and expect that sponsors will pay pharmacies for drugs dispensed under this rule, subject to any contractual provisions in the contract between the Part D sponsor and LTC pharmacy. Whether or not Part D plans receive credits and the affect on beneficiaries will be determined by the contract between the sponsor and the pharmacy and the terms of the benefit package. With respect to return and reuse, that is a practice governed by State law and the provisions of the contract between the Part D sponsor and the pharmacy. We do not believe it is necessary or desirable for CMS to preempt State laws on this issue. For these reasons, we decline to adopt the commenters' suggestions. If a pharmacy processes unused drugs and redispenses the drugs, then the pharmacy must abide with any conditions in its contract with the Part D sponsor regarding providing credit and the Part D sponsor must adjust the prescription drug event data and TrOOP accordingly for the original dispensing event.

Comment: We received comments that Part D sponsors should generally allow pharmacies to use currently accepted transactions unless the industry voluntarily adopts a single billing standard. Others recommended that we implement a specific billing standard. Some commenters recommended that we implement "post-consumption billing" as a standard billing methodology because there would be minimal need for drug returns, claim reversal, and TrOOP and drug spend adjustments. Some also stated that a post-consumption-billing method would reduce the potential for fraud.

Response: We defer to the appropriate industry standard-setting organizations and the HIPAA-mandated rulemaking process to determine billing standards and for this reason, decline to amend our regulations for this purpose at this time.

Comment: We received several comments concerned about copayment methodologies. Some commenters recommended that the copayment method not be linked to the dispensing methodology. Several commenters expressed concern over charging beneficiaries additional copays. Many recommended that the beneficiary only be charged one copayment per month. Other commenters believed that the beneficiaries' copayments should be prorated based on the number of days a Part D drug was dispensed in a month.

Response: As stated in the proposed rule, we expect that copayments will be billed on the first dispensing event of the month, the last dispensing event of the month, or prorated with each dispensing event. We leave the decision of which copayment collection methodology to use up to the parties involved in these transactions; however, in response to these comments, we will add a provision to the regulation to clarify our interest that regardless of the number of incremental dispensing events, the total cost sharing for a Part D drug to which the 14-day-or-less dispensing requirements apply shall be no greater than the total cost sharing that would be imposed for such Part D drug if the 14-day-or-less requirements did not apply. This requirement applies for all beneficiaries including low-income subsidy eligible beneficiaries. (We note that, for CY 2013, we are considering collection of daily copayment information in the PBP tool, and that such information would facilitate copayment proration.)

Comment: Some organizations expressed concern over "refill too soon" edits and utilization management requirements that may be placed on drugs dispensed in 7-day-or-less supplies. A majority of the organizations that commented on "refill too soon" edits requested that we issue guidance to Part D sponsors requiring them to turn off the "refill too soon" edit. These organizations were concerned that "refill too soon" edits on drugs dispensed in 7-day-or-less supplies would result in an increase in missed doses due to medication unavailability. Some commenters recommended that Part D sponsors would need to allow for all medications to receive a one-time prior authorization. We also received a comment recommending that prior authorization and step edits be eliminated for drugs dispensed in 7-day-or-less increments and arguing that the rationale behind these utilization management edits is to reduce costs and therefore, they would not be necessary under 7-day-or-less dispensing.

Response: We agree that customary "refill too soon" edits for traditional 30-days supplies will be inappropriate for 14-day-or-less supplies and could result in access issues. We do not agree that PA and step-therapy should be eliminated as they allow savings through use of less costly alternatives with potentially equivalent therapeutic value. We expect that the industry will modify utilization management edits, including refill too soon edits to prevent discriminatory practices that could result in Part D drug access issues.

Comment: We received comments that there may be penalties associated with billing Medicaid for quantities less than a 30-day supply. We also received comments that even the minimal Medicaid co-payment on a prescription becomes a financial burden on such patients if the states are allowed to impose the copayment obligations currently in effect on each 7-day fill.

Response: By statute, Medicaid cannot be billed for Part D drug claims. Therefore, this comment is beyond the scope of the rule because our final rule with respect to dispensing to LTC residents applies only to Medicare Part D.

Comment: We received many comments that did not support our proposal to grant a limited extension to independent community pharmacies servicing small LTC facilities in rural communities. Many commenters believe that it would be difficult to determine which pharmacies meet our proposed extension criteria. Some commenters requested that CMS keep a list of pharmacies that qualify for the extension to eliminate any confusion regarding those pharmacies that qualify for the extension.

Response: As discussed further below, we intend to delay the effective date of the dispensing and reporting requirements set forth in § 423.154 until January 1, 2013. For this reason, an extension for pharmacies servicing small LTC facilities in rural communities is no longer necessary. Instead, the delay in the implementation date will allow all pharmacies and LTC facilities time to evaluate dispensing methodologies and allow them to make a decision regarding the most effective and efficient systems for their facilities. We are amending the final regulation to eliminate the extension for certain pharmacies.

Comment: We received many comments in support of our proposal to waive the dispensing requirements when pharmacies are dispensing to Part D enrollees residing in intermediate care

facilities for the mentally retarded (ICF/MRs) and Institutes for Mental Diseases (IMDs). We also received comments that supported waiving the requirements when pharmacies dispense to similar facilities that meet and demonstrate the same criteria outlined in the proposed rule. We received specific requests to waive I/T/U pharmacies and Indian Health Service or tribal facilities from the requirement. We also received a request to waive this requirement for pharmacies when dispensing to PACE programs. Other commenters opposed any waivers. These commenters argued that the lack of data on unused Part D drugs in these facilities justifies the opposition to the waiver.

Response: We were persuaded by the comments that under certain circumstances, waivers should be granted. The requirements under § 423.154(a) will not apply to I/T/U pharmacies defined in § 423.100. We understand that the I/T/U system is understaffed. As a result, unlike in most LTC pharmacies, which have dedicated clinical pharmacy staff, pharmacists in the I/T/U system are often called upon to perform multiple non-dispensing tasks including providing patient care that would otherwise be provided by a physician. These pharmacists make medication deliveries to LTC facilities only on days when they provide consultant services. In addition, some of these pharmacists provide translation services and/or provide information in a culturally appropriate manner and protocol for the Indian population they serve. Further stressing the system, these pharmacies are called upon to support very remote health stations that are often accessible, in some cases, only on foot, by horseback, airplane, or via helicopter. The majority of the clinics and health stations serviced by I/T/U pharmacists are in remote areas where deliveries cannot be made on a daily basis. For these reasons, we believe that requiring the 14-day-or-less requirement is not feasible for I/T/U pharmacies and could increase rather than decrease costs associated with 30-day dispensing.

The 14-day-or-less dispensing requirements will generally not apply to PACE organizations because PACE programs provide community-based care. When PACE enrollees are in SNFs, we would expect that pharmacies servicing those facilities adhere to the 14-day-or-less dispensing requirement. Therefore, we are waiving these requirements for I/T/U pharmacies, but not for pharmacies when they serve PACE programs.

Comment: We received some comments requesting the CMS maintain a list of facilities for which the dispensing requirements have been waived along with the NCPDP patient resident code so that pharmacies could inform the Part D sponsors that the pharmacy is dispensing to an enrollee residing in a facility that has been waived.

Response: We will consider whether this is a practice that CMS should maintain. However, we currently believe Part D sponsors can adequately identify ICF/MRs, IMDs, and I/T/U pharmacies as these entities generally contract with and bill Part D sponsors directly.

Comment: We received many comments from organizations recommending that we delay the implementation of the requirements described under § 423.154. Many commenters requested a 1-year delay, but some commenters requested a 2-year delay. Most commenters argued that an implementation date of January 1, 2012 would not give sufficient time to renegotiate contracts between the Part D sponsors and the pharmacies or make necessary systems and operational modifications to comply with the requirements. Some commenters argued that maintaining the January 1, 2012 implementation date would lead to inaccurate bids for the 2012 contract year, since planning for systems changes and renegotiation of appropriate dispensing fees incorporating related costs would be expected to extend beyond the CMS bid submission deadline. One commenter indicated that without a delay to permit appropriate negotiation of pharmacy reimbursement, pharmacies would likely just convert existing 30-day punch card systems to 7-day punch card systems rather than make capital investment in more efficient and cost-effective methods for complying with the dispensing requirement. Commenters stated that conversely, the delay until at least January 1, 2013 would ensure that nursing facilities have sufficient time to evaluate dispensing system options (such as automated dose dispensing systems) with their contracted pharmacies and make clear capital investment decisions. A commenter expressed concern that without the delay, hasty business decisions made under pressure could put an otherwise stable pharmacy business at unnecessary risk for failure, particularly given that these decisions would involve capital investments that cannot easily be reversed. This commenter believes that as a result, there could be a decrease in the number of pharmacies that are able to serve LTC facilities. Commenters also expressed concern that the proposed implementation date of January 1, 2012 might put a strain on the supply of appropriate dispensing equipment. Several commenters stated that failure to delay the implementation date would likely result in rushed transitions to 7-day-or-less dispensing that might jeopardize patient safety (for example, because of inadequate staff training time). Commenters stated that given that the LTC facilities will dictate the uniform dispensing techniques to be used in their facilities, pharmacies may need to work with the facilities one at a time, which will require additional time and resources.

Response: We are persuaded by the comments that a 1-year delay in the implementation of these requirements is appropriate. Therefore, we are revising § 423.154 to specify that it will take effect January 1, 2013.

This delay will give LTC facilities and pharmacies more time to evaluate dispensing methodologies and make decisions regarding the most effective and efficient systems. In particular, we are persuaded by the comments that indicate that more pharmacies will convert to the more efficient dispensing systems if given more time to make arrangements for those systems. We also believe, based on the comments, that if the affected parties have more time to make measured and fully considered decisions about capital investments in dispensing technologies, they will be more likely to immediately extend shorter cycle dispensing to both brand and generic drugs in order to maximize the return upon their investment. We believe that these decisions will increase program savings in the long run and lead to greater savings than if, because of an earlier implementation date, the parties did the minimum necessary and merely made minor adjustments to their current systems to meet the requirements.

We also are persuaded by the comments suggesting that the delay will give Part D sponsors sufficient time to negotiate contractual changes and finalize dispensing fees with LTC pharmacies in advance of the 2013 bid deadline, thereby allowing Part D sponsors to submit accurate bids. We would be concerned that bids that could not accurately account for yet-to-be renegotiated dispensing fees would increase program costs in other ways and could potentially offset savings resulting from implementing the requirement for 2012, potentially defeating the purpose of section 3310 of the ACA.

We further are persuaded that, given that we do not have concrete data about the amount of savings that could be achieved, and consistent with our

incremental approach to the dispensing requirement, a 1-year delay will reduce the burden on Part D plans, pharmacies and LTC facilities by permitting a more orderly transition to the new dispensing requirement. In addition, the delay will more closely align the reporting requirement for unused drugs with the availability of an electronic informational reporting transaction that could be used for this purpose, which we believe will further reduce the burden of data collection on pharmacies and Part D sponsors. Finally, we are persuaded that that a delay will give pharmacies and LTC facilities more time to transition to different workflows, new systems and operational requirements, and conduct appropriate staff training. We believe this will mitigate any potential start up issues, such as medication errors, and thus will increase patient safety.

As a result of comments, in our final rule, we modify § 423.154(a)(1)(i) to dispense solid oral brand name drugs, as defined in § 423.4, to enrollees in LTC facilities in no greater than 14-day increments at a time. We modify § 423.154(a)(2) to collect and report information, in a form and manner specified by CMS, on the dispensing methodology used for each dispensing event described by paragraph (a)(1) of this section and on the quantity of unused brand and generic drugs, as defined in § 423.4. Reporting on unused brand and generic drugs is waived for Part D sponsors' when their pharmacies dispense both brand and generic drugs, as defined in § 423.4, in no greater than 7-day increments. We modify § 423.154(b) to exclude from the requirements under paragraph (a) of this section: (1) Solid oral doses of antibiotics; and (2) solid oral doses that are dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance (for example, oral contraceptives). We modify § 423.154(c) to include a waiver for I/T/U pharmacies. We modify § 423.154(d) to change the effective date from January 1, 2012 to January 1, 2013. We modify § 423.154(e) by eliminating the extension for certain pharmacies and adding a requirement that regardless of the number of incremental dispensing events, the total cost sharing for a Part D drug to which the dispensing requirements under this paragraph (a) apply must be no greater than the total cost sharing that would be imposed for such Part D drug if the requirements under paragraph (a) of this section did not apply. Finally, we modify § 423.154(f) by eliminating paragraph (f)(1) and combining paragraph (f)(2) with the introductory clause of paragraph (f).

12. Complaint System for Medicare Advantage Organizations and PDPs (§ 422.504 and § 423.505)

In our November 2010 proposed rule, we proposed to implement a new requirement under the authority of section 3311 of the ACA to require MA organizations and Part D sponsors to respond to complaints. Specifically, we proposed to require that MA organizations and Part D sponsors use our existing Health Plan Management System (HPMS) Complaints Tracking Module (CTM) to document the closure of complaints and provide a detailed complaint resolution summary when the complaint is resolved. That is, we proposed to require an MA organization or Part D sponsor to provide an explanation of the way in which the complaint was closed, rather than simply providing the words "complaint closed" in the CTM.

In our proposed rule, we proposed applying these requirements to both MA organizations and Part D sponsors ensure beneficiary access to medical services and drugs under the MA and Part D programs. We also indicated that we were considering adding a drop down checklist to CTM for MA organizations, and Part D sponsors to use as the documentation method when closing complaints, as opposed to requiring free text descriptions of complaint closure, and we invited comments on this approach.

As provided under section 3311 of ACA, we developed a model electronic complaint form on the Medicare.gov Internet Web site and on the Internet Web site of the Medicare Beneficiary Ombudsman. We proposed that plans be required to prominently display the CMS-developed complaint form on their Web site and directly link to the CMS Medicare.gov Web site and the Web site of the Medicare Ombudsman. As we explained in the proposed rule, when we completed our development of the model electronic complaint form was made available on the internet Web sites as in December 2010.

In our proposed rule, we stated the new requirement for plans to prominently display the electronic model on their Web sites would be effective January 1, 2012 and indicated that following the issuance of this final rule, we would be developing guidance to instruct MA organizations and Part D sponsors on how to comply with this new requirement.

Comment: We received a significant number of comments regarding our proposed requirement in § 422.405(a)(15)(i) and § 423.405(b)(22)(i) regarding the addition of a drop down checklist in CTM that would provide clear and consistent closure categories. Many commenters supported this proposed new requirement. Two commenters recommended that, in addition to the drop down menu, we include a text box for plans that desired to add comments about the resolution of complaints. These commenters believed that this modification would improve specificity of the responses. A few commenters requested that we define the term complaint in order that a complaint might be clearly distinguished from a grievance or an appeal.

Response: We appreciate the support expressed by the commenters. The purpose of the CTM system is to record and track complaints we receive from beneficiaries, provider, and others regarding Medicare health plans and prescription drug plans. While our current instructions to MA organizations and PDP sponsors indicate that when a complaint is resolved the plan should concisely summarize the complaint closure in CTM, we have found that many sponsors failed to do so. Rather, they have merely entered, "Complaint Closed" without any explanation of the action taken. After reviewing many complaint entries, we also discovered that "complaint closed" has often been used inappropriately. For example, it has been used when the sponsor has been unable to reach the beneficiary by phone, which alone does not constitute a reasonable basis for closing a complaint.

We agree with the commenters that a text box in addition to the drop-down menu in the CTM would be helpful for capturing information on the MA organization's or PDP sponsor's resolution of a complaint. Therefore, we are adding a text box to the complaint form. We will clarify in instructions that CMS and plan users must select at least one item in the drop down box or use the text box in CTM to resolve a complaint. Thus, the system will not permit the complaint to be resolved if at least one of the available options is not selected.

Regarding the commenters' request that we define a complaint, we note that the Frequently Asked Questions section of CTM describes the difference between a complaint and grievance. It states that grievances are received directly by the plan from beneficiaries and that plans are required to report

grievances to CMS per the Part D reporting requirements. CTM complaints, however, are received by CMS (through 1–800–Medicare call centers, phone calls to the CMS regional office, *etc.*) and are entered into CTM for resolution by either the plan or CMS. We require that plans track grievances separately from CTM complaints.

Comment: Many commenters supported our proposed requirements that MA organizations and PDP sponsors address and resolve all complaints in the CMS complaint tracking system and link to the electronic complaint form on the Medicare.gov and Internet Web site of the Medicare Ombudsman from each sponsor's main Web page. However, a few commenters expressed opposition to the requirement to link to the electronic complaint form, stating that a direct link on the plan's Web site could potentially discourage use of other plan resources available for issue resolution and confuse beneficiaries. One commenter suggested that, by imposing this requirement, we would create an additional administrative expense that would add little to enhance either the complaint resolution process or beneficiary satisfaction. Another commenter requested the opportunity to review and comment on the new electronic complaint form prior to its implementation.

Response: We appreciate the support commenters expressed for these requirements. Congress has directed the Secretary to annually report the number and types of complaints reported in CTM, any geographic variations that exist in the complaints, the timeliness of CMS' and the plan's responses, and the resolution of such complaints. Given the importance that Congress has placed on complaints and their resolution, it is important that we have reliable and complete data not only prepare our annual report to Congress, but also to monitor complaint resolution for oversight purposes.

We do not agree with those who claimed that having a direct link on the plan's Web site to the Medicare.gov Web site and the Web site of the Medicare Ombudsman would discourage use of plan resources for resolving issues, confuse beneficiaries or create additional administrative costs. It has been our experience that beneficiaries go directly to their MA organization or PDP sponsor with issues of concern, including complaints, prior to contacting CMS for assistance. We have no cause to believe that requiring sponsors to directly link to the Medicare.gov Web site and the Web site of the Medicare Ombudsman would alter the beneficiaries' practice of seeking to resolve their issues by first contacting their plan. We also do not believe that requiring a link from the sponsor's Web site to the Medicare Web sites will add significant administrative costs. Since the proposed requirement is similar to existing requirements regarding a plan's Web site, we expect that any costs related to this requirement are currently reflected in the organization's bid.

We appreciate the commenter's interest in commenting on the new electronic complaint form prior to its implementation, but as we noted previously, we have already posted the model electronic complaint form which is available at *https://www.medicare.gov/MedicareComplaintForm/home.aspx.*

For the reasons discussed previously, we are finalizing these requirements as proposed with an effective date of January 1, 2012 for the requirement that MA organizations and Part D plans create a link from their main Web page to the CMS-developed electronic complaint form on the *http://www.Medicare.gov* Web site.

13. Uniform Exceptions and Appeals Process for Prescription Drug Plans and MA–PD Plans (§ 423.128 and § 423.562)

Section 3312 of the ACA amends section 1860D–4(b)(3) of the Act by adding a new section (H) that requires, effective January 1, 2012, each PDP sponsor to use a single, uniform exceptions and appeals process (including, to the extent the Secretary determines feasible, a single uniform model form for use under such process) with respect to the determination of prescription drug coverage for an enrollee under the plan; and to provide instant access to such processes through a toll-free telephone number and an Internet Web site.

In accordance with the new section 1860D–4(b)(3)(H) of the Act, we proposed in the November 2010 proposed regulation to revise the regulation at § 423.562(a) to require Part D plans to use a single, uniform exceptions and appeals process that includes procedures for accepting oral and written requests for coverage determinations and redeterminations. In addition, we proposed to revise the regulation at § 423.128 paragraphs (b)(7) and (d) to identify specific mechanisms that plan sponsors must have in place in order to meet the uniform appeals requirements of section 1860D–4(b)(3)(H) of the Act. Most notably, at § 423.128(b)(7), we proposed adding paragraph (i) to require that plan sponsors make available a standard form to request a coverage determination and a standard form to request a redetermination, to the extent such standard request forms have been approved for use by CMS. (Note that in the context of appeals, the term "standard form" or "standardized form" is generally used to refer to a form that would be the only permissible vehicle for requesting a coverage determination or redetermination.)

Section 3312 of the ACA also requires plan sponsors to provide instant access to the coverage determination and appeals process through an internet Web site. Consistent with the requirement, we also proposed to add paragraph (ii) to § 423.128(b)(7), which would require sponsors to provide immediate access to the coverage determination and redetermination processes via an Internet Web site. We requested comments and ideas regarding how this should work and any issues that needed to be addressed before operationalizing this requirement. Section 3312 of the ACA also specifies that plan sponsors must establish a toll-free telephone line that provides instant access to the coverage determination and appeals processes. Because plan sponsors are currently required to offer a toll-free customer call center as part of the provision of information requirement at § 423.128(d), we proposed to revise § 423.128(d)(1) to include a requirement that sponsors provide enrollees with access to the coverage determination and redetermination processes through their toll-free customer call center.

To codify the proposals that plans make available standard forms for requesting coverage determinations and redeterminations (to the extent that standard request forms have been approved for use by CMS), and establish a toll-free telephone number and Web site for accepting requests for coverage determinations and redeterminations, we proposed to amend § 423.562 by adding a new paragraph (a)(1)(ii) which cross-references the requirements in § 423.128 paragraphs (b)(7) and (d)(1)(iii), and redesignating paragraphs (a)(1)(ii) and (a)(1)(iii) as paragraphs (a)(1)(iii) and (a)(1)(iv), respectively. Finally, we proposed that Part D sponsors modify their electronic response transactions to pharmacies so that they can transmit codes instructing the pharmacy to provide a standardized point-of-sale (POS) notice to enrollees when a prescription cannot be filled. Specifically, we proposed at § 423.128(b)(7)(iii) to require that Part D sponsors modify their systems so that the plan sponsors are capable of transmitting codes to their in-network

pharmacies and that the pharmacy will be notified to populate or provide a notice that can be printed by the pharmacist at the point of sale. We indicated that we would develop a model notice to ensure that messaging at the pharmacy is consistent with and in accordance with CMS rules. Consistent with this proposal, we also proposed to revise § 423.562(a)(3) by deleting the reference to posting the pharmacy notice and instead requiring the sponsor to arrange with its network pharmacies to distribute notices instructing enrollees how to contact their plans to obtain a coverage determination or request an exception if they disagree with the information provided by the pharmacist. We proposed that the pharmacy notice be provided in writing, consistent with the standards established in § 423.128(b)(7)(iii), and include instructions explaining how enrollees can request a coverage determination by calling their plan sponsor's toll free customer service line or accessing their plan sponsor's Web site.

Comment: We received a large number of comments on the merits of requiring the use of a standard form for requesting Part D exceptions and appeals. Several commenters expressed the belief that standard forms are not feasible, noting that a single form cannot accommodate the wide variations that exist among plan formulary and utilization management requirements, and would therefore hinder access to the exceptions and appeals processes. Some commenters stated that, particularly for biotech or other specialty drugs, drug-specific forms improve access to coverage because they give enrollees and prescribers clearer information on the specific plan requirements for coverage. Other commenters asserted that a single form would simplify the processes for enrollees, prescribers and plans.

Response: We have carefully considered all the comments we received on this issue, both in the context of the overarching statutory requirement that Part D plans use a "single, uniform exceptions and appeals process" as well as keeping in mind the requirements and procedures that are already in place with respect to requests for coverage determinations and appeals. (Note that, as set forth in detail in the existing regulations at § 423.578, the term "exception" refers to certain types of coverage determinations, such as a request for a non-formulary drug, that require an oral or written supporting statement from a prescribing physician or other prescriber.)

Our current regulations permit either written or oral requests for a coverage determination (§ 423.568), with the exception of requests for payment, which must be made in writing unless the sponsor has a voluntary policy of accepting oral payment requests. Standard redetermination requests generally are made in writing, under § 423.582; plans may also accept oral requests for standard redeterminations but are not required to do so. Plans must accept oral requests for expedited redeterminations (§ 423.584). Currently, we have developed model forms for requesting a coverage determination—one for beneficiaries and one for prescribers—but there are no comparable model forms for requesting redeterminations. It is also important to note that our existing subregulatory guidance specifies that *any written request* from an enrollee or prescriber is acceptable, and that plans may not require an enrollee or prescriber to make a written request on a specific form (see Section 40 of Chapter 18 of the Prescription Drug Benefit Manual, Part D Enrollee Grievances, Coverage Determinations and Appeals). We believe that the requirement that plans accept any written request builds significant enrollee protection into the coverage determination and appeals processes, and requiring the use of a "standard" form may inadvertently create barriers for enrollees accessing these processes. Thus, introducing a requirement that a standard form be used could actually conflict with the underlying statutory intent of the new provisions which are meant to enhance enrollee access to the exceptions and appeals processes.

Therefore, we are modifying the proposed regulatory language at § 423.128(b)(7)(i) by replacing the proposed reference to a "standard" form with the statutory language referencing use of a "uniform model form." In support of this requirement, we will work with plans, prescribers, and beneficiary advocates to revise the existing model coverage determination request form, including combining the existing enrollee and prescriber request forms into a single model form. We will also develop a separate model redetermination request form for use by enrollees and their prescribers and representatives. Plans will be required to make these model forms available to their enrollees via their websites, and to include the model redetermination request form with any coverage determination denial notice, consistent with the requirement under § 423.568(g)(4) that denial notices comply with notice requirements established by CMS.

The introduction of uniform model forms is not intended to interfere with the current requirements regarding acceptance of oral or written requests, nor does it preclude plans from developing and making available drug-specific coverage determination request forms to supplement the model forms to the extent such forms can enhance access to the exceptions and appeals process. Given that plan formularies, utilization management tools and step therapy requirements can vary widely, we believe that not allowing plans to continue making drug-specific forms available or precluding enrollees from making coverage determination requests through other written vehicles, may actually delay decision-making and/or result in additional unfavorable decisions based on a lack of adequate documentation. Thus, although we acknowledge that making multiple forms available for use may cause some confusion for enrollees, we believe that continuing to permit such variation is in the best interests of Medicare beneficiaries. Plans must comply with the appropriate marketing procedures for approval of forms, including CMS-approved model forms.

Comment: A few commenters noted that adopting a single form for both coverage determinations and redeterminations could lead to confusion and erroneous or unnecessary submissions from enrollees and prescribers because of the often-different rationales and necessary supporting documentation for these processes. This in turn would increase the burden on both enrollees and prescribers and cause delays in accessing prescription drugs.

Response: We agree with the commenters, and as stated previously, intend to develop separate model forms for coverage determinations and redeterminations.

Comment: We received a number of comments with recommendations that CMS work closely with stakeholders in developing standard forms. Some commenters also supported consumer testing and/or piloting standard forms before full implementation.

Response: We thank the commenters for their suggestions. As noted previously, rather than require a standard form, we intend to revise the existing model coverage determination form and develop a new model redetermination form. Stakeholders will have an opportunity to comment on draft versions of these forms via the same process used to solicit stakeholder input on changes to manual guidance.

Comment: Several commenters urged CMS to require that all plan sponsors make standard forms available in multiple languages and make them widely available in plan materials and on plan Web sites.

Response: The regulations in Subpart V of Part 423, and related subregulatory guidance, establish CMS' marketing rules with respect to translated materials. Model coverage determination and redetermination notices are considered post-enrollment marketing materials, and therefore must be translated in accordance with CMS marketing requirements, consistent with the related discussion above.

Comment: Although several commenters were supportive of the proposal related to providing instant access to the coverage determination and appeals process via an internet Web site, many commenters raised concerns about the administrative and technological burdens and costs associated with the development of a Web-based interface that would allow enrollees to access the coverage determination and appeals processes. Several commenters thought that the benefit to enrollees will be minimal compared with the additional costs and operational complexities. These commenters also claimed that plans will not be able to fully realize potential cost-savings in using such a system if they are also required to maintain processes for accepting requests via telephone and mail. CMS also received comments suggesting a pilot program, greater stakeholder input, delayed implementation, and making acceptance of electronic requests optional.

Almost all commenters, whether they opposed or supported the proposal, raised questions about systems specifications and functionality, including whether plan systems for accepting electronic requests must: (1) Accept electronic attachments such as clinical documentation, prescriber supporting statements, enrollee receipts for out-of-pocket expenses, and Appointment of Representative (AOR) forms or, alternatively, be equipped to generate a bar code or other receipt to allow for the separate submission of supporting documents via fax; (2) generate an auto-reply acknowledging receipt of the request; (3) have a user authentication feature; and (4) include mandatory fields or other specifications (for example, font type/size).

Response: As noted in the proposed rule, section 3312 of the ACA states that Part D plan sponsors shall provide instant access to the coverage determination (including exceptions) and appeals processes through an Internet Web site. In the proposed rule, we solicited comments on the viability of a Web-based electronic interface that would allow an enrollee (or an enrollee's prescriber or representative) to immediately request a coverage determination or redetermination via a plan's secure Web site. Our proposal indicated that the interface would be the "electronic equivalent" of the paper coverage determination and appeals forms proposed at § 423.128(b)(7)(i). The proposed rule described a system that would provide some level of interactive functionality on a plan's Web site, such as the ability to populate and submit an online request form.

However, after reviewing all of the comments on this provision, we agree that requiring plans to develop an interactive Web-based system by the 2012 plan year would impose significant costs and operational difficulties on many Part D plans. Therefore, although we are finalizing the regulatory language as proposed, we are clarifying that "immediate access" to the coverage determination and appeals processes can be satisfied through a variety of means. We strongly encourage plans to establish interactive, web-based systems to meet this requirement. At a minimum, however, plans must have a process for allowing an enrollee to initiate a coverage determination or appeal request by sending a secure e-mail to an e-mail address that is prominently displayed on the plan's Web site. In response to such requests, plans must provide notice of decisions in a timely manner, consistent with all existing requirements in Subpart M of our regulations. We believe that this approach takes into consideration the plans' differing technological capabilities, while implementing the statutory requirement that plans provide access to the coverage determination and appeals processes via plan Web sites. Although plans that have the capability to deploy a more robust and sophisticated Web-based system are encouraged to do so, we do not intend to specify systems functionality for plan Web sites, beyond the requirement that an enrollee (and an enrollee's prescriber or representative) be able to initiate a request by sending a secure e-mail via the plan's Web site.

Finally, we note that enrollees (and their prescribers and representatives) will retain the right to make requests for oral coverage determinations and expedited appeals which serve as another means of obtaining instant access to the coverage determination and appeals processes.

Comment: We received some comments regarding the requirement that plans provide immediate access to the coverage determination and redetermination processes through a toll-free phone number. Commenters opposed to this requirement indicated that maintaining a toll-free line creates an undue burden on plans, provides minimal benefit to enrollees and increases confusion among enrollees. These commenters also requested a delayed implementation date. Commenters who support the proposed requirement requested that CMS require plans to disseminate the toll-free number and related information widely in plan materials, and support stakeholder input in the development of model scripts for customer service representatives (CSRs) who staff these toll-free lines.

Response: The existing regulations at § 423.128(d)(1) already require plan sponsors to maintain a toll-free customer call center, and existing subregulatory marketing guidance clarifies applicable call center coverage requirements for coverage determinations and redeterminations. The proposed change we intend to finalize adds the requirement that plans provide immediate access to the coverage determination and redetermination processes through their toll-free customer call centers. If using an existing toll-free number for receiving and processing oral coverage determination and appeals requests could potentially cause delays and/or missed time frames, plans may establish a dedicated toll-free customer service line for receiving these requests. We note that plans are currently required under § 423.568(a) and § 423.570(b) respectively, to accept oral requests for both standard coverage determinations (excluding reimbursement requests) and expedited coverage determinations, and under § 423.584(b), to accept oral requests for expedited redeterminations. In the proposed rule, we noted that a CSR could potentially access the plan's web-based application for coverage determinations and appeals and enter information supplied by the enrollee via telephone. However, as discussed previously, we are scaling back our expectations with respect to plan capabilities for having an interactive web-based application for coverage determinations and appeals. As such, we expect that plans will continue to utilize existing mechanisms for receiving and processing oral coverage determination and appeal requests, including those received outside normal business hours. Requests made through the toll-free number would still be subject to existing processing guidelines

and timeframes outlined in Subpart M of the regulations.

Comment: Several comments were received regarding the proposed requirement that Part D sponsors revise their payment systems to notify network pharmacies that they need to generate a printed notice containing information for enrollees about how to contact their plan to request a coverage determination, including an exception, when a prescription cannot be filled as written. Commenters indicated that because the POS notice would not provide enrollees with any more information than what is already provided on their member ID cards, it is an undue burden on pharmacies, and is not "green."

Response: We disagree with the commenters' concerns regarding the lack of utility in the distribution of a POS notice. Other commenters have expressed concern that enrollees are not aware of their right to request a coverage determination and that having the notice posted at the pharmacy counter is only useful to the extent the enrollee is directed to it by his/her pharmacist.

We also do not agree that the distribution of the POS notice is an additional burden on pharmacies. It is likely the POS notice will relieve pharmacy staff from being queried by enrollees as to why their prescriptions could not be filled as written, because the notice refers the enrollee directly to their plan to obtain a coverage determination. Furthermore, we believe that eliminating the current option of directing enrollees to a posted notice and requiring that they receive a printed notice strengthens enrollee access to the coverage determination process because the enrollee will leave the pharmacy with printed instructions about contacting the plan to request a coverage determination.

Comment: Several of the comments regarding the proposed requirement to distribute POS notices incorrectly referred to the POS transaction at the pharmacy counter as a denial of prescription drug coverage (an adverse coverage determination).

Response: We reiterate our position in previous rulemaking and existing subregulatory guidance that plan sponsors are not required to treat the presentation of a prescription at the pharmacy counter as a request for coverage determination. Accordingly, the plan sponsor is not required to provide the enrollee with a written denial notice at the pharmacy as a result of the transaction.

Comment: Several commenters supported the requirement that a POS notice be distributed at the pharmacy, but stated that the notice should be tailored to each individual's situation, including a description of why the prescription could not be filled as written.

Response: We agree it would be useful for enrollees to have additional information such as the name of the drug and the specific reason(s) the prescription cannot be filled as written as part of the POS notice. However, such situation-specific messaging cannot be generated at this time. Until we have the opportunity to work with the industry, specifically the National Council of Prescription Drug Programs (NCPDP), to develop and standardize codes that will assist Part D sponsors, processors and pharmacies with generating this kind of information as part of the transaction, we cannot require Part D sponsors or their processors to code their systems to generate such a notice.

We are finalizing the proposed language in § 423.128(b)(7) and § 423.562, with the modifications to § 423.128(b)(7)(i) described previously. Consistent with section 3312 of the ACA, these new requirements will be effective January 1, 2012.

14. Including Costs Incurred by AIDS Drug Assistance Programs (ADAPs) and the Indian Health Service Toward the Annual Part D Out-of-Pocket Threshold (§ 423.100 and § 423.464)

Section 1860D–2(b)(4)(C) of the Act provides protection against high out-of-pocket expenditures for Part D eligible individuals. Under the standard Part D benefit, a beneficiary is entitled to reductions in cost sharing under the catastrophic phase of the benefit once his or her true out-of-pocket (TrOOP) expenditures reach the annual Part D out-of-pocket threshold. Prior to enactment of the ACA, TrOOP expenditures represented costs actually paid by the beneficiary, another person on behalf of the beneficiary, or a qualified State Pharmaceutical Assistance Program (SPAP).

Thus, prior to the passage of the ACA, supplemental drug coverage provided by the Indian Health Service (IHS), Indian tribes and organizations, and urban Indian organization facilities (as defined in section 4 of the Indian Health Care Improvement Act) were not considered to be TrOOP eligible because these entities fell under our definition of "government-funded health program," under § 423.100. Similarly, the Health Resources and Services Administration (HRSA) Ryan White HIV/AIDS Program-funded AIDS Drug Assistance Programs (ADAPs) cost sharing were not counted toward TrOOP for the purpose of meeting the out-of-pocket threshold at which catastrophic coverage under the Part D benefit begins. As explained in the preamble in the January 2005 final rule (see 70 FR 4240 and 4241) implementing the Part D program, ADAPs were not considered SPAPs because these programs received Federal funding. With the passage of the ACA, CMS regulations, as they relate to IHS/Tribes and ADAPs, have been superseded effective January 1, 2011. Section 3314 of the ACA amends section 1860D–2(b)(4)(C) of the Act to specify that costs borne or paid for by IHS, an Indian tribe or tribal organization, or an urban Indian organization, and costs borne or paid for by an ADAP will be treated as incurred costs for the purpose of meeting the annual out-of-pocket threshold. Based on these amendments, we proposed to revise the definition of incurred cost at § 423.100(2)(ii) to include payments by the IHS (as defined in section 4 of the Indian Health Care Improvement Act), an Indian tribe or tribal organization, or an urban Indian organization (referred to as I/T/U pharmacy in § 423.100) or under an AIDS Drug Assistance Program (as defined in part B of title XXVI of the Public Health Service). We also proposed to amend § 423.464(f)(2) to specifically exclude expenditures made by IHS, an Indian tribe or tribal organization, or an urban Indian organization (referred to as I/T/U pharmacy in § 423.100) or under an AIDS Drug Assistance Program (as defined in part B of title XXVI of the Public Health Service) from the requirement to exclude such expenditures for the purpose of determining whether a Part D enrollee has satisfied the out-of-pocket threshold.

Comment: We received a comment requesting that CMS revise regulations at § 423.100 and § 423.464(f)(2) to reference section 4 of the Indian Health Care Improvement Act in the parenthetical following the phrase "urban Indian organization," and replace the term "payments" in § 423.464(f)(2) with the phrase "costs borne or paid by" to more closely track the statutory language provided in 3314 of ACA.

Response: We agree with this comment and revise the regulation text at § 423.100 to reference section 4 of the Indian Health Care Improvement Act. In addition, in response to this comment and to avoid confusion, we are removing the redundant reference to ADAPs and IHS/tribes/tribal organizations in § 423.464(f)(2)(i)(B). Because costs borne or paid by these organizations already are included in the definition of "incurred costs" as

referenced in § 423.464(f)(2)(i)(A), they need not be expressly referenced in § 423.464(f)(2)(i)(B). We also revised § 423.100(2)(ii) to remove the cross reference to § 423.464.

Comment: Another commenter requests that CMS provide a list of ADAP BINs (bank identification numbers)/PCNs (processor control numbers) to ensure proper TrOOP calculation for ADAP members by the Part D sponsor.

Response: Both CMS and the Health Resources and Services Administration (HRSA) have provided training and assistance to ADAP grantees about CMS' coordination of benefits (COB) data exchange process and its relationship to the member's TrOOP calculation. Participation in this process will allow ADAPs to provide the BIN and PCN directly to CMS' COB contractor, who will then identify ADAPs as TrOOP-eligible payers as part of transactions sent from our TrOOP facilitator to Part D sponsors.

Except for the technical amendments to the proposed regulations text noted previously, we are finalizing the regulation as proposed.

15. Cost Sharing for Medicare-Covered Preventive Services (§ 417.454 and § 422.100)

Effective January 1, 2011, sections 4103 and 4104 of the ACA revised sections 1833 and 1861 of the Act to create new coverage of Personalized Prevention Plan Services (PPPS) or "annual wellness visits" and establish a requirement that no cost sharing may be charged to beneficiaries under Original Medicare for the annual wellness visit, the initial preventive physical exam (IPPE) and Medicare-covered preventive services graded as an A or B by the U.S. Preventive Services Task Force (USPSTF).

In light of the new legislative requirements for Original Medicare, and the importance of preventive services in managed and coordinated care, we included information related to coverage and cost sharing for preventive services in guidance issued via the Health Plan Management System (HPMS) on April 16, 2010 ("Benefits Policy and Operations Guidance Regarding Bid Submissions; Duplicative and Low Enrollment Plans; Cost Sharing Standards; General Benefits Policy Issues; and Plan Benefits Package (PBP) Reminders for Contract Year (CY) 2011") and May 20, 2010 ("Supplemental 2011 Benefits Policy and Operations Guidance on Application of the Mandatory Maximum Out-of-Pocket (MOOP) for Dual Eligible SNPs, and Cost Sharing for Preventive Services"). In this guidance, we strongly encouraged MA organizations to provide all in-network Medicare-covered preventive services without cost sharing charges under their MA plans in contract year 2011, indicated our intention to consider rulemaking to require that such preventive services be provided with no cost sharing, and provided instructions on how to reflect the zero cost sharing in their plan benefit package (PBP) submissions for contract year 2011.

As required at section 1852(a)(1)(A) of the Act (except as provided in section 1859(b)(3) of the Act for MSA plans and in section 1852(a)(6) of the Act for MA regional plans), each MA plan must provide to its members all Parts A and B benefits included under the Original Medicare fee-for-service program as defined at section 1852(a)(1)(B) of the Act. We agree that the utilization of preventive services should be encouraged by providing such services without cost sharing. Therefore, we believe it is necessary, and appropriate, to provide this same incentive to all Medicare beneficiaries, whether they receive their benefits through Original Medicare, under an MA plan, or under a section 1876 cost contract.

Therefore, under our authority in section 1856(b)(1) of the Act to establish MA standards by regulation, and our authority in section 1857(e)(1) of the Act to establish requirements we find "necessary and appropriate," we proposed to add a new paragraph (k) to § 422.100, and under our authority in section 1876(i)(3)(D) of the Act to impose "other terms and conditions" deemed "necessary and appropriate," new paragraph (f) to § 417.101, to require MA organizations and section 1876 cost plans to provide in-network Medicare-covered preventive benefits at zero cost sharing, consistent with the new regulations for Original Medicare-covered preventive benefits.

For specific information about the list of preventive services covered under Original Medicare without cost sharing and information about what is included in the annual wellness visit, we directed plans to go to the following Medicare Web sites: *https://www.cms.HospitalOPPS/* and *http://www.cms.gov/PhysicianFeeSched/*.

Comment: Commenters expressed their support for our proposal to require MA organizations and section 1876 cost plans to provide in-network Medicare-covered preventive benefits at zero cost sharing, consistent with the new regulations for Original Medicare-covered preventive benefits. Some of those commenters also requested that CMS clarify that only in-network preventive services will be required to have zero cost sharing and that MA plans will be required to cover the same preventive services at zero cost sharing as are provided under Original Medicare without cost sharing.

Response: We thank the commenters for their support. We clarify that the preventive services to be provided by MA plans without cost sharing are those provided in-network and that they are to be the same services that are covered under Original Medicare with zero cost sharing and will take into consideration the commenters' concerns as we move forward with other guidance and educational materials.

Comment: We received one comment requesting that we extend the requirement for preventive services' zero cost sharing to out-of-network settings. The commenter believes that because preventive services are so important for beneficiary health CMS should provide equal access to them no matter where the beneficiary receives them.

Response: Our policy for cost sharing is limited to in-network Medicare parts A and B services and we made no proposal to change that policy. Furthermore, we believe that the nature of the specified preventive services is such that there is not a need for beneficiaries to have the same access to them out-of-network as is provided in-network. We believe that the services are most beneficial to an enrollee when provided in-network because communication among the enrollee's providers is an integral part of a successful prevention plan. By receiving in-network preventive services the enrollee's needs for any follow-on services will be identified and furnished and this is less likely to occur if individual preventive services are received elsewhere.

Comment: We received a comment expressing concern that some of the policies related to implementation of zero cost sharing for Medicare-covered preventive benefits would create beneficiary confusion on specific elements and that such confusion would lead to complaints that could have an impact on plans' quality bonus payments.

Response: We appreciate the commenter's concern and going forward, we will continue to make every effort to educate beneficiaries and providers about the services and situations in which zero cost sharing applies.

Comment: We received a few comments requesting that additional services be included as Medicare-

covered preventive services with zero cost sharing.

Response: We thank the commenters for their suggestions but they are beyond the scope of this proposed rule.

Comment: Two commenters objected to our codification in the proposed rule of our proposal to extend the requirement for plans to charge zero cost sharing for CMS-specified in-network preventive services to section 1876 cost plans by adding new paragraph (f) to § 417.101, which otherwise does not govern cost plans. The commenters suggested that instead we may want to propose to add a new paragraph to § 417.454, Charges to Medicare Enrollees.

Response: We thank the commenters for alerting us to this codification issue. In this final rule, we will not make a change to § 417.101 and will instead add new paragraph (d) to § 417.454 to require that no cost sharing may be charged by section 1876 cost plans for CMS-specified in-network preventive services.

We have considered all of the comments received on this proposal and will finalize our proposed policy to amend § 422.100 by adding new paragraph (k) to require that there be no cost sharing for in-network Medicare-covered preventive services, as specified by CMS annually. In addition, we are adding new paragraph (d) to § 417.454 as previously specified.

16. Elimination of the Stabilization Fund (§ 422.458)

Section 221(c) of the MMA added section 1858 of the Act to establish rules for MA Regional Plans. Section 1858(e) established an MA Regional Plan Stabilization Fund (the Fund) for the purpose of providing financial incentives to MA organizations that offered new MA Regional Plans nationally, or in each MA region without one.

Section 10327(c) of the ACA repealed section 1858(e) of the Act, eliminating the Stabilization Fund. Therefore, we proposed to delete paragraph (f) from § 422.458, since the statutory basis for the Fund no longer exists. We received no comments on this proposal and therefore are finalizing this provision without modification. We are also adopting § 422.258(f) as proposed in this final rule.

17. Improvements to Medication Therapy Management Programs (§ 423.153)

As required by section 1860D–4(c)(1)(C) of the Act, Part D sponsors must establish Medication Therapy Management Programs (MTMPs). Section 1860D–4(c)(2) of the Act requires MTMPs to be designed to ensure that, with respect to targeted beneficiaries described in section 1860D–4(c)(2)(A)(ii) of the Act, covered Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events. As noted in our November 2010 proposed rule, these requirements are codified in § 423.153(d) of the Part D regulations.

Effective January 1, 2013, section 10328 of the ACA amends section 1860D–4(c)(2) of the Act to require prescription drug plan sponsors to perform a quarterly assessment of all "at risk" individuals who are not already enrolled in an MTMP, establish opt-out enrollment for MTM, and offer medication therapy management services to targeted beneficiaries. These MTM services must include, at a minimum, an annual comprehensive medication review (CMR) that may be furnished person-to-person or via telehealth technologies and a review of the individual's medications, which may result in the creation of a recommended medication action plan, with a written or printed summary of the results of the review provided to the targeted individual. The law also requires that the action plan and summary resulting from the CMR be written in a standardized format.

In our November 2010 proposed rule, we noted that prior to the passage of the new legislation, we had already made several improvements to the MTM program. We also indicated that in comparing the requirements in section 10328 of the ACA to those codified in the April 2011 final rule containing policy and technical changes under the Part C and Part D programs (see 75 FR 19772 through 19776 and 19818 and 19819), we found that a number of the provisions are consistent. Specifically, the April 2011 final rule requires the use of an opt-out method of enrollment for targeted beneficiaries, an annual comprehensive medication review (CMR) with a written summary, quarterly targeting of beneficiaries for enrollment into the MTMP, and quarterly targeted medication reviews for individuals enrolled in the MTMP with follow-up interventions when necessary. However, to ensure that our policies are fully consistent with the new requirements added by section 10328 of the ACA, we proposed to amend the current regulations to clarify the Part D MTMP requirements relating to the required use of a standardized format for the written summary and action plan that may result from the CMR. Thus, in our November 2010 proposed rule, we proposed to amend § 423.153(d)(1)(vii) to add the requirement that Part D sponsors use a standardized format for the action plan and summary resulting from a review of the targeted beneficiary's individual medications, and to provide the individual with a written or printed copy of the summary. We also noted our plan to award a contract to an outside entity, pending the availability of funding, to work in consultation with stakeholders in order to develop a standardized format for the action plan and summary which may result from annual or quarterly targeted medication reviews.

In our November 2010 proposed rule, we also proposed to amend the MTMP requirements at § 423.153(d)(1)(vii) to explicitly permit the use of telehealth technologies to conduct the required annual CMR as referenced under the ACA, to allow the sponsors to attempt innovative techniques that provide care at a distance in order to better serve the beneficiary, especially beneficiaries who cannot travel to the provider's location, or who reside in a remote location or in a different time zone. We emphasized as well that when using telehealth technologies, personal health information privacy and security must be ensured. This would involve the establishment of appropriate administrative, technical, and physical safeguards to protect the confidentiality of data and to prevent unauthorized use of, or access to, it. The safeguards must provide a level and scope of security that is not less than the level and scope of security requirements established by the Office of Management and Budget (OMB) in OMB Circular No. A–130, Appendix III—Security of Federal Automated Information Systems) as well as Federal Information Processing Standard 200 entitled "Minimum Security Requirements for Federal Information and Information Systems"; and Special Publication 800–53 "Recommended Security Controls for Federal Information Systems." The use of unsecured telecommunications, including the Internet, to transmit individually identifiable information would, therefore, be prohibited.

In addition to the proposed regulatory changes required to implement the ACA provisions, in our November 2010 proposed rule, we proposed to amend the MTMP requirements related specifically to MTM services furnished in LTC facilities. As provided under sections 1819(b)(4) and 1919(b)(4) of the Act, LTC facilities must provide, either directly or under arrangements with others, for the provision of pharmaceutical services to meet the

needs of each resident. In our November 2010 proposed rule, we noted this requirement is codified in regulations at § 483.60 which require LTC facilities to employ or obtain the services of a licensed pharmacist to provide consultation on all aspects of the provision of pharmacy services in the facility, including a drug regimen review at least once a month for each facility resident. We stated further that, although Part D sponsors are required to provide MTM services to all beneficiaries meeting the target criteria, it is not clear that these services are being made available to nursing home residents meeting these criteria. We noted our concern that if MTM is provided, in the absence of coordination, the MTMP and the consultant pharmacist's drug regimen review could result in conflicting recommendations relating to medication management. Therefore, we proposed to amend § 423.153(d)(5) to require Part D sponsors to contract with LTC facilities to provide appropriate MTM services to residents in coordination with the monthly medication reviews and assessments performed by the LTC consultant pharmacist. We expressed our belief that this approach would enable beneficiaries to receive the full benefits of the sponsor's MTMP and would also result in coordinated assessments that would be more likely to discover evidence of adverse side effects and medication overuse, and solicited comments from the public on how such coordination between sponsors and LTC facilities might work best.

Comment: One commenter noted that much evidence has been provided over the years indicating the superior results of face-to-face encounters between patients and health care providers and asked that the regulation specifically identify pharmacists as face-to-face providers.

Response: While we recognize that some MTM providers may prefer face-to-face encounters, section 1860D–4(c)(2)(C) of the Act requires the annual comprehensive medication reviews include either an interactive person-to-person or telehealth consultation. We believe that, given the variability of beneficiary circumstances and needs and the advances in technology such as telehealth, it is important that MTM providers take advantage of this flexibility in the methods of delivery of MTM services in order to maximize beneficiary access to these services. We note further that the proposed regulation at § 423.153(d)(1)(vii)(B) specifies that the annual comprehensive medication reviews must be performed by a pharmacist or other qualified provider. We will retain this requirement in the final rule.

Comment: Several commenters expressed strong support for the use of telehealth technologies in conducting CMRs; one commenter emphasized the importance of face-to-face counseling in the MTM context; and another commenter opposed the use of remote MTM for long term care (LTC) beneficiaries. This latter commenter noted that many LTC residents have cognitive impairments and, thus, will rarely be able to interact with, or respond to, MTM services.

Response: We appreciate the support commenters expressed for the use of telehealth technologies for CMRs, but note that use of these technologies is an option. The ACA amended section 1860D–4(c)(2) of the Act to require an annual CMR "furnished person-to-person *or using telehealth technologies*" (emphasis added). We agree that the use of telehealth technologies for conducting CMRs may not be appropriate for all beneficiaries. We also recognize and agree with the commenter that beneficiaries residing in LTC facilities who have cognitive impairments may be unable to participate in an interactive CMR. The current regulations at § 423.153(d)(1)(vii)(B) reflect this awareness by exempting sponsors from offering interactive CMRs to targeted beneficiaries in LTC settings. The Act, as amended by section 10328 of ACA, does not provide a basis for distinguishing the offering of MTM services based on setting. Since the ACA requirements are not effective until January 2013, we will undertake additional rulemaking to further amend the current regulations at § 423.153(d)(1)(vii)(B) to clarify the requirement for MTM programs to offer CMRs to targeted beneficiaries in LTC settings.

Comment: One commenter recommended that we ensure that when MTM services are provided by individuals who are not pharmacists and who have not received the extensive training in medications that a pharmacist receives, these individuals are qualified to provide MTM consultations.

Response: We are not aware of consensus within the industry regarding the qualifications necessary to provide MTM consultations. As a result, we are not prepared at this time to establish requirements regarding MTM provider qualifications. However, we may perhaps do so in the future and would welcome information to assist us in defining the qualifications.

Comment: Numerous commenters expressed support for a standardized format for the written summary and action plan resulting from an annual comprehensive medication review CMR). One commenter applauded our plan to work with stakeholders to develop the standardized formats. Another commenter asked how the stakeholders who would be included in the development of the standardized formats would be determined. Several more commenters recommended we consider input from all industry stakeholders, including plan sponsors, PBMs, pharmacy organizations, and current MTM providers. Two commenters expressed an interest in working on the development and testing of the formats. Two commenters noted that there may be substantial administrative costs associated with implementing these new standardized documents and recommended that we issue the formats in draft for comment and carefully review the comments received to minimize the implementation costs and burden.

Response: We appreciate the support as well as the interest expressed by commenters in participating in the development process and we agree with the recommendation to provide opportunity for the industry to review and comment on the draft formats. The statute specifies that the standardized formats for the action plan and summary will be developed in consultation with relevant stakeholders. It is our intention to examine existing model summaries and action plans in current use and to create draft formats based on the existing models. We have already begun to solicit copies of the existing models in use today and are in the process of reviewing the documents received in response to our request. Once the draft standardized formats have been developed, we will issue them for industry review and comment. We will consider the input from all stakeholders and revise the draft standardized formats based on the comments received. Additional opportunities for public review and comment will be available as the revised formats undergo the OMB approval process required by the Paperwork Reduction Act (PRA). We believe our plan for developing the standardized formats by offering multiple opportunities for public review and comment will be adequate to permit all relevant stakeholders to provide input. We will carefully consider the comments received at all points in the process to ensure that the standardized

formats do not present an undue implementation burden.

Comment: Several commenters suggested that the standardized formats should be limited and offer adequate flexibility for plan sponsors to tailor the summaries and action plans to meet the needs of beneficiaries, caregivers, and plan sponsors.

Response: As we interpret the statute, Congress asked for standardized formats. Therefore, although the specific content of the summary or action plan will be tailored to the beneficiary, there will not be much variability in the style, organization, and general appearance of these documents.

Comment: Two commenters noted that, with the exception of correcting his or her non-adherence, a beneficiary cannot make medication changes without a prescriber's intervention and, as a result, suggested that a copy of the CMR summary also should be provided to all the beneficiary's prescribers that are known to the plan.

Response: We believe the results of the medication review should be shared with the prescribing physicians as necessary, based on the professional judgment of the reviewer and needs of the beneficiary. In our view, mandating that review summaries are always sent to all prescribers would add unnecessary administrative burden and cost.

Comment: One commenter questioned whether the standardized format would require sponsors to use vendor software. This commenter also asked when the standardized formats would be available and if the formats would be required for the targeted medication reviews (TMRs) or only CMRs.

Response: Use of the standardized summary and action plan formats will not require sponsors to use a specific vendor's software. As noted previously, we expect to create draft formats based on existing models and issue the draft for review and comment. Since we have already begun the process of examining some of the existing models in use today, we hope to have a draft available for review within the next few months. With regard to the required use of the formats, the ACA amended section 1860D–4(c)(2) of the Act to require that a CMR include the provision of a written or printed summary and may also result in the creation of an action plan. The statute expressly required the development of standardized formats for summaries and action plans that are provided as part of the CMR. However, we would encourage plans to use these formats for TMRs as well.

Comment: One commenter requested that we define telehealth.

Response: Section 1860D–4(c)(2) of the Act states that an annual CMR must be "* * * furnished person-to-person or using telehealth technologies (as defined by the Secretary) * * *" The U.S. Department of Health and Human Services' Office of the National Coordinator for Health Information Technology (ONC) defines telehealth as "the use of telecommunications technologies to deliver health-related services and information that support patient care, administrative activities and health education. The technology is a means to improve access to care, while reducing cost of transportation and increasing convenience to patients care." This definition is available on the ONC Web site at *http://healthit.hhs.gov/portal/server.pt?open=512&objID=1224&parentname=CommunityPage&parentid=27&mode=2&in_hi_userid=11113&cached=true.*

The ONC Web site also includes descriptions of various telehealth applications that may be considered for performing a CMR, including for example—

- Live videoconferencing: Audio and video feeds used to connect two or more geographically dispersed health care facilities to enable patients and physicians to consult in real time; and
- E-visits/e-consults: Evolved from secure email or phone based encounters, e-visits can be offered by health insurers through a secure Web portal.

Whatever telehealth technology is used for the CMR, it must enable the MTM provider to perform an interactive consultation with the targeted beneficiary.

Comment: A few commenters suggested that we monitor the outcomes and methods for conducting CMRs, including tracking the technology used and outcomes for various telehealth technologies.

Response: We agree that it is important to evaluate outcomes and identify best practices in MTM, including possibly the use of telehealth technologies. We will consider such monitoring in the future.

Comment: A few commenters strongly supported our proposed requirement to coordinate MTM with LTC consultant pharmacist evaluation and monitoring. A large number of commenters, however, expressed concerns regarding the proposed requirement for Part D sponsors to contract with all the LTC facilities in which their Part D enrollees reside and many offered alternative contracting arrangements or approaches for ensuring that LTC beneficiaries receive the benefits of the sponsor's MTM program and that evidence of adverse side effects or medication overuse is discovered and addressed. Several commenters suggested we delay implementation and work with industry stakeholders to identify and evaluate alternatives.

Response: We appreciate the support expressed for our proposed requirement, but we also agree that there may be a less burdensome approach for achieving our goal. Therefore, we are not finalizing the proposed requirement in § 423.153(d)(5) and will work with stakeholders to develop an alternate proposal. We thank the many commenters who suggested alternative arrangements and will consider these recommendations as we seek to identify the best approach for coordinating MTM and LTC consultant pharmacist monitoring.

Based on the comments received, we are finalizing this provision with the amendments previously noted. This provision will be effective January 1, 2013.

18. Changes To Close the Part D Coverage Gap (§ 423.104 and § 423.884)

In our November 2010 proposed rule, we noted that paragraphs (b)(3) and (d) of section 1101 of the ACA amended section 1860D–2(b) of the Act by adding provisions that revise the Part D benefit structure to close the gap in coverage that occurs between the initial coverage limit for the year and the out-of-pocket threshold. We noted that the new provisions not only will revise the amount of coinsurance for costs of covered drugs above the initial coverage limit and below the out-of-pocket threshold (that is, within the Part D coverage gap) for applicable beneficiaries, but also will reduce the growth in the annual out-of-pocket threshold from 2014 to 2019.

As stipulated under the new provisions in section 1860D–2(b)(2)(C) and (D) of the Act, effective January 1, 2011, cost sharing in the coverage gap for "applicable beneficiaries" will be determined on the basis of whether the covered Part D drug is considered an "applicable drug" under the Medicare coverage gap discount program as defined at section 1860D–14A(g)(2). Section 1860D–14A(g)(2)(A) defines an applicable drug under the Medicare coverage gap discount program as a covered Part D drug that is either approved under a new drug application (NDA) under section 505(b) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under section 351 of the Public Health Service Act (BLA) (other than under section 351(k)). Under standard

prescription drug coverage, coinsurance for applicable beneficiaries in the coverage gap for drugs that are not applicable drugs under the Medicare coverage gap discount program (that is, generic drugs) will be either: (1) Equal to the statutory generic gap coinsurance percentage for the year; or (2) actuarially equivalent to an average expected coinsurance for covered Part D drugs that are not applicable drugs under the Medicare coverage gap discount program at the statutory generic gap coinsurance percentage for the year, as determined through processes and methods established under section 1860D–11(c) of the Act and implemented at § 423.265(c) and (d) of our regulations. In our November 2010 proposed rule, we explained that for applicable drugs under the Medicare gap coverage discount program, coinsurance in the coverage gap for the actual cost of the drug as defined at § 423.100 minus any applicable dispensing fees will be either: (1) Equal to the difference between the applicable gap percentage for the year and the discount percentage determined under the Medicare coverage gap discount program at section 1860D–14A(4)(A) of the Act; or (2) actuarially equivalent to an average expected payment of the coinsurance for applicable covered Part D drugs at the applicable gap percentage for the year, as determined through processes and methods established under section 1860D–11(c) of the Act and implemented at § 423.265(c) and (d) of our regulations. We stated that, as a result, when the applicable drug is purchased at a network pharmacy, the beneficiary will be fully liable for any dispensing fees, since the statute requires that the coinsurance apply only to the negotiated price of the drug minus dispensing fees.

We proposed to codify these new requirements in § 423.104(d)(4). Additionally, since the terms applicable drug, applicable beneficiary, and coverage gap have not been previously defined in regulation, we proposed new definitions for these terms at § 423.100. Consistent with section 1101 of the ACA, these reductions in cost sharing during the coverage gap will apply only to applicable beneficiaries. In defined standard coverage, cost sharing during the coverage gap will remain unchanged at 100 percent coinsurance for all other Part D beneficiaries (prior to application of any low-income cost sharing subsidy).

As provided under the new provisions in section 1860D–2(b)(4)(B)(i) of the Act, the rate of growth of the annual out-of-pocket threshold will be reduced from 2014 to 2019. In our November 2010 proposed rule, we proposed to amend § 423.104(d)(5)(iii) to state that the annual out-of-pocket threshold for years 2014 and 2015 will be the amount specified for the previous year, increased by the "annual percentage increase" in the average expenditures for Part D drugs per eligible beneficiary currently specified in § 423.104(d)(5)(iv), minus 0.25 percentage point. Further, we proposed to amend § 423.104(d)(5)(iii) and (v) to reflect that for years 2016 through 2019, the annual out-of-pocket threshold will be the amount specified for the previous year, increased by the lesser of: (1) the annual percentage increase in the consumer price index specified in § 423.104(d)(5)(v) for the year involved plus 2 percentage points; or (2) the "annual percentage increase" specified in § 423.104(d)(5)(iv), rounded to the nearest $50. We also noted that the new provisions in section 1860D–2(b)(4)(B)(i) of the Act require us to calculate the annual out-of-pocket threshold for 2020 and later as if no change had been made to the calculation of the out-of-pocket threshold for 2014 through 2019 under the ACA. Thus, we proposed to amend § 423.104(d)(5)(iii) to reflect this requirement.

In our November 2010 proposed rule, we noted the ACA also amended section 1860D–22(a)(2)(A) of the Act by adding a provision with regard to the actuarial equivalence of retiree prescription drug plan coverage to standard coverage. Specifically, the new provision requires that when attesting to the actuarial equivalence of the plan's prescription drug coverage to defined standard coverage, qualified retiree prescription drug plans not take into account the value of any discount or coverage provided during the gap in coverage that occurs between the initial coverage limit during the year and the out-of-pocket threshold for defined standard coverage under Part D. We proposed to codify this new requirement in § 423.884(d).

As indicated in section II.A. of this final rule, the regulations implementing these provisions are effective 60 days after the date of display of the final rule.

Comment: Several commenters expressed support for this provision and the proposed new definitions for "applicable drug," "applicable beneficiary" and "coverage gap." Two commenters urged us to provide stakeholders, including beneficiaries and independent pharmacists, with educational materials regarding program implementation as early as possible.

Response: We appreciate the commenters' support and we agree with those who encouraged us to provide educational materials to inform stakeholders of the changes to close the coverage gap for applicable beneficiaries.

Comment: We received many comments regarding various aspects of the Medicare coverage gap discount program.

Response: Since these comments pertain to the coverage gap discount program as specified in section 1860D–14A of the Act, rather than to the revisions to the Part D benefit structure specified in section 1860D–2(b) of the Act that were the subject of the November 2010 proposed rule, we believe these comments are outside the scope of the proposed rule. However we plan, to address the comments as appropriate in any future rulemaking regarding the coverage gap discount program.

Comment: One commenter requested that the regulatory language define the amount that will be counted toward the beneficiary's true out-of-pocket (TrOOP) cost when the "generic" gap cost-sharing is applied.

Response: We do not believe there is a need to address this issue in regulation. The amount of the applicable beneficiary's TrOOP for generic drugs in the coverage gap will be the coinsurance amount specified in § 423.104(d)(4)(i) and paid by the beneficiary, another individual on the beneficiary's behalf, or by a TrOOP-eligible payer under § 423.100.

Comment: Several commenters recommended revisions to our proposed definition of the term "applicable drugs." Two commenters suggested we exclude all "authorized generics" from the term and one commenter recommended we clarify whether or not the term includes "authorized generics." Another commenter requested we specify that a drug may be an "applicable drug" for a particular applicable beneficiary if the drug is provided through an exception or appeal to that particular applicable beneficiary.

Response: We believe "applicable drug" means all drugs approved under new drug applications (NDAs) and this includes those "authorized generics" licensed by sponsors of NDAs. It is our understanding that while most "authorized generics" are approved under NDAs, others may be approved under abbreviated new drug applications (ANDAs). However, only those "authorized generics" licensed by sponsors of NDAs are applicable drugs. To avoid confusion, we are defining "applicable drug" with respect to an applicable beneficiary as a Part D drug

that is approved under an NDA. We are also removing the superfluous parenthetical phrase that was inadvertently included in the proposed definition.

We agree with the commenter requesting that we specify that drugs provided through an exception or appeal are applicable drugs only for that particular beneficiary. As a result, we are revising the final clause in the definition to state that the drug "is provided to a particular applicable beneficiary through an exception or appeal for that particular applicable beneficiary."

Comment: One commenter indicated the part of the proposed definition of "applicable beneficiary" that addresses claims that straddle or span the benefit phases is confusing and should be deleted.

Response: We believe it is important to reference straddle claims in the definition of an applicable beneficiary. However, we agree that the punctuation in the proposed definition was incorrect and the source of potential confusion. As a result, we are retaining the clause pertaining to claims that straddle or span the benefit phases and revising the punctuation to clarify that this clause is part of the definition.

Comment: One commenter noted that, in the definition of "coverage gap" we should state that for purposes of applying the initial coverage limit, sponsors must apply their plan specific initial coverage limit under enhanced alternative benefit designs in addition to the basic alternative and actuarially equivalent benefit designs referenced in the proposed definition.

Response: We agree with the commenter and will revise this definition in the final rule to include a reference to enhanced alternative benefit designs.

Comment: One commenter suggested that we clarify that, in addition to dispensing fees, vaccine administration fees are not included in the definition of negotiated price and, therefore, should be excluded from the cost sharing reductions in the coverage gap.

Response: We agree with the commenter. In prior subregulatory guidance, we expressed our belief that vaccine administration fees are analogous to dispensing fees for purposes of the coverage gap discount program and, therefore, must be excluded from the definition of negotiated price for purposes of determining the applicable discount. We noted that unlike sales tax, dispensing fees, and vaccine administration fees pay for services apart from of the applicable drug itself. This is made clear by the fact that a vaccine administration fee may be billed separately from the dispensing of the vaccine. Further, as the commenter points out, the definition of negotiated price would not include a vaccine administration fee billed by someone other than the pharmacy.

Therefore, in finalizing the proposed rule, we will also exclude the vaccine administration fee from the cost sharing reductions and revise the regulatory language in § 423.104(d)(4)(ii) to specify coinsurance in the coverage gap is based on actual cost minus the dispensing fee and any vaccine administration fee.

We also clarify that the reductions to cost sharing in the coverage gap specified in § 423.104(d)(4) apply only to "applicable beneficiaries" by revising the title of this paragraph to "Cost-sharing in the coverage gap for applicable beneficiaries."

Comment: One commenter recommended that when attesting to the actuarial equivalence of a qualified retiree prescription drug plan's coverage to the defined standard coverage, the plan sponsor be permitted to account for the value of drug discounts and/or coverage provided during the coverage gap.

Response: As noted in the preamble to our November 2010 proposed rule, the ACA amended section 1860D–22(a)(2)(A) by adding a new provision requiring that when attesting to the actuarial equivalence of the plan's prescription drug plan coverage to defined standard coverage, qualified retiree prescription drug plans not take into account the value of any discount or coverage provided during the gap in coverage that occurs for defined standard coverage under Part D. Thus, this is a statutory requirement and we cannot accept the commenter's recommendation.

Comment: One commenter recommended that we permit Part D sponsors to use actuarially equivalent copayments as alternatives to the coinsurance amounts for generic drugs in the coverage gap as the enrollee cost-sharing is phased down to 25 percent in 2020.

Response: We agree with the commenter that § 423.104(d)(4)(ii)(B) of this regulation will permit actuarially equivalent cost sharing for generic drugs in the coverage gap. However, we believe that there is a high degree of risk associated with permitting actuarially equivalent copayments for generic drugs in the coverage gap. Due to significant variations in price for generic drugs and the coverage level for these drugs during the first few years of the transition to 25 percent cost sharing, actuarially equivalent co-payments for these drugs will often be higher than the actual cost for commonly used generic drugs. As a result, we are concerned that the majority of beneficiaries will not benefit from the cost sharing reductions in the coverage gap if we permit actuarially equivalent co-payments for these drugs.

We believe that the risk associated with permitting actuarially equivalent co-payments will be mitigated once coverage for generic drugs in the coverage gap reaches a reasonable coverage level for actuarial equivalence. We note that Chapter 4 of the Medicare Managed Care Manual Section 50.1 provides that for an Original Medicare item or service to be considered a reasonable benefit, cost-sharing for that service cannot exceed 50 percent of the plan's financial liability for the benefit. Consistent with this policy, we believe that 50 percent would be a reasonable benefit level at which to permit actuarial equivalence. Therefore, we anticipate permitting actuarially equivalent co-payments in the coverage gap for drugs that are not applicable (that is, generic drugs) starting in 2018 when beneficiary cost sharing for these drugs will be below 50 percent.

For these reasons, we will continue our current policy of not accepting actuarially equivalent co-payments in the coverage gap for drugs that are not applicable (that is, generic drugs) until 2018.

We are finalizing this provision with the amendments previously noted.

19. Payments to Medicare Advantage Organizations (§ 422.308)

In our November 2010 proposed rule, we proposed the revisions to the regulations described below in order to reflect changes in payment rules specified in statute and implemented in the Annual Announcement of MA Capitation Rates and MA and Part D Payment Policies.

a. Authority To Apply Frailty Adjustment Under PACE Payment Rules for Certain Specialized MA Plans for Special Needs Individuals (§ 422.308)

In our November 2010 proposed rule, we noted that section 3205 of the ACA provides the Secretary with the authority to apply a frailty adjustment to payments to certain Special Needs Plans (SNPs) that meet our definition of a fully integrated dual-eligible special needs plan at § 422.2, and have a similar average level of frailty as the PACE program, starting with plan year 2011. The statute permits the Secretary to apply the payment rules under section 1894(d) of the Act (other than paragraph (3) of such section), rather than the

payment rules that would otherwise apply under this part, but only to the extent necessary to reflect the costs of treating high concentrations of frail individuals.

We proposed that payments to Fully Integrated Dual Eligible SNPs that qualify for frailty adjusted payment continue to be calculated using the existing MA payment rules under which all SNPs are paid, with the sole exception of the application of a frailty adjustment. Further, we stated that the new law continued to allow us to use the same methodology to adjust payment to take into account the frailty of SNP enrollees as we use for the PACE program.

As the Secretary determines the adjustment methodology for frailty, which frailty scores will be considered "similar" to PACE program, and how to measure the "average level of frailty of the PACE program," we noted that we will announce any changes to the methodology used to pay for frailty, as well as how we determine PACE program averages, and which SNPs have similar levels of frailty to the PACE program, in the Advance Notice and Rate Announcement for the plan year in question.

In order to have a frailty score that can be compared to the PACE program, we proposed requiring MA organizations sponsoring a dual eligible SNP that meets our definition of a fully integrated dual-eligible SNP to fund any survey used by us to support the calculation of frailty scores. Moreover, we proposed requiring the survey to be fielded such that we can calculate a frailty score at the plan benefit package level for each SNP in question (currently the counts of limitations on activities of daily living (ADLs) used to calculate frailty scores are taken from the HOS or HOS–M), and to adhere to the methodological requirements of any such survey.

Comment: A commenter suggested that CMS should either allow the frailty adjustment to all plans based on a given set of criteria or drop it for all plans. In addition, another commenter suggested that CMS consider applying frailty adjustment on an individual basis instead of at the plan level.

Response: By law, we must use the same payment methodology for all MA plans, except as explicitly provided for in statute. Section 3205 of the ACA changed the law to permit CMS to make frailty-adjusted payments only to certain D–SNPs—those fully integrated dual-eligible special needs plans, as defined in § 422.2., that have similar average levels of frailty as the PACE program. We have considered making frailty payments to all MA plans, but decided that, given the use of the survey-based data collection method, that calculating frailty scores for every PBP across the entire industry was prohibitive. Further, frailty would need to be applied on a budget neutral basis. Given the survey-based methodology used for measuring frailty, a method of reliably calculating individual level frailty scores is not possible. We have explored other methods of measuring frailty, all of which posed substantial challenges to calculating accurate payments.

Comment: Several commenters requested that CMS provide specific and transparent criteria that would be used to determine those plans eligible for frailty in determining similar average frailty levels as PACE, including providing to plans actual frailty scores, the data to be used to calculate the scores and the source of the data, recommended criteria such as using a range of PACE frailty scores, using the same survey methods and data for both populations, and not basing the comparison on an average frailty across all PACE organizations, and requested that CMS provide plans with the eligibility criteria for frailty adjusted payments before plans are required to request participation in PBP level HOS surveys and before they submit their Notices of Intent to offer a Fully Integrated Dual Eligible SNP in the next contract year.

Response: We appreciate these comments and concerns; however, as required by law, CMS provides information on our payment methodology in the Advance Notice and Rate Announcement for the plan year in question.

Comment: A few commenters suggested that the intent of this provision in the ACA was to provide a frailty factor adjustment to all legacy SNPs (that is, the dully integrated plans in Minnesota, Wisconsin and Massachusetts that serve as models for SNP integration).

Response: Section 3205 of the ACA permits CMS to make frailty-adjusted payments to certain D–SNPs—those fully integrated dual-eligible special needs plans, as defined in § 422.2, that enroll beneficiaries with similar average levels of frailty the PACE program, and does not refer to specific plans to which it is to be applied.

Comment: One commenter expressed concerns regarding the requirement to have plans pay for the survey and urges CMS to be flexible in coordinating with and using ADL assessments from the states.

Response: It is a contract requirement that plans are financially responsible for the surveys that support measurement of their performance and quality, including the Consumer Assessment of Health Plan Satisfaction (CAHPS) and Health Effectiveness Data and Information Set (HEDIS), and for reporting payment-related data. The responsibility to finance the HOS is similar. Since SNPs bid and are paid at the Plan Benefit Package (PBP) level, CMS must be able to calculate a frailty score at the PBP level. Further, our frailty payment methodology is based on surveying plan enrollees to determine the plan's average frailty level and the use of assessments conducted by the plans was specifically ruled out in the development of this methodology. Therefore, we must require survey sampling at the PBP level, rather than coordinating with States.

Comment: A few commenters agree with the clarification provided regarding which plans will be eligible for frailty adjusted payments because they meet the definition of "fully integrated dual eligible SNP" as well as the "similar average frailty levels" as PACE plans eligibility criteria.

Response: We appreciate the support expressed for the proposed new provisions.

Comment: Several commenters inquired about the methodology and implementation of the HOS and CHAPS surveys.

Response: We appreciate these commenters' concerns. We will take these comments under advisement in the next survey update.

After considering the comments received, we are adopting § 422.308(a) as proposed into this final rule.

b. Application of Coding Adjustment (§ 422.308)

In our November 2010 proposed rule, we noted that the ACA adds new statutory language clarifying our existing authority to adjust risk scores for coding trends in the FFS sector, under CMS's general authority to conduct risk adjustment in an actuarially equivalent manner under 1853(a)(1)(C)(i) of the Act. Further, this new language extends the mandate that CMS adjust risk scores for differences in coding patterns between MA plans and FFS beyond 2010.

Previously, in accordance with the Deficit Reduction Act of 2005 (DRA), the Secretary was expressly required to conduct an analysis of the differences in FFS and MA coding patterns in order to ensure payment accuracy, and that such analysis was to be completed in time to ensure that the results of such analysis were incorporated into the risk scores

for 2008 through 2010. The ACA made four modifications to this requirement for analysis: (1) The analysis must now be conducted annually; (2) the data used in the analysis is to be updated as appropriate; (3) the results of the analysis are to be incorporated into risk scores on a timely basis; and (4) the application of an adjustment for differences in coding patterns is extended until the Secretary implements risk adjustment using Medicare Advantage diagnostic, cost, and use data.

Moreover, we mentioned that the ACA added two additional requirements to the DRA-mandated requirements. First, the ACA requires that the coding adjustment factor for 2014 be not less than the coding adjustment factor applied for 2010 plus 1.3 percentage points; for each of the years 2015 through 2018, not less than the coding adjustment factor applied for the previous year plus 0.25 percentage points; and for 2019 and each subsequent year not less than 5.7 percent. Second, the ACA requires the Secretary to apply the coding adjustment to risk scores until the implementation of risk adjustment using MA diagnostic, cost, and use data.

Comment: A commenter suggested that the coding intensity adjuster should be modified each year using payment adjustments from the RADV audit process which could be used to determine industry wide averages to estimate industry-wide accuracy. After making this modification, the coding adjuster should then be adjusted downward given that plan payments will be adjusted for inaccuracy through the RADV audits.

Response: As we have noted in previous guidance documents such as the Rate Announcements, the MA coding adjustment factor is not intended to adjust for inaccurate coding in a particular instance, and the specific affects on an individual's risk score, but for the impact on risk scores of coding patterns that differ from FFS coding, the basis of the CMS–HCC model and the Part C normalization factor. RADV audits have the purpose of validating that diagnosis codes submitted for risk adjustment are documented in the medical record and, therefore, are correctly reported for the beneficiary in question.

Comment: One commenter suggested that there should not be a minimum coding adjustment per year and that more detailed information should be released on the coding adjustment calculations for the industry to review.

Response: The minimum adjustment factors are specified in law. For additional information regarding our coding adjustment methodology, please refer to the 2010 Advance Notice and Announcement, published on February 20, 2009 and April 6, 2009, respectively. Any updates to our methodology will be published in the appropriate future Advance Notice.

After considering the comments we received, we are adopting § 422.308 (b) as proposed into this final rule.

c. Improvements to Risk Adjustment for Special Needs Individuals With Chronic Health Conditions (§ 422.308)

In the November 2010 proposed rule, we proposed for 2011 and subsequent years, for purposes of the adjustment under section 1853(a)(1)(C)(i) of the Act, using a risk score for chronic SNP enrollees that reflects the known underlying risk profile and chronic health status of similar individuals, as the Secretary is required to use such risk score instead of using the default risk score that is otherwise used in payment for new enrollees in MA plans.

The risk score developed for this purpose will be used in calculating payments for a special needs individual described in section 1859(b)(6)(B)(iii) of the Act who enrolls in a specialized MA plan for special needs individuals on or after January 1, 2011.

We proposed for 2011 and periodically thereafter, for the Secretary to evaluate and revise the risk adjustment system under this subparagraph in order, as accurately as possible, to account for higher medical and care coordination costs associated with frailty, individuals with multiple, comorbid chronic conditions, and individuals with a diagnosis of mental illness, and also to account for costs that may be associated with higher concentrations of beneficiaries with those conditions. We also noted that we will publish in the Rate Announcement, as described under section 1853(b) of the Act, a description of any evaluation conducted during the preceding year and any revisions made under such clause as a result of such evaluation.

Comment: Several commenters supported the provisions in the ACA that require the Secretary to evaluate and revise the risk adjustment system in order to, as accurately as possible, account for higher medical and care coordination costs associated with frailty, individuals with multiple comorbid chronic conditions, and individuals with a diagnosis of mental illness, and also to account for costs that may be associated with higher concentrations of beneficiaries with those conditions, as well as to publish as part of an announcement a description of any evaluation conducted during the preceding year and any revisions made as a result of such evaluation. In addition, several commenters pointed out that improving risk adjustment will decrease plan cherry-picking of healthier beneficiaries, improve the plans' incentive to focus on costs, reduce unnecessary costs and stop overpaying for low risk beneficiaries and underpaying for high risk beneficiaries.

Response: We appreciate the support expressed for the provision for an evaluation of the risk adjustment model.

Comment: A few commenters urge CMS to implement some risk adjustment model changes in 2012 and more in 2013 in addition to implementing the methodologies announced in the 2011 Advance Notice.

Response: We continually work to develop improvements to the risk adjustment model. Changes to the model for a particular year are discussed in that year's Advance Notice.

Comment: Several commenters recommended that we consider persistency of multiple comorbid chronic conditions and one suggested CMS use 2 years of data in the model beginning in 2012.

Response: We do not believe that using 2 years of data in the risk adjustment model will improve the risk scores, largely because a model developed using 2 years of diagnostic data would lower the model values for chronic conditions and decrease the predictive power of the model for those with conditions under treatment. While, theoretically, such a model may help plans that do not code well, CMS prefers that plans enrollees are seen by providers and that current diagnoses are documented as part of those visits.

Comment: One commenter recommended that CMS engage in active dialogue with MA organizations to permit CMS to consider MAO experience with these populations.

Response: We appreciate these comments and look forward to working with MAOs on this issue.

Comment: A few commenters expressed that they had no knowledge of any current evaluations performed by CMS evaluating the adequacy of the current risk adjustment methodology or of any CMS research exploring alternative methods of risk adjustment that would include methods such as frailty and disability factors, drug utilization information, or using multiple years of data to calculate risk scores, while a few other commenters expressed that they strongly support the provisions in the ACA, however, note that the proposed rule does not provide

any additional clarity about how CMS intends to implement these policies.

Response: We evaluate the performance of the model regularly. Please refer to the following publications for information on model development and performance: *http://www.cms.gov/HealthCareFinancingReview/Downloads/04summerpg119.pdf*. The ACA specified that the evaluation be published as part of the Announcement. We are planning to publish the evaluation in the 2102 Announcement, published on April 4, 2011.

Comment: One commenter requested that no delays in the evaluation be caused by the collection of encounter data.

Response: We appreciate the commenter's concern. Evaluations of the risk models are ongoing and are not related to the collection of encounter data.

Comment: A few commenters requested that CMS recognize problems in the 10 decile analysis for high risk chronically ill beneficiaries as the model inappropriately treats high spending chronically ill beneficiaries as healthy causing them to be assigned to a lower than "true" risk decile.

Response: We measure model predictive strength by comparing predicted costs to actual costs. We typically group beneficiaries into risk deciles, meaning that we create ten equal-sized groups of beneficiaries, ranging from the group with the highest predicted costs to the group with the lowest predicted costs. For each risk-based group, we then create ratios of predicted costs to actual costs. Using predictive ratios, we find that the CMS–HCC model performs well. Comparing predictive ratios across beneficiaries grouped by actual costs (as the comment implies) is not an actuarially sound way to look at the ability of the model to accurately predict costs. If one looks at the cost data retrospectively (after the fact) the result will always be that high cost beneficiaries are under-predicted as high cost is largely due to random events. Determining whether the costs associated with beneficiaries predicted to be high, medium or low cost is the only actuarially sound way to evaluate the risk adjustment model.

Comment: A commenter inquired as to whether the new C–SNP policy applies only to new Medicare Beneficiaries or to all existing Medicare beneficiaries who are newly enrolling in a C–SNP—and recommended that qualifying for the C–SNP should trigger the assumed payment adjustment.

Response: Current law requires the implementation of the new enrollee model for C–SNPs to apply only to new Medicare beneficiaries.

Comment: One commenter urged flexibility in expanding on the intent of the ACA in the area of risk adjustment for persons with chronic illness, and recommended that the process should apply to all SNPs, noting that persons under age 65 who become eligible for Medicare do so because of a disability and the duals under age 65 are even more likely to have a long history of chronic as well as disabling conditions. They are also more likely to have co-occurring mental health needs and the current risk adjustment system unfairly assumes these "new to Medicare" beneficiaries are healthier than their history shows.

Response: We believe that absent explicit statutory authority we cannot pay Dual or Institutional SNPs differently from regular MA plans. Further, we are not considering applying differential new enrollee risk scores to all SNP enrollees. We believe that for Dual-eligible and Institutional SNPs' our evidence shows that the new enrollee risk scores in the CMS–HCC model are adequate to address the aggregate risk faced by these plans because the current new enrollee risk score model captures the additional costs due to Medicaid and disabled status. In creating the C–SNP new enrollee model, we found that the new enrollee age/sex factors had a similar increment regardless of Medicaid status. This finding indicates that the costs for Medicaid and by age group (including the disabled) are fully accounted for in the current new enrollee model.

Comment: A commenter recommended that prior claims data, currently available through the Medicaid program, be used to set payment upon entry to a SNP.

Response: We disagree with the comment. New enrollee risk scores account for the average risk of the new enrollee population, and already account for additional costs attributable to Medicaid status with an explicit Medicaid status marker. Medicaid status for new enrollees is based on concurrent status in the payment year. This means that a dual Medicare/Medicaid enrollee to an MA plan (SNP or regular MA plan) receives an increment that is adjusted for their age/sex and Medicaid status in the payment year.

After considering the comments we received, we are adopting § 422.308(c) as proposed into this final rule.

20. Medicare Advantage Benchmark, Quality Bonus Payments, and Rebate (§ 422.252, § 422.258, and § 422.266)

a. Terminology (§ 422.252)

We proposed revising § 422.252 by adding two new terms and revising one term. We proposed adding the terms "new MA plan" and "low enrollment contract." A new MA plan means, for the purpose of quality ratings under § 422.258(d)(7) (discussed below), with respect to a year, a plan offered by an organization or sponsor that has not had a contract as an MA organization in the preceding 3-year period. A low enrollment contract is a contract that could not undertake Healthcare Effectiveness Data and Information Set (HEDIS®) and Health Outcome Survey (HOS) data collections because of a lack of a sufficient number of enrollees to reliably measure the performance of the health plan.

We also proposed revising the definition of Unadjusted MA area-specific non-drug monthly benchmark amount. Effective for 2012, the MA area-specific non-drug monthly benchmark amount is the blended benchmark amount determined according to the rules set forth under § 422.258(d). In addition, this revision clarifies that rate-setting rules for county capitation rates are specific to a time period, as set forth at § 422.258(a). Finally, this revision further clarifies that the term "unadjusted" refers to a standardized amount, reflecting a risk profile based on the national average.

We received no comments on these proposals and therefore are finalizing these provisions without modification. We are also adopting the definitions proposed for "new MA plan" and "low enrollment contract" in § 422.252 in this final rule.

b. Calculation of Benchmarks (§ 422.258)

Section 3201(b) of the ACA establishes a new blended benchmark as the MA county rate, effective 2012, and section 3201(c) of the ACA establishes quality-based increases to the blended benchmark. To implement these rate-setting rules, we proposed to amend § 422.258(a) and § 422.258(c)(3), and add a new paragraph § 422.258(d), which sets forth the provisions for MA blended benchmarks, including increases to the benchmarks for quality bonuses at § 422.258(d)(7).

Section 3201(b)(2) of the ACA introduces section 1853(n) of the Act, which creates a new type of county capitation rate, the "blended benchmark amount" for an area for a year, which also must be—used to determine MA

plans' service area-level benchmarks. Effective 2012 onward, the blended benchmark will be set at some percentage of the county's average FFS expenditure (the FFS rate). There are two components of the blended benchmark: the applicable amount determined under section 1853(k)(1) of the Act and described at § 422.258(d)(1); and the "specified amount" introduced at section 1853(n)(2) of the Act and described at § 422.258(d)(2). The two components must be combined using weights that are specific to the phase-in period assigned each area (county), according to rules set forth at sections 1853(n)(1) and (n)(3) of the Act and implemented at paragraphs (d)(8) and (d)(9) of § 422.258 of the regulations. At the conclusion of an area's phase-in period, the blended benchmark for the area for a year will be the area's specified amount under section 1853(n)(2) of the Act.

Specified Amount. Section 1853(n)(2) of the Act, as implemented by proposed § 422.258(d)(2), (d)(3), and (d)(4), sets forth the formula for the specified amount and the rules for tabulating the components of the formula. Specifically, the specified amount is the product of two quantities: the base payment amount defined at section 1853(n)(2)(E) of the Act (adjusted to carve-out the indirect medical education (IME) amount, as required at section 1853(k)(4)) of the Act and implemented at § 422.306(c); and the applicable percentage defined at section 1853(n)(2)(B) of the Act and implemented at § 422.258(d)(4).

The base payment amount for an area for 2012 is the average FFS expenditure amount determined for 2012, as specified in § 422.306(b)(2). For subsequent years, the base payment amount for an area is the average FFS expenditure amount specified in § 422.306(b)(2), which includes the requirement to rebase (update with more recent data) the FFS rates no less frequently than every 3 years.

The applicable percentage is one of four values assigned to an area (a county) based on our determination of the quartile ranking for the previous year of the area's average FFS expenditure amount (described at § 422.306(b)(2)) relative to this amount for all counties. The FFS rate used for the quartile ranking must be net of the IME amount determined under § 422.306(c) for the year. For the 50 States or the District of Columbia, counties whose FFS rates (net of the IME amount for the year) fall in the highest quartile of all such amounts for the previous year receive an applicable percentage of 95 percent, while counties falling in the second highest quartile receive an applicable percentage of 100 percent, counties falling in the third highest quartile receive an applicable percentage of 107.5 percent, and counties falling in the lowest quartile receive an applicable percentage of 115 percent.

After establishing the basic formula for the specified amount and setting the rules for calculating its components—the base payment amount and the applicable percentage, sections 1853(n) and (o) of the Act provide additional rules for determining the applicable percentage for a county for a year. There are four sets of rules: (1) When to re-rank the county FFS rates to determine whether some counties receive quartile reassignments; (2) how to transition a county from one quartile assignment to another; (3) how to assign a county its transition period of 2, 4, or 6 years, whereby at the conclusion of the transition period, the county's blended benchmark equals 100 percent of the specified amount; and (4) under what conditions the applicable percentage shall be increased to provide quality bonus payments to qualifying plans. The first three types of rules are discussed here, and the fourth rule on quality bonuses is discussed in the next section on paragraph § 422.258(d)(7).

First, section 1853(n)(2)(C) of the Act, implemented at § 422.258(d)(5)(i), provides that the quartile ranking of all county FFS rates (net of the IME carve-out) for a contract year must be re-ranked whenever the FFS rates for the year prior to the contract year are rebased FFS rates, per the rebasing rule set forth at § 422.306(b)(2). Second, section 1853(n)(2)(D) of the Act, implemented at § 422.258(d)(5)(ii), provides that for a year after 2012, if there is a change in a county's quartile ranking for a contract year compared to the county's ranking in the previous year, the applicable percentage for the area for the year shall be the average of the applicable percentage for the previous year and the applicable percentage that would otherwise apply for the area for the year in the absence of this transitional provision. Third, sections 1853(n)(2) and (n)(3) of the Act, implemented at § 422.258(d)(8) and (d)(9) respectively, establish the methodology that we must use to assign one of three transition periods to each county—a 2-year, 4-year, or 6-year transition to phase-in the blended benchmark amount to be equal to 100 percent of the specified amount. Assignment of a phase-in period is determined by the size of the difference between the 2010 applicable amount under section 1853(k)(1) of the Act at paragraph (d)(1) and "the projected 2010 benchmark amount" at (d)(8)(i), which is a quantity created at section 1853(n)(3)(C) of the Act solely for the purpose of assigning a transition period to each county. The projected 2010 benchmark amount is equal to one-half of the 2010 applicable amount and one-half of the specified amount; the latter is calculated as if the 2012 effective date for the specified amount were instead 2010. This modified specified amount for 2010 is the product of two quantities: The 2010 base payment amount adjusted as required under § 422.306(c); and the applicable percentage, which is determined under the rules set forth at proposed paragraph (d)(8)(ii)(B). Specifically, all applicable percentages are increased as if all counties were in qualifying plans in 2010 for the purpose of calculating the projected 2010 benchmark amount (thus adding 1.5 percentage points to each county's applicable percentage). Further, we must determine a list of 2010 qualifying counties using the criteria set forth for 2012 onward in proposed paragraph (d)(7)(ii), thus further increasing the applicable percentage of this subset of 2010 counties an additional 1.5 percentage points.

Once the special quantity "projected 2010 benchmark amount" is compared to the 2010 specified amount under section 1853(k)(1) of the Act, the phase-in assignments are made as follows. A county is assigned a 2-year phase-in period if the difference between the applicable amount and the projected 2010 benchmark amount is less than $30, a 4-year phase-in period if the difference is at least $30 but less than $50, and a 6-year phase-in period if the difference is at least $50.

Finally, section 1853(n)(3), implemented at § 422.258(d)(8), sets forth the rules for calculating the blended benchmark depending on the assigned phase-in period. For counties assigned the 2-year phase-in period, the blended benchmark for 2012 is the sum of one-half of the applicable amount at paragraph (1) and one-half of the specified amount at paragraph (2); and or subsequent years, the blended benchmark equals the specified amount. For counties assigned the 4-year phase-in period, the blended benchmark is calculated as follows: For 2012 the blended benchmark is the sum of three-quarters of the applicable amount for the area and year and one-fourth of the specified amount for the area and year; for 2013, it is the sum of one-half of the applicable amount for the area and year and one-half of the specified amount for the area and year; for 2014 it is the sum

of one-fourth of the applicable amount for the area and year and three-fourths of the specified amount for the area and year; and for subsequent years, the blended benchmark equals the specified amount. For counties assigned the 6-year phase-in period, for 2012, the blended benchmark is the sum of five-sixths of the applicable amount for the area and year and one-sixth of the specified amount for the area and year; for 2013 it is the sum of two-thirds of the applicable amount for the area and year and one-third of the specified amount for the area and year; for 2014 it is the sum of one-half of the applicable amount for the area and year and one-half of the specified amount for the area and year; for 2015 it is the sum of one-third of the applicable amount for the area and year and two-thirds of the specified amount for the area and year; for 2016 it is the sum of one-sixth of the applicable amount for the area and year and five-sixths of the specified amount for the area and year; and for subsequent years, the blended benchmark equals the specified amount.

Table 4 Blended Benchmark Calculations

	Two Year County Blend		Four Year County Blend		Six Year County Blend	
Year	Pre-ACA	ACA	Pre-ACA	ACA	Pre-ACA	ACA
2012	1/2	1/2	3/4	1/4	5/6	1/6
2013	0	100%	1/2	1/2	2/3	1/3
2014	0	100%	1/4	3/4	1/2	1/2
2015	0	100%	0	100%	1/3	2/3
2016	0	100%	0	100%	1/6	5/6
2017	0	100%	0	100%	0	100%

Comment: One commenter requested that CMS offer plans more information on how payments will be calculated, for example what years will be used for the calculations. *Response:* Detailed payment calculations are available in the Advance Notice of Methodological Changes for Calendar Year (CY) 2012 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2012 Call Letter, published on February 18, 2011 and the Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, published on April 4, 2011. These documents are available on the CMS Web site at: *http://www.cms.gov/MedicareAdvtgSpecRateStats/.*

Comment: Several commenters asserted that while counties are distributed evenly across the 4 quadrants, enrollment is skewed heavily toward the top 95 percent quartile. In order to address the inequities inherent in the new benchmark methodology, these commenters recommend that CMS examine alternative benchmark-setting formulas, such as re-stratifying the quartiles based on enrollment numbers, so as to address the disadvantaged plans in the 95 percent quartile that maintain a significant proportion of MA beneficiaries. Additionally, the commenters asserted that the FFS quartile rule causes problems at the cusps of the quartiles, due to the arbitrary drawing of a line between 2 FFS rates that may only be $0.20 different, with the result that gets 107.5 percent of the FFS rate, and the other only 100 percent of the FFS rate. The commenters recommend that CMS study alternative benchmark methodologies to address inequities in the current formula.

Response: The calculation of the blended benchmark and the quartiles are specifically laid out in 1853(n). Any changes to the calculation would require Congressional action.

We are finalizing this provision without modification. We are also adopting § 422.258 as proposed in this final rule.

c. Increases to the Applicable Percentage for Quality (§ 422.258(d))

We proposed regulations reflecting the new statutory requirements that, as of January 1, 2012, provided for increases in MA plan benchmarks based on an MA plan's score under a star quality rating system. For the purposes of this preamble, we refer to these quality-based increases in MA benchmarks as quality bonus payments (QBPs) for MA plans. The 5 star rating system that serves as the basis for making the bonus payment must be based on quality information collected by us under authority of section 1852(e) of the Act.

The blended benchmark for 2012 and future years reflects the level of quality rating at the organization or contract level that will be set forth in a notice to MA organizations for the calendar year in question. As discussed in section II.B.20.b of this final rule, the blended benchmark has two components—the applicable amount and the specified amount. Under the formula set forth in the ACA, a qualifying organization that receives 4 or more stars on a 5 star rating system would receive an increase in the specified amount component of the blended benchmark amount of 1.5 percentage points in 2012, 3.0 percentage points in 2013 and 5.0 percentage points in 2014 and in subsequent years. A qualifying organization in a qualifying county will receive double the applicable percentage increase. A qualifying county is defined as a county that has an MA capitation rate that, in 2004, was based on the amount specified in subsection c1b for a Metropolitan Statistical Area (MSA) with a population of more than 250,000; has at least 25 percent of MA eligible individuals enrolled in MA organizations as of December 2009; and has a per capita fee-for-service spending that is lower than the national monthly per capita cost for expenditures for individuals enrolled under the Original Medicare fee-for-service program for the year. The ACA specified that a new MA contract will receive an increase in the specified amount component of the blended benchmark amount of 1.5 percentage points in 2012; 2.5 percentage points in 2013; and 3.5 percentage points in 2014 and in subsequent years. The ACA provided that MA organizations that fail to report data as required by the Secretary would be counted as having a rating of fewer than 3.5 stars at the organization or contract level.

We proposed that the 5 star ratings system that will be used would be based on the Plan Rating system currently in place for beneficiary information and to identify contract performance issues. Under the Plan Rating system, if an MA–PD organization offers health and drug benefits, both Part C and Part D summary ratings scores are generated. In the Fall of 2010, MA–PDs received a combined Part C and D summary rating to summarize overall contract performance with respect to health and drug issues. This combined rating is used to determine the new QBPs based on quality for MA organizations offering prescription drug coverage. The Part C summary rating is used to determine the QBPs for MA only contracts.

As previously discussed, under § 422.252, we proposed definitions of a low enrollment contract and a new MA plan for the purpose of identifying qualifying organizations eligible to receive a bonus payment. Low enrollment contracts will be qualifying plans for 2012 and in subsequent years. For the purpose of awarding 2012 QBPs, we proposed to define low enrollment contracts as those that could not undertake HEDIS® and HOS data collections because of a lack of a sufficient number of enrollees to reliably measure the performance of the health plan. Under the ACA, new MA plans that meet criteria specified by the Secretary are also treated as qualifying organizations for the purposes of QBPs. We proposed to define a new MA plan as an MA contract offered by a parent organization that has not had another MA contract in the previous 3 years; these contracts will qualify for the QBP. Under our proposal, other MA contracts that open in a given year, but have had other contracts offered by the parent organization in the prior 3 years, would be assigned a star rating based on the average enrollment-weighted performance of the other contracts offered by the parent organization to reflect the overall performance of the organization.

In the proposed rule we discussed our plan to transform the rating system in future years in order to advance more ambitious and comprehensive quality improvement objectives. These objectives will include greater emphasis on demonstrable improvements in beneficiary access to care, beneficiary health status and outcomes, beneficiary satisfaction and engagement, prevention and management of chronic conditions as well as coordination across the continuum of care. By designing the MA quality rating system around these types of objectives, we expect to encourage and incentivize MA plans and affiliated providers to transform their delivery systems and processes to provide beneficiaries with high-quality and efficient care. Ultimately, we seek to design the MA quality rating system to ensure that Medicare beneficiaries enrolled in MA organizations receive efficient, high quality care and services every time. Future quality agenda and measurement development will be designed to ensure that MA organizations lead the healthcare industry in providing cutting edge, integrated and coordinated care for our beneficiaries using evidence-based and demonstrable metrics.

We also discussed potential guiding principles for the MA quality agenda. For instance, these principles could be based on aims from the 2001 Institute of Medicine (IOM) Report "Crossing the Quality Chasm: A New Health System for the 21st Century." From this IOM Report, the six aims that have been described are a framework for the MA Quality Strategic Plan. The IOM Report provides the following definitions for the six aims: Safe is defined as avoiding injuries to patients from the care that is intended to help them. Effective refers to providing services based on scientific knowledge to all who could benefit, and refraining from providing services to those not likely to benefit. Patient-centered is providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions. Timely is defined as reducing waits and sometimes harmful delays for both those who receive and those who give care. Efficient is avoiding waste, including waste of equipment, supplies, ideas, and energy. Equitable is providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status (IOM, 2001).

As a part of developing our long-term quality strategy, we discussed our work to identify measures that can be implemented in the near term to further the MA quality agenda. Looking beyond the 2012 Plan Ratings, we are exploring using measures, such as reportable adverse events and hospital acquired conditions, which are submitted via the Part C reporting requirements, and all-cause readmission rates. We are also examining the use of alternative measurement sets (for example, Assessing Care of Vulnerable Elders (ACOVE)), exploring the use of data collected in other settings (for example, data from the Hospital Inpatient Quality Reporting Program, formerly known as Reporting Hospital Quality Data for the Annual Payment Update (RHQDAPU)), considering incorporating encounter data into quality measures, and are considering development of additional outcome measures designed specifically for MA. The NCQA is also developing measures of ambulatory care sensitive conditions that we will look to implement as they become available.

Further, beyond broadening the goals of the MA quality rating system, for instance by incorporating more outcomes-based measures, we also discussed our desire to continually raise performance targets, so as to incentivize continual quality improvement across established metrics of performance and quality. We invited public comment on appropriate performance and quality benchmarks, and what approach should be used for updating these benchmarks, including frequency of updates. Additionally, we invited public comment on what types of principles or objectives that we should adopt for the MA quality rating system over the longer term. For instance, are there specific frameworks or elements that we should adopt from the National Quality Forum (NQF), National Committee for Quality Assurance (NCQA), the Agency for Healthcare Research and Quality (AHRQ) or other experts in this field? How should these objectives evolve over time so the rating system rewards continual improvement and innovation on the part of MA organizations?

Comment: Several commenters raised concern that the 5 star rating system for Plan Ratings is moving away from clinical measures and more towards regulatory compliance measures. Specifically, it was noted that the star rating system should be an appropriate mix of measures with an emphasis on giving greater weight to clinical or outcome measures that better reflect health outcomes. Another commenter was concerned that Part D measures inordinately weight the Part C and D summary calculations; the commenter suggested that CMS weight Part C and D measures based on the contribution towards health care quality.

One commenter encouraged CMS to consider new and revised metrics that focus more on patient care and experiences and less on administrative segments. Items listed that should receive priority include patient safety and reduction in preventable medical errors, hospital infections and re-admissions, to name a few. This commenter wants CMS to provide opportunities to comment on proposed measures on an annual basis. One commenter suggested that CMS refrain from adding additional measures to the star rating system at this time and recommended that CMS continue to rely

upon the existing indicators to allow plans to focus improvement efforts accordingly. Another commenter stated that many of the evaluation measures in the Staying Healthy domain focus on early detection instead of primary prevention. Also, this commenter suggested that measures should be used that emphasize patient safety and efficiency of care, consistent with the IOM's *Crossing the Quality Chasm* report.

Response: We are committed to continuing to improve the Part C and D quality performance measurement system to increase focus on improving beneficiary outcomes, beneficiary satisfaction, population health, and efficiency of health care delivery. To that end, CMS has been working on developing a more robust system to measure quality and performance of Part C and D contracts. As new measures are developed and adopted, they will be incorporated into the Plan Ratings published each year on the Medicare Plan Finder Web site.

We view the MA quality bonuses also referred to as value-based payments as an important step to revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations. As we add measures to the Plan Ratings over time, we will consider the following principles:

- Public reporting and value-based payment systems should rely on a mix of standards, process, outcomes, and patient experience measures, including measures of care transitions and changes in patient functional status. Across all programs, we seek to move as quickly as possible to the use of primarily outcome and patient experience measures. To the extent practicable and appropriate, outcomes and patient experience measures should be adjusted for risk or other appropriate patient population or provider characteristics.
- To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across Medicare's and Medicaid's public reporting and payment systems. We seek to evolve to a focused core-set of measures appropriate to the specific provider category that reflects the level of care and the most important areas of service and measures for that provider.
- The collection of information should minimize the burden on providers to the extent possible. As part of that effort, we will continuously seek to align its measures with the adoption of meaningful use standards for health information technology, so the collection of performance information is part of care delivery.
- To the extent practicable, measures used by CMS should be nationally endorsed by a multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures. Our strategy is to continue to adopt measures that are nationally endorsed and are in alignment with the private sector as we do today through the use of measures developed by NCQA and the Pharmacy Quality Alliance (PQA), and the use of measures that are endorsed by NQF.

As we modify the calculation approaches for the Plan Ratings, we are incorporating the following principles:

- Contracts should be scored on their overall achievement relative to national or other appropriate benchmarks. In addition, scoring methodologies should consider improvement as an independent goal.
- Measures or measurement domains need not be given equal weight, but over time, scoring methodologies should be more weighted towards outcome, patient experience and functional status measures.
- Scoring methodologies should be reliable, as straightforward as possible, and stable over time and enable consumers, providers, and payers to make meaningful distinctions among providers' performance.

A high priority for the 2012 Plan Ratings is to weight the outcome and clinical measures more than performance measures such as call center measures. This change would limit the impact of performance measures as well as create more incentives for MA plans to improve their outcome measures. Additionally, we are exploring incorporating additional measures focusing on health outcomes in the Plan Ratings. Potential outcome measures currently under consideration for incorporation into the Plan Ratings include: all-cause readmission rates and MA mortality rates. We will provide opportunities for comment on proposed measures annually through the draft Call Letter.

We believe that the current set of quality measures are not driving quality improvement as much as they could be. Many of the existing measures have been collected and reported to CMS for more than 10 years, such as HEDIS®, HOS, and CAHPS, so plans have had ample opportunity to focus on quality improvement. Given the increased focus on the star ratings, we are reevaluating the set of measures included in the star ratings.

In determining whether additional measures will be added to the star rating system, we will consider the value of the proposed measure in improving the star ratings and how it supports the IOM's six aims. These aims state that healthcare delivery should be safe, timely, effective, efficient, equitable and patient-centered. These aims will serve as a framework for selecting additional measures and making methodological enhancements to the Plan Ratings. The comment that new measures should focus on patient safety and efficiency of care is a good point, and one we need to consider in working with NCQA, PQA, and other consensus-building organizations in developing new measures.

The MA quality agenda will also be coordinated with the national priorities for quality that are being set as part of the ACA. As the national priorities for quality are shaped, the MA quality agenda will be aligned with these priorities. We are working on the MA quality agenda and have also established an agency-wide Quality Working Group Advisory Panel. Senior CMS leadership has convened this panel to facilitate the coordination of the CMS quality initiatives in support of the development of the HHS National Strategy for Quality that is required by the ACA. This working group will ensure that the MA quality agenda aligns with other components within CMS and with HHS' national goals. CMS' participation in the HHS-wide Interagency Quality Measures Workgroup will also further ensure that MA quality measures are developed in a coordinated way across the Department.

Accordingly, based on the preceding, we proposed to amend § 422.258 to add a new paragraph (d)(7) to reflect our authority to make bonus payments based on quality. Under § 422.252, we also proposed definitions of "low enrollment contract" and "new MA plan" for the purpose of identifying qualifying organizations eligible to receive a bonus payment.

While the regulations in this section will implement the QBP provisions specified in the ACA on a permanent basis, for CYs 2012 through 2014, MA payment will be determined under the terms of the national QBP demonstration project. Details on the demonstration are provided on CMS' Web site. During the demonstration, the rules for determining QBPs set forth in the ACA and in this final regulation will be waived, and QBPs will instead be determined under the terms of the demonstration.

Comment: We received a number of comments on the QBP Demonstration.

Response: Because this rulemaking establishes permanent regulations implementing the QBP system provided for in the ACA, the proposed regulations did not reflect the terms of the QBP Demonstration. Information on this demonstration project was made available for comment in the Advance Notice of Methodological Changes for Calendar Year (CY) 2012 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2012 Call Letter, which was published on February 18, 2011. We responded to comments in the Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, published on April 4, 2011. Both documents are available on the CMS Web site at: *http://www.cms.gov/MedicareAdvtgSpecRateStats/*.

Comment: Numerous commenters supported and encouraged CMS to develop the QBPs, including the current nationwide demonstration program in a fully transparent manner, while emphasizing patient-reported information in the star rating system. The commenters request information regarding the measures used to assess performance, including the method used to weight, score, determine cut points and four-star thresholds, identify benchmarks, and other details be fully disclosed to the public. Further, commenters recommended that CMS continue to include beneficiaries and their representatives in conversations regarding QBPs.

Response: The measures used to assess performance for MA plans are derived from four sources: (1) CMS administrative data; (2) surveys of beneficiaries; (3) plan-reported data; and (4) CMS contractor data. For each contract, and each individual measure, CMS groups the range of actual contract scores for each measure into one of the 5 star groupings and assigns a star-rating score based on a 5 star scale. In establishing individual measure star ratings, we consider whether the measure is intended to achieve a specified regulatory performance standard; if not, we examine the contract's performance on a measure relative to all other contracts' performance on the same measure. The segmentation of scores into groups is based on statistical techniques that minimize the distance between scores within a grouping and maximize the distance between scores in different groupings. Once the star rating of 1 through 5 for each measure is known, a summary score for the contract is computed by calculating a simple average of the individual measure ratings, and adding small consistent bump-up amounts to the average if a contract demonstrates consistency in 3, 4, or 5-star ratings among measures. More details on the methodology to calculate the star ratings are available through the technical notes that are available at *http://www.cms.gov/PrescriptionDrugCovGenIn/06_PerformanceData.asp*. The technical notes describe in detail how the star ratings are derived for each of the individual measures, domains, summary ratings, and the overall rating. To ensure contracts are fully aware of future enhancements to the Plan Ratings and have an opportunity to comment on the changes, we will include in the draft and final Call Letter expected changes in the star ratings 1 to 2 years in advance. We will also provide additional information through HPMS memos and presentations to the plans on User calls.

Comment: Some commenters recommended creating a separate star rating system for SNPs with SNP-specific measures that more accurately reflect the quality of care delivered by SNPs. The commenters argued that this will place more focus on the needs of their targeted populations. Some specific suggestions were to create "transitional star ratings" for SNPs until the current star ratings can be modified and to add one-half stars to SNPs that attain thresholds on SNP-specific measures.

Response: We understand that SNPs would like to be rated using SNP-specific measures and would like to be judged using different standards to account for their special populations. We anticipate adding some SNP-specific measures in the 2012 Plan Ratings. As part of the "Advance Notice of Methodological Changes for Calendar Year (CY) 2012 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies, and 2012 Call Letter," published on February 18, 2011, CMS sought comment on the feasibility of creating a methodology to incorporate SNP-specific measures into Plan Ratings. We are taking into consideration feedback we received as we continue to study SNP-specific measures.

In terms of using different standards for the SNPs, we do not agree and want to ensure performance standards are consistent across all contracts. That said, we typically case-mix adjust measures when the data originate from beneficiary surveys and we will continue to determine the need for case-mix adjustments of any outcome measures added over time. We do not believe a transitional system is needed as we are moving towards adding SNP-specific measures in the coming year.

Comment: Some commenters expressed concerns about the appropriateness and reliability of the HOS data in the star rating system. One commenter urged CMS to work with health plans, providers, and patients to reconsider the best mix of measures for the star rating system.

Response: There has been a published, peer-reviewed independent evaluation of the HOS in 2004 that found that it provides a rich and unique set of reliable data *http://www.hqlo.com/content/2/1/33*. For all measures, we will continue to examine the quality of the data and measure accuracy, validity, and stability. For those measures that are not proven to be reliable and valid, we will determine whether they are appropriate "display measures," which would appear on www.cms.gov but not be used in the plans' star ratings.

Comment: A few commenters recommended that the star ratings be made more equitable by taking geographic and demographic variations into account. One commenter recommended incorporating measures of care coordination, care transitions, readmissions, shared decision-making, health literacy, patient activation, and FFS/MA comparison into the star rating system.

Response: As we pursue more outcome measures, we will ensure that measures are case-mix adjusted. Currently, measures that originate from beneficiary surveys are case-mix adjusted. CMS does not consider geographic differences by themselves as sufficient reasons for adjusting Plan Ratings so every state or region may have a 5 star plan. However, CMS is exploring the feasibility of adjusting for provider shortages, such as Health Professional Shortage Areas (HPSAs).

We are also currently exploring the feasibility of incorporating potential survey measures of care coordination, care transitions and patient activation as well as an all-cause readmissions measure into the star rating system. In terms of the FFS and MA comparisons, we are working internally to identify additional FFS comparison measures.

Comment: Several commenters recommended that CMS periodically evaluate the star rating system and the measures selected for inclusion in the star rating system in order to reflect ongoing evolution of measures and to ensure that the system is more accurate, consistent, and transparent.

Response: We strongly agree with the need to periodically evaluate the star rating system. Given the need for the star ratings to adapt quickly to changes in clinical practices and the state-of-the-art in quality measurement, we plan to each year evaluate the measurement set. We will provide information in the draft and final Call Letters about specific expected changes in the star ratings system.

Comment: One commenter urged CMS not to factor Part D measures into the benchmarks. They argue that since benchmarks are established based on healthcare services provided, adding Part D measures into the benchmarks will not reveal an accurate reflection of the contracts' performance.

Response: Drug services are part of the continuum of care provided by MA organizations so are included in the overall rating.

Comment: A few comments expressed concern about how Medicare Cost contract organizations that convert to MA contracts will be treated for star rating and QBP purposes. It was suggested that instead of treating such converted organizations like other new MA organizations, CMS should recognize the star rating track record the organization earned as a Medicare Cost contractor and use this rating as the basis for the QBP until the converted organization can generate an MA track record.

Response: The contract number of a Medicare Cost contract which converts to an MA organization does not change. Since these cost contracts are required to collect and report the same data as MA contracts, they should have the data needed to continue to receive a star rating. The only difference is that they will be included in the list of contracts that receive a QBP rating because of their new organization type designation.

Comment: One commenter supported the implementation of enhanced, high-quality Medication Therapy Management (MTM) programs as a component of the quality rating system.

Response: For the 2013 Plan Ratings, we are developing MTM-specific measures.

Comment: A commenter asked for an explanation of the rationale for a new and small plan receiving enhanced payments prior to proving that corresponding level of performance.

Response: Under the ACA, the Secretary is required to consider a low enrollment contract that does not have sufficient data to compute a quality rating to be a "qualifying plan" and receive the QBP and that a new MA plan, defined as a plan offered by an organization or sponsor that has not had an MA contract in the prior 3-year period, would qualify for the QBP.

Comment: One commenter expressed concern that HEDIS® specifications for certain measures are inappropriate, irrelevant, potentially harmful and/or not validated by medical literature. For example, self-reported measures when the beneficiary is cognitively impaired or mentally ill were noted.

Response: Each HEDIS® measure does have specific exclusions relevant for that measure that NCQA has determined by the standards of care for that condition and each measure has gone through rigorous clinical review. Additionally, proxy respondents are allowed for the beneficiary surveys. More information about HEDIS® specifications can be found in the HEDIS® 2011 Technical Specifications, Volume 2.

Comment: One commenter questioned whether Plan D sponsors are rated using old data that may not be statistically accurate.

Response: We use the most recent data available in updating each measure. These data represent the best available measures of a plan's performance or quality of care. Some of the data we collect are based on statistical sampling. When samples are used, the sample sizes are chosen to ensure that we produce reliable estimates of true performance.

Comment: A few commenters stated that Part D plans achieve very different star ratings for identical services that are performed by the same Pharmacy Benefits Manager (PBM).

Response: The star ratings assigned to each contract are based on the service or performance in the specific measures, and therefore may differ across contracts associated with the same PBM or other entity. For example, the measures within the Drug Pricing and Patient Safety domain utilize each contract's enrollees' prescription drug event (PDE) data; this is separate and independent of a PBM's function as a Pharmacy & Therapeutics (P&T) committee, claims adjudicator, or exceptions/appeals processor for multiple Part D contracts. Enrollees' utilization patterns differ among contracts, thus the resulting star ratings for contracts will differ.

Comment: One commenter was concerned that the demonstration project would award low performing contract a QBP. The same commenter asked if the weighting can produce anomalous results.

Response: The demonstration project builds on the QBPs authorized in the ACA by providing stronger incentives for contracts to improve their performance thereby accelerating quality improvements during the 3-year period of the demonstration. Since the star ratings we are using for QBPs are the overall rating which combines both Part C and D measures, there are some contracts that have done poorly in Part C or Part D for each of the past 3 years (2.5 stars or below), but their overall rating was a 3. In most cases the Part D measures brought up the overall summary rating to a 3. This is an issue for the demonstration, but not for the ongoing QBP program since contracts after the demonstration will not receive a bonus if they have 3 stars. As changes are made in the weighting of clinical and outcome measures, these anomalies are likely to lessen.

Comment: One commenter suggested that CMS develop outcome measures relevant to Program of All-Inclusive Care for the Elderly (PACE) and institute QBPs for PACE programs.

Response: PACE programs are not MA plans and according to statute do not qualify for QBPs.

After consideration of the public comments we received, we are finalizing § 422.258(d) as proposed.

d. Beneficiary Rebates (§ 422.266)

The final rule for calculation of beneficiary rebates implements section 3202(b)(1) of the ACA, which reduces the amount of beneficiary rebate, and ties the level of rebate to a plan's star rating for quality of performance.

Section 3202(b)(1) of the ACA changes the share of savings that MA plans must provide to enrollees as the beneficiary rebate specified at § 422.266(a). Specifically, this provision mandates that the level of rebate is tied to the level of a plan's star rating for quality of performance. Under the new provisions, the highest possible rebate, for plans with a 4.5 star rating or higher, is set at 70 percent of the average per capita savings. The rebate is reduced further for plans with lower star ratings for a year. These new provisions are phased-in from 2012 through 2014. The demonstration project mentioned in section II.B.20.(c). of this final rule will not affect the rebate percentages associated with a particular star rating, under the terms of the ACA.

We revised § 422.266 by first redesignating paragraph (a) as paragraph (a)(1), and amending it to apply to years 2006 through 2011. We further added paragraph (a)(2), which sets forth the rebate determination rules for 2012 and subsequent years. Section 422.266(a)(2)(ii) states that for 2014 and subsequent years, the final applicable rebate percentage (the percentage applied to the savings amount to determine the rebate amount) is 70

percent in the case of a plan with a quality rating under such system of at least 4.5 stars; 65 percent in the case of a plan with a quality rating of at least 3.5 stars and less than 4.5 stars; and 50 percent in the case of a plan with a quality rating of less than 3.5 stars.

Section 422.266(a)(2)(i) describes the transition period during which the old 75 percent rule at paragraph (a)(1) will be phased-out and the (a)(2)(ii) rules phased in. For 2012, the rebate percentage equals the sum of: two-thirds of the old proportion of 75 percent of the average per capita savings; and one-third of the new proportion assigned the plan or contract under paragraph (ii), based on the plan's star rating for the year. For 2013, the rebate percentage equals the sum of: ⅓ of the old proportion of 75 percent of the average per capita savings; and two-thirds of the new proportion assigned the plan or contract based on the plan's star rating for the year.

Section 422.266(a)(2)(iii) describes the rules for low enrollment contracts. For 2012, the ACA requires that low enrollment contracts shall be treated as having a rating of 4.5 stars for the purpose of determining the beneficiary rebate amount. Section 422.266(a)(2)(iii) describes the rules for new MA plans. For 2012 or a subsequent years, a new MA plan defined at § 422.252 that meets the criteria specified by us for purposes of § 422.258(d)(7)(v) must be treated as a qualifying plan under paragraph (7)(i), except that plan must be treated as having a rating of 3.5 stars for purposes of determining the beneficiary rebate amount.

Comment: One commenter recommended that CMS allow part of the bonus to be reinvested into the carrier's quality program.

Response: The rebate amount must be credited to one of the uses described in section 1854(b)(1)(C) of the Act, as described in the Advance Notice of Methodological Changes for Calendar Year (CY) 2012 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2012 Call Letter, published on February 18, 2011 and the Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, published on April 4, 2011. These documents are available on the CMS Web site at: *http://www.cms.gov/MedicareAdvtgSpecRateStats/*. Quality improvement program costs are legitimate administrative costs and can be added as such to the plan's bid.

Comment: One commenter urged CMS to analyze the effect of rebate reduction on duals. The commenter believes that since the quality metrics are not scaled in any way by the risk of the population, beneficiaries in plans with high concentrations of complex needs will see a downward trend of available benefits.

Response: We will consider analyzing the effect of rebate reduction on duals. However, as stated previously, the statute at 1854(b)(1)(C) explicitly sets out the savings that MA plans can provide and star rating that the rebate is tied to. Any change to this formulation would require Congressional action.

We are finalizing this provision without modification. We are also adopting § 422.266 as proposed in this final rule.

21. Quality Bonus Payment and Rebate Retention Appeals (§ 422.260)

As noted in the proposed rule, while the ACA provisions establishing the QBP system do not specify a process for requesting an administrative review of the star ratings, historically, we have made an administrative review process available to MA organizations for certain payment determinations. Pursuant to our statutory authority to establish MA program standards under section 1856(b)(1) of the Act, we proposed to implement a process through which MA organizations may request an administrative review of their star rating ("QBP status") for QBP determinations. We proposed that this review process would also apply to the determinations made by us where the organization's Plan Rating sets its QBP status at ineligible for rebate retention.

For calendar years 2012 through 2014, we proposed that QBP payments would be awarded under the terms of a demonstration project; thus, we proposed these regulations would not take effect until after the demonstration project has terminated. We requested comment regarding our proposal to delay the effective date of the appeals process set forth in this final rule until after the end of the demonstration.

We received no comments on this specific proposal; however, based on other comments regarding the appeals process we are aligning the appeals process in the regulation with the administration review process that will be used under the demonstration project.

While we proposed to reserve the right to use the same star rating that applies to the Plan Rating for QBP determinations, we will provide MA organizations notice each year regarding their QBP status. QBP determinations would be considered made, subject to the appeal rights described in this section, when the notice of QBP status is released. We proposed MA organizations would have 5 calendar days from the date of CMS' release of QBP determinations to request from CMS a technical report explaining the development of their QBP status. As stated in the proposed rule, if, after reviewing the technical report, the MA organization believes that we were incorrect in its QBP determination, the MA organization may request an appeal to be conducted by a hearing officer designated by CMS. The organization would be required to make such a request within 7 calendar days of the MA organization's confirmed receipt of the technical report. We proposed the scope of the hearing would be limited to challenges of CMS' application of its QBP determination methodology to the appealing MA organization and, in very limited instances, the accuracy of the data we used to make the QBP determination. As a result, the appeals process would not be used as a means to challenge the validity of the adopted methodology. We also proposed limiting the scope of the hearing officer's consideration to data sets that have not been previously subject to independent validation. We solicited comments on whether this is an appropriate limitation on the scope of a QBP status appeal.

Comment: One commenter would like to be able to appeal audited data.

Response: The auditor and contract work together throughout the entire audit. Any questions about the data or the auditor's assessment of the plan are discussed and documented during the audit, and all resolutions are documented. A contract should raise any concerns with respect to audited data during their audit process. HEDIS® audits, for example, ensure accurate, reliable and publicly reportable data. For this reason, NCQA encourages the organization to collect data simultaneously with the audit. A concurrent audit lets the auditor detect errors in the organization's data collection process while there is time for the organization to correct its methods and minimize the possibility of *Not Reportable* rates.

As provided in the proposed rule, the hearing officer's decision would be final and binding on both the MA organization and CMS. In the event that the hearing officer finds that CMS' QBP determination was incorrect, we would be obligated to recalculate the organization's QBP status based on the hearing officer's findings. We proposed to maintain the right to revise an MA organization's QBP status at any time after the initial release of the QBP determinations through May 15 of each

year. We indicated that we may take this action on the basis of any credible information, including the technical report issued pursuant to the process identified here, which demonstrates that the initial QBP determination was incorrect. We are revising the date that CMS may, on its own initiative, revise an MA organization's QBP status after the initial release of the QBP determinations. While changes may occur after this date based on appeals of QBP status, CMS, on its own initiative, will only have through April 1 of each year to make changes to an MA organization's QBP status. This change will afford MA organizations more time to incorporate their QBP status into their plan bids, due to us by the first Monday in June. Additionally, we did not propose another level of administrative review beyond the hearing officer. We solicited comment on the need for an independent contractor-level review prior to an appeal to be conducted by a hearing officer designated by CMS or an Administrator-level review.

Comment: One commenter recommended that CMS have a three-level appeals process to ensure contracts have a robust mechanism to appeal (such as, Level 1 would be a request for reconsideration, Level 2 would be a request for a hearing, and Level 3 would be a request for CMS Administrator review). Another commenter recommended a second level of appeal for QBP determinations.

Response: Based on these comments, we are strengthening the administrative review process for MA organizations that appeal their star ratings for QBP. We are aligning the process in the regulation with the process used during the demonstration. We will modify § 422.260(d) to create a two-step administrative review process that includes a request for reconsideration and a request for an informal hearing on the record. MA organizations will no longer be requesting a technical report from CMS detailing the data and measures used to determine the QBP; however, as part of the reconsideration determination, MA organizations will receive information about how their star rating for the given measure in question was calculated and/or what data was included in the measure. The MA organization may appeal the reconsideration official's decision regarding its QBP status by requesting an informal hearing. The informal hearing will be conducted by a CMS hearing officer on the record.

Comment: A number of commenters requested more than 5 calendar days to submit a request for a technical report and additional days to request the appeal. Some commenters requested extension of the 5 calendar day window to 7 to 15 days, with clarification of calendar or business days.

Response: The timeframes are tight given we want to resolve any issues prior to contracts submitting their bids to CMS. However, in order to be responsive to this concern, we are revising the timeframes. MA organizations will have 10 business days from the time we issue the notice of QBP status to submit a request for reconsideration. MA organizations will have 10 business days after the issuance of the reconsideration determination to request an informal hearing on the record.

Comment: One commenter expressed concern that the appeals process is not fully transparent.

Response: The appeals process is outlined in this regulation. Also, each year MA contracts will receive additional details through HPMS memos about the timing for submitting an appeal.

Comment: A few commenters requested that CMS send technical reports to all contracts, without them having to request one.

Response: The technical notes published at *http://www.cms.gov/PrescriptionDrugCovGenIn/06_PerformanceData.asp* have detailed information about how each of the star ratings is calculated. Also, contracts may request information about how their scores were calculated at any time by e-mailing CMS at *PartCratings@cms.hhs.gov.*

Comment: A commenter requested that Medicare Cost contracts be permitted to submit requests for Technical Reports and have appeal rights.

Response: Medicare Cost contracts may request any additional information during the plan preview for Plan Ratings or at any time by e-mailing CMS at *PartCratings@cms.hhs.gov.* The appeals rights under this regulation are related to using the star ratings for payment for QBPs. Medicare cost contracts are not eligible for QBPs since they are not considered MA contracts.

Based on the comments, we are revising the proposed § 422.260(c) and § 422.260(d) to create a two-step administrative review process that includes a request for reconsideration and a request for an informal hearing on the record. We are also extending the timeframes for requests.

C. Clarify Various Program Participation Requirements

The provisions in this section of the final rule clarify existing regulations or implement new requirements consistent with existing policy guidance to assist sponsoring organizations with attaining the goals of the Medicare Advantage and Prescription Drug Benefit programs. These clarifications are detailed in Table 5.

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TABLE 5: Provisions to Clarify Various Sponsor Program Participation Requirements

PROVISION	PART 422		PART 423	
	Subpart	Section	Subpart	Section
Clarify Payment Rules for Non-Contract Providers	Subpart E	§422.214	N/A	N/A
Pharmacist Definition	N/A	N/A	Subpart A	§423.4
Prohibition on Part C and Part D Program Participation by Organizations Whose Owners, Directors, or Management Employees Served in a Similar Capacity with Another 0rganization that Terminated its Medicare Contract within the Previous 2 Years	Subpart K	§422.506 §422.508 §422.512	Subpart K	§423.507 §423.508 §423.510
Timely Transfer of Data and Files When CMS Terminates a Contract with a Part D Sponsor	N/A	N/A	Subpart K	§423.509
Review of Medical Necessity Decisions by a Physician or other Health Care Professional and the Employment of a Medical Director	Subpart M	§422.562 §422.566	Subpart M	§423.562 §423.566
Compliance Officer Training	Subpart K	§422.503	Subpart K	§423.504
Removing Quality Improvement Projects and Chronic Care Improvement Programs from CMS Deeming Process	Subpart D	§422.156	N/A	N/A
Definitions of Employment-Based Retiree Health Coverage and Group Health Plan for MA Employer/Union-Only Group Waiver Plans	Subpart C	§422.106	N/A	N/A

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1. Clarify Payment Rules for Non-Contract Providers (§ 422.214)

In our November 2010 proposed rule (75 FR 71223), we proposed adding a new paragraph (c) to § 422.214 to clarify that a request for payment from an MA organization by a non-contracted provider who is paid using a prospective payment system (PPS) methodology under Original Medicare is deemed to be a request to be paid at the Original Medicare payment rate unless the provider has notified the MA organization in writing that it wishes to bill less than the Original Medicare payment amount. We proposed this provision to codify the guidance for plans and out-of-network providers in CMS' Out-of-Network Payment Guide released February 25, 2010. This guidance, which was responsive to questions we had received about this issue, reflects CMS' longstanding policy that if a non-network facility such as a hospital, skilled nursing facility, or home health agency renders services which were not arranged by the plan, a non-private-fee-for-service MA organization may pay the lesser of the Original Medicare amount or a lower billed amount if it is clear that the provider is billing for less than the Original Medicare rate. The guidance also clarified that when a provider of services that is paid under a PPS system under Original Medicare submits the same information to an MA organization that it would submit to Original Medicare for the services in question, this should be considered a bill for the PPS amount (and not the "billed" or "charge" amount from the claim) that Original Medicare would pay in the case of the same submission.

We also proposed adding a new paragraph (d) to § 422.214 to clarify that an MA organization offering a regional PPO MA plan must always pay non-contracted providers at least the Original Medicare payment rate in those

portions of its service area where it is meeting access requirements by non-network means under § 422.111(b)(3)(ii). This is consistent with the Medicare access requirements at section 1852(a)(2)(A) of the Act—which specify that an MA plan may meet access requirements if it pays providers at the Original Medicare payment rate.

After considering the comments received, we are finalizing these provisions as proposed.

Comment: One commenter asked CMS to clarify that our proposed policy that a non-contracted provider's request for payment be deemed to be a request for the Original Medicare payment rate, unless the provider expressly notifies the MA organization in writing that it is billing a lesser amount, does not preclude health plans from negotiating payment terms with contracted providers. Another commenter requested clarification that MA plans can negotiate payment terms with providers for more than Original Medicare rates. Another commenter recommended that our proposed policy be applied in the Medicaid program such that non-contracted provider payments are limited to no more than what the provider would receive under the State's Medicaid fee-for-service program.

Response: Our proposed policy does not preclude MA plans from negotiating payment terms with providers. It implements section 1866(a)(1)(O) of the Act, which applies only where no agreement on payment levels is in place. Extending our proposed policy to the Medicaid program would be beyond the scope of this regulation, which only addressed payments to non-contracted providers for Medicare services provided to MA enrollees.

2. Pharmacist Definition (§ 423.4)

Pursuant to our authority under section 1860D–4(b)(3)(A)(i) and 1860D–4(c)(2)(A)(i) of the Act, we proposed to codify our understanding that, for purposes of the Part D program, a pharmacist is an individual with a current, valid license to practice pharmacy issued by the appropriate regulatory authority of any of the states or territories of the United States or the District of Columbia (DC) (collectively referred to as United States authorities). We proposed adding a definition for the word pharmacist to § 423.4 in Subpart A to reflect this understanding.

The change was prompted by recent Medicare Part D sponsor audit findings in which we found that at least some Part D sponsors were relying on pharmacists not licensed by United States authorities to make clinical judgments associated with the administration of the Part D benefit. As Medicare provides coverage for services throughout the United States, beneficiaries should be able to expect that individuals making clinical decisions related to their access to pharmaceuticals are experts in United States pharmaceutical practice. Requiring pharmacists to be licensed by United States authorities will help guarantee that Part D sponsors meet these expectations.

Comment: CMS received support for codifying this definition from numerous pharmacy associations, industry, and patient/beneficiary advocacy organizations.

Response: We agree with these commenters and appreciate the widespread stakeholder support for this definition. We received only supportive comments for this proposal; therefore, we are finalizing this provision without modification.

3. Prohibition on Part C and Part D Program Participation by Organizations Whose Owners, Directors, or Management Employees Served in a Similar Capacity With Another Organization That Terminated Its Medicare Contract Within the Previous 2 Years (§ 422.506, § 422.508, § 422.512, § 423.507, § 423.508, and § 423.510)

In the April 2010 final rule (75 FR 19678), we modified § 423.508 by adding two paragraphs stating that: (1) As a condition precedent to CMS' consent to a mutual termination, CMS requires language in the termination agreement prohibiting the sponsor from applying for new contracts or service area expansions for a period of up to 2 years absent special circumstances warranting special consideration; and (2) that as a necessary condition to contract as a Part D sponsor, an organization must not have terminated a contract by mutual consent within the 2 years preceding the application. Similar modifications were made for the MA regulations at § 422.508. These changes ensured consistency across all situations in which a sponsor elects— through non-renewal, termination, or mutual termination— to discontinue its participation in the Part C or Part D programs.

In the proposed rule, we proposed to amend the 2-year new contract prohibition in both § 422.508 and § 423.508 by adding a new paragraph entitled "Prohibition against Part C [and Part D] program participation by organizations whose owners, directors, or management employees served in a similar capacity with another organization that terminated its Medicare contract within the previous 2 years." We also proposed similar clarifying language to the existing language at § 422.506, § 422.512, 423.508, and § 423.510. We stated our belief that to carry out the intentions of the 2-year exclusion we would need to ensure that new contracting organizations are not actually repackaged versions of the same organizations that elected to discontinue their participation in the Part C and Part D programs. Therefore, we proposed to implement a requirement which would allow us to determine whether the primary players in the organization submitting the new application are the same as those in an organization that has recently non-renewed, terminated, or mutually terminated a Medicare contract.

We noted that the proposed requirement would assist CMS in prohibiting and preventing such organizations from gaming the Medicare program by reapplying for a contract as a new organization during the 2-year ban, when the applying organization has common ownership and management control. This proposed requirement would help to ensure that the provisions of the 2-year application prohibition are given full effect.

Therefore, we proposed that the 2-year ban on new Part C or Part D sponsor contracts to which non-renewing, terminating, or mutually terminating organizations are currently subject under the regulation be expanded to include organizations owned or managed by an individual (referred to as a covered person) who served in a similar capacity for a previously terminated or non-renewed Part C or Part D organization. To implement this provision, we proposed to require as part of the contract application process, that applicants supply CMS with full and complete information as to the identity of each covered person associated with the organization. In the proposed rule we defined covered persons to include—

- All owners of applicant organizations who are natural persons (other than shareholders who: (1) Have an ownership interest of less than 5 percent; and (2) acquired the ownership interest through public trading). In addition, is a natural person who is an owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the entity or any of the property assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the entity; or

• An officer or member of the board of directors or board of trustees of the entity, if the entity is organized as a corporation.

We solicited comments on whether plan sponsors, or other stakeholders consider the definition of 5 percent or more as truly representing current market conditions. We requested comment on this section because we do not want to arbitrarily decide on the percentage of interest the previously mentioned persons could have in an organization, especially if this percentage does not reflect standard business practices.

We proposed to amend § 422.508 and § 423.507 to make the 2-year exclusion applicable to organizations for which any covered persons were also covered persons for the excluded organization. We also proposed to make similar amendments to § 422.506, § 422.512, § 423.508, and § 423.510.

Comment: Several commenters stated that the definition of covered persons was too broad, and that it should not encompass senior executives of the excluded organization. They noted that in many instances, these executives were not responsible for the organization's decision to terminate or non-renew a Medicare contract, but were simply honoring their fiduciary duty to carry out the instructions of the sponsor's ownership. The regulation as proposed would unfairly limit the opportunities for these senior executives to obtain employment with other Medicare Advantage organizations or PDP sponsors as those employers may not want limit their ability to apply for new Medicare business by hiring such individuals. Also, the proposed language may also prompt senior executives to seek other employment when Medicare contract termination or non-renewal is even discussed within their organization to ensure that they preserve their eligibility for employment with the broadest possible range of other Medicare Advantage organizations or PDP sponsors.

Response: We agree that the definition of covered person, as proposed, is too broad. CMS' intention in drafting the provision was to make certain that organizations subject to the two-year application prohibition did not evade the restriction by simply forming a new corporation. Based on these comments, we have further clarified our thinking to conclude that the focus of the restriction should be on those individuals with absolute responsibility for control of and an ownership stake in the business decisions of the terminating and non-renewing sponsors—the owners of more than 5 percent of the shares of the sponsor and the members of the board of directors. Therefore, we have decided to modify the definition of covered person to delete the term "officer * * * of the entity" in the final rule.

Comment: One organization commented that the inclusion of individuals who own less than 5 percent of the total number of shares of a sponsor's stock acquired other than through public trading in the definition of covered person was unnecessarily broad and would unfairly include individuals who receive shares through an organization's employee stock ownership program.

Response: This comment is based in part on a typographical error in the proposed rule as published at § 422.506(a)(5)(i)(A), § 422.508(d)(1)(i), and § 422.512(e)(2)(i)(A). We intended for the prohibition to apply to individuals who own *more than* 5 percent of the shares of the sponsoring organization. However, in some parts of the proposed rule, the standard was mistakenly stated as *less than* 5 percent. In the final rule, we have corrected the error to make more than 5 percent the standard for stock ownership. Also, we acknowledge that making a distinction between stock shares obtained through public trading and shares obtained through all other means, as we proposed, would create an irrelevant and confusing distinction. This proposed provision was intended to restrict the ability to resume participation in the Medicare Advantage and Part D programs of individuals who could exercise control over a terminating or non-renewing organization through their ownership of a significant portion of the organization. We believe the level of an individual's control is established by the percentage of shares owned, not by the source of those shares. Therefore, we are also modifying the proposed rule to delete the language excluding shareholders who acquired their stock through public trading from classification as covered persons.

Comment: One organization expressed its concern that the inclusion of members of a terminating or non-renewing sponsor's board of directors in the definition of covered person would unfairly restrict organizations with overlapping board membership from eligibility to submit applications. The commenter noted that this could be a problem especially for subsidiaries of the same parent organization where this kind of arrangement is common.

Response: We believe that the arrangement the commenter described represents one of the situations we intended to address through this regulatory change. In drafting this provision, we are trying to make certain that the parties that were responsible for a decision to terminate or non-renew a Part C or D sponsor contract do not subvert the 2-year application prohibition by submitting a new application through the use of a different legal entity over which they similarly exert control. As the commenter has not presented a justification as to why an organization controlled by many or all of the same individuals who controlled a terminating or non-renewing organization should not be subject to the two-year application ban, we are making no change in the final rule to reflect this comment.

Comment: Two commenters asked that we clarify whether the new provision concerning covered individuals will apply to terminations only at the plan benefit package (PBP) level.

Response: The regulation change we make here is intended simply to define which individuals related to an organization already determined to be subject to the 2-year application restriction may cause a second organization to be similarly restricted when it has the same relationship with those individuals. The methodology CMS uses to determine whether organizations are subject to the two-year application restriction is outside the scope of the proposed regulatory change.

In summary, we received several comments on this proposal. In response to the comments opposing the inclusion of a contracting organization's senior management in the definition of a covered person, we have deleted the reference to officer from § 422.506(a)(5)(iii), § 422.508(d)(3), § 422.512(e)(2)(iii), § 423.507(a)(4)(iii), § 423.508(f)(3), and § 423.510(e)(2)(iii). Also, in response to the comments opposing the inclusion in the definition of covered person owners of small amounts of stock acquired other than through public trading, we deleted the phrase "acquired the ownership through public trading" from the proposed § 422.506(a)(5)(i)(B), § 422.508(d)(1)(ii), § 422.512(e)(2)(i)(B), § 423.507(a)(4)(i)(B), § 423.508(f)(1)(ii), and § 423.510(e)(2)(i)(B). We also corrected our typographical errors by replacing the statement "more than 5 percent with less than 5 percent" at the proposed § 422.506(a)(5)(i)(A), § 422.508(d)(1)(i), and § 422.512(e)(2)(i)(A), as we intended only to exclude from the definition of covered persons individuals whose ownership stake is less than 5 percent.

We received no responses to our request for comments concerning whether the use of the 5 percent ownership threshold for covered persons reflected current marketing conditions or standard business practices and have therefore otherwise made final this provision of the proposed rule.

4. Timely Transfer of Data and Files When CMS Terminates a Contract With a Part D Sponsor (§ 423.509)

Federal regulations at § 423.509(a) (1) through (a) (12) clearly define the circumstances under which we have the authority to terminate a Part D sponsor's contract. When we terminate a contract, we must have assurances that the terminated Part D sponsor will maintain sufficient staff and operations to make a smooth transition of the sponsor's enrollees to new Part D coverage in a fashion that facilitates continuity of care and fiscal responsibility. These responsibilities include providing timely documentation requested by CMS, retaining all documents for the periods specified in the Federal laws and CMS regulations (see § 423.505(d) and (e)) and otherwise providing the resources necessary for an orderly transition of Medicare beneficiaries to their newly assigned or selected plan.

In order for a timely and orderly transition to occur, the terminated Part D sponsor must provide us with certain critical Medicare beneficiary data including information to identify each affected beneficiary, pharmacy claims files, true out-of-pocket (TrOOP) cost balances, and information concerning pending grievances and appeals. Data such as TrOOP balances are necessary to place the beneficiary in the correct drug benefit phase and provide the catastrophic level of coverage at the appropriate time.

The requirement to provide such data and files is already clearly articulated for voluntarily non-renewing Part D plan sponsors (§ 423.507(a) (4)); for contracts terminated by mutual consent (§ 423.508(d)); and for contracts terminated by the plan sponsor for cause (§ 423.510(f)). However, the regulation is currently silent regarding contracts terminated by CMS. Therefore, in order to protect both Medicare beneficiaries and CMS and to ensure that the requirement to provide such data and files is clear for all types of contract non-renewals and terminations, we proposed to add a new section (e) Timely transfer of data and files to § 423.509 (Termination of Contract by CMS) to state that should the Part D plan sponsor's contract be terminated by CMS, the Part D sponsor must ensure the timely transfer of any data or files. This language would inform Part D sponsors being terminated by CMS that they are required by Federal regulation to timely transfer all requested data and files to CMS or its designee for the required time as specified under § 423.505(d) and (e). Because the failure to provide this information directly harms beneficiaries, plans that fail to comply with this requirement may be subject to a Civil Monetary Penalty as defined in § 422.752(c) and § 423.753(c).

Comment: Several commenters expressed their support for this provision. One commenter recommended that we go even further by specifying through regulations the time period which terminated Part D sponsors have to transfer data and files.

Response: We appreciate the commenters' support of our proposal. Further specifying the time period for transfer of data in regulation is not possible because circumstances vary from one CMS-initiated termination to the next. We will provide timeframes in guidance to the affected sponsor upon termination.

Comment: One commenter wanted CMS to specify through regulations a plan for the smooth transfer of beneficiaries to a new Part D plan to ensure that patients retain access to needed medications, and that pharmacies and other downstream entities receive the reimbursement for which they are entitled once a Part D plan sponsor is terminated.

Response: As explained in the proposed rule this provision merely adds § 423.509(e) to the existing regulations conforming the rules regarding the timely transfer of critical beneficiary data for Part D sponsors being terminated under any circumstance, and does not address the transfer of beneficiaries nor reimbursement. While these are important concerns, they are outside the scope of these proposed revisions. We do, in fact, have protocols in place to ensure the smooth transfer of beneficiaries to other Part D coverage with minimal interruption in access to medications. With regard to reimbursement of pharmacies, the statute and regulations governing Part D provide for CMS to contract with entities that apply to be Part D sponsors and are determined qualified as provided in § 423.503. Once we evaluate and determine an applicant is qualified to be a Part D sponsor, that sponsor retains the ultimate legal responsibility for adhering to and otherwise fully complying with all terms and conditions of its contracts with downstream providers, such as pharmacies. Nevertheless, we have recently strengthened its ability to ensure that sponsors promptly pay pharmacies by codifying at § 423.520 a requirement that the contract between CMS and all Part D sponsors contain provisions obligating the sponsor to promptly pay claims. As a result, Part D sponsors that do not meet the prompt payment requirements of § 423.520 may be subject to contract compliance actions by CMS.

Having received only support for this proposal, we are therefore finalizing this provision without modification.

5. Review of Medical Necessity Decisions by a Physician or Other Health Care Professional and the Employment of a Medical Director (§ 422.562, § 422.566, § 423.562, and § 423.566)

Based on sections 1852(g) and 1860D–4(g) of the Act, we have established procedures for making organization determinations and reconsiderations regarding health services under Part C, and for making coverage determinations and redeterminations regarding covered drug benefits under Part D. These requirements are codified in our regulations at part 422 subpart M and part 423 subpart M, respectively. In the proposed rule, we noted that although the Part C and Part D regulations require physician review of appeals of adverse organization determinations or coverage determinations, respectively, that involve medical necessity, the regulations do not specify who must conduct the initial determinations involving medical necessity. We proposed to modify our requirements in § 422.566 by adding a new paragraph (d) which would require organization determinations that involve medical necessity to be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of the Medicare program. We also proposed to require the physician or other health care professional to have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

As noted in the proposed rule, section 1860D–4(g) of the Act requires Part D plan sponsors to meet the requirements for processing requests for coverage determinations and redeterminations in the same manner as such requirements apply to Part C organizations with respect to organization determinations and reconsiderations. Consistent with the proposed changes to the Part C organization determination process, we

proposed similar changes to the Part D coverage determination process in new § 423.566(d).

Comment: Many commenters expressed strong support for this proposal as it relates to the Part C and Part D programs, but several of those commenters conditioned their support for the proposal on its applicability to only those cases where the plan's initial review (for example, by a non-clinician claims specialist) will result in an unfavorable decision. In other words, the commenters argued that if the initial review of the request will result in a favorable coverage decision for the enrollee, there is no need to involve a physician or other health care professional in reviewing the case. These commenters believe that the additional safeguards of this provision are only necessary if, based on the initial review of the request, the plan expects to issue an unfavorable decision.

Response: We acknowledge that it is common practice for an MA organization or Part D plan sponsor to use a claims specialist (who may not be a clinician) to conduct initial reviews of requests for organization and coverage determinations. We agree that if the initial review of an organization or coverage determination request will result in a fully favorable decision for the enrollee, the request does not require review by a physician or other appropriate health care professional. However, if the initial review of the request will result in the plan issuing a partially or fully unfavorable decision based on medical necessity, a physician or other appropriate health care professional must be involved in reviewing the request prior to the plan issuing a final decision. We believe this approach strikes an appropriate balance between ensuring that organization and coverage determination requests involving medical necessity decisions are subject to review by appropriate health care professionals and allowing MA organizations and Part D plan sponsors to appropriately and efficiently utilize health care professional staff resources. We revised proposed § 422.566 and § 423.566 to reflect this change.

Comment: Some commenters requested that CMS clarify that the statement appropriate health care professional includes a pharmacist for purposes of reviewing Part D coverage determinations involving medical necessity. A few commenters suggested that pharmacists be explicitly listed as health care professionals capable of reviewing medical necessity determinations.

Response: We do not believe it is necessary or advisable to explicitly list specific health care professionals who may appropriately review organization or coverage determinations involving medical necessity. The type of health care professional who may be appropriate to review a particular request will depend on the type of services being requested, related medical necessity issues, and whether the review is consistent with the health care professional's scope of practice under State law.

Comment: Some commenters asked that CMS clarify that the proposed change does not impose a requirement on plans to employ a particular number of physicians or other health care professionals for purposes of reviewing organization or coverage determinations. One commenter noted that the new requirement will result in undue increased cost to plans.

Response: We are not specifying the number or mix of physicians and other health care professionals MA organizations or Part D plan sponsors must employ or otherwise engage to review initial coverage decisions involving medical necessity. Plans are responsible for ensuring adequate staffing levels based on caseload mix and volume and other business factors. We believe that this flexibility, coupled with our clarification in the final rule that a physician or other appropriate health care professional must be involved in a medical necessity review only if the plan expects to issue an unfavorable decision significantly reduces or eliminates any potential burden to plan sponsors. We do not believe it is unreasonable or excessively burdensome for an MA organization or Part D plan to utilize the services of physicians and other health care professionals for medical review activities.

Comment: One commenter noted that, instead of requiring knowledge of the Medicare program as stated in the proposed rule, reviewers need only have knowledge of Medicare coverage requirements.

Response: We agree with the commenter that requiring knowledge of the Medicare program is unnecessarily broad, and that our primary expectation is based on reviewers having knowledge of Medicare coverage requirements. We are revising the proposed language accordingly. However, reviewers are expected to follow all applicable Medicare requirements, such as adjudication timeframes, in the performance of their duties. Plan sponsors are responsible for having adequate internal controls in place to ensure that their reviewers follow all of these requirements. Thus, this change does not in any way negate a plan sponsor's responsibility for ensuring compliance with Medicare's program requirements.

Based on our review and consideration of the comments received on this proposal, we are finalizing both § 422.566 and § 423.566 by revising them to include a new paragraph (d). Under new § 422.566(d) and § 423.566(d), if a plan expects to issue a partially or fully adverse medical necessity decision based on the initial review of the request, a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, must review the request before the plan issues its decision. We also require the physician or other health care professional to have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

In a related proposal to enhance the plans' clinical decision making process, we also proposed to revise § 422.562(a) by adding paragraph (4) and to revise § 423.562(a) by adding paragraph (5) to require MA organizations and Part D plan sponsors, respectively, to employ a medical director who is responsible for ensuring the clinical accuracy of all decisions involving medical necessity. We also proposed that the medical director must be a physician with a current and unrestricted license to practice medicine in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia. As noted in the proposed rule, we believe the requirement to employ a medical director will enhance the coordination and accountability of plan operations and strengthen quality assurance activities within these organizations. We received many comments on these proposed revisions.

Comment: One commenter sought clarification on whether the medical director must review all medical necessity determinations and appeals or whether plans will be required to establish a process for elevating reviews to the medical director. Other commenters sought clarification that the medical director would only review adverse organization determinations and would not review favorable organization determinations.

Response: Under our proposal, the medical director would have overall responsibility for the clinical accuracy of plan decisions. In this oversight role,

we expect there to be a process for elevating issues of concern to the medical director, but we do not expect that a plan's medical director will review each and every decision involving medical necessity. The medical director should collaborate with appropriate staff with respect to all plan operations that involve medical and utilization review, benefits and claims management, and quality assurance activities.

Comment: Some commenters argued that the proposed regulatory language should be revised to permit MA organizations and Part D plans sponsors to retain a medical director who is not directly employed by the MA organization or Part D plan sponsor, but rather performs this function under a contractual arrangement. A few commenters stated that plans may prefer to utilize physicians through a physician organization, or physicians who spend part of their time in clinical practice. One commenter strongly supported direct employment of a medical director, but sought clarification on whether a plan can fulfill this requirement by retaining multiple medical directors (such as, one for Part C and one for Part D).

Response: We acknowledge that plans utilize a variety of subcontracting arrangements to perform some or most of their functions, including subcontracting with physician groups to perform medical review activities. Proper claims adjudication and accurate clinical decision-making in organization and coverage determinations, reconsiderations, and redeterminations are integral to the successful performance of a plan's contract. Those decisions all involve items, services, or medications ordered or performed by a physician or other health care professional. In that vein, it is not unreasonable to expect a plan to employ a medical director to ensure that the decision-making process is clinically accurate, appropriate, and comports with Medicare coverage guidelines. We have already clarified that we do not expect that a medical director would review all decisions issued by the plan, but instead would have the primary responsibility of providing oversight for plan operations that involve medical and utilization review, benefit, formulary and claims management, and quality assurance activities.

It should be noted that all other entities that adjudicate Medicare cases are already required to employ a medical director, including the Medicare Part C and Part D Independent Review Entities (IREs). All Medicare Administrative Contractors (MACs) in the Original Medicare Program are required to employ a Medical Director, as are all of the IREs, known as Qualified Independent Contractors (QICs) in the Original Medicare program. The intent of imposing such a requirement on MA organizations and Part D plan sponsors is the same as it is for those entities—that is, to ensure that such decisions are clinically accurate, appropriate, and comport with Medicare coverage guidelines.

We note that plans are ultimately responsible for the clinical accuracy and appropriateness of their processes and decisions, which includes oversight of their first tier, downstream and related entities. Without a medical director employed by the plan to review decision making processes of contracted entities (such as IPAs or PBMs), the plan would be unable to ensure the decisions were clinically accurate or appropriate. A medical director employed by a contracted entity is ultimately responsible to that entity and is in no position to inform the plan if they believe their employer's procedures or decisions are inappropriate. MA organizations and Part D plan sponsors must evaluate CMS' requirements and make staffing arrangements that will ensure compliance with our requirements. Therefore, we will move forward with implementing the requirement that MA organizations and Part D plan sponsors employ a medical director. We will not, however, specify the staffing level needed for this position. Instead, we will allow plans the discretion to retain a medical director that works less than full time or multiple medical directors as they deem appropriate to comply with our requirements.

Comment: One commenter noted that CMS' rationale in support of the requirement that plans employ a medical director does not support the accompanying requirement that the medical director be a physician.

Response: We disagree with the commenter. In the proposed rule, we noted that MA organizations and Part D plan sponsors will be required to employ a medical director who would be responsible for ensuring the clinical accuracy of all decisions involving medical necessity. This physician oversight requirement is consistent with the existing statutory and regulatory requirements at 1852(g)(2)(B) of the Act and § 422.590(g)(2) and § 423.590(f)(2) that all medical necessity redeterminations and reconsiderations be reviewed by a physician with expertise in the field of medicine that is appropriate for the services at issue. We also noted that, with respect to the Part D program, the proposal to require the employment of a medical director who is a physician would enhance the performance of other critical plan functions such as formulary administration and application of plan coverage rules, and assist in the early identification and correction of potential quality concerns. Given this, we continue to believe that the role of a medical director requires the expertise of a physician, and are retaining the associated requirement.

After consideration of the comments on this proposal, and for the reasons noted previously, we are finalizing the proposal to require MA organizations and Part D plan sponsors to employ a medical director by adding paragraph (4) to § 422.562(a) and by adding paragraph (5) to § 423.562(a).

6. Compliance Officer Training (§ 422.503 and § 423.504)

Pursuant to our authority under section 1857(d) of the Act for Part C, and sections 1860D–4(c)(1)(D) and 1860D–12(b)(3)(C) of the Act (the latter of which incorporates section 1857(d) by reference), we proposed that MA organization and Part D sponsor compliance officers be required to complete annual MA and/or Part D compliance training starting in 2013. Organizations applying for the 2013 contract year that are new to the MA or Part D programs would have been required under this proposal to have their compliance officers obtain training in 2012 to prepare for the upcoming contract year. We proposed to add § 422.503(b)(4)(vi)(B)(1)(i) and (ii) to subpart K of Part 422 and § 423.504(b)(4)(vi)(B)(1)(i) and (ii) to subpart K of Part 423 to reflect this change. We proposed these training clarifications because our reviews have found that many MA and Part D compliance officers lack basic knowledge about the requirements of the MA and Part D programs. Our reviews have also found that many compliance officers do not seem to understand that we expect sponsors to actively ensure compliance with Medicare program requirements; that those requirements are distinct from any commercial health or drug plan benefits they may administer; and that they should not solely rely on subcontractors or CMS to identify and resolve Part C and Part D contract compliance matters for them. We stated our belief that requiring annual training for compliance officers would help to address the knowledge gap by emphasizing the necessity of compliance officer training and the compliance officer's critical role in

maintaining and ensuring program compliance. However, based upon the comments received, CMS will not be codifying these provisions at this time.

Comment: Most commenters supported CMS' proposal to require compliance officer training.

Response: We agree with these commenters that compliance officer training would address our aforementioned concerns about the level of knowledge compliance officers have about the Medicare Part C and D programs, but for reasons discussed below, we are not finalizing our proposals at this time.

Comment: The vast majority of comments regarding compliance officer training were requests for clarification from industry regarding who should take the training and the content, forum, format, and duration of the training. Specifically, commenters were unsure if CMS intended for the organization's corporate compliance officer or for its Medicare compliance officer to attend training. Other commenters suggested that only plan sponsors with poor audit results or significant compliance problems should be required to take training. Nearly all commenters wanted more details about the content or curriculum for the training. Some thought that training should be designed to allow the compliance officer to focus on areas or issues that presented the most risk to their organization. Other commenters wanted to know if the content would focus on compliance programs and plans or if it would focus on Medicare Part C and D programs and compliance with those requirements. With respect to the format of the training, some plan sponsors wanted only CMS to provide the training either in-person or via the Internet, while other plan sponsors wanted compliance courses and conferences offered by non-CMS entities to be counted towards the annual training requirement. Lastly, one commenter suggested that the training should not exceed 12 hours per year.

Response: We agree that more clarification is warranted regarding the audience, content, forum, format, and duration of proposed compliance officer training. Therefore we will not be codifying the proposed rule regarding compliance officer training at this time. We will carefully consider whether to propose a similar rule in the future that will address the clarifications suggested by industry.

Accordingly, we have not included Paperwork Reduction Act (PRA) paperwork burden or regulatory impact analysis estimate for this provision.

7. Removing Quality Improvement Projects and Chronic Care Improvement Programs From CMS Deeming Process (§ 422.156)

Under section 1852(e) of the Act, we have delegated our authority to evaluate whether an MA organization is in compliance with certain Medicare requirements to three private accrediting organizations. Currently, MA organizations may be deemed to meet requirements in a number of areas, including quality improvement (QI), as specified in § 422.156(b).

We currently require all MA organizations to submit their quality improvement projects (QIPs) and chronic care improvement programs (CCIPs) on an annual basis. In our November 2010 proposed rule (75 FR 71227), we proposed to amend § 422.156(b) to specify that, while QI would still be a component of the deeming process, QIPs and CCIPs would be excluded from the deeming process for QI. We also clarified that the QIPs and CCIPs would instead be reviewed and evaluated by CMS or an appropriate CMS contractor. After considering comments we received on this proposal, we are finalizing this provision without modification.

Comment: One commenter supported the removal of QIPs and CCIPs from the deeming process, to the extent that CMS intends to collect QIPs and CCIPs for review on an annual basis. This commenter recommended that, in order to avoid redundancy and unnecessary burden for plans, deeming authorities should not be allowed to request the submission of QIPs and CCIPs as part of the deeming process.

Two commenters stated that removing the QIPs and CCIPs from the deeming process would negatively impact staffing resources for health plan medical management, since both are reviewed by NCQA during site visits. These commenters believed that maintaining two unique reporting formats for the same quality programs would be duplicative.

Response: We appreciate commenters' concerns about duplication of efforts. In our proposed rule, we proposed to exclude the QIPs and CCIPs as components of the deeming process for QI precisely because we were aware of the duplication of effort associated with submission of this information to both CMS and NCQA, as well as auditing efforts by both entities. As we stated in our proposed rule, removing the QIPs and CCIPs from the deeming process for QI will avoid redundancy and reduce burden for MA organizations. We believe removal of QIPs and CCIPs from the deeming process for QI is essential to improving consistency in the evaluation and assessment of the QIPs and CCIPs, especially given that some elements therein may be incorporated into future plan ratings. Therefore, we are finalizing our proposal without modification.

Comment: One commenter advised that removing two important elements of the overall QI program would make it almost impossible for NCQA to provide a balanced and comprehensive assessment of the overall QI program and recommends that CMS reconsider this proposal.

Response: We disagree with the commenter's assertion that removal of QIPs and CCIPs will result in NCQA's inability to assess the QI program plans of its deemed entities. There are a number of quality performance measures that an accreditation organization may use to measure QI for purposes of deeming. Therefore, we are finalizing our proposal without modification.

Comment: Several commenters recommended that CMS consider allowing MA plans the flexibility to focus on QIPs and CCIPs that meet the unique needs of their target populations.

Response: Irrespective of whether or not CMS identifies a list of specific clinical and/or non-clinical topics for QIPs and CCIPs, MA plans will retain the flexibility to develop their own special projects. Furthermore, plans' QIPs and CCIPs must always address the target population for a specific plan in order to demonstrate QI under their plans. Identification of the appropriate target population is a key component for ensuring QI and is the first element CMS assesses when reviewing the QIPs and CCIPs.

Comment: One commenter recommended that CMS release standards that will be used in determining if QIP and CCIP program standards are met.

Response: We appreciate the commenter's interest in this issue. The submission of QIPs and CCIPs will be an ongoing annual QI assessment activity for all MA organizations and SNPs. In an effort to improve consistency, we are reviewing the current QIP and CCIP program standards in an effort to determine where improvement is necessary. Guidance regarding changes to the QIP and CCIP program standards will be provided in separate guidance such as an HPMS memoranda and annual call letters.

Comment: Several commenters recommended that CMS continue to permit MA organizations that currently use the deeming process to continue to

do so, and apply our proposed requirement only to MA organizations that avail themselves of the deeming process in the future.

Response: We disagree that our proposed requirement should apply only to MA organizations not currently using the deeming process. While MA organizations may continue to utilize the deeming process for areas specified in § 422.156, including QI, we are finalizing our proposal without modification and clarify that it will apply to all MA organizations including SNPs.

Comment: One commenter recommended that CMS should consider allowing plans with a high star rating on quality measures the option to use the deeming process.

Response: We clarify that the goal of our proposal in our November 2010 proposed rule was not to eliminate deeming, or even deeming for QI requirements but, rather, to exclude QIPs and CCIPs as deemable QI elements.

8. Definitions of Employment-Based Retiree Health Coverage and Group Health Plan for MA Employer/Union-Only Group Waiver Plans (§ 422.106)

In our November 2010 proposed rule (75 FR 71227), we stated our concern that, since enactment of the MMA, MA organizations have been contracting with entities that cannot properly be characterized as employment-based group health plan coverage (for example, professional or group associations) to provide coverage to MA beneficiaries via employer group waiver plans (EGWPs) or individual MA plans. Specifically, some MA organizations have characterized contracts with professional or group associations as employment/union coverage. We stated we believed that this was inconsistent with the requirement in section 1857(i) that such waivers facilitate a contract between an MA organization and employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or a 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, as this language is interpreted in guidance in Chapter 9 of the Medicare Managed Care Manual (*http://www.cms.gov/manuals/downloads/mc86c09.pdf*), entitled "Employer/Union Sponsored Group Health Plans. This guidance clearly restricts employer/union group health plan enrollment in EGWPs and individual MA plans to beneficiaries who are Medicare eligibles of an employer/union sponsored group health plan. Such a plan is one that is employment-based health coverage through an employer/union group health plan that has entered into a contractual arrangement with an MA organization to provide coverage or that has contracted directly with CMS to provide coverage for its Medicare eligibles. To clarify our requirements for offering employment-based retiree coverage via an MA plan, we proposed to codify definitions of the terms employer-sponsored group MA plan, employment-based retiree health coverage, and group health plan at § 422.106(d)(4) through (6). We also proposed to change the reference to an MA plan at § 422.106(d) to a reference to an employer-sponsored group MA plan. In proposing these definitions, we noted that they were consistent with those provided for Part D sponsors at § 423.454 and § 423.882. We solicited comment on our proposals to revise these definitions.

After considering comments received on these proposed changes, we are finalizing these provisions without modification.

Comment: One commenter agreed with CMS that membership in an association would by itself not have a sufficient employment nexus to qualify as employment-based coverage and also noted that our proposed definitions of the terms employer-sponsored group MA plan, employment-based retiree health coverage, and group health plan are consistent with the comparable definitions for Part D sponsors at § 423.454 and § 423.882.

Two commenters believed that our proposed definitions of the terms employer-sponsored group MA plan, employment-based retiree health coverage, and group health plan would unintentionally exclude coverage by associations that is truly tied to employment in such associations, and that a wholesale exclusion of associations and similar entities from the definition of employment-based retiree coverage would be overly broad and inconsistent with coverage in the commercial market. One of these commenters explained that there are a variety of types of associations, including (but not limited to) an association of farm bureaus, for which eligibility for health coverage is tied to membership in the association or bureau.

Response: We do not believe that Congress envisioned granting access to EGWP waivers based on membership in an association or any entity that did not meet the definition of a group health plan, as defined under the Employee Retirement Income Security Act (ERISA). Our intent in defining an employer-sponsored group MA plan, employment-based retiree health coverage, and a group health plan was not to preclude all associations from enrolling Medicare beneficiaries in EGWPs and individual MA plans, but, rather, to ensure that a beneficiary's enrollment in one of these MA plans is based on his/her receipt of employment-based health coverage from and employer/union group health plan sponsor. To the extent that membership in an association is based on employment, that association could meet the definition employment-based retiree coverage. For example, an association may elect to provide coverage via an EGWP or individual MA plan to retirees who were formerly employed by the association. We also clarify that we believe that employers such as school districts could form an association for the purpose of purchasing employer coverage on behalf of retirees from the school districts and that this would be acceptable because, independently, each school district would be eligible to enroll its retirees in an EGWP or individual MA plan. Therefore, two or more school districts could combine to form an association for the purpose of purchasing retirement coverage for their retired employees. However, an association of farm bureaus would not meet this test if membership in a farm bureau were not exclusively based on former employment by these farm bureaus.

Comment: Two commenters expressed concern that our proposed definitions of employment-based retiree coverage and a group health plan at § 422.106(d)(5) and § 422.106(d)(6), respectively, would preclude employers that do not contribute financially to retirees' health care costs—including cases where an employer plan is provided at no cost to the employer or the employer furnishes a pension in lieu of payment for health care coverage for its retirees—from enrolling retirees in an employer-sponsored group MA plan. This commenter recommended that CMS revise its proposed regulatory language to ensure that the definition of employment-based coverage is not tied to a financial contribution from the employer.

Another commenter stated that employers that are not contributing financially to retirees' health care costs, which is an increasing trend in the marketplace, can still meaningfully contribute to their retirees' health care coverage by bargaining with an MA organization on behalf of its retirees for

the best possible deal on premium and benefit design. This commenter also noted that employers may choose to assist their retirees by administering the MA plan premium payment process.

Response: Our proposed definitions would require that employment-based retiree coverage include coverage of health care costs in accordance with the ERISA definition of a group health plan. While there is not a minimum amount an employer must contribute toward such employment-based retiree coverage, we believe it is important that an employer make both a financial contribution toward coverage and negotiate on behalf of its retirees for a benefit package and cost sharing levels which are as favorable as possible for them. We are therefore finalizing our proposed revisions to § 422.106(d) without modification.

Comment: One commenter requested that CMS ensure that coverage offered by a union or trust is considered employment-based as recognized by the section 1857(i) of the Act.

Response: We agree that members or former employees of unions and trusts, as recognized under section 1857(i) of the Act, generally meet the definition of employment-based retiree coverage and could offer MA coverage to retirees who are Medicare eligible individuals through an EGWP or individual MA plan.

D. Strengthening Beneficiary Protections

This section includes proposed provisions aimed at strengthening beneficiary protections under Parts C and D. Some of the provisions affecting both Parts C and D include proposed regulations codifying the requirement that MA organizations and Part D sponsors provide interpreters for non-English speaking and limited English proficient callers, and periodically disclose to each beneficiary specific data for enrollees to use to compare utilization and out-of-pocket costs in the current plan year to the following plan year. Changes affecting only Part C include an extension of the mandatory maximum out-of-pocket (MOOP) amount requirements to regional PPOs, and under Part D, we address the delivery of adverse coverage determinations.

In the area of Parts C and D marketing, proposed provisions include a proposal requiring MA organizations' and Part D sponsors' agents and brokers to receive training and testing via a CMS endorsed or approved training program and a proposal to extend annual training and testing requirements to all agents and brokers marketing and selling Medicare products.

This information is detailed in Table 6.

TABLE 6: Provisions to Strengthen Beneficiary Protections

PROVISION	PART 422		PART 423	
	Subpart	Section	Subpart	Section
Agent and Broker Training Requirements	Subpart V	§422.2274	Subpart V	§423.2274
Call Center and Internet Website Requirements	Subpart C	§422.111	Subpart C	§423.128
Require Plan Sponsors to Contact Beneficiaries to Explain Enrollment by an Unqualified Agent/Broker	Subpart V	§422.2272	Subpart V	§423.2272
Customized Enrollee Data	Subpart C	§422.111	Subpart C	§423.128
Extending the Mandatory Maximum Out-of-pocket (MOOP) Amount Requirements to Regional PPOs	Subpart C	§422.100 §422.101	N/A	N/A
Prohibition on Use of Tiered Cost Sharing by MA Organizations	N/A	N/A	N/A	N/A
Delivery of Adverse Coverage Determinations	N/A	N/A	Subpart M	§423.568
Extension of Grace Period for Good Cause and Reinstatement	Subpart B	§422.74	Subpart B	§423.44
Translated Marketing Materials	Subpart V	§422.2264	Subpart V	§423.2264

1. Agent and Broker Training Requirements (§ 422.2274 and § 423.2274)

a. CMS Approved or Endorsed Agent and Broker Training and Testing (§ 422.2274 and § 423.2274)

In the November 2010 proposed rule, in implementing sections 1851(h)(2), 1860D–1(b)(1)(B)(vi), 1851(j)(2)(E), and section 1860D–4 (l)(2) of the Act, we proposed revising § 422.2274(b) and (c) and § 423.2274(b) and (c) to require MA organizations' and Part D sponsors' agents and brokers to receive training and testing via a CMS-endorsed or approved training program. We proposed this revision to move toward greater standardization of agent broker training and testing and ensure that agents and brokers selling Medicare products have a comprehensive and consistent base of understanding of Medicare rules.

In addition, we proposed that following the implementation of the final rule, we would review and endorse or approve one or more entities to provide annual testing and training to Medicare agents and brokers. We specifically requested comments and suggestions on alternatives to using a competitive request for proposals (RFP) process under the Federal Acquisition Rules to effectuate this effort.

We further proposed that these new requirements also be applicable to section 1876 cost contract plans, since in our April 2010 final rule (75 FR 19784 through 19785), we extended the MA marketing provisions in part 422 to section 1876 cost contract plans.

Comment: Many of the comments received supported the proposal and responded to our request for suggestions. The suggestions offered in conjunction with the approval were (1) provide a low-cost option to the public or non-profit sector; (2) provide uniform training and testing materials that can be graded by an outside independent entity; (3) create a separate test for the general Special Needs Plan (SNP); and (4) include information regarding SPAPs, COB rules and eligibility in the training.

Response: The purpose of standardizing the training and testing is to ensure continuity, accuracy and quality of training and testing vehicles. We will evaluate and approve vendor products by developing specific criteria against which training and testing programs will be assessed. We will take into consideration and evaluate the options for lower cost offerings to the public and non-profit sector and will also consider the suggestions for developing training and testing modules.

Comment: One commenter requested clarification of our use of the terms CMS "endorsed" training program and CMS "approved" program.

Response: Although the intent of the language was to use the two terms interchangeably, we note that the final selections of the developed vendor products will first be approved by our agency and subsequently certified or endorsed.

Comment: One commenter recommended that CMS apply the same bid process as we apply to the plans using the training portal. They expressed full support for having a certified company provide the training and a certification that they can accept without having to provide that training themselves.

Response: We believe this commenter was referring to our pilot agent/broker training and testing module in 2009. We do not believe the development approach taken for that module is appropriate for the current effort, given that we developed the training under that approach and solicited volunteer plan sponsors to train and test their agents via the pilot training and testing module. We will consider all access and value options prior to and throughout the solicitation of training and testing information and technical proposals.

Comment: One commenter supported CMS's proposal to require specific training for agents and brokers and also recommended that CMS training be specific to the plan the agent/broker is actually selling. Other commenters requested that plan sponsors be allowed the option of continuing to develop and administer training and testing that complies with CMS specified criteria. Specifically, the commenter stated that plans should continue to be responsible and held accountable for adequate training regimens, and requested that CMS continue to impose training obligations on plans rather than contracting with third-party entities to provide such training to plan employees and contractors.

Response: We do not have the resources at this time to initiate development by vendors of training and testing vehicles that would contain plan-specific details for each plan type for which organizations contract with CMS. Plan sponsors will continue to be responsible for administering plan specific training and testing to brokers and agents. Our development of an "approved or endorsed" training and testing program will ensure consistency and accuracy across plan sponsors.

Comment: One commenter proposed that we allow plans to review training and testing products before they are finalized and to make further recommendations regarding the specific companies and organizations that would develop the specific products. The commenter urged that CMS provide a transparent process and agreed with using the RFP process to develop an "approved or endorsed" training and testing curriculum. The commenter stated that the curriculum and its development should not be considered proprietary, even if it is developed by a private contractor.

Response: We will not consider a plan preview of products prior to finalizing our decisions. We will develop specific requirements and implement a process for reviewing proposals to ensure participants meet the requirements and develop a training and testing program as specified in future guidance. Furthermore, we believe that allowing plans to review the training and testing proposals and recommend approval of specific organizations might interfere with our ability to ensure a level playing field.

Comment: One commenter noted that it is not a practice of PACE programs to utilize agents and brokers in their efforts to inform the public about their program. The commenter requested the CMS clarify that the training and testing requirements to not supersede or modify the requirements currently applicable to PACE programs.

Response: PACE plans are governed by separate requirements which are not included in these provisions. These requirements do not supersede or modify the current requirements applicable to PACE programs.

b. Extending Annual Training Requirements to All Agents and Brokers (§ 422.2274 and § 423.2274)

In the November 2010 proposed rule, we proposed a change in the regulations text that would correct an omission in our current regulations at § 422.2274(b) and (c) and § 423.2264(b) and (c). These regulations currently require MA organizations and Part D sponsors to ensure that independent agents selling Medicare products are trained and tested annually on Medicare rules and regulations specific to the plan products they intend to sell. Consistent with our statutory authority at sections 1851(j)(2)(E) and 1860D–4(l)(2) of the Act, we proposed to revise § 422.2274 and § 423.2274 to correctly apply these requirements to all agents and brokers marketing and selling Medicare products, whether independent agents or employees.

In addition, we also noted that these new requirements would be applicable to section 1876 cost contract plans, since in our April 2010 final rule (75 FR 19784 through 19785), we extended the MA marketing provisions in Part 422 requirements to section 1876 cost contract plans.

After considering the comments we received, we are finalizing our proposal without further modification.

Comment: One commenter expressed support for correcting the error in § 422.2274(b) and (c) and § 423.2264(b) and (c) that applied training requirements only to independent agents and brokers.

Response: We agree that all agents and brokers, including those employed by MA and Part D plans, should be subject to the same training and testing requirements. Therefore, we are adopting as final our proposed correction to § 422.2274(b) and (c) and § 423.2264(b) and (c).

2. Call Center and Internet Web site Requirements (§ 422.111 and § 423.128)

a. Extension of Customer Call Center and Internet Web site Requirements to MA Organizations (§ 422.111)

Under the authority of section 1852(c) of the Act, which requires MA organizations to disclose MA plan information upon request, as well as the authority of section 1857(e) of the Act

to specify additional contractual terms and conditions the Secretary may find necessary and appropriate, we proposed to extend call center and Internet Web site requirements to MA organizations to parallel to those applicable to Part D sponsors. We proposed to amend § 422.111 by adding a new paragraph (g) to expressly require MA organizations to operate a toll-free customer call center that is open during usual business hours and provides customer telephone service in accordance with standard business practices, as well as to provide current and prospective enrollees with information via an Internet Web site and in writing (upon request). We proposed this amendment to ensure that current and prospective enrollees of MA plans have the same access to customer service call centers and information via an Internet Web site as current and prospective enrollees of a Part D plan in order to obtain more information about plan coverage and benefits. We also noted that although similar call center and Internet Web site requirements were never codified for MA plans, we have required through subregulatory guidance (the Medicare Marketing Guidelines at *http://www.cms.gov/ManagedCareMarketing/Downloads/R91MCM.pdf*) that MA organizations comply with the same requirements regarding customer service call centers as Part D sponsors, and, for those offering Part D benefits through MA–PD plans, all Part D sponsor Internet Web site requirements.

As part of the proposed rule, we also proposed removing paragraph § 422.111(f)(12), which requires that certain information—including the evidence of coverage, summary of benefits and information about network providers—be posted to an Internet Web site in the event that an MA organization has a Web site or provides MA plan information through the Internet, and moving these requirements to § 422.111(g)(2)(i).

After considering comments on our proposal, we are adopting these provisions as final with one modification, proposed paragraph (g) is redesignated as paragraph (h).

Comment: Several commenters expressed their support of our extending the call center and Web site requirements to MA plans. One commenter that supported our proposal believed that these requirements will serve to ensure beneficiaries receive the information needed to make informed decisions on their healthcare options.

Response: We thank the commenters for their response. We believe this change will allow MA enrollees the same access to customer service call centers services as a current or prospective members of a Part D plan. Therefore, we are finalizing our proposal without modification.

Comment: One commenter noted that regulations governing the PACE program provide for a waiver of the requirement to maintain customer call centers as well as the requirement to provide information via an Internet Web site.

Response: PACE plans are governed by separate requirements that are not included in these provisions. These requirements do not supersede or modify the current requirements applicable to PACE programs.

Comment: One commenter recommended that since the open enrollment period that existed for the first 3 months of the year has been replaced with a period during which an MA enrollee may disenroll from an MA plan, CMS should allow extended call center hours to coincide with the new 45-day annual period. Additionally, the commenter indicated that there is no need for continued weekend call center coverage by live agents after the 45-day period ends.

Response: We have taken these comments into consideration and will be proposing revisions to our Medicare Marketing Guidelines for contract year 2012 that would require all plan sponsors to have extended call center hours during the 45-day annual disenrollment period (January 1 to February 14 of each contract year).

b. Call Center Interpreter Requirements (§ 422.111 and § 423.128)

Pursuant to our authority under sections 1857(e)(1) and 1860D–4(a)(3)(A) of the Act to specify additional contractual terms and conditions the Secretary may find necessary and appropriate, we proposed to codify Medicare Part C and D requirements regarding current and prospective enrollee toll-free customer call centers. Specifically, we clarified that MA organizations and Part D sponsors must provide interpreters for all non-English speaking and limited English proficient (LEP) callers. We proposed to add new paragraphs § 422.111(g)(1)(iii) (redesignated as paragraph (h)) and § 423.128(d)(1)(iii), respectively, to reflect this clarification.

This clarification is a result of findings from our call center monitoring, which revealed that a significant percentage of MA organizations and Part D sponsors were not providing foreign language interpreters for non-English speaking callers. This clarification addressed the problem by explicitly codifying the requirement to provide interpreters for LEP callers in regulations.

Comment: Several commenters from advocacy groups and industry supported codification of CMS' requirement that MA organizations and Part D sponsors must provide interpreters for non-English speaking and LEP individuals.

Response: We agree with these commenters because requiring interpreters ensures LEP beneficiaries have access to Medicare Part C and D benefit information.

Comment: A few commenters asked for clarification regarding the requirement that interpretation services should be available for "all" languages. Commenters offered alternatives such as providing interpreters for languages that meet a 10 percent threshold or require plan sponsors to provide interpreters for all languages spoken by more than 10 percent of the plan's membership.

Response: We agree with commenters who noted that "all" may be too inclusive, as there are more than 6,000 languages spoken world-wide. As such, we are striking the word "all" from the proposed language. Based on data collected during the 2000 U.S. Census, more than 300 languages are spoken in the United States. We revised the regulatory language to read as follows, "Provides interpreters for non-English speaking and limited English proficient (LEP) individuals." Our expectation is that MA organizations and Part D sponsors' call centers will provide interpretation services for all languages that are served in common by the largest commercial interpretation service providers in the U.S., as these organizations are experts in assessing the languages for which interpretation services are needed. Currently these large organizations provide interpretation services for approximately 150 to 180 languages, which accommodates the vast majority of interpretation needs. Our Medicare Marketing Guidelines have long established the expectation that MA organizations and Part D sponsors provide interpretation services to any LEP caller. Our monitoring of this area has demonstrated that MA organizations and Part D sponsors' call centers are capable of providing interpreters to meet the needs of LEP callers when they use commercial interpretation service providers.

We do not accept the suggested alternatives, that is, to require that plan sponsors only provide an interpreter for languages that meet a 10 percent threshold or require plan sponsors to provide interpreters for all languages spoken by more than 10 percent of the

plan's membership. Because beneficiaries are not required to indicate their primary or preferred language when they enroll in a plan, it would be impossible for a plan sponsor to know all the languages they would need to interpret. Moreover, the availability of commercial interpretation service providers for these 150–180 languages is a cornerstone of CMS' effort to establish the widest practical safety net for providing access to those individuals who are outside of the translation threshold requirement for translating marketing materials found in § 422.2264 and § 423.2264.

Comment: One commenter asked CMS to clarify whether MA organizations and Part D sponsors are required to have interpreters on-site.

Response: We clarify that MA organizations and Part D sponsors may use on-site interpreters, contract with a commercial interpretation service provider, or employ some combination of both approaches. For instance, many MA organizations and Part D sponsors provide Spanish language interpretation on-site while using one of the numerous and readily available commercial interpreter services to providers for other languages.

Comment: One commenter requested clarification as to whether the Program of All-inclusive Care for the Elderly (PACE) program is subject to the requirement that plan sponsors maintain toll-free customer call centers.

Response: Although this comment is not within the scope of the proposed rule, we clarify that PACE programs are not subject to this requirement.

Comment: One commenter suggested that CMS provide best practices for plan sponsors regarding interpretation services. The commenter also asked CMS to discuss methods for preventing long wait times for non-English speaking callers.

Response: We agree with this comment, and we have made a concerted effort to disseminate best practices on this topic. In a Health Plan Management System (HPMS) memo published to all plan sponsors on January 2, 2008 entitled "Best Practices for Addressing the Needs of Non-English Speaking and Limited English Proficient (LEP) Beneficiaries," We provided guidance to plans, which addressed, among other topics, call center phone systems and customer service representative staffing, training, and oversight. Additionally, when we issue informational memos or compliance letters to plan sponsors regarding our call center monitoring results, we include a special section that lists tips for how an organization can improve its service to LEP beneficiaries.

With regard to concern about long wait times for LEP callers, data collected during our call center monitoring study indicated that the average hold time for an interpreter was one minute and sixteen seconds. This hold time is below our existing 2 minute hold time standard in the Medicare Marketing Guidelines.

In summary, we are finalizing this provision, and the only change from the proposed version is to strike the word "all."

3. Require Plan Sponsors To Contact Beneficiaries To Explain Enrollment by an Unqualified Agent/Broker (§ 422.2272 and § 423.2272)

Current regulations (§ 422.2272 and § 423.2272) require plan sponsors that use independent agents and brokers for their sales and marketing to only use State licensed and appointed agents or brokers. Under these provisions, plan sponsors must also report the termination of agents or brokers to the State. Based on information uncovered during program audits, we proposed revisions to § 422.2272(c) and § 423.2272(c) to require MA organizations and Part D sponsors to terminate unlicensed agents upon discovery and notify any beneficiaries who were enrolled in their plans by unqualified agents. Since beneficiaries rely heavily on information they receive from agents regarding plan benefits and costs, we believe they should have the opportunity to ask additional questions or reconsider their enrollment when they have been enrolled in a plan by an unqualified agent.

In addition, we noted that these requirements would be applicable to section 1876 cost contract plans, since in our April 2010 final rule (75 FR 19784 and 19785), we extended the MA marketing provisions in part 422 to section 1876 cost contract plans.

After considering the comments we received, we are modifying the proposal as described below.

Comment: Several commenters were concerned that the requirement to notify beneficiaries when they have been enrolled by an unqualified agent is duplicative of the outbound enrollment verification call requirement and is unnecessary.

Response: The intent of this provision is not to duplicate the outbound enrollment verification process. Rather, it is to ensure that beneficiaries are fully informed of the circumstances of their enrollment and to allow them the opportunity to reconsider their options given the new information about the agent. While we do not anticipate that many beneficiaries will want to make plan changes based on notification that the agent is unqualified, especially considering that the plan sponsor likely would have already conducted the required outbound verification call, we believe that it is important that beneficiaries are fully informed of the details of their enrollment in the event the agent misrepresented the package of benefits in any way. Additionally, to ensure that we do not confuse beneficiaries with duplicative information, we have modified our original proposal at § 422.2272(c) and § 423.2272(c) to indicate that plan sponsors are required to provide affected enrollees with information about their options to confirm enrollment or make a plan change (including a special election period) at the beneficiary's request.

Comment: A few commenters requested clarification of our proposal, since plan sponsors are not allowed to use unlicensed agents.

Response: In the proposed rule, we used the term "unlicensed" and "unqualified" interchangeably. However, there is an important difference between the two terms. Being unlicensed is just one criterion for determining whether an agent or broker is qualified to sell Medicare plans. In addition to having a license (in States that require one), agents and brokers must also be trained annually, pass a Medicare test annually (with a score of 85 percent or better), and be appointed in States with appointment laws.

The final provisions would require plan sponsors to terminate unlicensed agents and report them to the State upon discovery. However, we have modified our original proposal at § 422.2272(c) and § 423.2272(c) to replace the term "unlicensed" with "unqualified" with respect to the beneficiary notification requirement. We did not propose terminating all unqualified agents or brokers because there may be circumstances in which an unqualified licensed agent should not be terminated—for example, an agent who takes an automated test, but a software bug notifies the agent that he has passed the entire test when he only passed the first component of the test. In this case, the plan sponsor would not be required to terminate the agent or report him/her to the State upon discovery; however, the plan sponsor would be required to notify individuals enrolled by that agent of his/her unqualified status.

Comment: One commenter suggested that CMS sanction plans that have repeated instances of unlicensed agents selling for them, and that agents be

required to include their national producer number (NPN) on the application.

Response: Due to the fact that some States do not participate with the National Insurance Producer Registry (NIPR), we are not considering requiring the agent NPN on the enrollment application. However, we will continue to evaluate ways to better monitor agent behavior, as part of our current surveillance, compliance, and enforcement processes. We will also monitor plan compliance with this new requirement.

Comment: A couple of commenters stressed the importance that beneficiaries not be pressured to enroll in another plan offered by the plan sponsor during the notification call.

Response: The purpose of the call is to notify beneficiaries that an unqualified agent was involved in their enrollment, not to persuade them to join other plans. We anticipate that most beneficiaries will appreciate the notice and may have some questions, but we do not anticipate that the majority of them will want to make a plan change. Plan sponsors will be expected to take the lead from the beneficiary, rather than initiate conversation about plan changes. We will provide more specific instructions for plans in subregulatory guidance.

Comment: One commenter asked whether a special election period (SEP) would apply when a beneficiary is enrolled by an unqualified agent, if the requirement would apply only during the AEP or throughout the year and what should a plan sponsor do if it is unable to reach the beneficiary.

Response: There will be no SEP specifically tied to enrollment by an unqualified agent; however, these circumstances will be treated just like any other complaint regarding marketing misrepresentation by an agent. The requirement will apply throughout the plan year because beneficiaries eligible for an SEP (for example, dual eligibles and those who move outside their plan's service area) can enroll in a new plan at other times during the year, and plans can market to these individuals. The contact requirements will be similar to the contact requirements for outbound enrollment verification calls. We will provide more direction through subregulatory guidance.

Comment: One commenter asked whether this requirement applied to family, friends, or others presenting themselves as agents.

Response: This requirement does not apply to situations in which family members or friends (who are not agents) give advice or recommendations to beneficiaries. However, plan sponsors should report individuals impersonating agents to the State Department of Insurance as unlicensed agents.

4. Customized Enrollee Data (§ 422.111 and § 423.128)

In our November 2010 proposed rule (75 FR 71230), we discussed our concern that information that MA organizations and Part D provide their enrollees annually in the annual notice of change/evidence of coverage (ANOC/EOC) document may not be enough to prompt enrollees to actively evaluate their plans annually with respect to plan costs, benefits, and overall value. Therefore, we proposed to require MA organizations and Part D sponsors to periodically provide each enrollee with enrollee specific data to use to compare utilization and out-of-pocket costs in the current plan year to projected utilization and out-of-pocket costs for the following plan year. We proposed to add new paragraphs (12) and (11) to § 422.111(b) and § 423.128(b), respectively, to specify this requirement. Plans would disclose this information to plan enrollees in each year in which a minimum enrollment period has been met, in conjunction with the ANOC/EOC.

We discussed several options for implementing this data disclosure requirement (75 FR 71230 through 71233), and we noted that the proposed rule only specified our authority to require such a disclosure. We sought suggestions and comments from MA organizations, Part D sponsors, the beneficiary community, and other external stakeholders related to the design, content, and the cost calculations to assist us in implementing these provisions. In addition, we noted that we were considering implementing a pilot program for CY 2012 with a few MA organizations and Part D sponsors to test approaches to conveying customized beneficiary data, based on the comments and suggestions that we received.

We also solicited comments on the possibility of exempting dual eligible special needs plans (D–SNPs) from the requirement to provide such customized enrollee data through a customized out-of-pocket cost statement or an explanation of benefits (EOB), since enrollees in these plans generally do not incur out-of-pocket costs. We sought comment on exempting D–SNPs from this requirement.

After considering the comments we received, we are modifying our original proposal, as described below.

Comment: Many commenters expressed appreciation for our effort to identify the best ways to provide useful information to beneficiaries. However, while a few commenters supported requiring a customized statement that would provide an estimate of future costs, most commenters opposed this model, citing the administrative and financial burden on plans.

Many commenters stated that a customized estimate of future costs would create more significant administrative, financial and IT resource burdens on MA plans and Part D sponsors than CMS anticipated in its proposal. These commenters stated that the expense and operational burden of the proposal could not be justified relative to its value to beneficiaries, considering the potential for beneficiary confusion and dissatisfaction that may result from any projection of future costs. Other commenters stated that such a requirement would likely result in the need for additional funding of audits as well as rigorous quality assurance programs consistent with HIPAA requirements related to the dissemination of this type of document with the ANOC/EOC. Several commenters expressed concerns that such a requirement would result in a need to significantly increase call center or 1–800–Medicare staffing to handle the questions resulting from the documents; or that it would also result in more complaints to monitor in the Complaints Tracking Module. One commenter suggested that the significant costs of producing and distributing a custom statement would increase administrative costs that, in turn, might increase plan bids and result in a negative impact on benefits and or premiums.

Several commenters suggested that providing these reports for Part D benefits would be very burdensome, even assuming that drug prices will not change in the following year. They stated that it would be difficult to estimate future expenses related to the initial coverage limit and coverage gap. Several commenters also stated that since enrollees already receive Part D EOBs, a customized out-of-pocket cost statement would be redundant and confusing for beneficiaries. Another commenter asked how plans would be expected to coordinate between the medical and prescription drug portions of their benefit to the extent that we required a customized out-of-pocket cost statement to include information about Parts C and D costs.

Many stated that requiring a customized out-of-pocket cost statement to be "bundled with" the ANOC and EOC presents an insurmountable timing problem due to the change in the annual

enrollment period (AEP). They expressed concern that, due to the timing of bid approvals, usually in August, that the remaining four-to-six week period would be much too short to prepare these data and mail a customized statement to each beneficiary with his/her ANOC/EOC. Several commenters stated that it is an expensive and time consuming process to place an extra customized document into an envelope package with a standard ANOC/EOC. However, one commenter recommended that any customized enrollee data be based on current year utilization only and that data should be included in the ANOC instead of a separate document to save on costs associated with development, printing, and fulfillment of an incremental document while creating just one document for beneficiaries to read.

One commenter stated that a standard, CMS-designed report would eliminate the existing flexibility that plans have to tailor enrollee communications to their particular needs.

A few commenters expressed concerns related to the ability of network providers receiving capitated payments for medical services to calculate out-of-pocket costs. Several commenters noted that some plans have established limited mechanisms to calculate the MOOP, but that these systems may not incorporate necessary utilization data such as the specific service the enrollee received and that this information would have to be extracted from multiple sources.

Response: We appreciate the many thoughtful and detailed responses submitted by commenters. As we noted in our proposed rule (75 FR 71230), we have been concerned that the ANOC/EOC information alone may not be enough to prompt enrollees to actively evaluate their plans annually with respect to plan costs, benefits, and overall value. We also acknowledged receiving requests from the beneficiary advocacy community to require that MA organizations and Part D sponsors provide enrollees with a personalized dollar estimate of their out-of-pocket costs in the coming contract year based on their use of services in the current contract year. We noted in the proposal that we are aware of the inherent difficulties in accurately estimating future year plan costs, especially the unknown variable of specific service utilization, and presenting that information to beneficiaries in a clear, concise, and useful way. We also recognized the impact of an earlier annual election period (AEP) beginning in CY 2011, as well as plans' ability to gather a sufficient amount of utilization data to make useful and accurate projections of costs for the following contract year.

Based on the comments we have received, we are modifying our original proposal and finalizing § 422.111(b)(12) to state that CMS may require an MA organization to 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 benefits are provided under Part 422. We do not plan to test a customized out-of-pocket cost statement that estimates future costs in CY 2012. Rather, we intend to work with MA organizations, Part D sponsors and beneficiary advocates to develop an EOB for Part C benefits modeled after the EOB currently required for Part D enrollees at § 423.128(e), and we will test that model through a small pilot program with volunteer organizations in CY 2012. We will consider integration of Part C and Part D EOBs, level of detail, and frequency of EOB dissemination as part of the pilot program. Our goal is to finalize a model EOB document in the future based on the pilot program and to require all MA organizations to periodically send an EOB to enrollees for Part C benefits. In addition, since an EOB requirement already exists for Part D enrollees, we will not finalize the language proposed for § 423.128(b)(11). We believe that delaying full implementation of this requirement will provide MA organizations with sufficient time to prepare for periodic dissemination of a Part C EOB.

Comment: Many commenters expressed concerns that a customized statement, especially with future projections, would not be meaningful or useful for beneficiaries. Some stated that it would create significant confusion in relation to Part C costs and Part D costs as medical and medication requirements change over time or their Low Income Subsidy (LIS) status changes. One commenting organization stated that it has encountered problems with beneficiary understanding of the maximum out-of-pocket (MOOP) limit, believing that it is a financial obligation on the beneficiary. This commenter was concerned that a similar misunderstanding would accompany a customized EOB or statement with estimated future costs. Other commenters believed that it would create a false assurance of future costs as well as an expectation of what their costs will be in the following year, and significant dissatisfaction if their actual costs are higher than projected. They stated that if the beneficiary's costs are materially higher, beneficiaries are likely to be alarmed, dissatisfied or confused. Some commenters also expressed concern about beneficiaries' expectations of plan liability if their costs are higher than the estimate. Another commenter was concerned about perceived credibility of the plans to their enrollees if inadequate or confusing information was to prompt beneficiaries to move to a plan that turns out to be of lesser value.

Some commenters also stated that any information projecting future costs only for an enrollee's current plan would be of limited use to beneficiaries because it would provide no similar data for any alternative plan. They expressed concern that such a statement using partial year data would not provide information that is comparable to the annual cost estimates available through the Medicare Plan Finder (MPF) tool. These commenters disagreed that CMS would improved an enrollee's ability to compare plans to make better enrollment choices from year to year with a customized statement including estimated future costs.

In addition, many commenters raised concerns that fluctuations in utilization of services per year and past utilization of "one-time" services would mislead a beneficiary with respect to his/her decision. Some stated that beneficiaries would not consider what would happen if their health needs change. Another commenter stated that enrollee-specific information based on past utilization has the potential to de-emphasize the value of considering future needs. Another commenter suggested that any comparison of expenses should include a comparison to Medicare FFS and Medicare FFS with the most popular Medigap plan (Plan F) as benchmarks in order to give the data context and to facilitate informed choice.

Response: We agree with commenters' concerns that the information presented to beneficiaries must be clear, concise and useful, without creating a false expectation of costs. We had similar concerns and therefore requested comments about the types of information as well as the format plans could use to provide customized utilization data. We also agree that the data that is presented to beneficiaries should be of a type that it would lend itself to comparisons with Medicare FFS, as well as other plans' information, and could be understandable to beneficiaries with a range of levels of health literacy. As previously discussed, we intend to consider these issues in our CY 2012 pilot program.

Comment: Several commenters provided comments on the example tables we included in our proposed rule. A few commenters stated that Table 7 (75 FR 71232), which breaks out Medicare Part C services by inpatient care, outpatient care and supplemental services, would provide the most useful information to beneficiaries with respect to services. Several commenters suggested that this table should present premium data for the entire year instead of six months. Several other commenters recommended that Table 6 in our proposed rule (75 FR 71232), presenting an average monthly cost and combining all Medicare Part A and B services, but excluding supplemental services, would be the best choice.

Several commenters contended that data for a 6-month period does not generally accurately reflect the enrollee's year-long utilization or out-of-pocket cost-sharing. One of these commenters recommended that CMS use at least nine months of data and allow the out-of-pocket cost information to be sent after the ANOC/EOC to give beneficiaries a more complete picture and to reduce burden on MA organizations during the ANOC timeframes. Many commenters were also concerned about errors in estimating future costs and the limited value of these estimates due to future changes in beneficiary health status or one-time high expenditure items (such as a power wheelchair).

One commenter suggested that CMS study the feasibility of requiring plans to use a minimum of 12 months of data over 2 or more contract years and whether this would provide more reliable data. This commenter also suggested that CMS incorporate more information from the ANOC into the estimate, such as page references for more information about cost sharing for specific services.

Another commenter suggested that CMS implement procedures to ensure that the systems and calculations developed by plan sponsors are uniform, especially in regard to estimating future costs to minimize the potential for fraudulent and misleading practices by plans in order to retain members.

Response: We appreciate the detailed responses provided by commenters concerning the type and amount of data, the presentation of the data, and procedures to ensure uniform calculations and data population. As previously discussed, we believe that requiring an EOB that summarizes incurred costs but does not project future costs will address a number of these concerns. We will continue to take data calculation and presentation issues into consideration as we develop a model EOB.

Comment: Many commenters supported the use of an EOB to give enrollees ongoing information throughout the year about their Part C utilization and their cost-sharing and to help them in decision making during the AEP. One commenter recommended that a Part C EOB should clearly distinguish between in- and out-of-network costs and supplemental benefits, as well provider and date of service. Others commenters opposed an EOB and considered it too costly and burdensome to plans without clear value to beneficiaries in comparing utilization or costs from year to year. Commenters supporting an EOB model supported different frequencies of distribution, including monthly, quarterly, bi-annually and annually.

One commenter recommended requiring an annual EOB that contains utilization data for the months of January through September, to be received at the start of the annual election period, so that it would provide important information at the most appropriate time for the beneficiary. This commenter also stated that requiring a monthly EOB would not provide any additional benefit to beneficiaries beyond that of an annual EOB, but it would add significantly to plans' administrative expenses through printing, postage and increased volume of customer service calls.

One commenter recommended that instead of enrollee out-of-pocket expenses, CMS develop a list of common services for which plan sponsors would calculate out-of-pocket costs under the current plan year and the upcoming plan year. The commenter believed that this would create a comparable format, consistent across all plans, that would be a more economically viable option and could be produced in the limited time frame of the new AEP dates.

Another commenter asked that CMS consider allowing MA organizations to provide enrollees with comparison information upon request only. This commenter suggested that plans could advise members via their websites or in a notice with premium bills of the opportunity to receive this comparison.

Response: We agree with commenters that a Part C EOB without future projections would be a useful tool for beneficiaries, allowing them to keep track of costs throughout the plan year. While it would not achieve the goal of specifically linking utilization to projected costs, we do believe that it would be a valuable tool in annual plan choice decisions. We will also continue to consider commenters' suggestions for the development of a list of common services tied to utilization and the option of plans providing comparison information to beneficiaries upon request.

Comment: Several organizations supported the use of a pilot to test approaches to conveying custom beneficiary data, but requested that CMS delay finalizing the requirement in regulation until a pilot program can be conducted and evaluated. Another commenter requested that the pilot aim to identify other potential alternatives for providing this information, such as ways to enhance the MPF tool. Several commenters suggested that CMS conduct consumer focus groups to ascertain the type and extent of information consumers/beneficiaries would find useful. A commenter suggested that we include beneficiaries with a range of health literacy and decision making skills to determine which models are the most beneficiary-friendly and effective. Others recommended that CMS convene a CMS-industry-advocacy working group to examine the value in this proposed requirement and determine what design, content and timing might enhance that value.

Several commenters recommended that CMS instead put its resources into enhancing the MPF tool, since many beneficiaries already rely on and are familiar with this tool. They stated that these enhancements would permit enrollees to input their utilization data and receive direct comparisons of plans based on specific data. Another commenter stated that their plan already uses an online portal where members can view all claims made, pending, and paid. This commenter stated their belief that this "real time" data is more useful to beneficiaries to estimate their costs than 6 months of data the plans would use to estimate costs.

Other commenters requested that we put more resources instead into government agencies, community organizations and other groups that provide one-to-one counseling to beneficiaries to help them choose the best plans for them. One commenter requested that we retain existing market basket estimates instead of individual estimates, because they provide useful comparative information and accomplish some goals of this provision. Another commenter suggested that we require plans to make MOOP information more prominent in member materials instead of providing more information that would be marginally helpful.

Response: We appreciate the commenters' suggestions. We do not believe that it is necessary to delay finalizing the statement of authority in regulation, but we note that our final regulation text for § 422.111(b)(12), will allow us to move forward with a pilot program while allowing sufficient room to modify our initial requirements based the results of the pilot, to continue to modify requirements over time, or to extend the pilot program if necessary before full-scale implementation. We agree with commenters that enhancing the MPF tools to be able to input utilization data and generate enrollee specific information on plan choices would be an ideal option. However, we do not foresee this as an option that could be accomplished in a relatively short timeframe of a year or two. While the suggestion that CMS invest more resources into organizations that provide one-on-one counseling to beneficiaries is a valuable one, it is outside the scope of this regulation. Also, only MA organizations have the individual utilization data that would be needed to enhance the MPF tools and improve one-on-one counseling for beneficiaries. Therefore, both improving the MPF tool and improving one-to-one counseling would require plans to track and disclose individual Part C utilization data.

Comment: A few commenters recommended that EGWPs be exempt from the requirement to distribute customized beneficiary data. Commenters noted the limited range of choices available to beneficiaries who receive coverage through these plans; MA organizations' lack of knowledge regarding the contribution EGWP retirees make toward the cost of the premium for their plan; and changes made by the employers to their EGWP MA plans that are not known to the MA organization at the time these summaries are to be provided to enrollees. Another commenter stated that any summary sent to enrollees who have employer group commercial group coverage primary and Medicare as secondary payer, and who enroll in their employer's EGWP MA plan to obtain this Medicare secondary coverage, will not be accurate because it would be based on MA plan out-of-pocket cost-sharing but would not account for the commercial group coverage cost-sharing that these enrollees actually pay. This commenter also stated that some enrollees will not have had the "minimum enrollment period" of 6 months, so the plan would have to exclude them from receiving the summary.

Response: We disagree with these commenters and do not intend to exempt EGWPs from the requirement § 422.111(b)(12). Given that we are modifying our original proposal to provide CMS with authority, under to require an MA organization to furnish directly to enrollees, a Part C EOB, we do not believe that many of these comments are relevant. We also note that EGWPs currently must comply with all MA marketing requirements under § 422.111, although they have flexibility through previously granted waivers with respect to submission, CMS review, and timing requirements. Since a Part C EOB would be part of MA disclosure requirements under § 422.111, we expect EGWPs would be afforded these same times of flexibility but would still be required to comply with the requirement.

Comment: Several commenters responded to our request for comments related to exempting dual eligible special needs plans (D–SNPs) from the requirements. Several commenters recommended that D–SNPs and/or chronic and institutional care SNPs should be exempt from the requirement to furnish customized enrollee data on out-of-pocket costs. Another commenter recommended that CMS exempt any dual eligible beneficiary that enrolls in an MA plan that is not a D–SNP. These commenters believe that since the States' Medicaid plans generally pay enrollees' out-of-pocket costs, providing customized enrollee data through a customized out-of-pocket cost statement or an EOB would be unnecessary and confusing for enrollees.

Response: We appreciate the responses from commenters, but given the modification of our original proposal, we believe that an EOB allowing beneficiaries to track utilization of services as well as any out-of-pocket costs would be a useful tool for dual eligible MA enrollees. While we are not exempting any MA plan type from the requirements at § 422.111(b)(12) at this time, we intend to study the issue of applicability to dual eligible MA enrollees—regardless of whether they are enrolled in D–SNPs—further under our pilot program.

Comment: A few commenters requested confirmation that cost plans will be exempt from furnishing customized enrollee data, since we did not specifically include cost plans in the proposal. One commenter stated that cost plans should not have to provide an EOB due to the difficulty of gathering the information and the significant cost and time required. One commenter also stated that because out-of-network services are paid directly by Medicare Administrative Contractors (MACs), cost plans do not know a member's full out-of-pocket costs. This commenter also stated that for most cost plans, the MACs process claims before sending them to the cost plan; thus there could be a delay in receiving the information, resulting in an inability to produce customized enrollee documents in time to be distributed with the ANOC/EOC.

Response: We did not propose to include cost plans in the proposal for customized enrollee data and, therefore, will not include them in this final policy. However, we will continue to study whether to apply the EOB requirement to cost plans in the future.

5. Extending the Mandatory Maximum Out-of-Pocket (MOOP) Amount Requirements to Regional PPOs (§ 422.100 and § 422.101)

In our April 2010 final rule (75 FR 19709 through 19711), we established a mandatory maximum out-of-pocket (MOOP) requirement for local MA plans effective contract year 2011. As provided at § 422.100(f)(4), all local MA plans, including HMOs, HMOPOS, local PPO (LPPO) plans and PFFS plans, must establish an annual MOOP limit on total enrollee cost sharing liability for Parts A and B services, the dollar amount of which will be set annually by CMS. As provided at § 422.100(f)(5), LPPO plans are required to have a catastrophic limit inclusive of both in- and out-of-network cost sharing for all Parts A and B services, the dollar amount of which also will be set annually by CMS. Since a statutory MOOP requirement was already in effect with respect to RPPO plans, we had proposed to apply the new mandatory MOOP requirement only to local MA plans, and thus in our April 2010 final rule (75 FR 19711) subjected only local MA plans to the requirement that they meet the MOOP dollar amount specified. We encouraged RPPOs to adopt either the mandatory or voluntary MOOPs established in CMS guidance, stating that, to the extent an RPPO sets its MOOP and catastrophic limits above the mandatory amounts set by CMS for other plan types, it may be subject to additional CMS review of its Parts A and B services cost sharing amounts. We also expressed our intent to address this discrepancy in future notice-and-comment rulemaking.

In our November 2010 proposed rule (75 FR 71233 and71234), we proposed to extend these mandatory MOOP and catastrophic limit amount requirements to RPPO plans beginning in contact year 2012, in order to make it easier for beneficiaries to understand and compare MA plans. Each RPPO plan would establish an annual MOOP limit

on total enrollee cost sharing liability for Parts A and B services, the dollar amount of which would be set annually by CMS. All cost sharing (that is, deductibles, coinsurance, and copayments) for Parts A and B services would be included in RPPO plans' MOOPs. We proposed to codify this requirement by revising § 422.100(f) to include regional MA plans. In addition, we proposed revisions to paragraphs (d)(2) and (d)(3) of § 422.101(d) to specify that the catastrophic limits set by RPPOs may not be greater than the annual limit set by CMS.

After considering the comments received, we are finalizing these proposed provisions without further modification.

Comment: We received several comments on this proposal, most of which expressed support for our proposal to extend the mandatory MOOP and catastrophic limits to RPPOs and agreement that doing so would make it easier for beneficiaries to understand and compare plans.

However, a commenter argued that since CMS is paying MA plans based on projected costs of providing Parts A and B benefits under the fee-for-service program, we should not require MA plans to provide richer benefits than Parts A and B required benefits without being compensated for the additional cost.

Response: We agree with commenters that extending the MOOP and catastrophic limit requirements applicable to RPPOs will make plan-to-plan comparisons easier and will level the playing field for RPPOs relative to LPPOs.

We disagree with the commenter that recommended that MA plans be compensated for the additional cost of including MOOP and catastrophic limits in their benefit packages. As discussed previously in our April 2010 final rule (75 FR 19710), we believe that requiring the inclusion of a MOOP limit is an important step to ensure that individuals who utilize higher than average levels of health care services are not discouraged from enrolling in MA plans that do not have such a limit in place. Given that RPPO plans are required by statute to have such a liability limit in place, we were concerned that enrollees with high out-of-pocket costs would be discouraged from enrolling in RPPOs if similar protection from high out-of-pocket costs is not offered under those plans. We continue to believe that requiring a mandatory MOOP and catastrophic limits set by CMS does not unduly disadvantage MA plans relative to original Medicare.

We are therefore finalizing our proposal to extend the mandatory MOOP and catastrophic limit requirements to RPPO plans at § 422.100(f) and § 422.101(d). Effective contract year 2012, each RPPO plan must establish an annual MOOP limit on total enrollee cost sharing liability for Parts A and B services, the dollar amount of which would be set annually by CMS. All cost sharing (that is, deductibles, coinsurance, and copayments) for Parts A and B services will be included in RPPO plans' MOOPs and catastrophic limits.

Comment: Several commenters recommended that we eliminate the MOOP requirement for dual eligible SNPs (D–SNPs) because members are not responsible for out-of-pocket costs.

Response: We disagree with these commenters. As we explained previously in our April 2010 final rule (75 FR 19711), dual-eligible individuals entitled to have their cost sharing paid by the State and enrolled in a SNP may experience mid-year changes in their Medicaid eligibility. In those cases, these individuals may be required to directly pay the plan cost sharing that otherwise would be the obligation of the State. Accordingly, we will not exempt D–SNPs from the requirement that they implement MOOP and catastrophic limits as established annually by CMS. Like all MA plans, D–SNPs must establish a MOOP limit to provide this enrollee protection, even though the State Medicaid program is usually paying those costs on the enrollee's behalf. For purposes of tracking out-of-pocket spending relative to its MOOP limit, a D–SNP must count only the enrollee's actual out-of-pocket spending. Thus, for any D–SNP enrollee, MA plans must count only those amounts the individual enrollee is responsible for paying net of any State responsibility or exemption from cost sharing toward the MOOP limit rather than the cost-sharing amounts for services the plan has established in its plan benefit package.

6. Prohibition on Use of Tiered Cost Sharing by MA Organizations (§ 422.262)

As provided in section 1854(c) of the Act and implemented at § 422.100(d)(2), an MA organization offering an MA plan must offer the plan to all Medicare beneficiaries residing in the service area of the MA plan at a uniform premium, with uniform benefits and levels of cost sharing throughout the plan's service area, or segment of the service area, as provided at § 422.262(c)(2). In spite of this regulatory guidance, we have become aware that an increasing number of plans are charging beneficiaries different amounts of cost sharing for services depending on, for example, which provider group the beneficiary selects, the plan's network of hospitals, or how frequently the beneficiary uses selected services.

In an effort to ensure that MA organizations establish cost sharing that is fully consistent with the intent of the uniformity requirement in section 1854(c) of the Act, we proposed to revise § 422.262 to stipulate that MA organizations cannot vary the level of cost sharing for basic or supplemental benefits for any reason, including based on provider groups, hospital network, or the beneficiary's utilization of services.

Comment: We received many comments that opposed our proposal to prohibit "tiered" cost sharing on the basis of provider group or hospital network. Comments stated that prohibiting tiering would create an overly restrictive environment and would prevent plans from developing benefit designs that encourage enrollees to compare providers on the basis of price. For example, plans would be prevented from implementing various value-based insurance designs. Others asserted tiering allows plans to develop benefit designs that encourage enrollees to compare providers on the basis of price and is valuable component of the MA program. Further, some stated that tiered cost sharing is an integral component of HMO point-of-service and PPO plans' benefit structures and is generally an acceptable practice in health insurance. One comment stated that CMS should not restrict a plan's ability to create innovative benefit package designs that would encourage member participation in programs that support increased access to quality care and allow members to seek services from lower cost providers.

In addition, commenters expressed their concern that the CMS proposal failed to recognize the value of using cost sharing incentives to encourage enrolled beneficiaries to choose high quality, efficient providers. They stated the belief that tiered networks that group providers into tiers based on quality and efficiency may be used to promote quality, and that lower cost sharing could be used to encourage enrollees to receive care from high-value providers rather than low quality or inefficient providers. Other commenters mentioned that plans may use tiering to encourage enrollees to join patient-centered "medical homes" that improve quality while reducing hospitalizations, ER visits, and per capita cost.

Several commenters stated that rather than prohibiting tiered cost sharing for

medical services CMS should use revised summary of benefit (SB) sentences and plan benefit package (PBP) software revisions to make transparent plans' tiered cost sharing.

Response: Our proposal to prohibit tiering of medical benefits would not restrict the benefit design of PPO or HMO–POS plans, as beneficiaries are able to clearly distinguish cost sharing differences on the basis of in-network and out-of-network providers. Our proposal addressed designs that would create sub-networks with varying levels of cost sharing for in-network services that may not be clearly distinguishable and/or accessible by beneficiaries.

We do not disagree with commenters that believe it is important for plans to be able to design benefit packages that allow enrollees to choose providers based on both quality and cost. Our concerns about tiered cost sharing for medical services are focused on the potential barriers to access that may be created if plans implement differential cost sharing by provider network (or on any basis) and the lack of transparency to beneficiaries as they compare plans, and to providers and enrolled beneficiaries that are participants of any such benefit design. We require that all enrollees in a plan's service area must have adequate access to plan providers and that permitting different levels of cost sharing for provider networks or provider groups may create inconsistent access to providers at each cost sharing tier. We believe some enrollees in a service area could have access only to the highest cost providers or that implementation of tiered cost sharing could disrupt an established relationship with a provider that becomes one of those grouped into a higher cost sharing level or that the enrollee would begin paying the higher cost sharing, not realizing that lower cost providers are available.

We also are committed to ensuring that beneficiaries are able to understand their choices of plan offerings and there is currently no system to facilitate the disclosure of tiered cost sharing to beneficiaries as they compare plans or to beneficiaries that are enrolled in the plan. Further, tiered cost sharing based on provider group or network complicates referrals within the plan network as the providers themselves must be informed about the enrollee costs to see other plan providers to effectively manage enrollees' health care needs.

Finally, we are committed to ensuring that enrolled beneficiaries have access to high quality, efficient providers and to supporting MA plans that create innovative benefit packages that would provide enrollees with low cost, high quality services. We greatly appreciate the comments that expressed plans' same goal of providing enrollees with affordable, high quality care and their belief that enrollees appreciate having choices about providers and the amount they are spending for care.

To date, we are aware of only a few instances of tiered cost sharing for medical services but, in those cases, we believe the differential cost sharing was not based on quality of care or value but rather, on a plan's ability to negotiate favorable rates with providers. That is not to say that we are not persuaded that it may be possible to allow plans more flexibility to design benefit packages that include some differential cost sharing in order to encourage enrollees to seek care from the most efficient providers. In fact, we have decided that we will not finalize at this time our proposal to prohibit tiered cost sharing. After carefully considering all of the comments, we have determined that it would be appropriate for us to consider this policy more broadly. We will provide future guidance and investigate a number of aspects for possible future policymaking related to tiered cost sharing, including, but not limited to: possible revisions to the PBP and SB sentences that would enable transparency; methods for verifying that any tiered cost sharing for medical benefits does not impede access to care for a plan's enrollees; identifying methods for evaluating quality of care furnished by providers or provider networks; processes by which plans could submit for review proposed tiered benefit structures.

Further, we note that although we are not finalizing our proposal, based on our authority at section 1852(b)(1) of the Act and as codified at § 422.100(f)(2), we prohibit tiered cost sharing based on utilization as a type of cost sharing that discriminates against beneficiaries, promotes discrimination, discourages enrollment or encourages disenrollment, steers subsets of Medicare beneficiaries to particular plans or inhibits access to services. Thus, although we included tiered cost sharing based on utilization in our proposal to prohibit all tiered cost sharing, it is also prohibited because it is discriminatory against beneficiaries.

Comment: There were many comments that supported our proposal to prohibit tiered cost sharing on any basis.

Response: We thank the commenters for their support of the proposal but, as explained previous comment, we are not finalizing our proposal at this time.

Comment: There were two commenters that specifically supported the prohibition of tiering based on utilization and several others that stated tiering based on utilization could result in most plan members having lower cost sharing obligations because the first few provider services would have low cost sharing and only the minority of plan enrollees that over-utilize services would have to pay the higher cost sharing amounts charged for more frequent use of services.

Response: We believe that increasing enrollees' cost sharing to charge more to enrollees as they use more services is an example of discriminatory cost sharing which we prohibit under our authority as codified at § 422(f)(2). While the commenters believe that some enrollees are over-utilizing services, we must consider that the enrollees who use the most services may be the sickest enrolled beneficiaries who need more services than do most enrollees. We expect plans to manage enrollees' care and believe there are tools available that enable plans to do so without implementing policies that inappropriately create barriers to access to care. Our policies (for example, cost sharing standards, benefit package review) are designed to prevent discriminatory cost sharing and are in place to protect sicker enrollees from plan designs that charge higher costs for more frequent or more costly utilization in order to discourage use of needed services.

Comment: There were several commenters that requested general clarification of the proposal. There were other comments that stated the proposal was inconsistent with the objectives of the ACA. One plan's comment also requested clarification of what the proposal does to prohibit plans from varying cost sharing by place of service in order to manage cost. For example, lowering cost sharing for physical therapy delivered in the PCP's office compared to the hospital outpatient setting, since such variation is instrumental in plans' efforts to encourage enrollees to utilize the most effective setting for care and to manage cost. Another commenter explained tiering allows health plans to experiment with alternative cost sharing structures that promote better access to care for sicker beneficiaries and better compliance with treatment regimens. For example, by waiving co-payments for certain services provided to diabetics. The commenter also suggested that tiering can be found throughout the Medicare FFS and MA programs since plans are allowed to

charge different cost sharing for out-of-network services and providers.

Response: We believe these disagreements with our proposal are based on a misunderstanding of what we mean by tiered cost sharing, specifically the examples regarding the prohibition of higher cost sharing for out-of-network services and the special cost sharing arrangements for diabetic services/supplies. These examples cited by the commenters are not what we define as tiering of medical services. Therefore, we would like to clarify that even under our proposal, higher cost sharing would have been permitted for out-of-network services (for example, PPOs) and incentivizing enrollees through cost sharing to use more cost-effective settings to receive the same service (for example, charging lower cost sharing for the same service in a PCP's office than in the hospital outpatient department, or for services in a freestanding imaging facility than in the outpatient department of a hospital).

Comment: One commenter questioned CMS's elimination of tiered cost sharing, especially as the industry moves towards patient centered medical homes and accountable care organizations to ensure quality care and tiered cost sharing could be one way to encourage these types of organizations.

Response: We recognize that there is an evolving market for new models for care such as medical home and accountable care organizations. We do not believe that MA cost sharing standards create barriers to plans providing access to those high quality care delivery organizations. CMS will take these comments into consideration in future rulemaking.

Comment: One commenter wanted to clarify whether this prohibition of tiered cost sharing would be at the Plan Benefit Package (PBP) level.

Response: The tiered cost sharing we have observed has been at the PBP level and our proposal would have prohibited tiering at the PBP level.

Comment: One commenter sought clarification on whether or not the proposal applies to the drug portion of Part C plans and encouraged CMS to apply the proposed change to the drug portion of Part C plans. Another commenter proposed that CMS allow differential cost sharing based on provider group or hospital, or modify the meaningful differences test to allow for evaluation of differences in network or referral requirements between plans.

Response: Our proposal targeted tiering of all medical benefits, including Part B drugs under Part C. We thank the commenters and will include the suggestion that allowing differential cost sharing and including the resulting differentiation in provider networks to be considered in our evaluation of meaningful differences during bid review, in our future policy discussions and rulemaking.

Comment: One commenter stated that tiering is the core of modern drug therapy management.

Response: We would like to clarify that our proposal would have no effect on the drug tiering under the Medicare Part D drug benefit.

Comment: One commenter suggested expanding the proposed prohibition to the Part D Program.

Response: We thank the commenter for their suggestions but tiering within Part D is beyond the scope of this proposed rule.

Comment: One commenter requested that CMS establish an employer group waiver excepting MA plans offered through employer/union group health plans from the tiered cost sharing.

Response: We thank the commenter for the suggestion, but we believe that employer group plans must be subject to the same cost sharing as other MA plans in order to provide the beneficiaries enrolled in those plans the same protections as beneficiaries enrolled in other MA and cost plans.

Based on the comments received on this proposal, we will not finalize the proposal to amend § 422.262 by revising paragraph (c)(1). We will consider further rulemaking related to this practice in the future.

7. Delivery of Adverse Coverage Determinations (§ 423.568)

Section 1860D–4(g) of the Act requires Part D plan sponsors to establish procedures for processing requests for coverage determinations and redeterminations. Those procedures must apply to Part D plan sponsors in the same manner as they apply to MA organizations with respect to organization determinations and reconsiderations under Part C. Under § 422.568(d), an MA organization must provide written notice when it makes an unfavorable standard organization determination.

In accordance with section 1860D–4(g) of the Act, we created a parallel notice provision in § 423.568(f) for unfavorable Part D standard coverage determinations. We proposed to revise § 423.568(f) by allowing a Part D plan sponsor to first provide oral notice of an adverse standard coverage determination decision, so long as it also provides a written follow-up notice of the decision within 3 calendar days of the oral notification.

As noted in the proposed rule, we believe this change is necessary because of the short decision-making timeframes under Part D. As we also noted in the proposed rule, this change is consistent with § 422.572(c) whereby an MA organization may choose to meet the 72-hour notification timeframe for adverse expedited organization determinations by first providing oral notice of its decision within 72 hours, so long as it also sends a written follow-up notice within 3 calendar days after providing oral notice.

After considering the comments received in response to this proposal, we are adopting this provision without modification. Thus, we have revised § 423.568(f) to allow a Part D plan sponsor to provide initial notice of an adverse standard coverage determination decision orally, so long as it also provides a written follow-up notice within 3 calendar days of the oral notice.

Comment: Several commenters supported this policy. Some of the comments in support of the proposal also requested that CMS clarify that plan sponsors have 3 business days from the date of the oral notice to send written notice. Other commenters requested that plans have the option of mailing the notice within 3 days of receipt of the request if oral notice is not provided, citing the difficulty in providing oral notice in cases where the plan does not have a telephone number for the enrollee or the enrollee is difficult to reach by telephone.

Response: The regulations in Subpart M of Part 423 related to providing notice to enrollees refer to calendar days, not business days. We do not believe there is a good reason to deviate from that approach for purposes of § 423.568(f). Accordingly, if a plan chooses to provide the initial notice orally, the written follow-up notice must be mailed to the enrollee within 3 calendar days of the oral notice. We appreciate commenters' concerns about those instances where the enrollee cannot be reached by telephone. However, providing oral notice is optional. If the plan does not provide oral notice of a standard coverage determination to deny a drug benefit, the plan sponsor must notify the enrollee of its determination in writing as expeditiously as possible, but no later than 72 hours after receipt of either the request or, for an exceptions request, the physician or other prescriber's supporting statement.

Comment: One commenter expressed concern that the intent of the provision to provide enrollees with information quickly will be diminished if

beneficiaries have to wait to receive the written notice to learn the reason for the denial and appeal rights. The commenter requested that the regulation require the oral notice to include the reason for the denial and information about requesting a redetermination. The commenter also requested that CMS issue guidance to plans and develop model scripts.

Response: We believe that the written notice plans must send the enrollee following the oral notice is the most effective means of providing detailed information on the coverage decision and an explanation of appeal rights. However, we agree there is value in providing guidance to plans on the information that should be conveyed to enrollees when providing an oral decision. Therefore, we will provide guidance in relevant manual provisions regarding the content of oral notification provided by plans.

8. Extension of Grace Period for Good Cause and Reinstatement (§ 422.74 and § 423.44)

Section 1851(g)(3)(B)(i) of the Act provides that MA plans may terminate the enrollment of individuals who fail to pay basic and supplemental premiums after a grace period established by the plan. Section 1860D–1(b)(1)(B) of the Act generally directs us to use disenrollment rules for Part D sponsors that are similar to those established for MA plans under section 1851 of the Act. Consistent with these sections of the Act, the Part C and D regulations set forth our requirements with respect to involuntary disenrollment procedures under § 422.74 and § 423.44, respectively.

Currently, § 422.74(d)(1)(i)(B) specifies that an MA organization must provide, at minimum, a 2-month grace period before disenrolling individuals for failure to pay the premium. Similarly, under current regulations at § 423.44(d)(1)(ii), Part D sponsors must also provide a 2-month minimum grace period before disenrolling individuals for failure to pay the premium. For both Part C and Part D, involuntary disenrollments are not mandatory and, thus, organizations may choose to implement longer grace periods or forgo involuntary disenrollments entirely as long as they apply their policy consistently. MA and Part D plans that choose to disenroll beneficiaries for failure to pay premiums must notify the beneficiary of the delinquency and provide the beneficiary at least 2 months to resolve the delinquency. The plan must also be able to demonstrate to CMS that it has made reasonable efforts to collect the unpaid premium amounts.

Since beneficiaries who are disenrolled from an MA or Part D plan for failure to pay premiums generally are not eligible for a special enrollment period, the next opportunity to enroll in another plan is during the annual election period in the fall. As a result, these beneficiaries may lose their prescription drug coverage for the remainder of the year, and may incur a late enrollment penalty if they subsequently choose to re-enroll in Part D. For these reasons, and to be consistent with the provision for delinquent premium payments for Supplementary Medical Insurance (Part B of Medicare), we proposed to permit reinstatement of enrollment in an MA or Part D plan for instances in which the individual was involuntarily disenrolled for failure to pay plan premiums, but subsequently demonstrated good cause for failing to submit the premium payment timely. We proposed that good cause would be established only when an individual was prevented from submitting timely payment due to unusual and unavoidable circumstances beyond his or her control.

Specifically, we proposed amending § 422.74(d)(1) and § 423.44(d)(1) regarding disenrollment for non-payment of premiums to allow for the reinstatement of enrollment for good cause subsequent to an involuntary disenrollment associated with the failure to pay premiums within the grace period. A reinstatement of enrollment would remove the involuntary disenrollment from the enrollment record, resulting in continuous coverage as if the disenrollment never occurred. Further, before such reinstatement could occur, we proposed to require that the individual pay in full all premium arrearages on which the disenrollment was based, as well as all other premiums that would have been due since the disenrollment. Consistent with the provision for delinquent premium payments for Supplementary Medical Insurance (Part B of Medicare), we proposed that the disenrolled individual would have a maximum of 3 months from the disenrollment date in which to request the good cause reinstatement and resolve all premium delinquencies.

Comment: The overwhelming majority of commenters expressed support for the proposed regulatory revision. Several commenters further requested that CMS provide additional guidance to plans regarding the circumstances that would constitute "good cause" and would allow for reinstatement of enrollment following an involuntary disenrollment for failure to pay premiums. It was also suggested that CMS require plans to include in their information to beneficiaries an explanation of a grace period, including the eligibility criteria.

Response: We appreciate the support for this proposal and are adopting it as proposed. We will provide additional guidance regarding implementation of these new provisions in manual guidance (Chapter 2 of the Medicare Managed Care Manual and Chapter 3 of the Medicare Prescription Drug Benefit Manual).

Comment: A commenter favored an extension of the minimum required grace period for nonpayment of premium from 2 months to 3 months and supports the development of provisions for payment plans for circumstances in which the beneficiary owes more than 1 month's premium. Another commenter asked that CMS consider a waiver of the grace period requirements for employer group waiver plans (EGWPs), stating that some employers pay a portion of the beneficiary's premium and may not be financially able to incur the cost of members not paying their portion of the premium during a 2 month grace period.

Response: Issues involving the length and applicability of the minimum grace period have been the subject of recent rulemaking (see our April 2010 final rule (75 FR 19678)), and we do not believe it would be appropriate or warranted to revisit these issues in this final rule, given that they were not raised in the proposed rule. With respect to the request that we require plans to establish payment plans for premium arrearages, plans are by no means precluded from establishing such arrangements with beneficiaries, but we do not believe such arrangements should be mandatory.

Comment: Several commenters who supported our proposal expressed concern about the examples in the proposed rule preamble of circumstances that likely would not constitute good cause. They suggested certain scenarios they believed would warrant a good cause determination. For example, some commenters opposed the statement in the preamble indicating that we would not expect to find good cause in instances where an individual's legal guardian or authorized representative was responsible for making premium payments but failed to do so in a timely manner. The commenters indicated that beneficiaries may be penalized for errors made by their appointed representatives in situations when the beneficiary is unable to manage his or her affairs and may be unaware of the delinquency or

pending disenrollment. It was requested that CMS direct plans to find good cause in situations where a caregiver, authorized representative or legal guardian is responsible for making payment, but failed to do so timely. In addition, commenters suggested allowing for reinstatement of enrollment if the request is supported by a physician who states that any lapse in coverage could seriously jeopardize the beneficiary's health due to the potential for a disruption in care or if a member of a State Pharmaceutical Assistance Program (SPAP) is disenrolled because the SPAP failed to provide appropriate premium payments.

Response: The examples provided in the proposed rule were intended to be illustrative, and we do not intend to codify those principles in regulation. Accordingly, we will take these comments into consideration as we develop additional "good cause" guidance to plans in the Medicare Managed Care and Medicare Prescription Drug Benefit Manuals. However, we note that the fundamental basis of a good cause determination rests on the circumstances that prevented timely payment of the premium. Thus, a physician's statement about the health consequences of a coverage lapse would not appear to be germane to whether a good cause determination was warranted.

Comment: Two commenters requested clarification as to whether our proposal applied to cost plans.

Response: Cost plans were not a part of our proposal and we did not set forth any proposed changes to 42 CFR part 417. We may consider expanding this policy to cost plans in future rulemaking.

9. Translated Marketing Materials (§ 422.2264 and § 423.2264)

Pursuant to our authority under sections 1851(d)(2)(C), 1860D–1(c), and 1860D–4(a) of the Act, we proposed to codify existing MA and Part D guidance for marketing materials in markets with a significant non-English speaking population or large percentage of limited English proficient (LEP) individuals. We proposed to include a requirement in the regulations that plan sponsors must provide translated marketing materials in any language that is spoken by more than 10 percent of the general population in a plan benefit package (PBP) service area. We proposed revisions to § 422.2264(e) of Subpart V and § 423.2264(e) of Subpart V to reflect this clarification.

The proposed clarification would codify existing guidance regarding translated marketing materials. We proposed taking this step as a result of frequent complaints to CMS from beneficiaries and advocacy organizations that revealed plan sponsors were not providing translated marketing materials upon request in languages spoken by more than 10 percent of the general population of a particular PBP service area. The August 15, 2005 version of the Medicare Marketing Guidelines and every version thereafter, included language stating, "Organizations/plan sponsors should make marketing materials available in any language that is the primary language of more than 10 percent of a plan's geographic service area." Nevertheless, plan sponsors have indicated they were uncertain whether translated marketing materials were required. For example, plan sponsors we talked to were confused about whether the 10 percent threshold applied to a specific age group (for example, only those 65 and older, which does not take into account younger beneficiaries who are Medicare-eligible based on disability). Other plan sponsors assumed they did not have to conduct a language analysis for their plan because they were not aware of any LEP enrollees in their plans. By explicitly codifying the requirement to translate marketing materials for LEP individuals, we are addressing the problem of plan sponsor confusion by removing any ambiguity concerning the translation requirement that may have been created by differences between the language of § 422.2264 and § 423.2264 and the Medicare Marketing Guidelines. Additionally, Title VI of the Civil Rights Act of 1964 prohibits discrimination on the basis of race, color, or national origin by recipients of Federal financial assistance. Recipients must take reasonable steps to provide persons with limited English proficiency meaningful access to their programs and activities. This may require the translation or interpretation of certain information into languages other than English. Under an Executive Order 13166, issued in 2000 and reaffirmed in February 2011 by the Attorney General, each Federal agency must also implement a system by which LEP persons can meaningfully access the agency's programs. This codification is consistent with that obligation.

Comment: We received more than 100 comments regarding the proposal to codify the 10 percent threshold standard. The majority of commenters proposed new, more rigorous threshold standards. The most commonly suggested threshold standard was 5 percent of the population or 500 people in a service area, whichever is lower. A small number of commenters suggested a 1 percent threshold. None of these commenters quantified the improvement in access that these standards, particularly the 500 person minimum or 1 percent options, would bring. Some of the commenters recommending this translation standard were unaware that this regulation would only pertain to the Medicare population enrolled in Part C or D plans or that the proposed rule was only requiring translation of marketing materials and not lab test results or patient instructions. Additionally, some commenters supporting the 5 percent or 500 people threshold indicated that many of the LEP individuals they serve are illiterate in any language.

A variety of industry representatives indicated that they supported CMS' rule. Some of these commenters further recommended, however, that CMS base the standard on an individual's primary language in order to focus on individuals that were proficient in only a non-English language rather than those who were bi-lingual. One commenter from industry suggested the standard should be based on the Medicare population; another suggested the standard should be based on the PBP's membership; and another suggested we should look at only individuals age 65 and older. Industry commenters justified their suggestions for modifying CMS' current standard based on their experience that they only receive a few requests for hard copies of the materials each year. The industry commenters also expressed concern about the cost of developing and printing translated materials when they anticipate a low demand.

Response: In response to both industry and advocacy stakeholders that commented on the proposed rule, we will move the standard population-based translation threshold from 10 percent to 5 percent. Further, we will revise our methodology for calculating these thresholds by focusing on individuals who primarily speak a non-English language and who have a limited ability to read, write, speak, or understand English, as opposed to also including individuals who are at least bilingual. Specifically, we will require plan sponsors to translate marketing materials into any non-English language that is the primary language of at least 5 percent of the individuals who reside in a PBP's service area.

At this time, we will continue to use the U.S. Census Bureau's American Community Survey (ACS) data to determine the languages spoken in each sponsor's PBP's service area. However,

we recognize that the ACS data may be superseded by more accurate or timely data in the future; therefore, we will continue to monitor and review data sources that are available to all plan sponsors. In particular, we will continue to evaluate forthcoming data sources that most accurately identify individuals who are unable to read English-language materials, but are literate in non-English languages. We prefer to use data sources that are publicly available in order to reduce the burden on plan sponsors. We will, as we have done since 2009, continue to calculate, on behalf of all plan sponsors, the specific languages that meet the threshold for each PBP service area.

From a public policy perspective, moving to a 5 percent threshold and focusing on individuals' primary language produces the best outcome because it will focus sponsor resources on individuals with the most need for translated materials. We conducted an impact analysis of how this standard and revised methodology would change current translated materials offerings. The results of our analysis indicated moving to 5 percent and focusing on primary language will slightly reduce the burden on plan sponsors because a small number of them will no longer be required to translate materials at all. (There was a slight net reduction, which may vary from year to year. Under the new standard, some PBPs that did not require translation in the past will now be required to translate.) Additionally, focusing on the primary language spoken by individuals more closely aligns with the HHS definition of a LEP individual. The HHS Guidance to Federal Financial Assistance Recipients Regarding the Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons (HHS LEP Guidance) defines LEP individuals as those "who do not speak English as their primary language and who have a limited ability to read, write, speak, or understand English." Focusing on individuals' primary language is more consistent with the definition than our current practice of looking at any languages spoken by the general population.

We disagree with the other suggested translation threshold approaches from the commenters for several reasons. First, the suggested standard threshold of 5 percent or 500 people, whichever is less, would result in all PDPs and nearly all MAOs providing translated materials in all languages captured in the ACS data because 500 is such a small number of speakers. This would be a significant increase in the number of plan sponsors required to translate and the number of languages required for translation, and absent definitive evidence to support the sharp increase, this would result in insupportable costs and burden. The same argument holds true for the suggestion of a 1 percent standard. Second, the suggested standard of 10 percent of a plan's membership (as opposed to population data) would be impossible for plan sponsors or CMS to calculate because beneficiary language preference is an optional field for beneficiaries to complete on a plan enrollment form. There is no guarantee that all LEP beneficiaries would be counted by the sponsor. Also, because we do not collect the enrollment form language preference data from sponsors, we would need to establish a reporting requirement and then wholly rely upon sponsor-generated data when monitoring for compliance. With regard to the suggestion to only look at language data for those age 65 and older, we cannot lose sight of the fact that some individuals that qualify for Medicare (and for participation in the Part C and D programs) are younger than 65. However, we will conduct additional sensitivity analyses in the future to assess if applying a weighted-average to account for the age distribution of the Medicare population would affect translation requirements. Should we ever change our data source or methodology for calculating translation requirements, we will publish that information in subregulatory guidance.

Comment: One industry organization suggested that plan sponsors should not have to translate any documents, and beneficiaries should rely on oral interpretation services available through their call centers.

Response: We do not agree with this comment. In order to ensure that LEP beneficiaries have access to vital information needed to make appropriate decisions about their health care, our goal is to make marketing materials available to beneficiaries, wherever it is reasonable to do so. Because of the particular effort required to make these translations available, we must balance those resource costs with the likelihood of the documents being requested and used. As such, we apply a threshold, and thus our rules do not require translation of marketing materials into all languages. However, call center interpreters, must be made available in virtually all languages spoken in the U.S. Fulfillment of this requirement provides a safety net in geographic areas where only a few beneficiaries speak a particular non-English language. We reached our decision after conducting the four factor analysis in the aforementioned HHS LAP Guidance, and, based on this analysis, a mix of language services (that is, both oral interpretation services and written translated materials when a standard translation threshold has been met), is the most appropriate solution for the population served by the Medicare Parts C and D programs.

Comment: Several comments were outside of the scope of this proposed rule. The comments were technical and operations oriented, and are more appropriate as comments on the Medicare Marketing Guidelines. Industry requested that plans should not have to have pre-printed copies of translated materials on hand; rather, they preferred to meet the requirement through a print-on-demand capability and provide the translated material within a reasonable timeframe to the beneficiary. Another comment suggested CMS require plans to provide enrollment materials in any language that the plan was advertised in via any media (for example, print, radio, Internet, *etc.*). Lastly, a commenter requested clarification regarding which marketing materials required translation.

Response: We agree that these comments raise valid points that merit clarification, and we will consider them in the context of future revisions of the Medicare Marketing Guidelines. However, we remind MA organizations and Part D plan sponsors that, pursuant to the current Medicare Marketing Guidelines, all Medicare marketing materials that are required to be translated and available in print upon request are also required to be posted on the plan's Web site. The specific marketing materials required for translation are contained within the Medicare Marketing Guidelines.

Comment: One industry commenter suggested that CMS provide translations of the model evidence of coverage (EOC) in the top five languages other than English most commonly spoken by Medicare beneficiaries nationally.

Response: We are aware of the cost burden on plan sponsors to produce translated marketing materials, and CMS and beneficiary advocates have concerns about the quality and accuracy of translated materials provided to beneficiaries. In response, for the 2012 contract year, CMS anticipates providing a few translated versions of certain model marketing materials. Our aim is to reduce the burden on plan sponsors and increase the quality, consistency, and accuracy of these marketing materials for beneficiaries. By providing translations of some or all model materials in all languages in

which translation is required for at least one plan benefit package, plan sponsors would merely need to translate their own plan-specific inserts or modifications, in addition to required materials for which there is no model or translation available. In future years we would prefer to translate all required model marketing materials and will actively pursue this goal, but we are uncertain about viability of this practice because we cannot guarantee that we would be able to fund this initiative annually. Additionally, we are exploring creating a 1-page model document that would inform beneficiaries, in multiple languages, that free interpreter services are available when beneficiaries call the plan's customer service call center.

Comment: One commenter requested clarification as to whether the Program of All-inclusive Care for the Elderly (PACE) program is subject to the requirement that plan sponsors provide translated marketing materials.

Response: We clarify that PACE programs are not subject to this requirement.

In summary, we received numerous comments on this proposed rule. In response to commenters, we are finalizing the proposed rule, with modification. We factored in advocacy organizations' comments to reduce the percentage threshold and addressed industry's concerns by refining our methodology, which will slightly reduce sponsors' administrative burden. Further, the revised analysis methodology is more consistent with the HHS definition of an LEP individual than our current practice. Our final rule will require plan sponsors to translate marketing materials into any non-English language that is the primary language of at least 5 percent of the individuals in a PBP's service area. This new translation standard will go into effect for contract year 2012; therefore, 2012 enrollment materials must be produced with this new translation standard in mind, in keeping with all relevant deadlines that occur in 2011 in preparation for the 2012 marketing season. As in the past, we will continue monitoring sponsors' compliance with translated materials requirements.

E. Strengthening Our Ability To Distinguish for Approval Stronger Applicants for Part C and Part D Program Participation and To Remove Consistently Poor Performers

This section addresses a number of provisions designed to strengthen our ability to approve strong applicants and remove poor performers in the Part C and D programs. Since the implementation of revisions to the MA program and initial implementation of the prescription drug program in January 2006 as a result of the MMA, we have steadily enhanced our ability to measure MA organization and PDP sponsor performance through efforts such as the analysis of data provided routinely by sponsors and by our contractors, regular review of beneficiary complaints, marketing surveillance activities, and routine audits. This information, combined with feedback we have received from beneficiary satisfaction surveys, HEDIS data, and information from MA organizations and PDP sponsors themselves, has enabled us to develop a clearer sense of what constitutes a successful Medicare organization capable of providing quality Part C and D services to beneficiaries. This information has also allowed us to identify and take appropriate action against organizations that are not meeting program requirements and not meeting the needs of beneficiaries.

As our understanding of Part C and D program operations has deepened since implementation of the MMA, our use of our authority to determine which organizations are qualified to offer MA and PDP sponsor contracts, evaluate their compliance with Part C and D requirements, and make determinations concerning intermediate sanctions, contract non-renewals and contract terminations has evolved as well. The changes identified in this rule will further allow us to make these determinations more effectively. These provisions are described in detail in Table 7.

TABLE 7: Provisions to Strengthen Our Ability to Distinguish for Approval Stronger Applicants for Part C and Part D Program Participation and to Remove Consistently Poor Performers

PROVISION	PART 422		PART 423	
	Subpart	Section	Subpart	Section
Expand Network Adequacy Requirements to All MA Plan Types	Subpart C	§422.112	N/A	N/A
Maintaining a fiscally sound operation	Subpart A Subpart K	§422.2 §422.504	Subpart A Subpart K	§423.4 §423.505
Release of Part C and Part D Payment Data	Subpart K	§422.504	Subpart K Subpart R	§423.505 §423.884
Required Use of Electronic Transaction Standards for Multi-Ingredient Drug Compounds; Payment for Multi-Ingredient Drug Compounds	N/A	N/A	Subpart C	§423.120
Denial of Applications Submitted by Part C and D sponsors with Less than 14 months Experience Operating their Medicare Contracts	Subpart K	§422.502	Subpart K	§423.503

1. Expand Network Adequacy Requirements to All MA Plan Types (§ 422.112)

In our November 2010 proposed rule (75 FR 71236), we proposed applying the network adequacy standards at § 422.112(a)(10) to all MA plans that meet Medicare access and availability requirements by directly contracting with network providers, including MSA plans that choose to use a contracted networks of providers. This proposed change would bring MSA network adequacy requirements in line with those applicable to MA coordinated care (CCP) plans and network private-fee-for-service (PFFS) plans, per a provision finalized in our April 2010 final rule (75 FR 19691 through 19693). This rule established criteria that MA CCP and PFFS plans must meet so that we can ensure that the network availability and accessibility requirements specified in section 1852(d)(1) of the Act are satisfied. We are finalizing this provision without modification.

Comment: One commenter recommended that CMS require all MA plans, including non-network PFFS and MSA plans, to meet the network adequacy requirements at § 422.112(a)(10).

Response: We do not have the statutory authority to require that the network adequacy standards at § 422.112(a)(10) be applied to MSA plans that do not use a network of providers or to PFFS plans that are not required to have a network that meets network adequacy requirements. MSA plans are not required under section 1859 of the Act to establish networks of providers, and section 1852(d)(5) of the Act permits PFFS plans to operate without networks when fewer than two network-based plans are operating in an area.

2. Maintaining a Fiscally Sound Operation (§ 422.2, § 422.504, § 423.4, and § 423.505)

Under the authority of sections 1857(d)(4)(A)(i) and 1860D–12(b)(3)(C) of the Act, which establish requirements for MA organizations and PDP sponsors to report financial information demonstrating that the organization has a fiscally sound operation, we proposed in § 422.2 and § 423.4 to define a fiscally sound operation as one which, at the very least, maintains a positive net worth (total assets exceed total liabilities). We noted that the States' oversight and enforcement of financial solvency of MA organizations and PDP sponsors provides an important protection for Medicare beneficiaries enrolled in MA and Part D plans. However, we also noted that the requirement for plans to report financial information demonstrating that the organization has a fiscally sound operation and our authority to audit and inspect any books and records, is an indication that we have an interest in the organization maintaining a fiscally sound operation and that this interest is separate and apart from the State licensure and financial solvency requirements for an organization. Additionally, under the authority of sections 1857(e)(1) and 1860D–12(b)(3)(D) of the Act which afford the Secretary the authority to include terms and conditions in the contracts with MA organizations and PDP sponsors that are necessary and appropriate, we proposed the addition of a contract provision at § 422.504(a) and § 423.505(b)(23), under which the MA organization or Part D sponsor agrees to maintain a fiscally sound operation by at least maintaining a positive net worth (total assets exceed total liabilities).

Comment: One commenter suggested that the standard that "total assets exceed total liabilities" was insufficient and that CMS should set a higher threshold.

Response: We believe that the role of the state insurance departments in providing oversight and enforcement of licensure and financial solvency is the primary tool for financial oversight of organizations and therefore it is unnecessary for CMS to modify this standard.

Comment: One commenter asked if the fiscally sound operation requirement applied only to the Medicare lines of business or to all lines of business.

Response: We have not imposed any new reporting requirement and will rely on the financial reports that are submitted for the organization as a whole.

Comment: One commenter suggested that CMS should publish clear guidelines for when a plan's finances will be declared "unsound."

Response: We have specified in the definitions that a "fiscally sound operation" is one with a positive net worth. We already require that organizations submit the same information that is submitted to their state insurance departments under that state's requirements and guidelines. Therefore it is not necessary for us to set specific guidelines for calculating positive net worth.

Comment: One commenter suggested that CMS should publish its criteria for selecting alternative plans for receiving transitioned beneficiaries.

Response: When appropriate, we would follow all policies and procedures specified in the current guidance in Chapter 2 of the Medicare Managed Care Manual *http://www.cms.gov/MedicareMangCareEligEnrol/Downloads/FINALMAEnrollmentandDisenrollmentGuidanceUpdateforCY2011.pdf,* entitled "Passive Enrollment by CMS which are used for the smooth transition of beneficiaries to other plans when there are terminations for reasons other than failure to maintain a fiscally sound operation. For prescription drug plans, we would follow all policies and procedures specified in the current guidance in Chapter 3 of the Medicare Prescription Drug Benefit Manual, *http://www.cms.gov/MedicarePresDrugEligEnrol/Downloads/FINALPDPEnrollmentandDisenrollmentGuidanceUpdateforCY2011.pdf,* which contains the Part D guidance on passive enrollment.

Comment: One commenter agreed with the definition for "fiscally sound operation" with the understanding that "total assets" and "total liabilities" were to be as defined by the state insurance departments.

Response: We appreciate the commenter's support for the proposal and confirm that we have not changed our financial reporting requirements and that we continue to use the information that is submitted to the state based on the State's financial reporting requirements and guidelines.

Comment: One commenter suggested that CMS should take into consideration arrangements providing for the financial solvency of an MAO by the parent organization consistent with the treatment of those arrangements by the relevant State insurance department.

Response: We continue to consult regularly with state insurance regulators to ensure that sponsoring organizations are meeting State reserve requirements and solvency standards required for State licensure and their input is included in any action related to fiscal soundness.

Comment: One commenter requested that CMS clarify how the Part D fiscally sound requirement will apply to Medicare cost organizations that also offer Part D services.

Response: As mentioned previously, we will rely on the financial reports that are submitted for the organization as a whole. Therefore, the cost organization, including the Part D benefit, will be held to the fiscally sound operation requirement.

Comment: One commenter was concerned that the fiscally sound

requirement adds new reporting requirements.

Response: As noted in the preamble to the November 2010 proposed rule, a determination of whether there is a positive net worth will be made from the financial reports submitted under the currently approved financial reporting requirements. No additional filings will be required.

Comment: One commenter requested that CMS explain how traditional state regulation has not provided adequate consumer protection such that additional Federal oversight is required and suggested that the proposal be withdrawn to allow the states to maintain primary supervision of plans for fiscal soundness.

Response: As noted in the preamble to the November 2010 proposed rule, licensure does not deem an organization to meet other requirements imposed under Part C or Part D. The requirement for an organization to be licensed under State law and the requirement that an organization must report financial information demonstrating that the organization has a fiscally sound operation are separate requirements in the Act. The authority to license an MA organization or PDP sponsor and set solvency standards rests with the state licensing authority and therefore the primary supervision of plans for fiscal soundness continues to rest with the states. The proposed rule clarifies what we expect from a fiscally sound operation. Further, as stated previously, we consult regularly with state insurance regulators and their input is included in any action related to fiscal soundness.

Comment: One commenter asked how the requirement to maintain a fiscally sound operation will protect beneficiaries if the plan sponsor has already encountered the financial difficulties.

Response: We have historically been limited in our ability to take compliance and enforcement action against an organization solely on the basis of financial problems if the organization is still licensed by the state and is not otherwise out of compliance with CMS requirements. In some cases, we have been made aware by state insurance departments that an organization would inevitably lose its state licensure because of its poor financial condition, but we were unable to take action to terminate the organization's contract and ensure that beneficiaries were smoothly transitioned to a new organization or sponsor, until the full termination process was completed by the state. The proposed rule will allow us to work with the state insurance department and if appropriate, take timely contract action in order to avoid any additional potential risk to enrollees.

After consideration of the comments received in response to the proposed rule, in this final rule, we are adopting the provisions as proposed.

3. Release of Part C and Part D Payment Data (§ 422.504, § 423.505, and § 423.884)

This final rule provides for the Secretary to release Part C and D summary payment data. The Secretary believes these data should be made available because other publicly available data are not, in and of themselves, sufficient for the public (including policy analysts and researchers) either to understand expenditures for the MA and Part D programs, or to inform the public on how their tax dollars are spent.

In the proposed rule, we stated that in keeping with the President's January 21, 2009, Memorandum on Transparency and Open Government (74 FR 26277), we were proposing to routinely release summary Part C and Part D payment data. We stated that additional purposes underlying release of these data included allowing public evaluation of the MA, prescription drug benefit, and RDS programs, including their effectiveness, and reporting to the public regarding expenditures and other statistics involving these programs.

In the proposed rule, we stated our belief that the availability of the payment data would permit potential plan sponsors to better evaluate their participation in the Part C and D programs, as well as facilitate the entry into new markets by existing plan sponsors. As a result, the availability of plan payment data would enhance the competitive nature of the programs. We stated that in knowing the per member per month payment amounts and other components of plan payment (plan rebates and risk scores), new business partners might emerge, and better business decisions might be made by existing partners. Thus, we believed that including a provision in our contracts with plan sponsors regarding the release of summary payment data was both necessary and appropriate for the effective operation of those programs.

We proposed that these data would be routinely released on an annual basis in the year after the year for which payments were made. The data release would occur only after the final risk adjustment reconciliation has been completed for the payment year in question and, for Part D, after final payment reconciliation of the various subsidies. Thus, we would release data for payment year 2010 in the Fall of 2011.

We stated this proposed timeframe would not apply to the release of RDS payment data, since we do not reconcile RDS payment amounts until 15 months following the end of the plan year. The majority of our sponsors provide retiree drug coverage on a calendar year basis. Thus, if an applicable RDS plan year ended December 31, 2010, the payment reconciliation would not be due until March 31, 2012, which would be after the Fall 2011 target for release of other Part C and D payment data. Therefore, we proposed that we would release the most current RDS payment data available at the time the Part C and D payment reconciliation has been completed and at the same time those other Part C and D payment data are compiled and released.

Specifically, as we indicated in the November 2010 proposed rule, beginning in the Fall of 2011 we would release reconciled payment data as follows:

- Part C

++ Reconciled payment data summarized at the plan benefit package level including average per member per month (PMPM) payment for A/B (Medicare covered) benefits standardized to the 1.0 (average risk score) beneficiary and average PMPM rebate amounts.

++ The average Part C risk score for each plan benefit package.

++ Reconciled aggregated Part C payment data by county including the average PMPM payment amounts for A/B benefits standardized to the 1.0 (average risk score) beneficiary and average rebates amounts at the plan type (including HMO, PPO, RPPO, and PFFS) for each county in which such plan types are represented.

- Part D

++ Reconciled payment data summarized at the plan benefit package level including average PMPM payment for the direct subsidy standardized to the 1.0 (average risk score) beneficiary, the average low-income cost sharing subsidy, and the average Federal reinsurance subsidy.

++ The average Part D risk score for each plan benefit package.

++ Final payment reconciliation data arrayed by parent organization, number of plan benefit packages, the gross reconciliation amount broken out by risk sharing reconciliation amount, reinsurance reconciliation amount, and low income cost sharing reconciliation amount.

++ Retiree drug subsidy (RDS) data including the gross aggregate reconciled

subsidy amount paid to each eligible sponsor of qualified retiree prescription drug coverage and the total number of unduplicated Medicare eligible retirees for each sponsor.

We noted that because the proposed provisions would apply to all Part C and Part D sponsors, it would apply to any entity offering either Part C or Part D plans, including MA organizations offering and not offering prescription drug plans, as well as all Part D drug plan sponsors. It would also apply to sponsors entitled to Federal RDS subsidies.

We solicited comment generally on the public release of Part C and Part D payment data. We also specifically solicited comment on whether commenters believed that any of the Part C and Part D payment data we proposed to release contained proprietary information, and asked commenters to suggest, if they believed proprietary data were implicated, safeguards that might appropriately protect those data.

Comment: We received numerous comments on this provision of the proposed rule from beneficiary advocacy groups, researchers, PDPs, PBMs, associations, and MA organizations. The beneficiary advocacy group comments supported our proposal to release payment data. One beneficiary advocacy group supported release of all payment data, to the extent it could be done without compromising beneficiary personally identifiable health information, and recommended we codify release in regulation text.

Response: We accept the comment from the beneficiary advocacy group regarding codifying a process for release of summary payment data in regulation text. We believe that codifying the release in the Code of Federal Regulations will permit interested parties to have a better understanding of exactly what summary payment data to expect CMS to release and when to expect to be able to access it. As we indicated in the proposed rule, the Secretary has the authority to include in MA organization and Part D sponsor contracts any terms and conditions the Secretary deems necessary and appropriate. (See sections 1857(e)(1) and 1860D–12(b)(3)(D) of the Act, which incorporates section 1857(e) into Part D.) As we also stated in the proposed rule, our regulations at sections § 422.504(j) and § 423.505(j) permit us to include other terms and conditions in these contracts that we find necessary and appropriate to implement the Part C and D programs. Similarly, we stated that under § 423.884(c)(3)(i), RDS sponsors agree to comply with the terms and conditions for eligibility for a subsidy payment in our regulations and in related CMS guidance. Accordingly, we are codifying in our regulations at § 422.504(n) our intent to release Part C summary payment data as proposed, at § 423.505(o) our intent to release Part D summary payment data as proposed, and at § 423.884(c)(3)(ii) our intent to release summary RDS payment data as proposed. We will also modify MA organization and Part D sponsor contracts as well as RDS sponsor agreements to account for the release of summary payment data. As we discuss in more detail, below, in our response to comments opposed to our release of summary payment data, we believe we have the authority to promulgate these regulations providing for the routine release of these data.

Finally, in response to the statement from a beneficiary advocacy group that supported release only in the event that personally identifiable beneficiary health information could be protected, we will only release summary data to the extent individually identifiable information is protected—consistent with existing CMS policy. Thus, for instance, to the extent that less than 11 MA plan members of a specific MA plan type reside in a county, we will not release summary payment information or average Part C risk scores for that plan type in that county.

Comment: Some MA organizations supported release of payment data as proposed, while many of them recommended limiting data release in varying ways. Two recommended releasing only average monthly payments and rebates, while others suggested plans should have the right to veto release of any payment information prior to public dissemination. Another MA organization suggested aggregating data at a higher level, for instance by plan type, thus masking plan-specific data. A commenter stated that reporting or releasing payment data at the plan benefit package level is not aggregating or summarizing payment data at all and that such a release would be inconsistent with our stated intent to only release summary payment data. Some Part D plan sponsors recommended releasing Part D payment data on only an aggregate basis—where individual plan payment data would not be revealed. Some health plan associations also recommended releasing payment data on a more aggregated, non-plan-specific basis—for instance, releasing only aggregated Part C or D payment data at the county level with no plan identifiers.

Response: We do not believe it is appropriate to provide veto power to MA organizations regarding release of payment data. If we were to allow some MA organizations to withhold data, the value of the remaining, released data would be diminished and would potentially become useless to researchers and the public. Similarly, were we to aggregate payment data at a higher level prior to release, the public would know very little about what payments were being received by specific CMS contractors—which would undermine a specifically stated goal of release which was to inform the public on how their tax dollars are spent. Researchers would also be hampered in their ability to conduct meaningful studies that analyze the Medicare program and Federal expenditures. We believe we have identified the appropriate level of aggregation such that researchers and the public will have specific enough information to meet their needs, while we will continue to shelter from disclosure bidding and provider contracting information both MA organizations and Part D plan sponsors want protected.

Comment: Some MA organizations contended that proprietary plan payment information related to providers could be deduced from the payment data we proposed to release. Some Part D plan sponsors and associations stated that competitors would be able to reverse engineer bids. One commenter stated that the data we proposed to release could be used with other Part D data currently released by CMS, such as PDP enrollment information, plan premiums, and generic dispensing rates, to reverse engineer bid data and other sensitive information relevant to Part D sponsors' bidding and business strategies.

Response: We do not agree. The bid pricing tool (BPT) document that MA organizations and Part D plan sponsors submit to CMS as part of the annual bidding process asks the plans to provide detailed information on their costs to furnish Part C and D services. In the case of MA organizations, over a dozen initial values related to Part C costs are further broken out by costs for services, administrative costs, expected utilization and member cost sharing. These costs and others are trended from the base year (derived from costs from the calendar year before the bid is submitted) to the year for which plans are bidding. Thus, the input values in the bids are already composed of aggregated cost and utilization information. Information provided on the BPT is aggregated in a number of ways—across providers, beneficiaries, and sites of service. Additionally, the different components of cost—direct

medical, indirect medical, administrative, profit, *etc.* are also aggregated. Thus, to suggest that a competitor would be able to derive or disaggregate specific bidding information from the aggregated payment data we proposed to release, or, much less, that a competitor would be able to derive payment information related to any specific provider, is simply not credible.

A similar argument applies to Part D bid submissions in the sense that dozens of input values representing type of drug (generic, preferred brand, specialty, etc.), expected utilization and cost information aggregated over a number of provider types, and a multitude of contracting entities ensures sufficient protection for plan bidding information. While the payment data proposed for release will be very helpful in understanding the payments received by Part D sponsors and their ability to estimate their revenue needs in their Part D bids, we do not believe that this information will be sufficient for others to determine sensitive components of the Part D bids, such as expected manufacturer rebates and profits. The Part D data to be released do not provide information about administrative costs and drug costs incurred by Part D sponsors in sufficient detail for other parties to determine the sensitive components of bid data. In the few numbers we will release, no specific provider contractual information is in danger of being exposed. Those viewing and using the aggregated data will have no way to disaggregate the data since there are dozens, if not hundreds, of individual components that are used to build up the few data elements that will be released.

Comment: Some commenters stated that by reviewing 2 or more years of payment data, an MA organization of Part D sponsor would be able to determine the cost trends of their competitors. The commenters stated that these entities would be able to determine where their competitors are heading, which would jeopardize the fairness and competitive dynamics of the bidding process. The commenters also stated that competitors would gain information about business strategies that could undermine the bidding process and the competitive nature of the Part C and D programs. Other commenters stated that release would undermine the integrity of the bid process and alter the competitive marketplace.

Response: We do not agree that release of summary payment data as we proposed would affect the integrity of the bidding process in either the Part C or D programs. First of all, as we described briefly in response to an earlier comment, bids are built up of costs related to a multitude of components (plan costs for health care services, administrative activities, utilization, and profits). Further, such costs must be trended from the base year—the calendar year before the bid—to the year for which the bid is submitted—the year after the year in which bids are submitted in June. Utilization, costs, and trends must be certified by a qualified, independent actuary prior to bid submission. Since we will continue to require actuarial certification, integrity is unaffected. Second, the MA and Part D programs are not competitive in the way that term is normally understood. Although Part C and D plans do compete for members, primarily through the benefits offered and the cost (member cost sharing and premium) of those benefits, they do not directly compete for the payments that CMS makes. Rather, we approve all sustainable bids that are otherwise qualified without preference for the lowest bidder. The fact that MA-eligible Medicare beneficiaries can, on average, select from over 2 dozen MA and Part D plans in every county of the nation is ample evidence that competition is robust. As we mentioned in the preamble of the proposed rule, we believe the availability of the summary payment data we proposed to release will permit potential plan sponsors to better evaluate their participation in the Part C and D programs, as well as facilitate the entry into new markets by existing plan sponsors. In other words, we believe competition, if anything, will be enhanced by release rather than harmed in any way. Further, although trends from one year to the next might be revealed through release of payment data for sequential years, the fact remains that such trends will be stale (at least 2 years old) and reveal little about competitive strategies in future years. Finally, where plans are free to modify the actual competitive components that are used to build up bids, such as benefit offerings and member cost-sharing, little is left of the argument that revealed cost trends will have an impact on the competitive nature of the programs.

Comment: One commenter stated that payment data release would work to the programs' detriment.

Response: We do not agree. We believe that a more extensive knowledge of summary payment data will not only not harm competition in the Part C and D programs, but rather that it will permit both existing and potential plan sponsors to better assess the business opportunities available to them.

Comment: Many commenters stated release of summary payment data was prohibited under Exemption 4 of the Freedom of Information Act (FOIA), others cited a prohibition on release based on Exemption 6, still others cited both Exemptions 4 and 6 as prohibiting release under the FOIA. Some provided extensive arguments, citing case law to support their positions. These, and other commenters, also invoked the Trade Secrets Act and argued that there was a strong potential for compromising proprietary information of both Part C and D plan sponsors. Still others stated that the Privacy Act is implicated because release of risk scores might allow someone to identify the health status of an individual enrollee or enrollees.

Response: In response to comments arguing that the Trade Secrets Act (18 U.S.C. 1905) or FOIA exemptions prohibit release of this information or citing past practices of this agency with respect to FOIA requests, as noted previously, we do not believe that the release of the data at issue necessarily would be subject to the FOIA exemption for information protected by the Trade Secrets Act, because we do not believe the data we would be releasing could be used to obtain proprietary information. However, with respect to the data we are proposing to release, we believe the merits of such arguments are moot in light of the fact that we have decided through this rulemaking to require the disclosure of data at issue. Section 1106(a) of the Act (42 U.S.C. 1306(a)) provides authority to enact regulations that would enable the agency to release information filed with this agency. (*See Parkridge Hospital, Inc.* v. *Califano,* 625 F.2d 719, 724–25 (6th Cir. 1980). We have engaged in notice-and-comment rulemaking to promulgate regulations to enable the disclosure of the summary payment information. The Trade Secrets Act permits government officials to release otherwise confidential information when authorized by law. A substantive regulation issued following notice-and-comment rulemaking, such as this one, provides the authorization of law required by the Trade Secrets Act. Because the Trade Secrets Act would allow disclosure, Exemption 4 (5 U.S.C. 552(b)(4)), which is as co-extensive with the Trade Secrets Act, would also not preclude disclosure with respect to the information that would be released under this final rule. This conclusion would not apply to other payment data with respect to which a Trade Secrets Act argument might be made.

With respect to the commenters, who argued that FOIA Exemption 6 (5 U.S.C. 552(b)(6)) protects information that would cause a clearly unwarranted invasion of an individual's personal privacy and argued that releasing plan payment and risk score data could lead to the disclosure of the name or health status of an individual enrollee, we disagree, because the concerns expressed are too speculative to lead to a legitimate privacy interest. Furthermore, there is a substantial public interest in the release of this summary payment data which can be used to shed light on the government's operation of the Part C and D programs, outweighing the speculative privacy interest.

Finally, with regard to protection of individually identifiable data through the release of risk scores, as we stated previously, we will not release summary payment information or average Part C or D risk scores when the small number of enrollees in a plan or in an area might reasonably permit disaggregation such that individually identifiable information could be revealed.

Comment: Some commenters stated release of payment data would harm business partners and thus, the Part D program.

Response: We do not agree. As we have already explained, we are not releasing payment data at a sufficient level of granularity to permit extrapolation of specific contract terms or purchase information. Rather, we will only be releasing summary payment and risk score data that is sufficiently aggregated to prevent extrapolation to any individual provider's or manufacturer's terms with any plan sponsor.

Comment: Some Part D sponsors and one association cited Congressional Budget Office (CBO) and Federal Trade Commission (FTC) letters warning that release of rebate information could lead low bidders to increase their bids compared to the bids they would have submitted without such information on competitor prices. They argued that release of rebate data might foster collusion or otherwise undercut vigorous competition on drug pricing.

Response: These commenters seem to be conflating the release of summary data on the component of savings in the Part C payment calculation known as the Part C rebate with the release of Part D drug manufacturer rebate information. In the CBO and FTC documents we were able to review, warnings were provided solely related to the release of the latter. In the proposed rule we did not propose the release of any Part D drug manufacturer rebate information. The Part C rebate information we proposed to release is solely related to Part C and represents 75 percent of the difference between the plan risk-adjusted statutory non-drug monthly bid amount and the plan risk-adjusted area-specific non-drug monthly benchmark amount—when the bid is below the benchmark. (See § 422.264(ff).) Revealing this Part C rebate information is little different than revealing the Part C plan basic beneficiary premium amount (see § 422.262), release of which is already required by regulation. (See § 422.111(f)(6).)

Comment: Some commenters cited past practices by CMS where CMS specifically denied release of similar data by invoking Exemptions 4 and 6 of the FOIA.

Response: As we previously indicated, the data that would be released under this rule have been specifically limited in nature, and as to the year involved to avoid proprietary data issues. It thus is not necessarily the case that previous denials of FOIA requests would apply to these data. Also, as noted previously, the issue of whether these data would be withheld from release in response to a FOIA request absent this final rule is moot in light of the fact that we have now engaged in notice-and-comment rulemaking to promulgate regulations which clearly enable the disclosure of this information regardless of whether it would have been disclosable in the absence of this final rule.

Comment: Some commenters stated that release of this summary payment data would have limited value to researchers. One researcher cited more than 20 scholarly articles that he and colleagues had written using data on MA payments and enrollment since 2000 and urged us to release the type of MA payment data discussed in the proposed rule for years between 2006 and 2010. An additional commenter also urged the release of the same payment data for years prior to 2010, and argued that this notice and comment process would apply equally to such prior year data.

Response: First, we would note that researchers have informed us that they believe the data we proposed releasing does have value to them. With respect to 2006 through 2009 payment data, while the proposed rule referenced 2010 data in discussing the timing of our release of payment data, we agree that the same analysis and rationale would apply equally to data for prior years as well, and that through our publication of a proposed rule and our response to comments, we have satisfied the requirements in section 1106(a) of the Act (42 U.S.C. 1306(a)) for a regulation that authorizes release of this information for any year. Given the interest of these commenters in such prior year data, we will release data for these prior years as well as 2010, and will release data for future years on the schedule set forth in the proposed rule.

Comment: One commenter stated that we had not stated what public policy goal was being served by releasing payment data at the plan level. Another commenter stated that currently available data are sufficient to CMS' stated purposes for release.

Response: We do not agree that currently available data are sufficient to accomplish the broad public policy purposes supporting release of this information, which we discussed in the proposed rule. In the preamble of the proposed rule we explained that other publicly available data are not, in and of themselves, sufficient for the studies and operations that researchers want to undertake to analyze the Medicare program and Federal expenditures, and to inform the public on how their tax dollars are spent. This is so because currently available data do not provide researchers a means of analyzing payment data at a granular enough level to draw conclusions about regional variations in CMS payment—such as rural/urban differences or the payment variances between MSAs. We also cited the President's January 21, 2009, Memorandum on Transparency and Open Government. Finally, we stated that additional purposes underlying release included allowing public evaluation of the MA, prescription drug benefit, and RDS programs, including their effectiveness, and reporting to the public regarding expenditures and other statistics involving these programs.

Comment: Some commenters stated that release would not help beneficiaries select the MA or Part D plan that is best for them. Others stated that release would adversely impact beneficiaries due to related impacts on MA and Part D plan offerings. Still others stated that release of payment data would be misinterpreted by MA enrollees.

Response: The intent of releasing summary payment data and risk score information is not necessarily to help Medicare beneficiaries to select the right plan for them. When the data are published we will provide appropriate disclaimers to ensure the greatest likelihood of understanding by researchers, enrollees, and other interested parties. As far as the potential for adverse impacts on beneficiary offerings, we have already addressed the issues of competition and collusion and explained our belief that release will

neither limit competition nor engender collusion.

Comment: One commenter noted that release of this information was not authorized by the Social Security Act.

Response: We do not agree. Section 1106(a) of the Act (42 U.S.C. 1306(a)) provides authority to enact regulations that enable the agency to release information filed with this agency.

Comment: One commenter stated that there was a unique situation in their State where they are the largest MA organization offering MA plans. This commenter stated that its primary competition is from Medicare Cost HMOs/CMPs and Medigap insurers—neither of which are impacted by this regulation. The commenter stated it was unfair that its aggregate payment information would be released, while that of Cost HMOs/CMPs with which it was competing would not be released.

Response: While it might be true that in some markets a single MA organization is predominant, it is also true that a valid public policy goal related to the release of summary payment data is to encourage competition. Although Cost HMOs/CMPs and Medigap insurers are not subject to this rulemaking, information on medical loss ratios for Medigap insurers should be available from the State Insurance Department. Thus, while the payment data we release will be available with respect to MA plans but not Cost HMOs/CMPs or Medigap plans, Medigap MLR data will be available with respect to Medigap plans but not MA plans.

Comment: A commenter recommended that when CMS modifies the MA organization contracts, as it proposed in the proposed rule, it should modify them *only* to say that CMS will release the specifically described payment data. The commenter suggested that the new contractual language should not simply reference MA data, as this could be construed to permit CMS to release data that was not the subject of this notice and comment process.

Response: We agree with the commenter and when modifying MA plan contracts, we will limit language regarding payment data disclosure to only the items discussed in the proposed rule. In a similar manner we have limited the regulatory language we are adding to sections § 422.504(n), § 422.505(o) and § 423.884(c)(3)(ii) to provide for disclosure of only those items specifically proposed in the rule.

Comment: One commenter argued that section 1860D–12(b)(3)(D) of the Act, as amended by section 181 of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA), specifically prohibited release of payment data since the only authorized release would be under the conditions enumerated in that section of the law. The commenter argued that the law authorizes release *only* when one of the following conditions is met: (1) To carry out Part D; (2) to improve public health through research on the utilization, safety, effectiveness, quality, and efficiency of health care services; or (3) to release the data to Congressional support agencies for Congressional oversight purposes.

Response: The summary payment data that CMS proposed to release are not data that are provided by Part D sponsors—either under section 1860D–12 or under section 1860D–15 of the Act. Rather, the data that CMS proposed to release are CMS data. The data are compiled and derived solely from CMS internal payment files.

Further, we do not agree with the commenter's interpretation of law. In reviewing the House Ways and Means summary of section 181 of MIPPA, we find that Congressional intent in adding the matter after the first sentence in section1860D–12(b)(3)(D) of the Act was to provide a directive to the Secretary to release claims data to appropriate Congressional support agencies. The Ways and Means summary of section 181 reads, in full: "Clarifies the use of Part D data collected under section 1860D–12 of the Act for research and other purposes. Requires the Secretary to release Part D claims data to Congressional support agencies to the extent that the agencies have authority to request the data in their respective authorizing statutes." In effect, the legislation was intended to require the Secretary to release claims data to Congressional support agencies and not to prohibit its release to any others. Section 1860D–12(b)(3)(D)(i) of the Act reads, in full: "[Information provided to the Secretary] may be used for the purposes of carrying out this part, improving public health through research on the utilization, safety, effectiveness, quality, and efficiency of health care services (as the Secretary determines appropriate;)" Thus, the law provides discretion to the Secretary to use the data broadly for these purposes, "as the Secretary determines appropriate." Although it is clear to us that the provision was narrowly intended and meant to cover release of only PDE data—"Part D claims data"–because that language only appears in the Ways and Means summary, and not in the statute, we must assume broad application. However, the statutory language, provides discretion to the Secretary, "as the Secretary determines appropriate," to use the data for the purpose of "research on the efficiency of health care." In our proposed rule we cited research and analysis of the Medicare program as one of the reasons for our proposed disclosure of Part C and D summary payment data and risk scores. We stated, "the Secretary believes these data should be made available * * * for the studies and operations that researchers want to undertake to analyze the Medicare program and Federal expenditures." We believe studies related to the efficiency of Part D services are coextensive with our stated purposes for release. As explained earlier, by engaging in notice-and-comment rulemaking to promulgate regulations, proactive disclosure of summary Part C and D payment data is now permitted.

Comment: Some commenters stated that CMS should not release retiree drug subsidy (RDS) payment data. Some stated that RDS plans are not public plans and therefore no payment data should be released for them. Others stated that RDS data should not be released because data would be based on member utilization in commercial prescription drug plans. One commenter stated that RDS plans are private plans in the private market and release of the subsidy amount is tantamount to release of private payment data since the former is a simple 28 percent of the latter. This commenter went on to say that they were unaware of any precedent for releasing private plan data and that they knew of no public policy data analysis that could be conducted using such data. Finally, one commenter stated that they opposed release of RDS data because RDS is a competitive commercial program and there is no basis for release.

Response: We do not agree that RDS summary payment data should not be released. In the proposed rule we stated we would release the gross dollar amount paid to eligible sponsors and the total number of unduplicated Medicare eligible retirees. While we agree that RDS sponsors are private plans, we do not agree that no data should be released. Taxpayers and interested parties should be apprised of how their tax dollars are being spent. To the extent the RDS is a "simple 28 percent of private payment data, "this is merely a consequence of the way the RDS payment is authorized in statute. Knowing that 28 percent of a specific *portion* of the cost of such plans is being paid by CMS does not reveal the final cost of the plan for a number of reasons, not the least of which is that we are not publishing member months, but only

the number of unduplicated Medicare eligible retirees. There are other factors that confound the relationship between the RDS subsidy CMS pays and the cost of a private plan, including the fact that CMS only pays 28 percent of the allowable retiree costs—which are defined in § 423.882. Further, we note that all MA and Part D plans are private plans and the release of summary data regarding payments to RDS plan sponsors is no different than the release of MA and Part D plan summary payment data. As we have noted earlier in this section in our response to other comments, having engaged in notice-and-comment rulemaking to promulgate regulations, disclosure of summary RDS payment data is now permitted.

Comment: Some commenters stated that the 2008 Part D Data rule regarding the release of PDE data should be followed and that no additional payment data should be released. They stated that CMS needs to protect commercially sensitive data and that the threat of release is just as great today as it was in 2008. Others stated that release of summary Part D payment data is contrary to the 2008 Medicare Part D Claims Data final rule regarding limited release of PDE data.

Response: We do not agree. The Part D Data rule (73 FR 30664) published in the **Federal Register** on May 28, 2008, addressed limits on release of Part D claims data—so called PDE (prescription drug event) data. In the proposed rule, we did not propose any changes to the process finalized in the Part D Data rule with respect to release of PDE data. Rather, we proposed to release summary Part D payment data and risk scores. As we have explained in our responses to previous comments, we do not believe that the summary payment data we will be releasing can be disaggregated in such a way as to gain granular knowledge of PDE data. Therefore, while we will continue to follow the guidelines we set out in the Part D Data rule with respect to PDE data, we will also proceed with the release of summary Part D payment and risk score data, consistent with our proposed rule.

For the reasons outlined in our responses to comments and consistent with our proposed rule, we are finalizing our proposal to release summary Part C and D payment data and average risk scores and are codifying this policy in our regulations at § 422.504(n), § 423.505(o) and § 423.884(c)(3)(ii).

4. Required Use of Electronic Transaction Standards for Multi-Ingredient Drug Compounds; Payment for Multi-Ingredient Drug Compounds (§ 423.120)

As provided under section 1860D–4(b)(2)(A) of the Act and codified in § 423.120(c) of the regulations, Part D sponsors must issue (and reissue, as appropriate) a card or other technology that may be used by an enrollee to assure access to negotiated prices under section 1860D–2(d) of the Act. Under section 1860D–4(b)(2)(B) of the Act we must provide for the development, adoption, or recognition of standards relating to a standardized format for the card or other technology that are compatible with the HIPAA administrative simplification requirements of part C of Title XI of the Act and consult with the NCPDP and other standard setting organizations, as appropriate.

In our November 2010 proposed rule, we noted that the NCPDP Telecommunications Standard Version D.0 (Version D.0), which was adopted as the HIPAA standard that must be used by HIPAA covered entities for retail pharmacy drug claims on and after January 1, 2012, standardizes claims processing for compounded drugs. Unlike the current version, in 2012 the pharmacy claim will reflect all ingredients of a drug compound. Since under § 423.120(c)(2), Part D sponsors will be required to adhere to the new standard, we proposed adding a new paragraph (d) to § 423.120 to clarify how Part D sponsors must treat compounded products under the Part D program.

Our preamble observed that a compounded product as a whole generally does not satisfy the definition of a Part D drug; only costs associated with ingredients of a compounded product that satisfy the definition of a Part D drug are allowable costs under Part D. Since pharmacy transactions prior to the new standard have not captured all ingredients of a billed compounded drug, under our current policy Part D plans generally pay for the most expensive Part D drug ingredient in a compound and submit that ingredient on the prescription drug event record for Part D payment reconciliation purposes. Our guidance to date has been limited to clarifying that the dispensing fee may include the labor costs associated with mixing the compounded product (provided that at least one ingredient of the compound is a Part D drug) and providing direction regarding appropriate cost-sharing.

Given that the new standard, Version D.0, will provide plan sponsors with access to information regarding ingredients, we thought it appropriate to clarify the treatment under Part D of compounds in general and, in particular, those that contain non-Part D ingredients. We proposed to codify our existing guidance that only compounded products that contain at least one ingredient that independently meets the definition of a Part D drug may be covered under Part D. Consistent with our current policy, we proposed to clarify that—subject to the exception for compounds containing Part B ingredients—sponsors may cover the Part D ingredients even if the compounded product as a whole does not satisfy the definition of a Part D drug.

We further explained that the aforementioned exception for Part B ingredients is based both on current Part B payment policy and section 1860D–2(e)(2)(B) of the Act, and proposed codifying the following: if a compound includes a Part B drug ingredient, no ingredients of the compound may be covered under Part D, even if one or more ingredients of the compound would individually meet the definition of a Part D drug.

In our November 2010 proposed rule, we proposed that Part D sponsors determine cost-sharing for Part D ingredients of Part D compounds and, in so doing, apply either a flat copayment amount equal to the copayment of the tier for the most expensive Part D ingredient or a coinsurance amount based on the tier of the most expensive Part D ingredient. In both cases, we proposed applying cost-sharing to the whole amount of the Part D claim. In the case of low income subsidy (LIS) beneficiaries, we recommended that sponsors select the cost-sharing amount based on whether the most expensive Part D ingredient is a generic or brand-name drug.

In our preamble, we identified an underlying premise of our policy: if a compound as a whole is considered by a Part D sponsor to be on-formulary at the time of adjudication, for the sake of consistency, then all Part D ingredients of that compound would be considered on-formulary, even if any individual Part D ingredients would be considered off-formulary as single drug claims. Accordingly, we proposed that if a Part D sponsor considers a Part D compound as a whole to be on-formulary, it must adjudicate the Part D ingredients as formulary drugs.

Stating in our November 2010 proposed rule that the government could not require Part D sponsors to reimburse pharmacies for non-Part D drugs in Part D compounds, we

proposed three options for a sponsor: Contract with the pharmacy to pay for the non-Part D ingredients without reporting these costs to us; deny payment, but allow the pharmacy to balance bill the beneficiary; or both deny payment and prohibit balance billing. Noting that limiting reimbursement of ingredients in Part D compounds might deter pharmacies from compounding services and subsequently affect beneficiary access to drugs, we invited comment.

Comment: One commenter requested that we clarify that Part D compounds could include certain non-Part D ingredients such as over-the-counter (OTC) products or excluded Part D drugs that may or may not be covered under a supplemental benefit.

Response: As proposed in § 423.120(d)(1), a compound is considered a Part D compound if it contains "at least one Part D drug that independently meets the definition of a Part D drug" and does not contain any ingredients covered under Part B as prescribed and dispensed or administered. As long as a Part D compound satisfies these two requirements, we clarify that it also may include other non-Part D ingredients such as OTC products and excluded Part D drugs.

Comment: One commenter questioned if there will be additional new reporting requirements for purposes of validating Part D coverage of compounds.

Response: We are not proposing any new reporting requirements specific to Part D compounds in this rule.

Comment: One commenter contended that the policy of allowing coverage for only Part D ingredients of a Part D compound is inconsistent with and contradicts our combination drug product policy. It stated that the combination drug product policy provides a product is covered under Part D if it contains at least one Part D drug ingredient even if one of its ingredients would separately be covered under Part B.

Response: We disagree with the commenter. The combination drug product policy does not apply to Part D compounds. As stated in Chapter 6, section 10.3 of the Prescription Drug Benefit Manual, the combination drug product policy applies to commercially available combination prescription drug products. Part D compounds are extemporaneously compounded by pharmacies and not otherwise commercially available. Nevertheless, neither commercially available combination prescription drug products nor extemporaneously compounded prescription drug products can be covered under Part D if payment is available for these products under Part B as prescribed and administered or dispensed.

Comment: One commenter requested that CMS clarify when an ingredient is considered covered under Medicare Part B so that the compound cannot be covered under Part D.

Response: This rulemaking is intended to address when Part D covers a multi-ingredient compound and is not intended to address coverage rules under Part B. For purposes of determining Part D coverage of a compound, we consider a compound to be covered under Part B (for purposes of § 423.120(d)(1)(i)) if, as prescribed and dispensed or administered, it meets the definition of a drug in section 1861(t) of the Act, fits within a Part B benefit category, and otherwise meets Part B coverage requirements. However, the fact that a compound meets the criteria in § 423.120(d)(1)(i) does not guarantee coverage of that compound under Part B. That stated, we will revise § 423.120(d)(1)(i) to clarify that the criteria applies when an ingredient in the compound is covered under Part B "as prescribed and dispensed or administered."

Comment: One commenter asked us to waive the 60 day notice when individual Part D ingredients within the compound change formulary or tier status.

Response: We decline to adopt this recommendation. We do not see a compelling reason to deny beneficiaries notice of changes in formulary status for Part D drugs they take simply because they take those drugs in a compounded form. However, if a Part D sponsor's formulary includes Part D compounds (that is, identified as such rather than by Part D ingredient), and the formulary status of the compound as a whole remains unchanged, then it follows that there would be no formulary change with respect to that compound about which beneficiaries would need to be notified.

Comment: Most commenters supported the proposed policy that if a Part D compound as a whole is considered by a Part D sponsor to be on-formulary, then all Part D ingredients within the Part D compound must be considered on-formulary even if a specific Part D ingredient would be considered off-formulary if it were provided separately. However, a few commenters recommended that CMS give Part D sponsors the option to determine formulary status not only by the Part D compound as a whole, but also Part D ingredient by Part D ingredient for purposes of meeting transition fill requirements.

Response: We appreciated the comments that supported the proposed policy to consider Part D compounds as a whole as either on-formulary or off-formulary. However, we disagree that Part D sponsors should determine formulary status of a compound on an ingredient-by-ingredient basis. We believe such an approach would be confusing for beneficiaries.

Comment: While strongly supporting the classification of compounds as either on-formulary or off-formulary, one commenter requested that CMS require Part D plans both to include commonly used compounds on their formularies to ensure adequate access and to provide criteria to pharmacy and therapeutic committees in making the formulary classification, for instance, tailored separately for parenteral nutrition.

Response: We did not propose to make any changes with respect to which drugs plans must include on their formularies and, therefore, we believe this comment is beyond the scope of this regulation.

Comment: One commenter asked that CMS clarify whether compounded drugs would still be eligible for the generic drug cost-reduction in the coverage gap in 2013 when, under the ACA, the brand drug cost-sharing will be reduced in the coverage gap.

Response: We believe this commenter is asking if our existing policy with respect to determining the cost-sharing of a compound will change in 2013 and, therefore, we confirm that at this time we have no plans to change the existing policy.

Comment: A few commenters stated that CMS should not require Part D sponsors to base Part D compound cost-sharing on the most expensive Part D ingredient and instead allow Part D sponsors to determine which cost-sharing tier (copayment or coinsurance) under the benefit plan applies to a Part D compound. One commenter recommended that Part D sponsors have the option to base Part D compound cost-sharing on the highest unit cost or a specific copayment/coinsurance that would apply to all Part D compounds because this would allow for a more consistent beneficiary experience since beneficiaries are not aware of the individual ingredients within a Part D compound. Another commenter asked us to clarify that Part D cost-sharing cannot apply to or be based on non-Part D ingredients. One commenter supported the proposal to base the low-income subsidy (LIS) cost-sharing on the most expensive ingredient, while

another commenter recommended that the LIS cost-sharing should be brand cost-sharing when compounds contain both generic and brand name Part D ingredients (that is, when not all Part D ingredients are generic).

Response: We agree with the commenters' recommendation not to require Part D sponsors to establish Part D compound cost-sharing based upon the tier associated with the most expensive Part D drug ingredient. We recognize that there are reasonable alternative methods for determining which cost-sharing tier should apply to Part D compounds and believe that each Part D sponsor should have the discretion to determine the cost-sharing for Part D compounds within its existing benefit design and in accordance with CMS tier requirements (for example, specialty tier cost threshold).

While we have decided that a Part D sponsor can determine which existing cost-sharing tier (copayment or coinsurance) applies to Part D compounds under its benefit design, CMS maintains that the cost-sharing for low-income subsidy (LIS) beneficiaries (as described in § 423.782) must be based on whether the most expensive Part D ingredient is a generic or brand-name drug regardless of which cost-sharing tier the Part D compound is placed on for non-LIS beneficiaries. We believe that this will ensure the LIS cost-sharing for Part D compounds will be consistent across all Part D plans regardless of benefit design in the same manner that LIS cost-sharing is consistent across Part D plans for non-compounded Part D drugs. Therefore, based on the comments, we are revising § 423.120(d)(ii) to remove the requirement to base non-LIS cost-sharing on the most expensive Part D drug ingredient.

Comment: Several commenters asked CMS to clarify that the most expensive Part D ingredient refers to the highest line item computed Part D ingredient cost (unit cost multiplied by quantity) and not the unit cost alone.

Response: We agree with these commenters and clarify that by most expensive Part D ingredient we mean the Part D ingredient with the highest line item computed ingredient cost (unit cost multiplied by the quantity) of that ingredient.

Comment: A few commenters supported the flexibility proposed for addressing non-Part D ingredients included in a Part D compound. However, a number of commenters did not support the proposed approach for several reasons. Some recommended that we require Part D sponsors to cover all Part D and non-Part D ingredients in a Part D compound or always allow balance billing. These commenters reasoned that the proposed approach would deter pharmacies from continuing to provide compounding services because they might not be paid for all ingredients. Others suggested that CMS should not allow Part D sponsor pharmacy contracts to allow pharmacies to balance bill for non-Part D ingredients because it could substantially increase beneficiary cost-sharing and create access problems for beneficiaries who could not afford the additional costs for any unpaid ingredients. Another commenter stated that current Part D sponsor pharmacy contracts generally do not allow member billing for anything other than what is specified as beneficiary cost-sharing on the paid response returned by the Part D sponsor on the pharmacy claim. These commenters also wrote that balance billing would confuse beneficiaries because they would not know which ingredients were not covered and the amounts listed on the explanation of benefits would differ from what the beneficiaries actually paid at the pharmacies. Another commenter stated that balance billing for only some ingredients in the compound would be difficult if secondary payers were involved.

Response: Based on the comments, we have reconsidered this issue, and we now agree with the commenters that recommended that Part D sponsors not allow their network pharmacies to balance bill beneficiaries above and beyond the Part D beneficiary cost-sharing specified on the paid response returned by the Part D sponsor on the pharmacy claim. The proposed policy would have allowed for balance billing based upon the premise that only a portion of some Part D compounds are covered because non-Part D ingredients included within the compound might not be directly paid for by the Part D sponsor and cannot be reported as Part D ingredient costs on PDEs, and we recognize that some commenters are concerned that pharmacies simply will stop preparing Part D compounds if they believe they are insufficiently compensated for that service. However, after considering the comments, we believe a better approach to this issue is one that is more straightforward for beneficiaries, Part D sponsors, and pharmacies. Thus, we are amending our final regulation to prohibit balance billing for non-Part D ingredients of Part D compounds.

Further, in response to concerns about pharmacy reimbursement, we wish to clarify that Part D sponsors and pharmacies are able to negotiate prices for covered Part D compounds that account for non-Part D ingredients. We believe they can accomplish this in one of two ways: (1) Part D sponsors can directly pay for non-Part D ingredients on the pharmacy claim (without charging the beneficiary or reporting these costs on the PDE to CMS); or (2) Part D sponsors can reimburse pharmacies for these ingredients as part of the dispensing fee. In addition, we note that, in our view, our definition of dispensing fees supports the proposition that pharmacies already are reimbursed by the plan for those ingredients of a Part D compound that do not independently meet the definition of Part D drug. For these reasons, we further do not believe that the billing and payment of specific line items on a pharmacy claim for a Part D compound determines whether a Part D sponsor has paid the full negotiated price for the entire Part D compound. Instead, we believe that Part D sponsors and pharmacies have negotiated how Part D compounds are priced in general and that such prices adequately account for any non-Part D ingredients, which usually account for a small portion of the overall cost, regardless of how an individual paid claim represents payment for individual ingredients. Consequently, because the plan's payment to the pharmacy represents payment in full, there are no remaining unpaid amounts to be balance billed. We believe this policy appropriately protects beneficiaries by ensuring that they only pay Part D negotiated prices for Part D compounds without interfering with the ability of pharmacies to negotiate prices that provide adequate reimbursements for Part D compounds. Based on the comments, we are revising § 423.120(d) to prohibit Part D sponsors from balance billing (or permitting pharmacies to balance bill) beneficiaries for non-Part D ingredients in Part D compounds.

Comment: Several commenters stated separately that the proposed approach for covering Part D compounds might increase Medicare costs significantly and noted that CMS did not estimate the savings, if any, this policy would bring to the beneficiary or the Medicare Part D program.

Response: We disagree with the commenters that the proposed approach might significantly increase Medicare costs. The proposed approach to allow reimbursement only for ingredients that independently meet the definition of a Part D drug is not new policy but rather a clarification of existing policy in light of the changing pharmacy billing standard that makes pharmacy claims for compounded drugs more

transparent. We also note that Part D compounds represent significantly less than one percent of the PDEs submitted to CMS. Additionally, as noted previously, CMS revisited its policies in light of a new industry standard rather than to achieve specified savings per se. For these reasons, we do not believe any further action is necessary.

Comment: A number of commenters disagreed with the preamble discussion on PDE reporting for compounds. Specifically, these commenters stated that the quantity reported on the PDE should not reflect only the quantity of the most expensive Part D ingredient national drug code (NDC) submitted on the PDE, but rather should reflect the total quantity of the Part D compound as a whole.

Response: We agree with the commenters that our preamble incorrectly suggested the current PDE guidance requires Part D sponsors to submit the quantity for the most expensive Part D ingredient NDC only. In fact, current PDE guidance does not specify whether the PDE should reflect the quantity of the most expensive NDC only or the total quantity of the Part D compound as a whole. Until further PDE guidance is issued, we will allow Part D sponsors to submit either quantity. However, given the industry consensus for reporting total quantity as reflected in the comments, we recommend that Part D sponsors submit the total quantity of the Part D compounds as a whole.

The final provision, amended as discussed in this section, will apply to plan years on and after January 1, 2012.

5. Denial of Applications Submitted by Part C and D Sponsors With Less Than 14 Months Experience Operating Their Medicare Contracts (§ 422.502 and § 423.503)

Each year, as part of the application evaluation process, we conduct a comprehensive review of each Part C and D sponsor's past performance in the operation of its Medicare contract(s). Current regulations provide that organizations with current or prior contracts with CMS are subject to CMS denial of any new applications for additional or expanded Part C or D contracts if they fail during the preceding 14 months to comply with the requirements of the Part C or D programs, even if their applications otherwise demonstrate that they meet all of the Part C or D sponsor qualifications. In the absence of 14 months of performance, however, this leaves a gap whereby CMS must either assume full compliance and exempt the entity from the past performance review, or deny additional applications from such entities until the applicant has accumulated 14 months' experience, during which it complied fully with the requirements of the Part C and/or Part D programs.

Our interest in protecting Medicare beneficiaries and limiting program participants to the best performing organizations possible strongly suggests that we take the latter approach. Our justification for proposing this change was two-fold. First, we would ensure that new entrants to the Part C or Part D program could fully manage their current contracts and books of business before further expanding. Second, this change would require that entities rightfully focus their attention on launching their new Medicare contracts in a compliant and responsible manner, rather than focusing attention almost immediately on further expansions.

Therefore, we proposed modifying § 422.502(b) and § 423.503(b) by adding additional language at § 422.502(b)(2) and § 423.503(b)(2) that in the absence of 14 months' performance history, we may deny an application based on a lack of information available to determine an applicant's capacity to comply with the requirements of the Part C or Part D program, respectively.

Comment: Several commenters requested that CMS clarify at what organizational level this provision would apply. Specifically, to determine whether an applying organization met the 14-month performance history threshold, would CMS review—(1) its experience in offering a particular plan benefit package (PBP); (2) its experience in operating a particular Part C or D contract it holds with CMS; (3) its experience in operating all contracts it holds with CMS; or 4) the experience of its parent organization's operation of all of the Medicare contracts held by its subsidiaries?

Response: These provisions only pertain to applying entities that currently operate Part C or Part D contract(s) but have done so for less than 14 months, and further, are unrelated (by virtue of being subsidiaries of the same parent) to any other contracting entity with at least 14 months' experience. So long as a contracting entity or another subsidiary of its parent organization has operated one or more Medicare contracts for the requisite period of time, applications for new contracts or service area expansions submitted by a current contracting entity will not be subject to denial under § 422.502(b)(2) and § 423.503(b)(2). Rather, these contracting entities will be subject to the past performance review under § 422.502(b) and § 423.503(b), which CMS will conduct according to the "2012 Application Cycle Past Performance Review Methodology" document CMS issued in December 2012 and expects to update each year.

Comment: One organization requested that CMS specify approval criteria for service area expansion.

Response: We have already published our criteria for approving applications, including service area expansions. This information can be found within the Part C and Part D application solicitation materials, and in the memo published on December 12, 2010 entitled, "2012 Application Cycle Past Performance Review Methodology." All of these documents are posted on CMS' Web site (*http://www.cms.gov*).

Comment: CMS received two comments concerning its application of the past performance methodology generally. One organization urged CMS to limit denials based on past performance to instances where the extent and intent of the plan's non-compliance amounts to consistent and willful inappropriate behavior or misrepresentation by a particular plan to beneficiaries. Another organization expressed concern that the past performance review CMS conducts on all applying organizations pursuant to § 422.502(b) and § 423.503(b) (that is, including those with more than 14 months' Part C or D experience) creates an uneven playing field for existing and new sponsors, giving new carriers a competitive advantage since they do not undergo a past performance review.

Response: These comments concern our general authority to deny applications based on an applicant's past Medicare contract non-compliance pursuant to § 422.502(b) and § 423.503(b). The latter comment, in particular, concerns the application of the past performance methodology to entities with established relationships with CMS versus those entities with no prior Part C or Part D relationship with CMS. Neither comment addresses the issue of how CMS should treat entities with less than 14 months experience (neither long-established nor brand new). As such, these comments fall outside the scope of this proposal.

In summary, for the reasons stated in the proposed rule, and after consideration of the comments received in response to the proposal, we are finalizing this provision without modification.

F. Other Clarifications and Technical Changes

We have identified seven technical changes in this section, affecting as

noted in Table 8, cost contract plans, MA plans, or Part D plans.

TABLE 8—Provisions on Other Clarifications and Technical Changes

PROVISION	PART 417/422		PART 423	
	Subpart	Section	Subpart	Section
Clarification of the Expiration of the Authority to Waive the State Licensure Requirement for Provider-Sponsored Organizations	Subpart A	§422.4	N/A	N/A
Cost Plan Enrollment Mechanisms	Subpart K	§417.430	N/A	N/A
Fast-track Appeals of Service Terminations to Independent Review Entities (IREs)	Subpart M	§422.626	N/A	N/A
Part D Transition Requirements	N/A	N/A	Subpart C	§423.120
Revision to Limitation on Charges to Enrollees for Emergency Department Services	Subpart C	§422.113	N/A	N/A
Clarify Language Related to Submission of a Valid Application	Subpart K	§422.502	Subpart K	§423.503
Modifying the Definition of Dispensing Fees	N/A	N/A	Subpart C	§423.100

1. Clarification of the Expiration of the Authority To Waive the State Licensure Requirement for Provider-Sponsored Organizations (§ 422.4)

We clarified in our November 2010 proposed rule (FR 75 71242) that we will no longer waive the State licensure requirement for organizations seeking to offer a provider-sponsored organization (PSO) because, under section 1855(a)(2)(A) of the Act and § 422.370 of our regulations, we had the authority to waive the State licensure requirement for PSOs only for requests for waivers submitted prior to November 1, 2002. While we currently contract with organizations that have previously met the conditions for becoming a PSO and will continue to contract with these organizations, organizations that do not meet State licensure requirements can no longer offer new PSOs because waiver of State licensure laws is necessary in order to offer a PSO. A PSO is defined in section 1855(d) of the Act, and that definition is codified in § 422.350.

Even though the authority to waive the State licensure requirement for PSOs expired on November 1, 2002, and we have not granted waivers of State licensure requirements since that time, we took the opportunity to clarify this policy in our November 2010 proposed rule because of questions we have received. Accordingly, we proposed to revise paragraph (a) of § 422.4 to clarify that we no longer have the authority to waive the State licensure requirement for PSOs. We received no comments on this proposal; therefore, we are finalizing this provision without modification.

2. Cost Plan Enrollment Mechanisms (§ 417.430)

As part of the enrollment process, § 417.430 requires that application forms be submitted to an HMO or CMP and must include a beneficiary's signature. The organization must provide the beneficiary with written notice of acceptance or rejection of the application. We proposed changes to § 417.430(a)(1) to allow us to approve other enrollment mechanisms for cost plans in addition to paper forms, such as electronic enrollment. We also proposed to streamline § 417.430(b)(3) and § 417.430(b)(4)(i) to allow for notice delivery options other than the traditional mailing of documents. These changes take into consideration the advancement of communication technology and comport with revisions we made with respect to the MA program under § 422.50(a)(5) and § 422.60(e).

Comment: Commenters voiced support for this proposal. They believed that alternative enrollment mechanisms provide easier access for beneficiaries to cost plans and lower plan administrative costs.

Response: We appreciate the commenter's support of our proposal and are finalizing this provision without modification.

3. Fast-Track Appeals of Service Terminations to Independent Review Entities (IREs) (§ 422.626)

To correct a typographical error in § 422.626(g)(3), we proposed to remove the word "to" after the word "may" in the regulation text. However, in the proposed rule, we erroneously referred to § 422.626(f)(3) as containing the typographical error rather than § 422.626(g)(3). We are correcting both of these errors in the final rule.

Although we did not include this change in the proposed rule, we are using this opportunity to make a technical correction to a cross-reference in § 422.622 (Requesting immediate QIO review of the decision to discharge from the inpatient hospital). Specifically, we are amending paragraph (g)(1) to refer to § 422.626(g) rather than § 422.626(f).

We did not receive any comments on these proposed revisions and are finalizing these technical corrections with the modifications previously noted.

4. Part D Transition Requirements (§ 423.120)

We explained in our November 2010 proposed rule that as a result of section 3310 of the ACA and the proposed rule at § 423.154, we proposed revising the existing transition policy for enrollees residing in LTC facilities to be more consistent with 7-day-or-less dispensing. We proposed a revised transition fill supply from 93 days to 91 days to accommodate multiple dispensing events associated with 7-days-or-less dispensing in LTC facilities whenever § 423.154(a) applies to drugs dispensed in 7-day-or-less supplies. We explained that the proposed change to a 91-day supply will permit exactly 13 weeks of 7-day transition fills. Under this proposed requirement, a Part D sponsor would be required to provide a LTC resident enrolled in its Part D plan a temporary supply of a prescription when presenting in the first 90 days of enrollment up to a 91-day supply, with supply increments consistent with § 423.154 (unless the prescription is written for less), with refills provided, if needed.

We also proposed amending § 423.120(b)(3)(iii) to clarify the transition notice requirements. Under this requirement, notices must be sent to beneficiaries within 3 business days of adjudication of a temporary fill. We proposed that a written notice be sent to each affected enrollee, and in the case of a LTC enrollee impacted by the dispensing requirement in § 423.154, the written notice be sent within 3 business days after adjudication of the first transition fill. We explained that we were persuaded by feedback from the LTC industry that beneficiaries may be confused when receiving multiple transition notices within 7 to 10 days of each 7-day-or-less dispensing event. We solicited comments on this provision in our proposed rule.

As described earlier in this final rule, we modified the proposed rule at § 423.154 to reflect a 14-day-dispensing requirement. The responses below reflect that modification. As a result of comments received, in this final rule, we are modifying the proposed rule at § 423.120(b)(iii)(B) to state that the temporary supply of non-formulary drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) must be for up to at least 91 days, and up to 98 days, consistent with the dispensing increment, for beneficiaries residing in a long-term care setting.

Comment: We received comments requesting that we change the transition fill supply requirement in the LTC setting to 91 days across all claims submitted in that setting. Commenters stated that two different systems (91 days for 7-day-or-less-dispensing and 93 days for 31-day dispensing) would be confusing and add unnecessary complexity.

Response: We believe that commenters want a transition requirement that is straightforward, and we believe a transition requirement that is consistent with the way drugs are dispensed will address the commenters' concerns. Therefore, we will modify the proposed rule to require Part D sponsors provide a temporary supply of up to 91, and up to 98 days if the plan desires to have the transition supply mirror the dispensing increment, with refills provided, if needed, unless a lesser amount is actually prescribed by the prescriber. For ease of dispensing, plans can require that the temporary supply be evenly divisible by the quantities dispensed (for example, up to 93 days for a 31-day dispensing increment, up to 91 for a 7-day dispensing increment, or up to 98 days for a 14-day dispensing increment). As long as the beneficiary who is receiving a transition fill can obtain at least 91 days of medication (unless a lesser amount is actually prescribed by the prescriber), plan sponsors will have the flexibility to implement the transition to match the dispensing increment if desired.

We encourage Part D sponsors to establish policies and procedures that will assist in the effectuations of meaningful transitions prior to the exhaustion of a transition fill. However, also consistent with previous guidance, we encourage Part D sponsors to make arrangements to continue to provide necessary drugs to an enrollee by extending the transition supply period, on a case-by-case basis, if the enrollee's exception request or appeal has not been processed by the end of the minimum transition period.

Comment: Several commenters supported our proposal to send one transition notice at the start of the transition period. Some commenters urged us to require another transition notice prior to conclusion of the transition period to ensure that enrollees have access to medication beyond the transition period.

Response: As stated in the proposed rule, beneficiaries may be confused if they were to receive multiple transition notices for a drug dispensed in multiple increments consistent with § 423.154. As such, we believe that an additional notice sent prior to the end of the transition period may lead to confusion.

We require Part D sponsors to send a transition notice to inform enrollees (and their caregivers) about the options for ensuring that the enrollee's medical needs are safely accommodated within the Part D sponsor's formulary. We require that transition notices be sent within 3 business days of the transition fill to allow for sufficient time for the enrollee to be switched to a therapeutically equivalent drug that is on the formulary or for time to process an exceptions request. Based on previous Part D experience, we believe that one notice sent within 3 business days of the first temporary fill is adequate notice to effectuate a meaningful transition.

Comment: A commenter recommended that the transition notices be sent to the pharmacies as well as beneficiaries residing in long-term care facilities.

Response: Beginning in contract year 2010, we permitted Part D sponsors the option of sending the required transition fill notices to network LTC pharmacies. For more details, see Chapter 6 of the Medicare Prescription Drug Benefit Manual, available at *http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage.* We decline to require Part D sponsors to do this, however, because the pharmacy is not directly involved with effectuating a meaningful transition. As stated in previous guidance, the purpose of a transition supply is to allow the sponsor and/or the enrollee sufficient time to work out with the prescriber an appropriate switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons. Pharmacies may assist in the process, but cannot effectuate a meaningful transition by switching the enrollee to a therapeutically equivalent medication or by requesting an exception under § 423.578(b).

As a result of comments received, in this final rule, we are modifying the proposed rule at § 423.120(b)(iii)(B) to state that the temporary supply of non-formulary drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) must be for up to at least 91 days, and up to 98 days, consistent with the dispensing increment, for beneficiaries residing in a long-term care setting. This provision will be effective January 1, 2012.

5. Revision to Limitation on Charges to Enrollees for Emergency Department Services (§ 422.113)

As provided under section 1852(d)(1) of the Act and codified at § 422.113(b)(2)(v). MA organizations are financially responsible for emergency and urgently needed services. Under § 422.113(b)(2)(v), charges to enrollees for emergency department services may not exceed $50, or what an MA organization would charge an enrollee if he or she obtained the services through the MA organization, whichever is less. This limit on cost sharing was first included in the regulations at § 422.112(b)(4) in the June 26, 1998 interim final rule (63 FR 35081) as the cost sharing limit for emergency services received out-of-network. Subsequently, new section § 422.113 was added to the regulations in the June 29, 2000 final rule (65 FR 40322) and required that same limit on cost sharing for emergency services regardless of whether they were received in- or out-of-network.

In our proposed rule, we explained that because we believe the current limit on cost sharing is outdated and has constrained MA organizations' ability to control unnecessary use of emergency departments we proposed to revise § 422.113(b)(2)(v) to remove the $50 amount and replace it with language indicating that we will evaluate and annually determine the appropriate enrollee cost sharing limit for emergency department services. We would inform MA organizations of any changes to the limit in annual guidance, such as the Call Letter.

Comment: We received many comments expressing support for our proposal to eliminate the $50 maximum for emergency department services and CMS' annual evaluation and determination of the appropriate limit on enrollee cost sharing. However, a few commenters who were generally supportive of our proposal also expressed their interest in CMS providing notice of the methodology that would be used annually to determine the cost sharing limit and to specify what services are to be included in that cost sharing. In addition, we received one comment that supported our proposal but suggested the limit for ER services be no more than $100.

Response: We thank the commenters for their support. CMS' methodology for developing the cost share limit for CY 2012 would be based on CY 2010 total costs for emergency department services visits under Original Medicare. We would calculate a weighted average for these visits and then determine the cost sharing limit to ensure that MA plans would be responsible for at least 50 percent of the total cost of the visit. Although we would not specifically limit the cost sharing to $100 as requested by a commenter, we believe our method takes into account plans' desire to manage utilization and beneficiary access and protections from high out-of-pocket costs to result in appropriate and affordable care.

After consideration of all the public comments received on this proposal, we are finalizing our proposal to amend § 422.113 by revising paragraph (v) to replace the $50 amount with language indicating that CMS will evaluate and determine an appropriate enrollee cost sharing limit annually and that the enrollee would be required to pay the lesser of that amount or the amount the plan would charge the enrollee if he or she obtained the services through the MA organization.

6. Clarify Language Related to Submission of a Valid Application (§ 422.502 and § 423.503)

Since we began our contracting efforts under the MMA in 2005 in preparation for the statute's 2006 effective date, we have established strict deadlines for the initial submission of applications for qualification for contracts to operate as Medicare Part C or D sponsoring organizations and the resubmission of materials needed to cure identified deficiencies. Consistent with that policy, we do not review applications that are submitted after the established deadline, meaning that an organization that misses the deadline would not receive a Part C or D sponsor contract for the following benefit year. Because we do not review such applications, we do not provide a notice of intent to deny under § 422.502(c)(2) or § 423.503(c)(2), nor is the organization entitled to a hearing under § 422.660 or § 423.650.

To avoid the consequences of missing the initial submission deadline, some organizations have submitted applications that we considered so lacking in required information or correct detail as to fail to constitute a valid, timely submission. We suspect that in many instances, these organizations expected to take advantage of our policy of affording applicants two later opportunities during the review process (including the 10-day cure period following the issuance of a notice of intent to deny an application issued under § 422.502(c)(2) and § 423.503(c)(2)) to make their applications complete by providing information that had been omitted from the initial submission. Organizations that provide substantially incomplete applications are effectively submitting "placeholders" designed to save their eligibility to participate in the application review process until they can produce all the required materials. We find this practice to be an abuse of the application review process that defeats the purpose of the established deadline.

We believe that confusion about our authority to enforce the application deadline may be created by the provisions of § 422.502(c)(2)(i) and § 423.503(c)(2)(i), which state that we will provide an applicant a notice of intent to deny when the organization "has not provided enough information to evaluate the application." We intended this language to afford an organization that had made a good faith effort to complete a contract qualification application the opportunity to provide the materials necessary to cure a discrete application deficiency. As noted in our November 2010 proposed rule, it appears that this language could provide an unintended protection to an organization that circumvented our established application deadline by submitting a "placeholder" application.

We believe that the language in § 422.502(c)(2)(i) and § 423.503(c)(2)(i), stating that the agency will issue a notice of intent to deny if CMS finds that the applicant does not appear qualified to contract as a Part C or D sponsor, combined with the language of § 422.502(c)(2)(ii) and § 423.503(c)(2)(ii) allowing the organization to "revise its application to remedy any defects CMS identified" is sufficient to authorize us to consider additional curing materials submitted by a good faith applicant. Therefore, to remove all ambiguity that may exist concerning our authority to decline to accept or review substantially incomplete applications, we proposed to revise the provisions of § 422.502(c)(2)(i) and § 423.503(c)(2)(i) to delete the phrase, "and/or has not provided enough information to evaluate the application."

Comment: Several commenters expressed their general opposition to the proposed regulatory provision as they were concerned that CMS would be arbitrary in determining whether an organization had submitted an invalid application. They also stated that should CMS adopt the provision in the final rule, we should create exceptions that would require us to accept applications where the applicant had a good reason for failing to complete the application and could demonstrate a good faith effort to submit a valid application. Another commenter advised that CMS should establish

objective criteria for determining whether an application is so incomplete as to constitute an invalid submission.

Response: We do not believe that any modification of the proposed regulatory provision is necessary to address the commenters' concerns. With respect to the recommendation that we provide guidance to applicants on our criteria for identifying an invalid application, we already provide instructions in the annual solicitation for applications where we make clear our expectation that organizations submit a complete application by the established deadline and provide guidance on how sponsors can achieve that goal. To provide guidance on how to submit successfully something less than a complete application would undercut our existing direction and undermine the meaning of the application deadline. Also, we do not hold applicants to an unreasonable standard of perfection as our regulations provide organizations that met the deadline an opportunity to submit curing information during the application review process.

We accept contract qualification applications in all instances where there is evidence that the applicant made a good faith effort to submit a substantially complete application by the established deadline. For example, we already make exceptions to the application deadline when there has been a technical systems error on our part that prevented the submission of a valid application. Beyond that limited circumstance, we cannot foresee any other legitimate reason for which we should grant a waiver of our application deadline.

Simply put, this authority is not applicable to applications that are missing only a few required elements but otherwise demonstrate that the submitting organization has completed the arrangements necessary to operate a Part C or D contract. As we noted in our proposed rule, we intend to declare an application invalid when it is so incomplete as to constitute little more than a placeholder submission that the applicant is attempting to use to meet the application deadline and then use the cure period to complete work that should have done prior to the deadline. To illustrate our point, we provide here examples, but not an exhaustive list, of characteristics of an invalid application.

To complete a Part C or D contract qualification application, an organization must execute electronically a series of attestations and provide documentation demonstrating its financial wherewithal and relationships with first tier or downstream entities with which it has contracted to provide required services on its behalf under its contract with CMS. While the attestations are important to the application process, it is the documentation concerning elements such as the applicant's authority to operate as a risk bearing entity, its relationships with first tier and downstream entities (including fully executed contracts), and the extent of its contracted provider network that most clearly substantiate an applicant's ability to administer Medicare benefit plans. These elements also require the most effort on the part of the applicant as each completed document represents the culmination of extensive work with regulators and other business partners. Failure to provide these kinds of documents would be the most likely reason that we would determine that the organization has not submitted a valid application by the stated deadline. Further, if these documents are submitted but are either: (1) Blank or substantially blank, such as a retail pharmacy network list missing data in more than one required column; (2) a Part C document submitted for a Part D application and vice versa, in the absence of the correct documents; or (c) otherwise incorrect attachments, in the absence of other correct documents, CMS may consider the application incomplete.

An example of an application we have received in past years that would have been excluded from further consideration is one where the applicant provided no information concerning its Part D pharmacy network; that is, no list of contracted pharmacies, no pharmacy contract templates, and no report demonstrating the network's compliance with Part D pharmacy access requirements. Further, the applicant presented no evidence of licensure as a risk bearing entity and no executed contracts with the first tier and downstream entities the applicant had identified in the body of its application as providing Medicare-related services on its behalf. In this instance, it was clear that the deficiencies were not the result of an honest mistake on the part of the applicant, but instead indicated that it had not finished the work necessary to submit a substantially complete application before the deadline. We should not grant such an organization the opportunity to continue with the application review process when its work shows that it ignored a deadline that other organizations made their best effort to meet.

We already have significant experience, through our administration of the annual bid and formulary review processes, in assessing the validity of submissions for the purposes of determining compliance with a submission deadline. Since 2005, we have declined to accept a handful of bid and formulary submissions that were so lacking in detail that we could not consider the submitting organizations to have met the deadline. None of our decisions in those cases has been successfully challenged, and we intend to apply the same level of judgment and analysis used in those decisions to our determinations concerning valid contract qualification applications.

Comment: A commenter urged that CMS provide appeal rights to those organizations whose applications CMS excludes from consideration pursuant to this proposed regulatory provision.

Response: The point of the proposed provision is to document our authority to determine when an organization has even qualified for further consideration of its application, including the rights that attach to that process, such as the opportunity to cure deficiencies and appeal a denial, by meeting the submission deadline. To afford appeal rights in instances where we have determined that an organization submitted an invalid application would re-create the very program vulnerability this provision is intended to eliminate.

Having addressed the comments in the previous discussion, we are finalizing this provision without modification.

7. Modifying the Definition of Dispensing Fees (§ 423.100)

In the November 2010 proposed rule, we proposed a simplified and clarified definition of "dispensing fees" under § 423.100. We explained in our proposed rule that "dispensing fees," as defined in the final rule issued January 28, 2005, implied that the salaries of pharmacists and other pharmacy workers were reasonable pharmacy costs only for pharmacies owned and operated by a Part D plan itself. We proposed to clarify that the salaries of pharmacists and other pharmacy workers may be reasonable pharmacy costs for any pharmacy. We also proposed to modify the definition of "dispensing fees" under § 423.100 to include costs associated with the acquisition and maintenance of technology to maintain reasonable pharmacy costs. We proposed adding to the definition of "dispensing fees" a restocking fee associated with return for credit and reuse in long-term care pharmacies when return for credit and reuse is permitted under State law and is allowed under the contract between the Part D sponsor and the pharmacy.

We explained in the proposed rule that it was not our intent to include all activities that are "reasonable costs" in the definition of "dispensing fees," but in light of the statutory requirements regarding LTC pharmacy dispensing, we believed that it was particularly important to highlight the potential pharmacy costs aimed at reducing the volume of unused Part D drugs and increasing efficiency of dispensing. We also stated that we believe dispensing fees should differentiate among the costs associated with different dispensing methodologies and appropriately address costs that are incurred to offset the amount of unused Part D drugs.

We proposed to clarify the definition of "dispensing fees" by modifying § 423.100 and eliminating the distinction between pharmacies owned and operated by a Part D plan itself and all other pharmacies. We also proposed to modify § 423.100 by adding to the definition that dispensing fees should take into consideration the number of dispensing events in a billing cycle, the incremental costs associated with the type of dispensing methodology, and with respect to Part D drugs dispensed in LTC facilities, the techniques to minimize the dispensing of drugs that go unused. Additionally, we proposed adding that dispensing fees may also take into account restocking fees associated with return for credit and reuse in long-term care pharmacies, when return for credit and reuse is permitted under State law and is allowed under the contract between the Part D sponsor and the pharmacy. As a result of comments, in this final rule, we further modify the definition to account for costs associated with data collection on unused Part D drugs in LTC facilities.

Comment: Commenters supported our proposal to modify the definition of dispensing fees. Some commenters requested that we amend the definition of dispensing fees to include other costs associated with the dispensing requirement under § 423.154. Some of the commenters requested that we add costs associated with the return and report requirement described in § 423.154(f)(1) and § 423.154(a)(2).

Response: In the proposed rule, we modified the definition of "dispensing fees," in part, to highlight the potential pharmacy costs aimed at reducing the volume of unused Part D drugs and increasing the efficiency of dispensing. As we stated in the proposed rule, it is not our intent to provide a comprehensive list of all activities that are "reasonable costs" in the definition of "dispensing fees." However, in this final regulation, we amend the definition of "dispensing fees" to include costs associated with the data collection on unused Part D drugs.

Comment: Some commenters wanted us to provide assurances that dispensing fees would appropriately reflect the increased costs associated with dispensing requirements under § 423.154 in LTC facilities and to monitor dispensing fees to pharmacies dispensing to enrollees in LTC facilities to ensure that dispensing fees are adequate.

Response: As provided in section 1860D–11(i) of the Act, we are prohibited from interfering with negotiations between Part D plans and pharmacies.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-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 an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 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 following sections of this document contain paperwork burden but not all of them are subject to the information collection requirements (ICRs) under the PRA for reasons noted.

A. ICRs Regarding Cost Sharing for Specified Services at Original Medicare Levels (§ 417.454 and § 422.100)

Under § 417.454(d) and § 422.100(g) and (h), we clarify that MA organizations may not impose cost sharing that exceeds that required under Original Medicare. We evaluate the following services annually to ensure that MA plans are charging cost sharing in the upcoming contract year that does not exceed cost sharing in Original Medicare. Specifically, chemotherapy administration services that include chemotherapy drugs and radiation therapy integral to the treatment regimen, renal dialysis as defined at section 1881(b)(14)(B) of the Act, and skilled nursing care defined as services provided during a covered stay in a skilled nursing facility would be subject to this limitation. The burden associated with this requirement is the time and effort necessary for MA organizations and section 1876 cost contracts to submit their benefit designs, including cost-sharing amounts, via the Plan Benefit Package (PBP) software. While this requirement is subject to the PRA, the burden associated with it is currently approved under OMB control number (OCN) 0938–0763 with a May 31, 2011, expiration date.

B. ICRs Regarding SNP Provisions (§ 422.101, § 422.107, and § 422. 152)

1. Dual-Eligible SNP Contracts With State Medicaid Agencies (§ 422.107)

Section 422.107(d)(ii) extends the deadline for new and existing dual-eligible SNPs (D–SNPs) to operate without a contract with their respective State Medicaid agency(ies). New D–SNPs and D–SNPs not seeking to expand their service areas can continue to operate without a State contract until December 31, 2012.

For new and existing D–SNPs that are seeking to expand in contract years 2011 through 2013, the burden associated with this requirement is the time and effort put forth by each dual eligible SNP to confer and develop a contract with the State Medicaid agency. While this requirement is subject to the PRA, this burden is already approved, under OCN 0938–0753, with a November 30, 2011, expiration date.

2. ICRs Regarding NCQA Approval of SNPs (§ 422.101 and § 422.152)

Sections 422.101 and 422.152 provide for the approval of all SNPs, existing and new, by NCQA beginning in 2012. The burden associated with this requirement is the time and effort put forth by MA organizations offering SNPs to submit their MOC to CMS for NCQA evaluation and approval as per CMS guidance. Although the submission of the MOC document is already part of the application process, scrutiny of these documents by NCQA for approval is a new requirement. Previously, all SNPs were not required to complete the SNP proposal portion of the application each year. Under the new requirement, we require all SNPs (that is, all of the SNP plans offered by an MA organization) must complete the SNP proposal portion of the application. We estimate that it will take each SNP plan 40 hours to complete the annual application. Within those 40 hours, it will take each SNP plan 6 hours to

complete the SNP portion of the application. For the existing 544 SNPs, we estimate the burden associated with completing the SNP section only is 3,264 hours.

The number of new plans each year will vary and cannot easily be predicted. However, based on the number of new plans that submitted SNP Proposals during the application period in February 2010 for operation in 2011, we estimate that approximately 15 new applications will be submitted annually. Thus, for 15 new plans at 40 hours each, we estimate the total annual burden hours to be 600. The burden associated with the proposed requirement for the new plans is currently approved under OCN 0938–0935 with a January 21, 2011 expiration date.

C. ICRs Regarding Voluntary De Minimis Policy for Subsidy Eligible Individuals (§ 423.34 and § 423.780)

Our regulatory modifications pursuant to section 3303 of the ACA ensure that our regulations reflect the new statutory prohibition on reassigning LIS beneficiaries from Part D plans that waive a de minimis amount of their premium on the basis that the premium exceeded the low-income premium benchmark. Further, the regulatory modifications reflect statutory discretion for us to auto-enroll or reassign LIS beneficiaries to Part D plans that waive the de minimis amount of the premium. The modifications to § 423.34 do not by themselves impose any new information collection requirements on any external entity.

However, related proposals to modify § 423.780 do impose new information collection requirements. Specifically, the modifications provide for the process for a Part D plan to volunteer to waive a de minimis amount over the monthly beneficiary premium for certain low income subsidy eligible (LIS) individuals. As specified in proposed changes to § 423.34, we are prohibited from reassigning LIS beneficiaries from Part D plans that waive the de minimis amount of the premium based on the fact that their premiums exceed the LIS benchmark premium amount, and we may choose to auto-enroll or reassign LIS beneficiaries to such plans.

The burden associated with this requirement is the time and effort necessary for a Part D plan to submit data to us indicating its decision to volunteer to waive the de minimis amount. Since we will collect this information as part of an already established system, we estimate that it will take an additional 10 minutes annually for plans to read the instructions, select an online check box, and submit the information. The de minimis amount will be established each year, and the amount may vary among years. For purposes of estimating the burden, we assume that the de minimis amount will be $1.00, and that all Part D plans with premiums within the de minimis amount over the regional LIS benchmark will volunteer to waive it. We estimate 150 Part D plans will qualify for de minimis in a given fiscal year. For 150 plans at 10 minutes each fiscal year, we estimate the total annual burden hours to be 25. We assume an hourly wage of $23.92 for a compliance officer, resulting in a total annual labor cost of $598.

D. ICRs Regarding Increase in Part D Premiums Due to the Income Related Monthly Adjustment Amount (Part D—IRMAA) (§ 423.44)

Section 423.44(e)(4) requires PDPs to provide Part D enrollees with a notice of termination in a form and manner determined by CMS. We estimate that approximately 1.05 million of the 29.2 million Medicare beneficiaries enrolled in the Part D program will exceed the minimum income threshold amount and will be assessed an income related monthly adjustment amount. We also estimate that approximately 80,000 beneficiaries will be directly billed for the Part D—IRMAA because they are not receiving monthly benefit payments from SSA, the OPM, or the RRB, or the monthly benefit payment is not sufficient to have the Part D—IRMAA withheld.

Of the 80,000 Part D enrollees who will be directly billed for the Part D—IRMAA, CMS cannot estimate how many might accrue Part D—IRMAA arrearages and be subsequently terminated. However, in the event that the 80,000 Part D enrollees who pay the Part D—IRMAA through direct billing become delinquent, PDPs would be required to send all 118,000 enrollees a notice of termination in accordance with § 423.44(e)(4), and the burden associated with this requirement would be the time and effort that it takes a PDP to populate the notice with a beneficiary's information. Termination notices are generally automated; therefore, CMS estimates that it will take 1 minute to generate a termination notice. As such, the total maximum annual hourly burden associated with this requirement is 1,333 hours (1 minute multiplied by 80,000 enrollees, divided by 60 minutes). We estimate that the hourly wage paid to an individual tasked with generating the automated letters is $40 (based on U.S. Department of Labor statistics for hourly wages for administrative support). The associated burden amount for this work is $53,320. Additionally, Part D plan sponsors will have to retain a copy of the notice in the beneficiary's records. We estimate 5 minutes multiplied by 80,000 enrollees divided by 60 minutes. This equates to 6,666 hours at approximately $40 an hour (based on U.S. Department of Labor statistics for hourly wages for administrative support). This associated burden amount is $266,640. We estimate the total maximum annual burden for all Part D plan sponsors resulting from this proposed provision to be $319,960.

E. ICRs Regarding Elimination of Medicare Part D Cost-Sharing for Individuals Receiving Home and Community-Based Services (§ 423.772 and § 423.782)

We are amending § 423.772 and § 423.782 in accordance with section 3309 of the ACA. Specifically, the changes provide for a definition of an individual receiving home and community based services, and for zero cost-sharing for Medicare Part D prescriptions filled by full-benefit dual eligible beneficiaries receiving such services.

To carry out these provisions, we require State Medicaid Agencies to submit data at least monthly identifying these individuals. There is already an established data exchange for States to identify their dual eligible individuals to CMS at least monthly. We will leverage that data exchange by adding a new value for the existing institutional status field, which will prompt CMS to set a zero copayment liability for full-benefit dual eligible beneficiaries who qualify for HCBS zero cost-sharing, as set forth under section 3309 of the ACA. The estimated size of the population to be reported as being full benefit dual eligible and receiving home and community-based services is 600,000.

We estimate the burden associated with the requirement for States to provide CMS with the specified information including a one-time development cost and ongoing annual costs. The startup development effort is estimated at 20 hours per State, or an additional 1,020 hours for all 51 State Medicaid Agencies (50 States and the District of Columbia), in the fiscal year prior to the effective date of this provision. Assuming an hourly salary of $34.10 for computer programmers, this results in a development cost of $34,782. Once implemented, the information collection burden is estimated to be 1 hour each month, or 612 hours in each fiscal year for 51 State

Medicaid Agencies. Assuming an hourly salary of $34.10 for computer programmers, we estimate an ongoing cost of $20,862 per fiscal year.

F. ICRs Regarding Appropriate Dispensing of Prescription Drugs in Long-Term Care Facilities Under PDPs and MA–PD Plans (§ 423.154) and Dispensing Fees (§ 423.100)

Under § 423.154 (a), we implement provisions of section 3310 of the ACA, which require Part D sponsors to use specific, uniform dispensing techniques such as weekly, daily, or automated dose dispensing when dispensing covered Part D drugs to enrollees who reside in long-term care facilities in order to reduce waste associated with 30-day fills. The collection burden associated with this proposed provision is the reporting requirement and re-negotiation of contracts.

We are introducing a new requirement under § 423.154 (a)(2) for Part D sponsors to collect and report to CMS the method of dispensing technique used for each dispensing event described under § 423.154 (a) and on the nature and quantity of unused brand and generic drugs. We anticipate a billing standard that incorporates the collection of the method of dispensing technique. So, pharmacies and plans will not have to create unique data collection processes to collect that data. We estimate that 40 sponsors-contractors (28 drug claim processors and 12 sponsors that process their drug claims and data collection) will be subject to this requirement. For the collection of data on unused drugs, we estimate that it will take a total of 2400 hours for 10 vendors (software vendors plus pharmacies with proprietary systems) to develop the programming for this requirement. The estimated total cost associated with the software development is equal to the number of software vendors plus the number of pharmacies with proprietary systems (10) times an hourly rate of $145.37 (this includes $43.35 in direct wages and an additional $102.02 in fringe benefits/overhead/general and administrative costs/fee) times 240 (estimated number of hours to design and program one system; the cost is $348,888. The aforementioned burden will be included in a revision of the collection currently approved under OMB Control No 0938–0992.

The requirements will necessitate the renegotiation of contracts between Part D sponsors and the pharmacies servicing LTC facilities. We anticipate dispensing fees will increase, consistent with our proposed change in the definition of dispensing fees (§ 423.100), with the relative investment in the dispensing technologies and corresponding dispensing efficiencies associated with the dispensing technologies used in § 423.154.

We estimate that the total annual hourly burden for negotiating a contract between the Part D sponsors and entity contracting with the pharmacies servicing long-term care facilities (for example, PBM) to be equal to the number of Part D sponsors (731) multiplied by the average estimated hours per sponsor (10), equaling 7,310 hours. We estimate the number of entities contracting with pharmacies servicing long-term care facilities to be 40 (28 processors and 12 other entities). We estimate the total annual hourly burden for negotiating a contract between an entity described previously and the pharmacies servicing LTC facilities to be the number of entities (40) multiplied by the average estimated hours per entity (80), which is 3,200 hours. The total number of hours for contract renegotiation is estimated to be 10,510 hours (7,310 hours + 3,200 hours). The estimated hourly labor cost for reporting is $150.20. The total estimated cost associated with these contract negotiation requirements is $1,578,602. We estimate that the total burden cost associated with this provision is $1,927,490.

Comment: We received comments regarding the burden associated with the reporting requirements. Many commenters believed that the Controlled Substance Act, hazardous waste laws, and State laws would be a barrier to LTC facilities returning unused drugs to pharmacies. Commenters stated that manual reporting of unused drugs would create a burden on the pharmacy and sponsor and require additional staffing to accommodate the increased workload.

Response: In response to the comments, we will eliminate the requirement that unused drugs be transferred to the pharmacy and instead retain only the requirement that Part D sponsors collect information from the network LTC pharmacies to determine the amount of unused drugs. We believe that this information can be collected by the pharmacies from the LTC facilities or determined by calculating the difference between the quantity dispensed and the quantity consumed which can be used to calculate the amount of unused medication. We are revising the PRA package for the Part D Reporting Requirements (OMB Control No. 0938–0992) to reflect this approach. Please comment on our approach in the Part D Reporting Requirement PRA package.

G. ICRs Regarding Complaint System for Medicare Advantage Organizations and PDPs (§ 422.504 and § 423.505)

Under § 422.504(a) and § 423.505(b) we would require MA organizations and Part D sponsors to address and resolve all complaints in the CMS complaint tracking system and to include a link to the electronic complaint form at *http://www.medicare.gov* on their main Web page. This requirement would allow thorough monitoring of complaints through the tracking system by identifying how plan sponsors resolve and close complaints and allow members to access complaint forms electronically on *http://www.medicare.gov.*

The burden associated with this proposed provision is the time and effort of the MA organizations and Part D sponsors in recording complaint closure documentation in the CTM and training staff, as well as posting and maintaining a link from their Web site to the electronic complaint form at the Medicare.gov Internet Web site. While this requirement is subject to the PRA, we believe this burden is exempt as defined in 5 CFR 1320.3(b)(2). That is, the time, effort, and financial resources necessary to comply with the requirement would be incurred by the Part D sponsors in the normal course of their business activities.

Comment: We received comments from one commenter expressing support for the use of a drop-down checklist of complaint closure reasons. However, the commenter was concerned that a new electronic complaint form that could be accessed through the plan's Web site as well as *http://www.medicare.gov* would be seen as a substitute for beneficiaries' current avenues for issue resolution. The commenter additionally recommended that CMS establish a strict process for monitoring and reviewing how these complaints are resolved.

Response: Sections 422.504(a) and 423.505(b) require MA organizations and Part D sponsors to address and resolve all complaints in the CMS complaint tracking system and to include a link to the electronic complaint form at *http://www.medicare.gov* on their main Web page. The requirement allows complaint monitoring through the tracking system by identifying how plan sponsors resolve and close complaints, and allows enrollees to access complaint forms electronically on *http://www.medicare.gov.* We are therefore not modifying the burden estimate in our proposed rule in this final rule.

H. ICRs Regarding Uniform Exceptions and Appeals Process for Prescription Drug Plans and MA–PD Plans (§ 423.128 and § 423.562)

In accordance with the new section 1860D–4(b)(3)(H) of the Act, we proposed revising § 423.128 at paragraphs (b)(7) and (d) in our proposed rule to specifically provide three mechanisms that plan sponsors must have in place in order to meet the uniform appeals requirements of 1860D–4(b)(3)(H) of the Act.

We proposed adding paragraph (i) to § 423.128(b)(7) to require that plan sponsors make available standard forms to request coverage determinations and redeterminations (to the extent that standard request forms have been approved for use by CMS). In this final rule, we modify the language of the proposed rule to instead require plan sponsors to make available uniform model forms for requesting coverage determinations and appeals, and we clarify that we intend to revise our existing model forms.

We also proposed adding paragraph (ii) to § 423.128(b)(7), requiring sponsors to develop a Web-based electronic interface that allows an enrollee (or an enrollee's prescriber or representative) to immediately request a coverage determination or redetermination via a plan's secure Web site. The interface would be the "electronic equivalent" of the paper coverage determination and appeals forms referenced at § 423.128(b)(7)(i). Based on comments we received, we are finalizing the language related to instant access to coverage determinations and appeals processes via the plan's Web site, but have clarified in the preamble that we are interpreting instant access to mean, at a minimum, the ability of Part D plan sponsors to accept e-mail requests. Similarly, we are revising § 423.128(d) to require sponsors to provide a toll-free telephone line for requesting coverage determinations and redeterminations. The burden associated with these requirements involves collecting the coverage determination request information submitted through the various processes.

We estimated that all 731 plan sponsors would receive a total of 484,468 coverage determination requests submitted by mail, with some using the standardized coverage determination request form, if available. We further estimated that it would take 10 minutes to enter the information submitted from each request into a claims processing system, for a potential total annual burden of 80,745 hours. Although this final rule modifies the proposed language to include a reference to a model coverage determination request form, we do not expect this modification to impact our estimated burden for coverage determination requests submitted by mail. In the proposed rule, we estimated that all plan sponsors would receive a total of 52,086 coverage determination requests submitted through secure websites, but that this process would not create an additional burden for plan sponsors beyond that required for requests submitted by mail because enrollees would enter information into a claims processing system themselves. In this final rule, we scale back the Web site requirement to mean, at a minimum, the ability to accept requests via e-mail. We expect plan sponsors to process the e-mail requests in the same manner as requests received by mail, and estimate that it will take 10 minutes to enter the information submitted from each request into a claims processing system, for a potential total annual burden of 8,681 hours. Finally, we estimated that all plan sponsors would receive a total of 690,064 coverage determination requests submitted by telephone, and it would take 10 minutes to enter the information submitted by phone into the claims processing system, for a total annual burden of 115,011 hours. The burden associated with the redetermination process is exempt under 5 CFR 1320.4(a)(2) because a redetermination is an administrative action. Information collected when conducting an administrative action is not subject to the PRA.

Our final rule requires Part D sponsors to modify their electronic transactions to pharmacies so that they can transmit codes instructing pharmacies to distribute notices at the POS. That is, pharmacies and processors will be required to program their systems to relay the message at the pharmacy to distribute the POS pharmacy notice that instructs the enrollee to contact the plan sponsor to request a coverage determination. In cases when a prescription cannot be filled as written, Part D sponsors would be required under § 423.562(a)(3) to arrange with their network pharmacies to distribute a pharmacy notice that advised the enrollee of his or her right to contact the plan to request a coverage determination. We estimate that the burden on processors will be the programming to send the code or billing response to the pharmacy, as well as revisions to the contract requirement with the pharmacy. We estimate that the number of hours for each processor (28 PBMs and 12 plan organizations) to perform these tasks will be 40 hours per processor or plan organization, for a total one-time burden of 1600 hours. The estimated one-time cost associated with the processor or plan organization tasks is $64,000 (1600 hours × $40). Each pharmacy will need to program to receive the code and print the response. Programming by the pharmacies (40 pharmacy software vendors) in order to receive the code will be 10 hours, for a total of 400 hours. The estimated one-time cost associated with the processor tasks is $16,000 (400 hours × $40).

We estimate that the average time to process a coverage determination is 10 minutes (0.167 hours), and that an average of 734 coverage determination requests received by mail or secure Web site (e-mail) will be processed for each respondent (n=731). Therefore, we estimate that requiring plan sponsors to process the information submitted in model coverage determination request forms (§ 423.128(b)(7)(i)) will result in an annual burden of 89,605 hours (731 entities × 734 contracts per entity × .167 hours per contract to process). At an estimated cost of $40.00 per hour, the estimated total annual cost of this change is $3.58 million. We estimate that processing coverage determination requests that are received by telephone (§ 423.128(d)) will take an average of 10 minutes (0.167 hours) per request and that entities (n=731) would process on average 944 coverage determination requests. We expect this to result in an annual burden of approximately 115,240 hours (731 entities × 944 determination requests per entity × 0.167 hours per determination request). At an estimated cost of $40.00 per hour, the estimated total annual cost of this change is $4.6 million (115,240 hours × $40.00 per hour). We estimate that contracting entities (n=731) will distribute an average of 2,200 pharmacy notices.

Therefore, requiring plan sponsors to arrange with their network pharmacies to distribute pharmacy notices at the point-of-sale when prescriptions cannot be filled as written (§ 423.562(a)(3)) is estimated to result in an annual burden of 53,071 hours (2 minutes or 0.033 hours at point-of-sale × 731 contracts × 2200 pharmacy notices per contract). At an estimated cost of $40.00 per hour, the estimated total annual cost of this change is $2.1228 million.

Comment: One commenter believed that our estimate of $40 an hour was too low for processing coverage determinations and redeterminations.

Response: We disagree with the commenter. The estimated hourly rate of $40 is a composite rate based upon

the Bureau of Labor Statistics National Compensation Survey.

Comment: One commenter asked CMS if the agency expects the pharmacy to maintain a copy of the POS notice according to the 10-year record retention requirement. If so, the commenter believed that this requirement would increase dispensing fees and present an additional hurdle for pharmacies and PBMs in response to CMS audit requests, thereby increasing the burden estimate.

Response: Part D sponsors are responsible for determining which pertinent documents they must retain. CMS does not specify which specific records Part D sponsors must require their network pharmacies to retain for audit purposes. Therefore, the burden estimate associated with the POS notice does not account for record retention requirements provided at § 423.505.

I. ICRs Regarding Including Costs Incurred by AIDS Drug Assistance Programs and the Indian Health Service toward the Annual Part D Out-of-Pocket Threshold (§ 423.100 and § 423.464)

Revising the definition of "incurred cost" at § 423.100 to include the costs associated with IHS/ADAPs towards the TrOOP does not impose new information collection for CMS' COB contractor or ADAPs. The COB contractor currently collects data-sharing agreements from ADAPs under the MSP information collection process. The burden associated with this collection is accounted for under OMB 0938–0214.

J. ICRs Regarding Improvements to Medication Therapy Management Programs (§ 423.153)

This final rule amends § 423.153(d)(1)(vii) to require Part D sponsors to use a standardized format for the action plan and summary resulting from the annual comprehensive medication review, and permit the use of telehealth technology in the conduct of the CMR.

The burden associated with a number of the new MTM program requirements in the ACA, including the requirement for a written summary of the CMR, was summarized in our April 2010 final rule (75 FR 19678 through 19826) and approved under OCN 0938–0964 with an expiration date of September 30, 2012. We believe the burden associated with the requirement in § 423.153(d)(1)(vii)(D) to provide an action plan and summary in a standardized format is generally part of that burden. Therefore, we do not estimate an additional burden for this requirement in this final rule. Further, since the use of telehealth technology to conduct the CMR is permitted but not required, there is no burden associated with this change.

In our proposed rule, we estimated an ICR burden associated with the proposed requirement for Part D sponsors to coordinate MTM program quarterly medication reviews with LTC consultant pharmacist monitoring for Part D enrollees in LTC facilities. We are not finalizing this requirement and are eliminating this burden from our estimates. As a result, there is no burden associated with this provision.

K. ICRs Regarding Changes to Close the Part D Coverage Gap (§ 423.104 and § 423.884)

Section 423.104(d)(4) requires the approximately 40 pharmacy claims processors currently responsible for adjudication of pharmacy benefits to identify the applicable Part D covered drugs in their systems and apply a different cost-sharing percentage when processed in the coverage gap than the percentage applied to non-applicable drugs. We estimate a one-time burden to be 12,000 hours per processor to make the initial coding changes necessary to implement this requirement and an annual burden of 250 hours per processor to perform periodic updates of the applicable drugs in their systems. There are an estimated 40 processors. At an average labor cost of $105 per hour for a senior computer programmer, we estimate the first fiscal year annual burden associated with this requirement to be 480,000 hours (12,000 hours × 40 processors) at an estimated total cost of $50.4 million. After the first fiscal year, the estimated burden associated with this requirement would be 10,000 hours (250 hours × 40 processors) at an estimated total annual cost of $1,050,000.

L. ICRs Regarding Medicare Advantage Benchmark, Quality Bonus Payments, and Rebate (§ 422.252, § 422.258 and § 422.266)

Under § 422.258(d)(6) we base the 5-star rating system for quality bonus payments on a modified version of the plan ratings published each fall on *http://www.medicare.gov.* The 5-star rating system for quality bonus payment will require no additional burden. The data collection for the 5-star rating is currently approved under the following OCNs:

OCN	Expiration Date
0938-1028	November 30, 2011
0938-0732	November 30, 2010
0938-0701	August 31, 2010

We have included new calculations for the benchmarks and rebates in § 422.252, § 422.258, and § 422.266. The burden associated with the bid data used in these calculations is included in the burden estimate associated with the Bid Pricing Tool which is currently approved under OCN 0938–0944 with a May 31, 2011, expiration date.

M. ICRs Regarding Quality Bonus Appeals (§ 422.260)

We add a new § 422.260 to state that each MA organization is afforded the right to request an administrative review of CMS' determination concerning the organization's qualification for a quality bonus payment. The burden associated with this proposed provision is MA organizations' time and effort in developing and presenting their case demonstrating that they should qualify for the quality bonus payment to a CMS official and, ultimately, to the CMS Administrator. Eligibility for quality bonus payments will be based largely on CMS' application of a publicized methodology for assigning star ratings to MA organizations. These star ratings will be calculated using a combination of the MA organization's performance scores across a variety of quality assessment measures. MA organizations will have the opportunity to challenge

CMS' application of the methodology to their performance.

We estimate that the total hourly burden in a fiscal year for developing and presenting a case to us for review is equal to the number of organizations likely to request an appeal multiplied by the number of hours for the attorneys of each appealing MA organization to research, draft, and submit their arguments to CMS. Based on the star rating distributions of previous contract years, out of the approximately 350 MA contracts that are subject to star rating analysis (that is, those not excluded from analysis because of low enrollment, contract type not required to report data, or new contract with no performance history), approximately 250 may receive less than a four-star rating. We estimate that 10 percent of those contracts (25) will request an appeal of their rating under the proposed rule. We further estimate that one attorney working for 8 hours could complete the documentation to be submitted to CMS for each contract, resulting in a total burden estimate of 200 hours (8 hours × 25 contracts = 200 hours). The estimated fiscal year cost to MA organizations associated with this provision (assuming an attorney billing rate of $250 per hour) is $50,000 (200 hours × $250).

N. ICRs Regarding Timely Transfer of Data and Files When CMS Terminates a Contract With a Part D Sponsor (§ 423.509)

In this final rule, we are amending § 423.509 to state that when CMS terminates a contract with a Part D plan sponsor, the Part D plan sponsor must ensure the timely transfer of any data or files. Our intent is to ensure that terminated Part D plan sponsors transfer to CMS the necessary data to provide a smooth transition for beneficiaries into a new Part D plan similar to when the Part D sponsor terminates the contract or CMS and the Part D plan sponsor mutually terminate the contract. The burden associated with this proposed provision is the time and effort that Part D plan sponsors must undertake to transfer the requisite data and files to CMS. We have not developed a burden estimate for this requirement because we do not believe that we will exceed the PRA threshold of 9 organizations per any 12-month period.

O. ICRs Regarding Agent and Broker Training Requirements (§ 422.2274 and § 423.2274)

Sections 422.2274(b) and (c) and 423.2274(b) and (c) would require MA organizations' and Part D sponsors' agents and brokers to receive training and testing via a CMS endorsed or approved training program. We are considering implementing this requirement through a RFP competitive process. The burden associated with this requirement is the time and effort put forth by plan sponsors and/or third party vendors to submit their proposals for CMS review. We estimate that about 12 entities (plan sponsors and/or third party vendors) will submit a proposal and the average estimated hours per entity to complete the proposal is 100 hours. The total estimated hourly burden associated with this requirement is equal to the estimated number of entities (12) multiplied by the estimated hours per entity (100) resulting in a total of 1200 hours. We estimate the hourly labor cost of $59.20 for the preparer (based on hourly wages for management analysts reported by the U.S. Department of Labor Bureau of Labor Statistics). We estimate that the total annual labor cost of this proposal preparation is $71,040 ($59.20 × 1200 hours) per fiscal year.

Also at § 422.2274 and § 423.2274, we clarify that the annual agent and broker training requirements apply to all agents and brokers selling Medicare products and not just independent agents and brokers. The burden associated with this requirement is the time and effort put forth by the MA organization or Part D sponsor to ensure all agents and brokers selling Medicare products are trained and tested annually. While this requirement is subject to the PRA, the burden is exempt as defined in 5 CFR 1320.3(b)(2). The time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their business activities.

P. ICRs Regarding Call Center and Internet Web site Requirements (§ 422.111 and § 423.128)

At § 422.111(g)(1)(2)(3) (redesignated as § 422.111(h)(1) through (3)), we require MA organizations to operate a toll-free customer call center that is open during usual business hours and provides customer telephone service in accordance with standard business practices, as well as to provide current and prospective enrollees with information via an Internet Web site and in writing (upon request). In § 422.111(g)(1)(iii) and § 423.128(d)(1)(iii) (redesignated as (h)(1)(iii)) we codify provisions from the Medicare Marketing Guidelines (August 15, 2005 version and all subsequent versions) that require plan sponsors to provide call center interpreters for non-English and LEP beneficiaries. The burden associated with this requirement is the time and effort necessary to maintain a customer call center and Internet Web site, to provide information to beneficiaries in writing upon request, and to provide call center interpreters. While this requirement is subject to the PRA, we believe this burden is exempt as defined in 5 CFR 1320.3(b)(2). The time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their business activities.

Q. ICRs Regarding Requiring Plan Sponsors to Contact Beneficiaries to Explain Enrollment by an Unqualified Agent/Broker (§ 422.2272 and § 423.2272)

Sections 422.2272(e) and 423.2272(e) require MA organizations and Part D sponsors, respectively, to notify Medicare beneficiaries upon discovery that they were enrolled in a plan by an unqualified agent. While this requirement is subject to the PRA, the burden is exempt as defined in 5 CFR 1320.3(b)(2). The time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their business activities.

R. ICRs Regarding Customized Enrollee Data (§ 422.111 and § 423.128)

As discussed in our November 2010 proposed rule (75 FR 71249 through 71250), proposed § 422.111(b)(11) and § 423.128(b)(12) authorize CMS to require MA organizations and PDP sponsors to periodically provide each enrollee with enrollee specific data to use to compare utilization and out-of-pocket costs in the current plan year to projected utilization and out-of-pocket costs for the following plan year. Plans would disclose this information to plan enrollees in each year in which a minimum enrollment period has been met, in conjunction with the annual renewal materials (currently the annual notice of change/evidence of coverage, or ANOC/EOC).

Plan sponsors already collect enrollee utilization and cost-sharing information as part of their claims processing operations. In our proposed rule, we stated that the burden associated with this proposed requirement would be the time and effort necessary for a plan sponsor to complete program development and testing, and to disclose (print and mail) this information to each beneficiary. We anticipated that it would take 30 hours per MA organization and 20 hours per Part D sponsor to develop and submit the required information. This included 2 hours for reading CMS' published

instructions, 20 hours per MA organization and 10 hours per Part D sponsor generating the document or documents, and 8 hours printing and disclosing to enrollees. We developed this burden estimate using our burden estimates for the ANOC/EOC documents under OCN 0928–1051 as a baseline, then expanded on that baseline, and factored in expected programming and development costs to provide beneficiary specific information. We estimated that 564 MA organizations and 85 Part D sponsors would be affected annually by this requirement. We proposed that the total annual burden associated with this requirement would be 18,620 hours in a fiscal year.

In our proposed rule, we estimated the subsequent annual burden associated with this proposed requirement by the time and effort necessary for a plan sponsor to disclose (print and mail) this information to each beneficiary. We anticipated that it would take 20 hours per MA organization and 15 hours per Part D sponsor to develop and submit the required information. This included 1 hour for reading CMS' published instructions, 10 hours per MA organization and 5 hours per Part D sponsor generating the document or documents, and 6 hours printing and disclosing to beneficiary. We estimated that 564 MA organizations and 85 Part D sponsors would be affected annually by this requirement. We estimated the total annual burden associated with this proposed requirement would be 12,555 hours in a fiscal year (20 hours for each of the 564 MA organizations + 15 hours for each of the 85 Part D sponsors). Based on the comments we received on our proposed rule, we are modifying our burden estimate as described below.

Comment: As discussed in section II.D.4 of this final rule, we received many comments on our proposal to authorize CMS to require MA organizations and Part D drug sponsors to periodically provide each enrollee with enrollee specific data to use to compare utilization and out-of-pocket costs in the current plan year to projected utilization and out-of-pocket costs for the following plan year. Commenters were particularly concerned with the administrative and cost burdens associated with providing beneficiaries with customized enrollee data that included an estimate of future costs. Several of the commenters stated that our analysis of the burden associated with this proposed requirement, which we developed by expanding on the baseline burden estimates for the ANOC/EOC documents under OCN 0928–1051, was undervalued. One commenter stated that the estimate did not take into account the size of organizations' memberships, sophistication of IT systems, variances in benefit designs or delivery systems. Several commenters stated that creating systems to compile current year information as well as to calculate future year information would require many more hours of IT and staff time than we estimated. Commenters offered estimates such as "more than 30 hours per plan option per product" and "thousands of hours."

Response: As discussed in section II.D.4 of this final rule, we are modifying our original proposal to authorize CMS to require that MA organizations periodically provide each enrollee with enrollee specific data. We are finalizing § 422.111(b)(12) to state that we may require an MA organization to 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 benefits are provided under part 422. As discussed in section II.D.4 of this final rule, we intend to work with MA organizations, Part D sponsors and beneficiary advocates to develop an explanation of benefits for Part C benefits modeled after the EOB currently required for Part D enrollees at § 423.128(e). We plan to continue the research and development process through a small pilot program with volunteer organizations in CY 2012 with the hope of implementing an EOB requirement for all MA plans beginning in the future.

Based on the comments received, and our modified final policy, we have recalculated our estimate of the burden, based on the annual burden to Part D plan sponsors to furnish enrollees with an EOB for prescription drug benefits under OMB 0938–0964. MA organizations already collect enrollee utilization and cost-sharing information as part of their claims processing operations. In the first year that the pilot program is implemented, the burden associated with this proposed requirement would be the time and effort necessary for 564 MA organizations to complete program development and testing of an explanation of benefits when Part C benefits are provided, and to disclose (print and mail) this information to each beneficiary. Given that stand alone PDPs already produce an EOB in accordance with § 423.128(e), the revised burden estimate includes only MA organizations. We estimate that in the first year it will require each entity 200 hours on an annual basis to disseminate the required materials, for a total annual burden of 112,800 hours. We calculate the total labor cost estimate based on the hourly rate of $34.92 for a GS–11/step 6 analyst. This first year estimate builds from the estimated annual burden for the Part D EOB. Our revised estimate increases the number of hours organizations will need to initiate and complete program development and testing of an EOB.

In subsequent years, the burden associated with this requirement will be the time and effort necessary for about 564 MA organizations to provide an EOB when Part C benefits are provided to enrollees. We estimate that it will require each entity 160 hours on an annual basis to disseminate the required materials, for a total annual burden of 90,240 hours. We calculate the total labor cost estimate based on the hourly rate of $34.92 for a GS–11/step 6 analyst. The decreased estimate of burden hours relative to the first year reflects the completion of program development in the first year and brings the estimated hours in line with the current estimated number of hours for the Part D EOB.

S. ICRs Regarding Extending the Mandatory Maximum Out-of-Pocket (MOOP) Amount Requirements to Regional PPOs (§ 422.100(f) and § 422.101(d))

In this final rule, we are extending the mandatory MOOP and catastrophic limit requirement to RPPO plans at § 422.100(f) and § 422.101(d). Each RPPO plan will establish an annual MOOP limit on total enrollee cost sharing liability for Parts A and B services. We will set the dollar amount of the MOOP limit annually. RPPO plans' MOOPs will include all cost sharing (that is, deductibles, coinsurance, and copayments) for Parts A and B services. These requirements will not result in an additional data collection burden for RPPOs since they already collect this data to establish their own in-network MOOP and catastrophic limits under § 422.101(d)(4). While this requirement is subject to the PRA, the burden is exempt as defined in 5 CFR 1320.3(b)(2). The time, effort, and financial resources necessary to comply with the requirement is incurred by persons in the normal course of their business activities.

T. ICRs Regarding Prohibition on Use of Tiered Cost Sharing by MA Organizations (§ 422.100 and § 422.262)

Section § 422.262 clarifies that MA organizations may not impose cost sharing that varies across enrollees for any reason, including provider group,

hospital network or enrollees' utilization of services. The burden associated with this proposed revision is the time and effort necessary for MA organizations and section 1876 cost contracts to submit their benefit designs, including cost-sharing amounts, via the Plan Benefit Package (PBP) software. While this requirement is subject to the PRA, the burden associated with it is currently approved under OCN 0938–0763 with a May 31, 2011 expiration date.

U. ICRs Regarding Translated Marketing Materials (§ 422.2264 and § 423.2264)

This clarification at § 422.2264(e) and § 423.2264(e) does not impose any additional burden upon MA organizations because they have been required to provide translated marketing materials pursuant to § 422.2264(e) and § 423.2264(e) (previously numbered § 422.80(c)(5) and § 423.50(d)(5)). We believe the burden associated with these proposed requirements is exempt from the requirements of PRA as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

V. ICRs Regarding Expanding Network Adequacy Requirements to Additional MA Plan Types (§ 422.112)

Our amendment to § 422.112(a)(10) ensures that any MA plan that meets Medicare access and availability requirements through direct contracting network providers does so consistent with the requirements at § 422.112(a)(10). We do not include MA MSAs in § 422.112(a)(10) because MSA plans historically have not had networks and enrollees in MSA plans may see any provider. However, MSA plans are not prohibited from having networks as long as enrollee access is not restricted to network providers. While there are currently no MA MSA network plans, we are aware of possible interest in offering such plans.

The burden associated with this requirement is the time and effort required by MA organizations to submit network adequacy data to CMS for review and approval as part of the application process. This burden is already accounted for under OCN 0938–0935. However, since this amendment will extend the current network adequacy requirements only to Medicare MSA plans, and there is currently only one Medicare MSA contract (which does not use a network of providers), we believe that fewer than 10 applications would be subject to this proposed requirement in each fiscal year.

W. ICRs Regarding Maintaining a Fiscally Sound Operation (§ 422.2, § 422.504, § 423.4, and § 423.505)

Sections 422.504(a) and 423.505(b) add a contract term under which an MA organization or PDP sponsor agrees to maintain a fiscally sound operation by at least maintaining a positive net worth. A determination of whether there is a positive net worth will be made from the financial reports submitted under the current financial reporting requirements. The burden associated with this requirement is the time and effort necessary to submit these financial reports. While this requirement is subject to the PRA, the associated burden is currently approved under OCN 0938–0469 with an expiration date of April 30, 2013.

X. ICRs Regarding Release of Part C and Part D Payment Data (Parts 422 and 423, Subpart K)

This provision permits the Secretary to release Part C and D summary payment data for research, analysis, and public information functions. The Secretary believes these data should be made available because other publicly available data are not, in and of themselves, sufficient for the studies and operations that researchers want to undertake to analyze the Medicare program and Federal expenditures, and to inform the public on how their tax dollars are spent.

These data will be routinely released on an annual basis in the year after the year for which payments were made. The data release will occur after final risk adjustment reconciliation has been completed for the payment year in question and, for Part D, after final payment reconciliation of the various subsidies. Thus, we will release data for payment year 2010 in the fall of 2011. This timeframe will not apply to the release of RDS data, since we do not reconcile RDS payment amounts until 15 months following the end of the plan year. The majority of our sponsors provide retiree drug coverage on a yearly basis. If an applicable plan year ended December 31, 2010, the payment reconciliation is not due until March 31, 2012, which would be after the fall 2011 target for other Part C and D payment data. We will release the most current RDS payment data available at the time Part C and D payment reconciliation has been completed and those data are compiled and released.

Since we are not seeking additional information from MA organizations or from Part D sponsors, there are no PRA implications. Payment data are quite different than the bid data plans submit and for which we have existing OMB authority for collection (OCN 0938–0944). The gross payment data we are proposing to disclose are not derived from information plans submit to us, but rather are compiled and derived solely from CMS internal payment files.

Comment: One commenter argued that CMS should release MA payment data in accordance with the Freedom of Information Act (FOIA) and the current administration's FOIA policy. The commenter believed that these data were necessary to assess the impact and operation of the MA program, requested immediate release of 2006–2009 data, and asked CMS to release 2010 data as soon as possible.

Response: We disagree with the commenter's argument that we must proactively release MA payment data in accordance with FOIA. Accordingly, we have engaged in notice and comment rulemaking pursuant to our authority under section 1106(a) of the Social Security Act to authorize the proactive release of data from 2010 and beyond. We are therefore finalizing our burden estimate as proposed.

Y. ICRs Regarding Revision to Limitation on Charges to Enrollees for EmergencyDepartment Services (§ 422.113)

At § 422.113(b)(2)(v) we eliminate the current $50 cost-sharing limit on emergency department services and, instead, to require CMS to evaluate and determine the appropriate enrollee cost sharing limit for emergency department services on an annual basis. The burden associated with this proposed requirement is the time and effort necessary to for MA organizations to submit their benefit designs, including cost-sharing amounts, via the Plan Benefit Package (PBP) software. While this proposed requirement is subject to the PRA, the associated burden is currently approved under OCN 0938–0763 with an expiration date of May 31, 2011.

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Table 9—Estimated Fiscal Year Reporting Recordkeeping and Cost Burdens

Regulation Sections	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting[1] ($)	Total Labor Cost	Total Capital/ Maintenance Costs ($)	Total Cost ($)
§422.101 and §422.152	0938-0935	544	544	6	3,264	55.46	181, 021	0	181, 021
§423.780(f)	0938-New	150	150	0.167	25	23.92	598	0	598
§423.44	0938-New	80,000 731	80,000 80,000	0.017 0.083	1,333 6,666	40.00 40.00	53,320 266,640	0	53,320 266,640
§423.772 and §423.782 (Start-up)	0938-New	51	51	20	1020	34.10	34,782	0	34,782
§423.772 and §423.782 (Annual)	0938-New	51	51	12	612	34.10	20,869	0	20,869
§423.154 and §423.100	0938-0992	731 40 40	731 40 10	10 80 240	7,310 3,200 2,400	150.20 150.20 145.37	1,097,962 480,640 348,888	0 0	1,097,962 480,640 348,888
§423.128(b)(7)(i)	0938-New	731	536,554	0.167	89,605	40.00	3,584,200	0	3,584,200
§423.128(d)	0938-New	731	690,064	0.167	115,011	40.00	4,600,440	0	4,600,440
§423.562(a)(3)	0938-New	731 40 40	1,608,200 40 40	0.033 40 10	53,071 1,600 400	40.00 40.00 40.00	2,122,840 64,000 16,000	0 0 0	2,122,840 64,000 16,000

[1] Bureau of Labor Statistics, U.S. Department of Labor, **National Compensation Survey: Occupational Earnings in the United States, 2009**. United States Government Printing Office. July 2009. Retrieved from http://www.bls.gov/ncs/ncswage2009.htm

Regulation Sections	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting[1] ($)	Total Labor Cost	Total Capital/ Maintenance Costs ($)	Total Cost ($)
§423.104(d) (Start-up)	0938-New	40	40	12,000	480,000	105.00	50,400,000	0	50,400,000
§423.104(d) (Annual)	0938-New	40	40	250	10,000	105.00	1,050,000	0	1,050,000
§422.260	0938-New	25	25	8	200	250	50,000	0	50,000
§422.2274 and §423.2274	0938-New	12	12	100	1,200	59.20	71,040	0	71,040
§422.111 and §423.128 (Start-up)	0938-New	564	564	200	112,800	34.92	3,938,976	0	3,938,976
§422.111 and §423.128 (Annual)	0938-0964	564	564	160	90,240	34.92	3,151,181	0	3,151,181
Total		81,485	2,997,720		979,957		71, 352,376	0	71,352,376

[1] Bureau of Labor Statistics, U.S. Department of Labor, **National Compensation Survey: Occupational Earnings in the United States, 2009**. United States Government Printing Office. July 2009. Retrieved from http://www.bls.gov/ncs/ncswage2009.htm

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IV. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)). Executive Orders 12866 and 13563 direct 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 impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated an "economically" significant rule under section 3(f)(1) of Executive Order 12866, and a major rule under the Congressional Review Act. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.0 million to $34.5 million in any 1 year; for details, see the Small Business Administration's Web site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=2465b064ba6965cc1fbd2eae60854b11&rgn=div8&view=text&node=13:1.0.1.1.16.1.266.9&idno=13).* Individuals and States are not included in the definition of a small entity.

MA organizations and Part D sponsors, the entities that will largely be affected by the provisions of this rule, are not generally considered small business entities. They must follow minimum enrollment requirements (5,000 in urban areas and 1,500 in nonurban areas) and because of the revenue from such enrollments, these entities are generally above the revenue threshold required for analysis under the RFA. 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. A fraction of MA organizations and sponsors are considered small businesses because of their non-profit status. HHS uses as its measure of significant economic impact on a substantial number of small entities, a change in revenue or costs of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this final rule because this final rule will have minimal impact on small entities. Therefore, an analysis for the RFA will not be prepared because the Secretary has determined that this final rule will not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an 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. We are not preparing an analysis for section 1102(b) of the Act because the Secretary certifies that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately $136 million. This final rule is not expected to reach this spending threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Based on CMS Office of the Actuary estimates, we do not believe that this final rule imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We note that we have estimated that our provision to eliminate, pursuant to section 3309 of the ACA, Medicare Part D cost-sharing for full-benefit dual eligible individuals receiving home and community based services at § 423.772 and § 423.782 will have a very small cost impact on States resulting from the need to identify eligible individuals and provide data to CMS. As discussed elsewhere in this RIA, we estimate the annual cost associated with the requirement for States to provide CMS with this data to be $34,782 in the first year and $20,869 for subsequent years.

B. Statement of Need

The purpose of this final rule is to make revisions to the Medicare Advantage (MA) program (Part C) and Prescription Drug Benefit Program (Part D), to implement provisions specified in the ACA and make other changes to the regulations based on our continued experience in the administration of the Part C and Part D programs. These latter revisions are necessary to, (1) clarify various program participation requirements, (2) make changes to strengthen beneficiary protections, (3) strengthen our ability to identify strong applicants for Part C and Part D program participation and remove consistently poor performers, and (4) make other clarifications and technical changes.

C. Overall Impact

The CMS Office of the Actuary has estimated savings and costs to the Federal government as a result of various provisions of this final rule. As detailed in Table 11, we expect savings to the Federal government of approximately $82.42 billion for fiscal years (FYs) 2011 through 2016 as a result of the implementation of the following provisions:

Payment Changes Related to MA benchmarks, Quality Bonus Payments, Rebates, and Application of Coding Adjustment	$76.47 billion
Increase in Part D premiums Due to Income Related Monthly Adjustment Amount (D-IRMAA)	$4.77 billion
Appropriate Dispensing of Prescription Drugs in Long-term Care Facilities under PDPs and MA-PD plans and Dispensing Fees	$1.00 billion
Elimination of the Stabilization Fund	$181 million

In Table 10, we estimate total costs to the Federal government, States, Part D sponsors, MA organizations, and other private sector entities as a result of various provisions of this final rule. As detailed in Table 10, we expect costs of approximately $5.35 billion for FYs 2011 through 2016 as a result of the implementation of various additional provisions of this final rule. Following are the provisions with the most significant costs (that is, costs greater than $100 million between FY 2011 and FY 2016) in this final rule:

Changes to Close the Part D Coverage Gap	$3.67 billion
Determination of Part D Low-Income Benchmark Premium	$770 million
Including Costs Incurred by AIDS Drug Assistance Programs (ADAPs) and the Indian Health Service (IHS) Toward the Annual Part D Out-of-Pocket Threshold	$460 million
Voluntary De Minimis Policy for Subsidy Eligible Individuals	$170 million
Cost-Sharing for Medicare Covered Preventive Services	$148 million

Tables H2, H3, and H4 detail the breakdown of costs by cost-bearing entity. Specifically, Table 11 describes costs and savings to the Federal government, Table 12 describes costs to MA organizations and/or PDP sponsors and third party entities, and Table 13 describes costs to States.

Taking into account both costs and savings estimated in this RIA, we estimate a net savings of $76.17 billion as a result of the provisions in this final rule over FYs 2011 to 2016. Therefore, this final rule is "economically significant" as measured by the $100 million threshold, and is a major rule under the Congressional Review Act. Accordingly, we have prepared an RIA that details anticipated effects (costs, savings, and expected benefits), and alternatives considered by this requirement. For collection of information burden associated with our requirements and the bases for our estimates, refer to the collection of information section of this final rule.

1. Expected Impact on States, Plans and the Medicare Program

a. Cost Sharing for Specified Services at Original Medicare Levels (§ 417.454 and § 422.100)

We estimate that our implementation of section 3202 of the ACA will result in no additional program costs. In our November 2010 proposed rule (75 FR 71250) we had proposed cost sharing limits for in-network home health services provided under MA plans in addition to the ACA-required limits on cost sharing in MA plans for chemotherapy services, renal dialysis services, and skilled nursing facility care. We are not finalizing our proposed requirement to requiring cost sharing limits for in-network home health services provided by MA plans. We estimate that the Federal fiscal year 2012 (FY 2012) costs to Medicare of limiting cost sharing in MA plans for the service categories specified in the ACA (that is, chemotherapy and radiation services, renal dialysis, and skilled nursing facility care) will be zero because we already require plans to charge in-network cost sharing for these three service categories that does not exceed cost sharing under Original Medicare. In fact, we believe that Congressional intent was to require that CMS maintain the limits on in-network cost sharing that we had already implemented for SNF care, renal dialysis services, and Part B chemotherapy services. Thus, we expect that there will be no effect on plans or beneficiaries as a result of our implementation of the cost sharing limits specified in section 3202 of the ACA. We believe MA organizations will continue to have adequate flexibility to design plan benefits that are responsive to beneficiary needs and preferences while providing access to high quality and affordable health care.

b. Approval of SNPs by NCQA (§ 422.4, § 422.101, and § 422.152)

The burden associated with this requirement is the time and effort put forth by MA organizations offering SNPs to submit their model of care (MOC) to CMS for NCQA evaluation and approval as per CMS guidance. Although the submission of the MOC is already part of the application process, review of this document by NCQA for approval is a new requirement. This requirement is for all new and existing SNPs. We estimate that it will take each SNP plan 40 hours to complete the annual application. Within those 40 hours, we estimate it will take SNP plans 6 hours to complete the SNP proposal portion of the MA application. Currently, there are 544 existing SNP plans. We estimate of the 6 hours, it will take existing SNPs 2.5 hours to complete the MOC for the SNP approval process. For the existing 544 SNPs, we estimate the burden associated with completing the MOC for the SNP approval process only is 1,360 hours. For the existing plans to complete the SNP sections only, the burden associated with this new requirement is 3,264 hours.

The number of new plans each year will vary and cannot easily be predicted. However, based on the number of new plans that submitted SNP Proposals during the application period in February 2010 for operation in 2011, we estimate that approximately 15 new applications will be submitted annually. For the estimated 15 new plan

applications, we estimate of the 6 hours to complete the SNP portion of the application it will take new SNPs 2.5 hours to complete the MOC for the SNP approval process. For the 15 new plan applications, we estimate the burden associated with completing the MOC for the SNP approval process only is 38 hours. Thus, for 15 new plans at 40 hours each, we estimate the total annual burden hours to be 600.

The estimated costs associated with the burden hours are summarized in Tables 10 through 12. Table 10 summarizes the estimated total costs for the Federal government and MA SNP plans from FYs 2011 to 2016. The costs in Table 11 reflect the contract award to NCQA for $1 million and a contract award at the level of $500,000 for years 2012 to 2016. The additional costs incurred in this table are for the Federal salaries for two GS–13 step 10 analysts and a GS–15 manager. Table 12 contains the projected costs to the SNPs for preparing the SNP sections of the application. These costs are primarily labor costs for staff employed by the plans to complete the required materials. The salaries are equivalent to that of one GS–13 step-10 analyst at a salary of $55.46 an hour.

c. Determination of Part D Low-Income Benchmark Premium (§ 423.780)

Beginning in 2011, section 1860D–14(b)(3)(B)(iii) of the Act requires CMS to calculate the LIS benchmarks using basic Part D premiums before the application of Part C rebates each year. This final rule updates our regulations at § 423.780(b)(2)(ii)(C) to codify this provision. This provision will decrease the number of reassignments of low-income beneficiaries from plans that are above the low-income benchmark because it will increase the benchmark, thereby producing more zero-premium plans. We believe this provision will lead to additional costs to the Federal government of approximately $90 million for FY 2011.

The estimated cost to the Federal government between FY 2011 and FY 2016 is $770 million. The year-by-year impacts in millions of dollars are shown in Tables 10 through 12. Table 11 shows that the bulk of this total cost is due to increased Federal premium subsidy payments, which are the result of generally increasing the low-income benchmarks. The higher benchmarks allow a greater number of low-income beneficiaries to remain in their current plan, rather than reassigning them to a lower cost plan. In each region, the low-income benchmark essentially functions as a ceiling for the Federal premium subsidy for low-income beneficiaries. That is, the Federal premium subsidy covers the full cost of the plan's basic Part D premium for a full-subsidy beneficiary, up to the low-income benchmark amount.

This approach maintains a strong incentive to bid low to keep and possibly add LIS beneficiaries. Absent the provision, there may be a "winner take all" outcome in certain regions with one organization acquiring all of the LIS beneficiaries in the region. It is difficult to predict what will happen in the absence of this provision, but we expect some organizations will be induced to bid even lower, while other organizations will give up on this population and bid higher.

We expect this rule to reduce the administrative costs for plan sponsors associated with the reassignment of LIS beneficiaries. These costs include the production of new member informational materials by the new plan, increased staffing of call centers to field beneficiary questions, and costs associated with implementing transition benefits for new enrollees. The cost estimate for the LIS benchmark methodology change in Table 10 does not include a projection for administrative savings.

We believe this final rule will have an effect on the number of reassignments, and the number of zero-premium plans available to full-subsidy eligible individuals in each region. This final rule will reduce the number of reassignments and increase the number of zero premium organizations available to beneficiaries. This is because, under the higher benchmarks, more PDPs are likely to have premiums that are equal to or less than the low-income benchmark and, as a result, will be fully covered by the premium subsidy. Low-income subsidy beneficiaries will be able to remain in these PDPs and will not be reassigned to other lower-premium PDPs. Under the current framework we would expect 1.9 million reassignments. Under the formula for calculating benchmarks we will expect 900,000 reassignments, or approximately one million fewer reassignments. We expect the formula to increase the number of zero premium organizations available to beneficiaries in 21 of the 34 PDP regions.

Although there is no quantifiable monetary value to CMS to reducing reassignments, we believe this benefit is important, as it will increase program stability and continuity of care.

d. Voluntary De Minimis Policy for Subsidy Eligible Individuals (§ 423.34 and § 423.780)

The new voluntary de minimis provisions in § 423.34(d) and § 423.780(f) permit Part D plans to volunteer to waive a de minimis amount of the Part D premium above the LIS benchmark. We expect that the only Part D plans that will volunteer to do so are those PDPs that would otherwise lose LIS beneficiaries to reassignment. We will establish a new de minimis amount in August of each year, and the de minimis amount may vary by year. For purposes of illustration, if the de minimis amount were $1.00, we would estimate 800,000 LIS beneficiaries would have an average of $0.50 per month waived by Part D plans, resulting in a total annual cost to all de minimis plans of $5 million per year. Table 12 shows that this would result in a total cost of $30 million to PDPs from FY 2011 to 2016. If the de minimis amount were $2.00, we would estimate that 1,200,000 LIS beneficiaries would have an average of $0.93 per month waived by Part D plans, resulting in a total annual cost to all de minimis plans of $10 million per year.

Our voluntary de minimis provisions are estimated (based on the assumption of a $1.00 de minimis amount) to cost the Medicare Trust Fund $140 million over the 6-year period from FY 2011 to FY 2016. Tables 11 and 12 illustrate how these costs are borne by the Federal government and PDPs, respectively. PDPs that volunteer to waive a de minimis amount will not have their LIS beneficiaries reassigned to a zero premium plan. The additional costs are attributable to low-income beneficiaries staying in higher cost plans. The result of staying in higher costs plans is that Medicare's low-income premium and cost-sharing subsidy and reinsurance payments will be greater than would have been the case if CMS reassigned these beneficiaries to lower-cost plans.

e. Increase in Part D Premiums Due to the Income Related Monthly Adjustment Amount (D–IRMAA) (§ 423.44)

Section 423.44(e)(3) requires PDPs to provide Part D enrollees with a notice of disenrollment in a form and manner determined by CMS. PDPs will provide disenrollment notices to enrollees who were required to pay the Part D—IRMAA because their modified adjusted gross income exceeded the income threshold amounts set forth in 20 CFR 418, but failed to pay it after a grace period and appropriate notice has been provided.

Consistent with data from individuals paying the Part B IRMAA (1.8 million) and enrolled in a Part D plan, we estimate that approximately 1.05 million of the 29.2 million Medicare beneficiaries enrolled in the Part D program will exceed the minimum income threshold amount and will be assessed an income related monthly adjustment amount. Out of the 1.05 million affected beneficiaries, we estimate that 0.22 million will drop the Part D coverage in 2011. Under Part B, approximately 122,000 (14.8 percent) of the 1.8 million beneficiaries assessed an IRMAA are billed directly. This constitutes 5.17 percent of the Medicare population. We estimate that approximately 80,000 (7.6 percent) of the 1.05 million beneficiaries enrolled in Part D who must pay the Part D—IRMAA will be directly billed for the Part D—IRMAA either because they are not receiving monthly benefit payments from SSA, OPM, or the RRB, or the monthly benefit payment is not sufficient to have the Part D—IRMAA withheld.

Of the 80,000 Part D enrollees who will be directly billed for the Part D—IRMAA, we cannot estimate how many might accrue Part D—IRMAA arrearages and be subsequently terminated. However, in cases where the PDP is required to send an enrollee a notice of termination in accordance with § 423.44(e)(4), the burden associated with this requirement would be the time and effort it takes the PDP to populate the notice. Termination notices are generally automated; therefore, assuming all 80,000 Part D enrollees that have a Part D—IRMAA become delinquent, we estimate 1 minute × 80,000 enrollees divided by 60 minutes. This equates to an annual burden for PDP sponsors of 1,333 hours at approximately $40/hour (based on U.S. Department of Labor statistics for hourly wages for administrative support). The associated burden amount for this work is $53,320. Additionally, Part D plan sponsors would have to retain a copy of the notice in the beneficiary's records. We estimate 5 minutes × 80,000 enrollees divided by 60 minutes. This equates to 6,666 hours at approximately $40/hour (based on U.S. Department of Labor statistics for hourly wages for administrative support). This associated burden amount is $266,640. We estimate the total maximum annual burden for all Part D plan sponsors resulting from this provision to be $319,960. Therefore, as shown in Table 12, we estimate this provision to result in a maximum burden cost, to PDP sponsors, in the amount of $1.92 million for FYs 2011 through 2016. During calendar year 2011, we expect that implementation of the Part D—IRMAA provisions, at § 423.286(d)(4) and § 423.293(d), will increase the Medicare Trust Fund by $270 million, with a net Federal government savings of approximately $4.77 billion from FY 2011 through FY 2016 from increased premium payments by Medicare beneficiaries. We describe these savings to the Federal government in Table 11, and describe total year-by-year impact for the Federal government and Part D sponsors in Table 10. Also, because the income thresholds do not increase between 2011 and 2019, we anticipate that more beneficiaries will be affected by the IRMAA provision over time and this, in turn, will produce significant growth in the savings associated with this program.

f. Elimination of Medicare Part D Cost-Sharing for Individuals Receiving Home and Community-Based Services (§ 423.772 and § 423.782)

We are amending § 423.772 and § 423.782 pursuant to section 3309 of the ACA. Specifically, the changes provide for a definition of an individual receiving home and community based services, and for zero cost-sharing for Medicare Part D prescriptions filled by full-benefit dual eligible beneficiaries receiving such services. As illustrated in Table 12, this provision will not increase costs for MA organizations or PDP sponsors. The affected beneficiaries already have LIS as full duals and are, therefore, low-income individuals. Their Part D copayment level is likely to be low prior to the elimination of copayments. The elimination of copayments will allow them additional disposable income for other expenses. The reduction in the copayments to zero will be fully offset by increasing low income subsidy cost sharing subsidy payments we make to their Part D plans. The formal elimination of the fund will have little or no impact on the current operation of the MA program. We believe the impact on the Federal government will be minimal given that most of the impacted individuals are already at a low copayment level and the shift from the low copayment level to zero copayment is small.

This provision will impact States, as they will have to identify eligible individuals and provide data to CMS. They will send the new data on an existing monthly data exchange already used to identify dual eligible beneficiaries. We estimate the cost for States to comply with this requirement to include a one-time development cost of $34,782 in FY 2011, and as well as an ongoing annual cost of $20,869 starting in FY 2012.

g. Appropriate Dispensing of Prescription Drugs in Long-Term Care Facilities Under PDPs and MA–PD Plans (§ 423.154) and Dispensing Fees (§ 423.100)

We are adding a new regulation at § 423.154 to require Part D sponsors to utilize uniform dispensing techniques in increments of 14-days-or-less when dispensing covered brand name Part D drugs to enrollees who reside in long-term care (LTC) facilities. Based on our discussions with industry, we estimate that 75 percent to 80 percent of the cost related to drug waste arises from 20 percent of the drugs. That 20 percent is made up of brand name medications. In an effort to target the drugs resulting in the most financial waste and to lessen burden for facilities transitioning from 30-day supplies to 14-day-or-less supplies, we are initially limiting the requirement for 14-day-or-less dispensing to brand name drugs as defined in § 423.4.

Pharmacies servicing LTC facilities may have upfront costs associated with software upgrades, packaging and hardware changes, and ongoing costs of transaction fees, and additional deliveries. These costs were not reflected in Table 10 of the proposed rule; instead, we solicited comments on these costs. We expect some of these expenses to be offset by an increase in dispensing fees consistent with § 423.100. In addition, a decrease in volume of drugs dispensed may result in lower revenues and rebates.

We expect most pharmacies to initially convert from a 30-day punch card system to a 14-day punch card system. Our conversations with manufacturers of the 30-day punch card systems have indicated that there is minimal capital investment conversion needed for the transition from 30-day to 14-day packaging. We expect only a relatively small number of pharmacies will convert to an automated dose dispensing system in the very short-term due to the acquisition costs of the technology. We anticipate costs associated with the change in software and training of pharmacy staff associated with the change. We also expect a few pharmacies to incur a small additional expense related to the number of deliveries required to service a facility with a 14-day-or-less dispensing technique.

We anticipate that dispensing fees will be developed to take into account the marginal costs associated with additional dispensing events in a single billing cycle for a single prescription

and consider costs undertaken to acquire and maintain technology aimed at reducing waste. We would expect dispensing fees to be greater when a Part D drug is dispensed using automated dose dispensing technology, as opposed to a Part D drug dispensed via a 14-day blister pack, due to substantially greater marginal costs of acquiring and implementing automated dose technology than in adjusting current systems and workflows to dispense in 14-day rather than 30-day quantities. For purposes of scoring this final rule, we project that the current aggregate level of dispensing fees will double. It is not at all clear that negotiated dispensing fees must or will increase directly in proportion to the number of dispensing events per month as some, but not all, commenters assert. Nonetheless, in order to be as conservative as possible in projecting cost increases, we have assumed a doubling of the current aggregate level of dispensing fees. In addition, the information we have to work with in projecting potential savings reflects widely divergent estimates. The variation in savings estimates range from as low as approximately 3 percent to as high as 17 percent for 7-day supplies, and as high as 20 to 25 percent for automated dose dispensing. Given the divergence in estimates and the uncertainty in the rate of conversion to the more efficient methodologies, we have elected to be very conservative in estimating savings in this final rule in order to ensure that savings do result from the implementation of this provision.

We estimate the total yearly burden for negotiating a contract between the Part D sponsor and the entity (for example, PBM) contracting with the pharmacies servicing LTC facilities to be equal to the number of the Part D sponsors (731) × the average estimated hours per sponsor (10). This equals 7,310 hours. We estimate the number of entities contracting the pharmacies servicing LTC facilities to be 40 (28 processors and 12 sponsors). We estimate the total yearly hourly burden for negotiating a contract between the entity described previously and the pharmacies servicing LTC facilities to be the number of entities (40) × the average estimated hours per entity (80). This is 3200 hours. The total number of hours for contract negotiation is estimated to be 10, 510 hours. The estimated hourly labor cost for reporting is $150.20. Hourly rates in the RIA include fringe benefits and overhead. This estimate is a compilation of the hourly rate for a lawyer and support staff from the Bureau of Labor Statistics. The total estimated cost associated with these contract negotiation requirements is $1,578,602 ($150.20 × (3,200 + 7,310 hours) = $1,578,602) and is described in Table 12. This is a one-time contract negotiation cost.

We are introducing a new requirement under § 423.154 (a)(2) for Part D sponsors to collect and report to CMS the method of dispensing technique used for each dispensing event described under § 423.154 (a) and on the nature and quantity of unused brand and generic drugs. We anticipate a billing standard that incorporates the collection of the method of dispensing technique. So, pharmacies and plans will not have to create unique data collection processes to collect that data. We estimate that 40 sponsors-contractors (28 drug claim processors and 12 sponsors that process their drug claims and data collection) will be subject to this requirement. For the collection of data on unused drugs, we estimate that it will take a total of 2,400 hours for 10 vendors (software vendors plus pharmacies with proprietary systems) to develop the programming for this requirement. The estimated total cost associated with the software development is equal to the number of software vendors plus the number of pharmacies with proprietary systems (10) times an hourly rate of $145.37 (this includes $43.35 in direct wages and an additional $102.02 in fringe benefits/overhead/general and administrative costs/fee) times 240 (estimated number of hours to design and program one system; the cost is $348,888. The total cost associated with this provision is $1,927,490 and is described in Table 12.

We anticipate that the initial upfront costs to convert to a 14-day-or-less dispensing technique will eventually be more than offset by the savings to the Federal government associated with dispensing (see Table 10 for estimates of the year-by-year savings). We expect this provision to reduce in Part D program expenses, pharmaceutical waste, environmental disposal costs impact, and the risk of pharmaceutical diversion associated with unused drugs in 30-day fills.

Comment: Several commenters believed that we failed to adequately analyze the financial impact of the 7-day-or-less dispensing requirement. Some commenters also stated that we failed to consider the increased costs associated with hiring pharmacists and pharmacy technicians that would be needed to keep up with the 7-day-or-less dispensing requirement.

Response: As discussed earlier in this final rule, we modified the proposed rule at § 423.154 to reflect 14-day-or-less dispensing as opposed to 7-day-or-less dispensing. Given that the requirement is for 14-day-or-less dispensing and is limited to brand name drugs only (which make up only 20 percent of the drugs dispensed), we do not believe there will be a significant increase in pharmacy staff. In addition, this final rule modifies our proposed rule in such a way as to reduce the burden associated with this provision. As previously discussed, we eliminated the requirement for Part D sponsors' pharmacies to collect unused Part D drugs the pharmacies had originally dispensed to enrollees, and we simplified the reporting requirements associated with this provision by allowing pharmacies to calculate the number of doses that go unused by enrollees in LTC facilities by utilizing the discontinuation dates of the prescription and the quantities dispensed to the enrollee. Also, by changing the requirement from 7-day-or-less dispensing to 14-day-or-less dispensing, we reduce the burden associated with filling the prescriptions by the pharmacies and checking-in prescriptions by the LTC facilities. The burden reduction should translate into a reduction in costs associated with this provision because, for example, fewer additional staff will be needed to implement the requirements of § 423.154. We also believe that at least some of the costs associated with implementing this requirement will be offset by the increase in dispensing fees. We have, however, modified our impact estimate to reflect the assumption that dispensing fees will double and to take into consideration that the implementation date is January 1, 2013.

Comment: Several commenters stated that we failed to take into consideration the costs associated with collecting unused drugs from the LTC facilities and the costs associated with disposal of those unused drugs.

Response: We have eliminated the requirement for Part D sponsors contracted pharmacies to collect unused Part D drugs from LTC facilities. Therefore, the pharmacies will not incur increased costs associated with the collection of unused drugs or the disposal of those drugs as a result of this final rule.

h. Complaint System for Medicare Advantage Organizations and PDPs (§ 422.504 and § 423.505)

The burden associated with this provision is the time and effort of the MA organizations and Part D sponsors in training staff and recording complaint closure documentation in the CTM, as

well as posting and maintenance of a link from their Web site to the electronic complaint form at *http://www.medicare.gov.* We estimate that the total annual hourly burden for training staff and recording complaint closure in the CTM is equal to the average estimated hours per sponsor for documentation for each complaint closure (.25) × the average number of complaints per sponsor (102) plus the average estimated hours per sponsor for training (8 hours), multiplied by the average cost of a technical health care worker ($15) × the number of Part C and D contracts (757). We also estimate that the total annual hourly burden for posting and continued maintenance of a link is 20 hours × the average cost of a Web site developer ($34) × the number of Part C and D contracts (757). We estimate the annual burden associated with all these changes equals 40,500 hours. The average cost per hour is approximately $22.10. The estimated annual cost associated with these requirements is $895,160.

i. Uniform Exceptions and Appeals Process for Prescription Drug Plans and MA–PD Plans (§ 423.128 and § 423.562)

We are modifying our proposal in our November 2010 proposed rule (75 FR 71250) to include a reference to the availability of model forms for requesting coverage determinations and appeals, as opposed to requiring use of a standardized form. We are finalizing the language related to instant access to the coverage determination and appeals process via the plan's Web site, but have clarified in the preamble that we are interpreting instant access to mean, at a minimum, the ability of Part D plan sponsors to accept e-mail requests. We expect that streamlining the appeals and exceptions process will allow beneficiaries to access appeals more quickly and will ensure beneficiaries have access to covered medications in a timely manner. MA organizations and Part D sponsors will be required to process coverage determination requests submitted by mail or via an Internet Web site (§ 423.128(b)(7)(i) and (ii)), which is estimated to result in an annual burden of 80,745 hours. At an estimated cost of $40.00 per hour, the estimated total annual cost of this requirement is $3.23 million. Also, processing coverage determination requests that are received by telephone (§ 423.128(d)) is estimated to result in an annual burden of 115,010 hours. At an estimated cost of $40.00 per hour, the estimated total annual cost of this requirement is $4.6 million.

In cases when a prescription cannot be filled as written, Part D sponsors are required under § 423.562(a)(3) to arrange with their network pharmacies to distribute a pharmacy notice advising the enrollee of his or her right to contact the plan to request a coverage determination. Under this provision, Part D sponsors are required to modify their electronic transactions to pharmacies so that they can transmit codes instructing pharmacies to distribute notices at the POS. That is, pharmacies and PBMs are required to program their systems to relay the message at the pharmacy to distribute the POS pharmacy notice that instructs the enrollee to contact the plan sponsor to request a coverage determination.

We estimate the burden on plan processors will be the programming to send the code or billing response to the pharmacy, as well as revising the terms of their contracts with pharmacies. We estimate that the number of hours for each processor (28 PBMs and 12 plan organizations) to perform these tasks will be 40 hours per processor or plan organization, for a total one-time burden of 1,600 hours. The estimated one-time cost associated with the processor or plan organization tasks is $64,000 (1600 hours × $40). Each pharmacy will need to program to receive the code and print the response. Programming by the pharmacies (40 pharmacy software vendors) in order to receive the code by each pharmacy will be 10 hours, for a total of 400 hours. The estimated one-time cost associated with the processor tasks is $16,000 (400 hours × $40).

We estimate that the 731 contracting entities would distribute an average of 2,200 pharmacy notices. Therefore, requiring plan sponsors to arrange with their network pharmacies to distribute pharmacy notices at the point-of-sale when prescriptions cannot be filled as written (§ 423.562(2)(3)) would result in an annual burden of 53,071 hours (2 minutes or 0.033 hours at point-of-sale × 731 contractors × 2,200 pharmacy notices per contract). At an estimated cost of $40.00 per hour, the estimated total annual cost of this change would be $2.12 million.

Comment: One commenter believes that our estimate of $40 an hour was too low for processing coverage determinations and redeterminations.

Response: We disagree. The estimated hourly rate of $40 is a composite rate based upon the Bureau of Labor statistics National Compensation Survey.

Comment: One commenter asked CMS if we expect the pharmacy to maintain a copy of the POS notice according to the 10 year record retention requirement. The commenter argued that this would increase the burden estimate since it would likely increase dispensing fees and present an additional hurdle for pharmacies and PBMs in response to CMS audit requests.

Response: We do not specify which specific records must be retained by Part D sponsors for audit purposes. Part D sponsors are responsible for determining which pertinent documents their network pharmacies must retain. Therefore, the burden estimate associated with the POS notice does not account for the record retention requirements provided under § 423.505.

j. Including Costs Incurred by the AIDS Drug Assistance Program (ADAP) and the Indian Health Services (IHS) Toward the Annual Part D Out-of-Pocket Threshold (§ 423.100 and § 423.464)

As provided under § 423.100 and § 423.464, Part D sponsors are required to count ADAP and IHS costs towards a beneficiary's TrOOP costs, allowing the beneficiary to move through the coverage gap portion of the benefit and into catastrophic coverage phase. There is no burden on IHS facilities since claims will be identified as IHS provider claims by the National Provider Identifier (NPI). However, ADAPs will be requested to submit information to CMS Coordination of Benefits (COB) contractor via a voluntary data sharing agreement (VDSA), which will be sent to the TrOOP facilitator to ensure proper calculation of the TrOOP amounts. Several ADAPs already participate in the COB file exchange and have submitted their VDSAs. The approximate cost associated with this submission is 30 minutes to complete the VDSA per entity. We estimate a negligible one-time annual cost to 50 ADAPs that require VDSAs.

The burden associated with this provision is not expected to impact sponsor organization costs, with the exception of up-front programming costs, which we estimate will be 1 hour per sponsor for an approximate cost of $40 per sponsor. Including these costs toward TrOOP impacts how fast a beneficiary will reach the catastrophic limit, triggering Federal reinsurance payments. Sponsors will not incur additional costs due to this requirement. The Federal cost impact is estimated at $460 million from FY 2011 to FY 2016. The additional cost to the Federal government (Medicare program) is due to more individuals reaching the catastrophic coverage phase under the Part D benefit. Overall, we expect this provision to reduce the costs to ADAPs and IHS.

k. Cost Sharing for Medicare Covered Preventive Services (§ 417.454 and § 422.100)

We estimate that our implementation of sections 4103, 4104, and 4105 of the ACA will result in additional program costs as beneficiaries will pay no portion of the costs for the Personalized Prevention Plan Services, the Initial Preventive Physical Exam and Medicare-covered preventive services for which cost sharing is waived under Original Medicare (§ 417.454 and § 422.100). We estimate that the FY 2012 costs to Medicare for increasing access to clinical preventive services in accord with sections 4103, 4104, and 4105 of ACA will be $410 million.

Although slightly less than 30 percent of Medicare expenditures for Parts A and B are for MA enrollees, we estimate that the cost to the MA program of increasing access to clinical preventive services as described by sections 4103, 4104, and 4105 of the ACA will be significantly less than 30 percent of the estimated cost to the Medicare program for implementation of these provisions. In contrast to the Original Medicare program, most MA plans already provide some in-network preventive services without charging beneficiary cost sharing. In contract year 2010, at least 78 percent of plans provide many, or all, of the Medicare-covered preventive services without charging beneficiary cost sharing. In fact, almost all MA plans currently provide a few of the Medicare-covered preventive benefits without cost sharing. Therefore, we estimate that our requirement for MA plans to provide the Medicare-covered preventive services without beneficiary cost sharing will not increase plan costs by a significant amount.

Based on our finding that 78 percent of plans provide some preventive benefits without cost sharing in contract year 2010, we estimate that for FY 2012 plans will incur approximately $27.1 million in costs by providing in-network Medicare preventive services without charging beneficiary cost sharing as provided under § 417.454 and § 422.100. Over time, we estimate that the relative cost to the MA program for provision of improved access to Medicare-covered preventive services will be consistent with the estimated cost for Medicare, which increases with growth in the Medicare population. We estimate the total cost of this provision to be $147.9 million between FYs 2011 and 2016.

Further, although not included in our estimates, we believe that the increased emphasis on provision of preventive services may also result in improved beneficiary well-being and subsequently decrease their need for, and utilization of, more costly medical and surgical interventions and may decrease overall program costs.

l. Elimination of the Stabilization Fund (§ 422.458)

Section 10327(c) of the ACA repealed section 1858(e) of the ACA, eliminating the stabilization fund. Therefore, we are deleting paragraph (f) from § 422.458, since the statutory basis for the Fund no longer exists. The elimination of the stabilization fund will have the effect of savings for the Federal government, but will also result in a loss of financial incentives for regional plans to operate in regions with no or low MA penetration.

We expect the Federal government to save approximately $181.2 million for the fiscal years 2011 through 2016 from the implementation of this provision. The savings are a result of the elimination of the national bonus payment and recruitment and retention bonus payments to MA plans that would operate in regions with no or low MA penetration.

The fund will no longer offer a financial incentive for regional organizations to offer plans in regions with low or no MA penetration. The funds have never been accessible, however, because, since the fund's inception, payments have been delayed through legislation. Therefore, the formal elimination of the fund will have little or no impact on the current operation of the MA program.

m. Improvements to Medication Therapy Management Programs (§ 423.153)

Our proposed rule estimated first year costs associated with the requirement for Part D sponsors to contract with all LTC facilities in which their Part D enrollees reside to provide appropriate MTM services in coordination with independent consultant pharmacist evaluation and monitoring was $96,709,680 ($402,957 estimated cost per parent organization or sponsor × 240 parent organizations or stand alone sponsors with Part D LTC residents = $96,709,680 estimated cost). Annual costs for updating the contracts for subsequent years were estimated to be $32,236,560 ($134,319 estimated cost per parent organization or sponsor × 240 parent organizations or sponsors with Part D LTC residents = $32,236,560 estimated cost). After considering comments on our proposal, we are not finalizing the proposed requirement that Part D sponsors contract with LTC facilities for appropriate MTM services in coordination with LTC consultant pharmacist evaluation and monitoring, and, therefore, are not finalizing our original cost estimate associated with this proposal.

Comment: Two commenters requested that we include in our costs estimate include all costs related to the provision of MTM services in LTC settings and not merely those costs associated with Part D sponsor contracting.

Response: We are not finalizing the proposed requirement for Part D sponsors to coordinate MTM with LTC consultant pharmacist evaluation and monitoring, and are, therefore, not finalizing our original impact estimate. We plan to work with the industry to develop an alternate proposal and a more inclusive estimate of the associated costs.

n. Changes To Close the Part D Coverage Gap (§ 423.104 and § 423.884)

With the implementation of provisions related to closing of the Part D coverage gap, Medicare beneficiaries will have improved access to the prescription drugs in the coverage gap. They will likely enter the catastrophic phase of the benefit earlier in the benefit year as a result of our changes to close the Part D coverage gap, because they will be more likely to obtain necessary drugs in the coverage gap, thereby bringing them to the catastrophic phase sooner. Beneficiary cost sharing in the coverage gap would be determined on the basis of whether the covered Part D drug is considered an applicable drug under the Medicare coverage gap discount program. Different cost sharing levels will apply during the coverage gap to the drugs that are applicable and not applicable under the coverage gap discount program. In addition to the cost sharing changes, the rate of growth of the annual Part D out-of-pocket threshold would be reduced from FY 2014 to FY 2016. Further, in attesting to the actuarial equivalence of qualified retiree prescription drug plans to the standard Medicare Part D coverage, sponsors would not take into account the value of any discount or coverage provided during the coverage gap.

For changes associated with closing the Part D coverage gap, we estimate a one-time total cost of $50,400,000 (12,000 burden hours for each processor × 40 processors × $105 for the average labor cost of a senior programmer based on data from the Bureau of Labor Statistics) in the first year for the 40 pharmacy claims processors to implement systems changes. In subsequent years, the estimated total annual cost is $1,050,000 (250 burden hours per processor × 40 processors ×

$105 for the full cost of labor of a senior programmer) to identify changes to the applicable drugs under the Medicare coverage gap discount program and update systems with this information each month. The total estimated costs to the Medicare program for the adjustments to beneficiary cost sharing in the coverage gap are $130,400,000 in the first year (FY 2011), increasing in subsequent years as the coverage gap closes and the Part D enrollment increases. The estimated annual cost to the Medicare program associated with decreasing the rate of annual growth in the Part D out-of-pocket threshold is $40,000,000 in FY 2014, increasing in subsequent years as the Medicare Part D enrollment increases and the coverage gap closes.

o. Medicare Advantage Benchmark, Quality Bonus Payments, and Rebate and Application of Coding Adjustment (§ 422.252, § 422.258, § 422.266, and § 422.308)

Prior to enactment of the ACA, MA payment benchmarks (county rates) were established only partially in relationship to average fee-for-service costs in a county. Section 1102 of reconciliation amendments links all county benchmarks to FFS costs, effective 2012. As a transition, the ACA sets the 2011 MA benchmarks equal to the benchmarks for 2010; for subsequent years it specifies that, ultimately, the benchmarks will be equal to a percentage (95, 100, 107.5, or 115 percent) of the fee-for-service rate in each county. During a transition period, the benchmarks will be based on a blend of the pre-ACA and post-ACA benchmarks. The phase-in schedule for the new benchmarks will occur over 2 to 6 years, with the longer transitions for counties with the larger benchmark decreases under the new method.

The ACA, as amended, also introduces MA bonuses and rebate levels that are tied to the plans' quality ratings. Beginning in 2012, benchmarks will be increased for plans that receive a 4-star or higher rating on a 5-star quality rating system. The bonuses will be 1.5 percent in 2012, 3.0 percent in 2013, and 5.0 percent in 2014 and later; these bonuses increase the new benchmark portion of the blended benchmark until all transitions are complete. An additional county bonus, which is equal to the plan bonus, will be provided on behalf of beneficiaries residing in specified counties. The percentage of the "benchmark minus bid" savings provided as a rebate, which historically has been 75 percent, will also be tied to a plan's quality rating. In 2014, when the provision is fully phased in, the rebate share will be 50 percent for plans with a quality rating of less than 3.5 stars; 65 percent for a quality rating of 3.5 to 4.49; and 70 percent for a quality rating of 4.5 or greater. This provision will provide incentives for plan quality to increase. Plans will be paid based on quality performance rather than just the specific services they provide. However, the rules for determining quality bonus payments for CY 2012 through 2014 will be modified under the terms of the national quality bonus payment demonstration project.

The ACA amended the statutory provision that requires us to make an adjustment to MA risk scores for differences in coding patterns between MA and FFS. The ACA made four modifications to this requirement: The analysis must be conducted annually; the data used in the analysis is to be updated as appropriate; the results of the analysis are to be incorporated into risk scores on a timely basis; and the application of an adjustment for differences in coding patterns was extended past 2010 indefinitely. Further, the ACA provides for minimum adjustments for MA coding in future years.

Our changes to § 422.252, § 422.258, and § 422.266 codify section 1102 of the ACA, which links county benchmarks to FFS costs and provides eligible plans with a quality bonus. These provisions will lower payments from us, bringing MA payments in line with FFS payments. The new provisions will also generally reduce MA rebates and benchmarks for plans and thereby result in less generous benefit packages. We estimate that the Federal government will save approximately $40.56 billion from FY 2011 to FY 2014. The Federal government will save approximately $76.470 billion from the FY 2011 to FY 2016. The year-by-year savings in millions of dollars are shown in Table 10.

p. Quality Bonus Appeals (§ 422.260)

We estimate a minimal overall impact as a result of this provision, as we expect only a minority of MA organizations to take advantage of the opportunity to appeal CMS' annual quality rating. Of those organizations that do appeal their rating, a minimal number of professional staff working over a short period of time would be required to prepare and present an organization's appeal.

We estimate that the total annual hourly burden for developing and presenting a case to us for review is equal to the number of organizations likely to request an appeal multiplied by the number of hours for the attorneys of each appealing MA organization to research, draft, and submit their arguments to CMS. Based on the star rating distributions of previous contract years, out of the approximately 350 MA contracts that are subject to star rating analysis (that is, those not excluded from analysis because of low enrollment, contract type not required to report data, or new contract with no performance history), approximately 250 may receive less than a four-star rating. We estimate that 10 percent of those contracts (25) will request an appeal of their rating under the final rule. We further estimate that one attorney working for eight hours could complete the documentation to be submitted to us for each contract, resulting in a total burden estimate of 200 hours (8 hours × 25 contracts = 200 hours). The estimated annual cost to MA organizations associated with this provision (assuming an attorney billing rate of $250 per hour) is $50,000 (200 hours × $250 = $50,000). Our intent in finalizing this provision is to ensure that MA organizations are afforded the benefit of reasonable opportunity to challenge CMS determinations that ultimately affect an organization's payments from the Medicare Trust Fund. Granting organizations an avenue to challenge CMS' determinations will enhance the transparency and credibility of the process CMS uses to determine the recipients of quality bonus payments.

q. Timely Transfer of Data and Files When CMS Terminates a Contract With a Part D Sponsor (§ 423.509)

We anticipate minimal financial impact from our requirement that terminated Part D plan sponsors help to effectuate a smooth transition for their enrollees by providing CMS with Medicare beneficiary data including information to identify each affected beneficiary, pharmacy claims files, true out-of-pocket (TrOOP) cost balances, and information concerning pending grievances and appeals.

We estimate that the total annual burden for this provision to be the cost of maintaining sufficient staff to transfer the data required under § 423.509. As a result, we estimate the total annual burden to be the number of Part D sponsors we anticipate terminating in a contract year (2) × the hourly rate of staff to transfer the required data ($75/hour) × the number of hours required to provide data to us (20 hours). Therefore, the estimated annual cost associated with these requirements is $3,000. We do not anticipate that this provision will

result in a financial benefit to the terminated Part D sponsor.

r. Review of Medical Necessity Decisions by a Physician or Other Health Care Professional and the Employment of a Medical Director (§ 422.562, § 422.566, § 423.562, and § 423.566)

We are modifying the language in the proposed rule with respect to the requirement for a physician or other health care professional to review initial determinations involving medical necessity. Under this final rule, if the plan expects to issue a partially or fully adverse decision based on the initial review of the request, a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, must review the request for medical necessity before the plan issues its decision.

We are finalizing our modifications to § 422.562, § 422.566, § 423.562, and § 423.566 to require MA organizations and Part D plan sponsors to employ a medical director. We estimate that 95 percent of MA organizations and Part D sponsors already have a medical director overseeing decisions of medical necessity. Therefore, we believe that there will be no increase in cost for the majority of MA organizations and Part D sponsors. We anticipate that 5 percent of MA organizations and Part D sponsors will incur a financial impact as a result of this provision.

Of the 5 percent of MA organizations and Part D sponsors that do not currently employ a medical director, we estimate that the total annual burden for employing a medical director is equal to 5 percent of the number of MA organization and Part D sponsors (757), which equals 38 organizations and sponsors, at a salary of $250,000 per year. Therefore, the estimated annual cost associated with these requirements is $9,500,000.

We believe this approach balances the need to ensure proper medical review of initial coverage determinations with the ability of MA organizations and Part D plan sponsors to manage health care professional staff resources. We believe these provisions will enhance medical review activities and overall coordination and accountability of plan operations.

s. Agent and Broker Training Requirements (§ 422.2274 and § 423.2274)

Sections 422.2274(b) and (c) and 423.2274(b) and (c) require MA organizations' and Part D sponsors' agents and brokers to receive training and testing via a CMS endorsed or approved training program. We are considering implementing this requirement through a Request for Proposal (RFP) competitive process. The burden associated with this requirement is the time and effort put forth by plan sponsors and/or third party vendors to develop and submit their proposals for CMS review. We estimate that about 12 entities (plan sponsors and/or third party vendors) will submit a proposal annually and that the average estimated hours per entity to complete the proposal is 100 hours. The total estimated hourly burden associated with this requirement is equal to the estimated number of entities (12) multiplied by the estimated hours per entity (100) = 1,200 hours. We estimate the hourly labor cost for the preparer of the proposal will be $59.20 (based on the U.S. Department of Labor statistics for hourly wages for management analysts). The annual cost of proposal preparation is estimated to be $71,040 ($59.20 × 1200 hours).

t. Call Center Interpreter Requirements (§ 422.111 and § 423.128)

We estimate the cost for our call center requirements at the parent organization level because most parent organizations have one call center for all of their contracts. For the parent organizations that currently and consistently provide interpreters, their costs will not increase. Organizations that provide interpreters, but not consistently, will need to train their CSRs on how to use the interpreter service, which can be included in regularly scheduled training meetings at no increased cost. Lastly, we expect the cost for each of the two parent organizations that currently do not provide interpreters to increase by $9,933 per year. This estimated cost is based on 1–800–MEDICARE foreign language interpreter use, which is 4.5 percent of all calls. If 4.5 percent of calls could require an interpreter over the course of a standard 12-hour call center day, this would translate into using interpreter services for 33 minutes each day. Over the course of a year for the 301 days a call center is required to be open, and at a rate of $1.00 per minute, based on CMS market research in for interpreter costs, the cost for each of the two parent organizations would increase by $9,933 per year, which is $19,866 for both in FY 2012.

u. Customized Enrollee Data (§ 422.111 and § 423.128)

In proposed rule (75 FR 71261 through 71262), proposed § 422.111(b)(11) and § 423.128(b)(12) would require MA organizations and PDP sponsors to periodically provide each enrollee with enrollee-specific data to use to compare utilization and out-of-pocket costs in the current plan year to projected utilization and out-of-pocket costs for the following plan year. Plans would disclose this information to plan enrollees in each year in which a minimum enrollment period has been met, in conjunction with the annual renewal materials (currently the annual notice of change and evidence of coverage documents).

We estimated that the initial year burden associated with this requirement would be the time and effort necessary for a plan sponsor to complete program development and testing, and to disclose (print and mail) this information to each beneficiary. We developed this burden estimate using our experience with burden estimates for the ANOC/EOC documents under OMB control number (OCN) 0928–1051as a baseline, then expanding on that baseline, and factoring in expected programming and development costs to provide beneficiary specific information. We estimated the total annual burden hours associated with this provision at 18,620 hours for the 564 MA organizations and 85 Part D sponsors that would be affected annually by this requirement. Using the same wage/cost estimate as the ANOC/EOC documents, we applied an hourly wage cost for GS–10, step 1 analyst at an estimated cost of $27.24 per hour. Therefore, the estimated total initial year cost of this requirement is approximately $507,208.00.

In subsequent years, we estimated that the burden associated with this requirement would be the time and effort necessary for a plan sponsor to disclose (print and mail) this information to each beneficiary. We estimated the total annual burden hours associated with this provision at 12,555 hours for the 564 MA organizations and 85 Part D sponsors that would be affected annually by this requirement. At an estimated cost of $27.24 per hour, the estimated total initial year cost of this requirement would be approximately $342,000.

After considering comments on our proposed policy, we have modified both the final policy and our cost estimate, as described below.

Comment: Many commenters stated that a customized estimate of future costs would create significant administrative, financial, IT resource, and call center burdens on MA plans and Part D sponsors, much more than CMS has anticipated. They stated that the expense and operational burden of

the proposal cannot be justified economically or in value to beneficiaries, considering the potential for beneficiary confusion and dissatisfaction that may result from relying on estimated future costs. One commenter suggested that the significant costs of producing and distributing a custom statement will increase administrative costs that in turn may increase plan bids and result in a negative impact on benefits and or premiums. As discussed in section II.D.4 of this final rule, we received many comments on our proposal to authorize CMS to require MA organizations and Part D drug sponsors to periodically provide each enrollee with enrollee specific data to use to compare utilization and out-of-pocket costs in the current plan year to projected utilization and out-of-pocket costs for the following plan year.

Response: Based on the comments received, and our modified final policy, we have also recalculated our estimate of the burden based on the annual burden to Part D plan sponsors to furnish enrollees with an EOB for prescription drug benefits under OMB—0938–0964. MA organizations already collect enrollee utilization and cost-sharing information as part of their claims processing operations. In 2012, the burden associated with this proposed requirement would be the time and effort necessary for 564 MA organizations to complete program development and testing of an explanation of benefits when Part C benefits are provided, and to disclose (print and mail) this information to each beneficiary. Given that stand alone PDPs already produce an EOB in accordance with § 423.128(e), the revised burden estimate includes only MA organizations. We estimate that in the first year it will require each entity 200 hours on an annual basis to disseminate the required materials, for a total annual burden of 112,800 hours. This first year estimate builds from the estimated annual burden for the Part D EOB, expanding the total hour requirement to include additional hours required to initiate and complete program development and testing of an EOB. The estimated first year cost is $3,938,976. This estimate is based upon the hourly rate at the GS–11/step 6 ($34.92) multiplied by the number of burden hours (112,800).

In subsequent years, the burden associated with this requirement will be the time and effort necessary for about 564 MA organizations to provide an explanation of benefits when Part C benefits are provided to enrollees. We estimate that it will require each entity 160 hours on an annual basis to disseminate the required materials, for a total annual burden of 90,240 hours. The decreased estimate of burden hours relative to the first year reflects the completion of program development in the first year and brings the estimated hours in line with the current estimated number of hours for the Part D EOB. The estimated annual cost is $3,151,181. This estimate is based upon the hourly rate at the GS–11/step 6 ($34.92) multiplied by the number of burden hours (90,240).

The anticipated effect of our modified provision to require MA organizations to provide an explanation of Part C benefits would be greater access to individualized information for beneficiaries to track their own utilization of services and to use in making decisions about their enrollment and their health care options. While this new EOB requirement will result in less of a cost burden for MA plans than the burden of calculating out-of-pocket costs including an estimate of costs in the next plan year, we continue to believe that plans should already have the systems in place to collect the required out-of-pocket cost information as part of their claims processing operations and for calculating MOOP limits. Therefore, over time, we anticipate that plans would continue to refine and work to make their processes for disclosing this information as well as the annual notice of change, evidence of coverage, and other plan documents more efficient, thereby mitigating the burden in future years.

v. Extending the Mandatory Maximum Out-of-Pocket (MOOP) Amount Requirements to Regional PPOs (§ 422.100 and § 422.101)

Sections 422.100(f) and 422.101(d) extend the mandatory MOOP and catastrophic limit requirements to RPPO plans. Each RPPO plan must establish an annual MOOP limit on total enrollee cost sharing liability for Parts A and B services, the dollar amount of which would be set annually by CMS. All cost sharing (that is, deductibles, coinsurance, and copayments) for Parts A and B services will be included in RPPO plans' MOOPs. While this change is significant in that it will help beneficiaries to understand and anticipate their possible health care expenditures, as with the requirement to establish a mandatory MOOP for local MA plans, we do not believe that this change would by itself have a significant cost impact on RPPO plan participation or plan costs.

We estimate that any impact on enrollee premiums will be very limited for several reasons. First, since implementation of the MMA, RPPOs have been required to establish a MOOP for in-network cost sharing and a catastrophic limit; however those amounts are currently at the discretion of MA organizations offering RPPO plans. For FY 2011, we encouraged RPPO plans to adopt either the mandatory or voluntary MOOPs established in CMS guidance. For FY 2011, the voluntary MOOP limits for local PPO plans were set at $3,400 in-network and $5,100 catastrophic (in- and out-of-network), and the mandatory MOOP limits for local PPO plans were set for FY 2011 at $6,700 in-network and $10,000 catastrophic (in- and out-of-network). Based on data for FY 2011 approved bids, we found that only 3 regional PPO plans (4 percent of all RPPOs) did not meet or exceed our voluntary or mandatory in-network or catastrophic maximum out-of-pocket limits. Based on this information, it is our expectation that the impact on RPPO plans will be very small.

Second, it is our intention to continue setting both the MOOP and Parts A and B cost-sharing thresholds at levels that, while affording reasonable financial protection for those beneficiaries with high health care needs, do not result in significant new operating costs for MA plans or increased out-of-pocket costs for beneficiaries to the extent that MA plans pass along any increased costs to their enrollees in the form of premium increases. Given a competitive marketplace and Medicare beneficiary sensitivity to premium amounts, we believe that MA plans may choose instead to modify their benefit packages to reduce costs elsewhere. Furthermore, we estimated that beneficiaries in regional PPO plans that currently offer the FY 2011 voluntary or mandatory MOOP limits (about 92 percent of RPPO plans) would experience no cost increases as a result of these provisions. In our April 2010 final rule, we estimated that the maximum impact of these requirements on beneficiary premiums for those plans that currently have no MOOP limit of any kind (8 percent of all prospective FY 2011 RPPO plans) would average $5 in the absence of other adjustments to benefit packages to account for the annual MOOP requirements. However, in this case, the RPPO plans already offer MOOP and catastrophic limits, so we estimated that any premium impact would be less than $5.

By setting the parameters for the annual mandatory MOOP limit, we believe that we will make it easier for plans to compete on a level playing field.

w. Translated Marketing Materials (§ 422.2264 and § 423.2264)

Our final rule slightly modifies existing subregulatory guidance, so the impact to plan sponsors (MA organizations and PDP sponsors) depends upon whether, and to what extent, they are currently translating marketing materials. In the preamble, we indicate that moving to a 5 percent translation standard (from 10 percent) and focusing on the primary language spoken by individuals in the service area who have limited ability to read, write, speak, or understand English will result in a slight burden reduction. For 2011, 321 contract sponsors are required to translate marketing materials at the 10 percent translation standard. Under the 5 percent primary language translation standard, we used 2011 data to determine that sponsors would be required to translate marketing materials for only 305 contracts, which is 16 contracts fewer than under the 10 percent standard. In 2010, sponsors were required to provide translated marketing materials for 307 contracts. Because the number of contracts (307) from 2010 is extremely close to the revised number of contracts (305) that we estimate for 2011, we are not changing our impact estimate from the 2010 estimate. We acknowledge that the original estimates would have been higher if we had used 2011 data when originally compiling these estimates. At the beginning of 2010, we conducted a translated marketing material monitoring study in which preliminary findings revealed that some sponsors had produced a few materials. However, we do not yet know the specific number of sponsors that are providing all translated materials. Our research indicates that the average translation cost is 20 cents per word, and that will cost approximately $18,325 for a sponsor to produce all of the required plan materials in one language for the first year because there are approximately 17 documents containing 91,623 words for translation. In subsequent years, sponsors will only need to edit existing documents with the new data and any changes required by CMS, which could result in approximately 5 percent of the documents being changed. As a result, after the first year of translating all required documents, plan sponsors will need to spend $916 updating translated materials. Because we do not have final data from our translated materials study, we do not know what proportion of sponsors would have to develop a complete set of translated materials for the first year and what proportion would only need to update existing documents. Because not all required translated marketing materials are plan benefit package (PBP) specific, if a plan sponsor translates the document for one PBP, it could use the document for all PBPs offered that year. For the purpose of this analysis, we assume that the sponsors of all 307 contracts would have to translate all materials for the first year at a total cost of $5,625,775. In subsequent years, sponsors will only need to edit existing translated documents, which we estimate will cost a total of $281,212 annually for all sponsors. As mentioned in the preamble, CMS hopes to further reduce burden in the future by providing pretranslated model materials. However, as we do not have funding committed for this effort at this time, we have not changed the burden estimates to reflect this goal.

Comment: One industry commenter identified that this impact analysis did not include the cost of an employee's time involved with coordinating the translated materials effort.

Response: We did not include employee time because, as stated in the Collection of Information Requirements section of this final rule, the requirement to provide translated materials is not a new responsibility for Medicare Part C and D plans. We do not have complete data on which plan sponsors are providing translated materials, and which ones are not. The number of employees that would be involved with coordinating this effort is also unknown. Therefore, to err on the side of caution, we presumed all sponsors would have to develop first year translations. Thus, we believe the overall cost is an over estimate that would more than compensate for not including employee coordination time. We are therefore finalizing our proposed impact estimate without modification.

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Table 10: Estimated Costs and Savings by Provision for Fiscal Years 2011 Through 2016
($ in millions)2

Provision(s)	Regulation Section(s)	Fiscal Year 2011	2012	2013	2014	2015	2016	Total ($ in millions) (FYs 2011-2016)
Approval of SNPs by NCQA	§422.4 §422.101 and §422.152	1.75	1.24	1.24	1.24	1.24	1.24	7.95
Determination of Part D Low-Income Benchmark Premium	§423.780	90.00	120.00	130.00	140.00	140.00	150.00	770.00
Voluntary De Minimis Policy for Subsidy Eligible Individuals	§423.34 and §423.780	25.00	25.00	25.00	25.00	35.00	35.00	170.00
Increase In Part D Premiums Due to the Income Related Monthly Adjustment Amount (D-IRMAA)3	§423.44	-269.68	-269.68	-649.64	-899.61	-1139.60	-1349.59	-4,767.78
Elimination of Medicare Part D Cost-Sharing for Individuals Receiving Home and Community-Based Services	§423.772 and §423.782	0.03	0.02	0.02	0.02	0.02	0.02	0.14
Appropriate Dispensing of Prescription Drugs in Long-term Care Facilities Under PDPs and MA-PD Plans	§423.154	1.93	0.00	-10.00	-20.00	-30.00	-40.00	-98.07
Complaint System for Medicare Advantage Organizations and PDPs	§422.504 and §423.505	0.00	0.90	0.90	0.90	0.90	0.90	4.48
Uniform Exceptions and Appeals Process for Prescription Drug Plans and MA-PD Plans	§423.128(b)(7)(i)	0.00	3.23	3.23	3.23	3.23	3.23	16.15
	§ 423.128(d)	0.00	4.60	4.60	4.60	4.60	4.60	23.05
	§423.562(a)(3)	0.00	2.20	2.12	2.12	2.12	2.12	10.68
Including Costs Incurred by the AIDS Drug Assistance Program (ADAP) and the Indian Health Services (IHS) toward the Annual Part D Out-of-Pocket Threshold	§423.100 and §423.464	50.00	70.00	70.00	80.00	90.00	100.00	460.00
Cost Sharing for Medicare Covered Preventive Services	§417.454 and §422.100	0.00	27.10	27.10	28.40	31.00	34.30	147.90
Elimination of the Stabilization Fund	§422.458	0.00	0.00	0.00	-43.50	-63.40	-74.30	-181.20
Changes to Close the Part D Coverage Gap	§423.104 and §423.884	130.40	171.05	381.05	601.05	931.05	1,451.05	3,665.65
Medicare Advantage Benchmark, Quality Bonus Payments, and Rebate and Application of Coding Adjustment	§422.252 §422.258 §422.266 and §422.308	-5,260.00	-8,570.00	-11,890.00	-14,840.00	-16,860.00	-19,050.00	-76,470.00
Quality Bonus Appeals	§422.260	0.00	0.05	0.05	0.05	0.05	0.05	0.25
Timely Transfer of Data and Files When CMS Terminates a Contract with a Part D Sponsor	§423.509	0.00	0.004	0.005	0.006	0.007	0.00	0.02

2 Estimates of costs and savings reflect scoring by the Centers for Medicare and Medicaid Services, Office of the Actuary, and 2009 wage data from the United States Department of Labor, Bureau of Labor and Statistics.
3 Estimated total savings includes annual cost burden to all Part D sponsors (see section V.B.5. of this final rule).
4 Costs appear as zero due to rounding. CMS estimates actual costs of 0.003 million.

Provision(s)	Regulation Section(s)	Fiscal Year 2011	2012	2013	2014	2015	2016	Total ($ in millions) (FYs 2011-2016)
Review of Medical Necessity Decisions by a Physician or other Health Care Professional and the Employment of a Medical Director	§422.562, §422.566, §423.562 and §423.566	0.00	9.50	9.50	9.50	9.50	9.50	47.50
Agent and Broker Training Requirements	§422.2274 and §423.2274	0.00	0.07	0.07	0.07	0.07	0.07	0.36
Call Center Interpreter Requirements	§422.111 and §423.128	0.02	0.00	0.00	0.00	0.00	0.00	0.02
Customized Enrollee Data)	§422.111 and §423.128	0.00	3.94	3.15	3.15	3.15	3.15	16.54
Translated Marketing Materials	§422.2264 and §423.2264	5.63	0.28	0.28	0.28	0.28	0.28	7.03
Total		-5,224.92	-8,590.48	-11,891.33	-14,903.50	-16,840.79	-18,718.38	-76,169.39

5 Costs appear as zero due to rounding. CMS estimates actual costs of 0.003 million.
6 Costs appear as zero due to rounding. CMS estimates actual costs of 0.003 million.
7 Costs appear as zero due to rounding. CMS estimates actual costs of 0.003 million.

Table 11: Estimated Costs and Savings to the Federal Government by Provision for Fiscal Years 2011 through 2016 ($ in millions)[8]

Provision(s)	Regulation Section(s)	Fiscal Year 2011	2012	2013	2014	2015	2016	Total ($ in millions) (FYs 2011-2016)
Approval of SNPs by NCQA	§422.4 §422.101 and §422.152	1.40	0.89	0.89	0.89	0.89	0.89	5.85
Determination of Part D Low-Income Benchmark Premium	§423.780	90.00	120.00	130.00	140.00	140.00	150.00	770.00
Voluntary De Minimis Policy for Subsidy Eligible Individuals	§423.34 and §423.780	20.00	20.00	20.00	20.00	30.00	30.00	140.00
Increase In Part D Premiums Due to the Income Related Monthly Adjustment Amount (D-IRMAA)	§423.44	-270.00	-459.98	-649.96	-899.93	-1,139.92	-1,349.91	-4,769.70
Elimination of Medicare Part D Cost-Sharing for Individuals Receiving Home and Community-Based Services	§423.772 and §423.782	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Appropriate Dispensing of Prescription Drugs in Long-term Care Facilities Under PDPs and MA-PD Plans	§423.154	0.00	0.00	-10.00	-20.00	-30.00	-40.00	-100.00
Complaint System for Medicare Advantage Organizations and PDPs	§422.504 and §423.505	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Uniform Exceptions and Appeals Process for Prescription Drug Plans and MA-PD Plans	§423.128(b)(7)(i)	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	§ 423.128(d)	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	§423.562(a)(3)	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Including Costs Incurred by the AIDS Drug Assistance Program (ADAP) and the Indian Health Services (IHS) toward the Annual Part D Out-of-Pocket Threshold	§423.100 and §423.464	50.00	70.00	70.00	80.00	90.00	100.00	460.00
Cost Sharing for Medicare Covered Preventive Services	§417.454 and §422.100	0.00	27.10	27.10	28.40	31.00	34.30	147.90
Elimination of the Stabilization Fund	§422.458	0.00	0.00	0.00	-43.50	-63.40	-74.30	-181.20
Changes to Close the Part D Coverage Gap	§423.104 and §423.884	80.00	170.00	380.00	600.00	930.00	1,450.00	3,610.00
Medicare Advantage Benchmark, Quality Bonus Payments, and Rebate and Application of Coding Adjustment	§422.252 §422.258 §422.266 and §422.308	-5,260.00	-8,570.00	-11,890.00	-14,840.00	-16,860.00	-19,050.00	-76,470.00
Quality Bonus Appeals	§422.260	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Timely Transfer of Data and Files When CMS Terminates a Contract with a Part D Sponsor	§423.509	0.00	0.00	0.00	0.00	0.00	0.00	0.00

8 Estimates of costs and savings reflect scoring by the Centers for Medicare and Medicaid Services, Office of the Actuary, and 2009 wage data from the United States Department of Labor, Bureau of Labor and Statistics.

Provision(s)	Regulation Section(s)	Fiscal Year						Total ($ in millions) (FYs 2011-2016)
		2011	2012	2013	2014	2015	2016	
Review of Medical Necessity Decisions by a Physician or other Health Care Professional and the Employment of a Medical Director	§422.562, §422.566, §423.562 and §423.566	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Agent and Broker Training Requirements	§422.2274 and §423.2274	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Call Center Interpreter Requirements	§422.111 and §423.128	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Customized Enrollee Data)	§422.111 and §423.128	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Translated Marketing Materials	§422.2264 and §423.2264	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Total		-5,288.60	-8,621.99	-11,921.97	-14,394.14	-16,871.43	-18,749.02	-76,387.15

Table 12: Estimated Costs to MA Organizations and Part D Sponsors by Provision for Fiscal Years 2011 Through 2016 ($ in millions)[9]

Provision(s)	Regulation Section(s)	Fiscal Year 2011	2012	2013	2014	2015	2016	Total ($ in millions) (FYs 2011-2016)
Approval of SNPs by NCQA	§422.4 §422.101 and §422.152	0.35	0.35	0.35	0.35	0.35	0.35	2.10
Determination of Part D Low-Income Benchmark Premium	§423.780	0.0010	0.0011	0.0012	0.0013	0.0014	0.0015	0.0016
Voluntary De Minimis Policy for Subsidy Eligible Individuals	§423.34 and §423.780	5.00	5.00	5.00	5.00	5.00	5.00	30.00
Increase In Part D Premiums Due to the Income Related Monthly Adjustment Amount (D-IRMAA)	§423.44	0.32	0.32	0.32	0.32	0.32	0.32	1.92
Elimination of Medicare Part D Cost-Sharing for Individuals Receiving Home and Community-Based Services	§423.772 and §423.782	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Appropriate Dispensing of Prescription Drugs in Long-term Care Facilities Under PDPs and MA-PD Plans	§423.154	1.93	0.00	0.00	0.00	0.00	0.00	1.93
Complaint System for Medicare Advantage Organizations and PDPs	§422.504 and §423.505	0.00	0.90	0.90	0.90	0.90	0.90	4.48
Uniform Exceptions and Appeals Process for Prescription Drug Plans and MA-PD Plans	§423.128(b)(7)(i)	0.00	3.23	3,23	3.23	3.23	3.23	16.15
	§ 423.128(d)	0.00	4.60	4.60	4.60	4.60	4.60	23.00
	§423.562(a)(3)	0.00	2.20	2.12	2.12	2.12	2.12	10.68
Including Costs Incurred by the AIDS Drug Assistance Program (ADAP) and the Indian Health Services (IHS) toward the Annual Part D Out-of-Pocket Threshold	§423.100 and §423.464	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Cost Sharing for Medicare Covered Preventive Services	§417.454 and §422.100	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Elimination of the Stabilization Fund	§422.458	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Changes to Close the Part D Coverage Gap	§423.104 and §423.884	50.40	1.05	1.05	1.05	1.05	1.05	55.65

9 Estimates of costs and savings reflect scoring by the Centers for Medicare and Medicaid Services, Office of the Actuary, and 2009 wage data from the United States Department of Labor, Bureau of Labor and Statistics.

10 Costs appear as zero due to rounding. CMS estimates actual costs of 0.0006 million.

11 Costs appear as zero due to rounding. CMS estimates actual costs of 0.0006 million.

12 Costs appear as zero due to rounding. CMS estimates actual costs of 0.0006 million.

13 Costs appear as zero due to rounding. CMS estimates actual costs of 0.0006 million.

14 Costs appear as zero due to rounding. CMS estimates actual costs of 0.0006 million.

15 Costs appear as zero due to rounding. CMS estimates actual costs of 0.0006 million.

16 Costs appear as zero due to rounding. CMS estimates actual costs of 0.0036 million.

Provision(s)	Regulation Section(s)	Fiscal Year 2011	2012	2013	2014	2015	2016	Total ($ in millions) (FYs 2011-2016)
Medicare Advantage Benchmark, Quality Bonus Payments, and Rebate and Application of Coding Adjustment	§422.252 §422.258 §422.266 and §422.308	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Quality Bonus Appeals	§422.260	0.00	0.05	0.05	0.05	0.05	0.05	0.25
Timely Transfer of Data and Files When CMS Terminates a Contract with a Part D Sponsor	§423.509	0.00	0.00	0.00	0.00	0.00	0.00	0.02
Review of Medical Necessity Decisions by a Physician or other Health Care Professional and the Employment of a Medical Director	§422.562, §422.566, §423.562 and §423.566	0.00	9.50	9.50	9.50	9.50	9.50	47.50
Agent and Broker Training Requirements	§422.2274 and §423.2274	0.00	0.07	0.07	0.07	0.07	0.07	0.36
Call Center Interpreter Requirements	§422.111 and §423.128	0.02	0.00	0.00	0.00	0.00	0.00	0.02
Customized Enrollee Data	§422.111 and §423.128	0.00	3.94	3.15	3.15	3.15	3.15	16.54
Translated Marketing Materials	§422.2264 and §423.2264	5.63	0.28	0.28	0.28	0.28	0.28	7.03
Total		63.65	31.49	30.62	30.62	30.62	30.62	217.62

Table 13: Estimated Costs and Savings to States by Provision for Fiscal Years 2011 Through 2016 ($ in millions)

Provision (s)	Regulation Section(s)	Fiscal Year 2011	2012	2013	2014	2015	2016	Total ($ in millions) (FYs 2011-2016)
Elimination of Medicare Part D Cost-Sharing for Individuals Receiving Home and Community-Based Services	§423.772 and §423.782	0.03	0.02	0.02	0.02	0.02	0.02	0.14

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2. Expected Effects on Beneficiaries

a. Cost Sharing for Specified Services at Original Medicare Levels (§ 417.454 and 422.100)

We believe that the requirement that MA plan cost sharing may not exceed that required under Original Medicare for chemotherapy services, renal dialysis services, and skilled nursing facility care will provide additional transparency and cost sharing and predictability for beneficiaries as they evaluate their health plan options, and also will strengthen our beneficiary protections against discriminatory cost sharing and benefit designs.

b. Approval of SNPs by NCQA (§ 422.4, § 422.101, and § 422.152)

We believe that our requirement that all SNPs be approved by NCQA based on evaluation of each plan's model of care (MOC) will result in SNP options that are appropriate for special needs beneficiaries and address their targeted populations' particular health care needs. SNP MOCs provide the structure for care management processes and systems that enable SNPs to provide coordinated care for special needs individuals. By ensuring that these documents provide an adequate framework for coordinated care for the vulnerable beneficiaries eligible to enroll in SNPs through the NCQA SNP approval process, we believe the quality of care under SNPs will be positively impacted.

c. Determination of Part D Low-Income Benchmark Premium (§ 423.780)

This final rule supports pharmacy and formulary consistency for the beneficiary. Particularly in regions with high MA–PD penetration, this final rule will reduce the year-to-year volatility in reassignments of LIS beneficiaries and would help avoid the disruption that is inherent anytime a beneficiary is switched from one plan to another.

d. Voluntary De Minimis Policy for Subsidy Eligible Individuals (§ 423.34 and § 423.780)

The voluntary de minimis provisions permit Part D plans to volunteer to waive a de minimis amount of the Part D premium above the low income benchmark and, thus, avoid losing LIS beneficiaries to reassignment. We perform reassignments to ensure that beneficiaries whom we originally assigned to a zero premium plan will not incur a new premium liability when their current plan's premium goes above the LIS benchmark in the following year. The number of reassignments has ranged between 1 and 2 million over each of the past 4 years. While reassignments are effective at avoiding new premium liabilities, they can create confusion and disrupt continuity of care. We expect that the de minimis provisions will reduce reassignments.

e. Increase in Part D Premiums Due to the Income Related Monthly Adjustment Amount (D–IRMAA) (§ 423.44, § 423.286, § 423.293)

Beginning in CY 2011, we estimate that approximately 1.05 million of the 29.2 million Medicare beneficiaries enrolled in the Part D program will exceed the minimum income threshold amount and will be assessed an income related monthly adjustment amount. During calendar year 2011, we expect that implementation of the Part D—IRMAA provisions, at § 423.286(d)(4) and § 423.293(d), will increase the Medicare Trust Fund by $270 million, with a net increase to the Medicare Trust Fund over a 5-year period from FY 2011 through FY 2016 of $4.77 billion. The Part D—IRMAA 2011 income levels and premium adjustment amounts are as follows:

	Beneficiaries who file individual tax returns with income that is:	**Beneficiaries who file joint tax returns with income that is:**	**Part D-Income Related Monthly Adjustment Amount will be:**
Income Threshold Tier 1	Less than or equal to $85,000	Less than or equal to $170,000	$0.00
Income Threshold Tier 2	Greater than $85,000 and less than or equal to $107,000	Greater than $170,000 and less than or equal to $214,000	$12.00
Income Threshold Tier 3	Greater than $107,000 and less than or equal to $160,000	Greater than $214,000 and less than or equal to $320,000	$31.10
Income Threshold Tier 4	Greater than $160,000 and less than or equal to $214,000	Greater than $320,000 and less than or equal to $428,000	$50.10
Income Threshold Tier 5	Greater than $214,000	Greater than $428,000	$69.10

	Beneficiaries who are married but file separate tax returns from their spouses with income that is:	**Part D-Income Related Monthly Adjustment Amount will be:**
Income Threshold Tier 1	Less than or equal to $85,000	$0.00
Income Threshold Tier 2	Greater than $85,000 and less than or equal to $129,000	$50.10
Income Threshold Tier 3	Greater than $129,000	$69.10

Approximately 3.6 percent of Medicare beneficiaries will be impacted. We estimate that the number of beneficiaries impacted per tier will be as follows:

Income Threshold	Estimated number of beneficiaries impacted
Tier 1	0
Tier 2	397,249
Tier 3	340,147
Tier 4	123,002
Tier 5	192,945

f. Elimination of Medicare Part D Cost-Sharing for Individuals Receiving Home and Community-Based Services (§ 423.772 and § 423.782)

The expected benefit of the elimination of the Medicare Part D cost-sharing for individuals receiving home and community based services provision is greater access to prescription drug coverage for a population that traditionally has high medical needs. These individuals are already eligible for the full low income subsidy, and likely qualify for the $1.10/$3.30 copayment level now. The elimination of the copayment will provide financial relief for those who are able to pay at that level and greater access for those who are not.

g. Appropriate Dispensing of Prescription Drugs in Long-Term Care Facilities under PDPs and MA–PD Plans (§ 423.154) and Dispensing Fees (§ 423.100)

We expect that Part D enrollees who use a 14-day supply (or less) of Part D drugs described in the requirements under section 423.154 (a) will benefit from the savings resulting from a reduction in cost sharing that would be associated with a full 30-day supply whenever a Part D drug is discontinued within the first 2 weeks from the start date of the drug. We would expect that many drugs discontinued due to adverse drug reactions or side effects will be discontinued within the first 2 weeks. In addition, Part D enrollees residing in LTC facilities that elect to use more efficient dispensing systems, such as automated dose dispensing, may also benefit from additional interactions with nursing staff a result of decreased medication preparation time associated with automated dose dispensing. Over time, we expect a decrease in drug expenditures in the Part D program will be reflected by a reduction in Part D premiums.

h. Complaint System for Medicare Advantage Organizations and PDPs (§ 422.504(a) and § 423.505(b))

We expect this provision to reduce the volume of calls using 1–800–MEDICARE as members will have online access to the complaint tracking system to file complaints regarding their MA or prescription drug benefit plan. We also expect the provision will benefit Medicare beneficiaries by offering another means for them to file their complaints. Electronic complaint filing should also save time for those beneficiaries who choose to use this method.

i. Uniform Exceptions and Appeals Process for Prescription Drug Plans and MA–PD Plans (§ 423.128, and § 423.562)

We expect that as a result of implementation of this provision, beneficiaries and the health care providers or representatives that assist them will benefit from a more streamlined approach to the exceptions and appeals process than what is in place currently. They will have access to the appeals process via a Web site or a customer call center, if their plan sponsor has not already adopted this approach.

j. Including Costs Incurred by the AIDS Drug Assistance Program (ADAP) and the Indian Health Services (IHS) Toward the Annual Part D Out-of-Pocket Threshold (§ 423.100 and § 423.464)

Prior to implementation of this provision, beneficiaries in both programs had difficulty reaching the catastrophic phase of the Part D benefit. This provision will not only enable beneficiaries to reach the catastrophic limit where they will experience significant reductions to their drug costs, but will relieve the ADAPs and IHS from incurring excessive prescription costs.

k. Cost Sharing for Medicare Covered Preventive Service (§ 417.454 and § 422.100)

We believe that our requirement for MA organizations and section 1876 cost plans to provide in-network Medicare-covered preventive benefits at zero cost sharing puts MA enrollees on a level playing field with enrollees in Original Medicare. Furthermore, we believe that the increased emphasis on provision of preventives services will result in improved beneficiary well-being and subsequently decrease their need for, and utilization of, more costly medical and surgical interventions, and possibly in decreased overall program costs.

l. Elimination of the Stabilization Fund (§ 422.458)

As previously stated, the formal elimination of the fund will have little or no impact on the current operation of the MA program. Thus, we do not believe this provision will have any impact on beneficiaries.

m. Improvements to Medication Therapy Management Programs (§ 423.153)

We expect that beneficiaries will benefit from this provision. Standardized formats for the action plan and summary resulting from annual Comprehensive Medication Reviews (CMR) will enable beneficiaries to have a better understanding of the CMR review findings and recommendations. Also, the opportunity for sponsors to use telehealth technology will improve access to MTM services for beneficiaries, particularly those in remote locations or unable to travel.

n. Changes To Close the Part D Coverage Gap (§ 423.104 and § 423.884)

Under these provisions to close the Part D coverage gap, beneficiaries would pay less for drugs in the coverage gap, and would reach the out-of-pocket threshold earlier in the benefit year. We expect that, because beneficiaries should find their prescription drugs

more affordable, there would be greater adherence to drug therapies and fewer instances of adverse health outcomes arising from failure to take medications as prescribed.

o. Medicare Advantage Benchmark, Quality Bonus Payments, and Rebate and Application of Coding Adjustment (§ 422.252, § 422.258 and § 422.266, and § 422.308)

We have not determined an impact on beneficiaries as a result of this provision.

p. Quality Bonus Appeals (§ 422.260)

While we expect the QBP system will encourage and incentivize MA plans to transform their delivery systems and processes to provide beneficiaries with high-quality and efficient care, we do not anticipate the QBP appeals process will have any effect on beneficiaries.

q. Timely Transfer of Data and Files When CMS Terminates a Contract With a Part D Sponsor (§ 423.509)

Our intent in implementing this provision is to ensure that terminated Part D plan sponsors transfer to CMS the necessary data to provide a smooth transition for beneficiaries into a new Part D plan similar to when the Part D sponsor terminates the contract or CMS and the Part D plan sponsor mutually terminate the contract. We anticipate that this provision will benefit beneficiaries by ensuring that TrOOP and gross covered drug cost data are transferred from the terminated plan to the beneficiaries' new plan, enabling the members to be correctly positioned in the new plan's benefit.

r. Review of Medical Necessity Decisions by a Physician or other Health Care Professional and the Employment of a Medical Director (§ 422.562, § 422.566, § 423.562, and § 423.566)

We are modifying the language in the proposed rule with respect to the requirement for a physician or other health care professional to review initial determinations involving medical necessity. Under this final rule, if the plan expects to issue a partially or fully adverse decision based on the initial review of the request, a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, must review the request for medical necessity before the plan issues its decision. This requirement will favorably impact beneficiaries by ensuring their requests for coverage receive medical review by an individual with appropriate clinical expertise, without imposing any burden on beneficiaries because the requirements for requesting an organization or coverage determination are not modified by this requirement.

s. Agent and Broker Training Requirements (§ 422.2274 and § 423.2274)

Requiring all agents and brokers to receive training and testing via a CMS endorsed or approved training program will further ensure that beneficiaries are educated about Medicare health plan options by plan agents and brokers who are thoroughly and consistently trained on the fundamentals of Medicare regulations. We believe that such thorough and consistent training will help ensure that beneficiaries receive accurate information about their Medicare health care options and make the best choices about their health care coverage options for their particular health care needs.

t. Call Center Interpreter Requirements (§ 422.111 and § 423.128)

The expected benefit of our call center interpreter requirements is that all beneficiaries, regardless of language spoken, will have access to all the information they need to make appropriate decisions about their health care to utilize their Medicare benefits most effectively.

u. Customized Enrollee Data (§ 422.111 and § 423.128)

We believe that our requirement that MA organizations send enrollees an explanation of benefits will ensure that the beneficiaries periodically receive information about their Part C utilization and out-of-pocket costs to help them make the best choices about their health care coverage options for their particular health care needs.

v. Extending the Mandatory Maximum Out-of-Pocket (MOOP) Amount Requirements to Regional PPOs (§ 422.100 and § 422.101)

We believe extending the mandatory MOOP requirement to RPPOs will provide significant protection for MA enrollees from out-of-pocket costs so that beneficiaries will better understand and anticipate their out-of-pocket expenditures. This requirement increases transparency for beneficiaries, and will ensure all RPPO plan enrollees are protected against high out-of-pocket costs and are better able to compare plans by focusing on differences in premium and plan quality.

w. Translated Marketing Materials (§ 422.2264 and § 423.2264)

The expected benefit of our requirement to codify existing subregulatory guidance with respect to translated marketing materials is to help limited-English proficient beneficiaries obtain access to the information they need to make appropriate decisions about their health care to utilize their Medicare benefits most effectively.

Comment: One commenter indicated that the impact analysis in the proposed rule improperly indicated that we would be helping *all* beneficiaries have access to translated materials.

Response: We agree with the commenter, and have revised the impact discussion in this final rule to remove language insinuating that *all* beneficiaries speaking *all* languages will have access to translated materials.

E. Alternatives Considered

The alternatives that were considered are summarized as follows.

1. Cost Sharing for Specified Services at Original Medicare Levels (§ 417.454 and § 422.100)

We considered using the authority granted to the Secretary by section 3202 to limit MA cost sharing for service categories in addition to those specified in the ACA. However, we decided that it is preferable to restrict our implementation of section 3202 of the ACA to the specified service categories, allowing ourselves time to evaluate the effects of those provisions, as well as other recently-established policies before using the new authority to adopt those cost sharing limits for an expanded list of service categories.

Although we proposed to use our authority under sections 1856(b)(1) and 1857(e)(1) of the Act to limit the cost sharing for home health services to Original Medicare levels we have decided not to finalize our proposal, as discussed elsewhere in this final rule.

2. Cost Sharing for Medicare-Covered Preventive Services (§ 417.454 and § 422.100)

We are proposing to implement regulations to require MA organizations and 1876 cost plans to provide in-network Medicare-covered preventive benefits at zero cost sharing, consistent with the new regulations for Original Medicare-covered preventive benefits. More specifically, we are requiring that all MA organizations provide Medicare-covered preventive services, as specified by CMS, without enrollee cost sharing charges.

We considered allowing plans to charge cost sharing for Medicare-

covered preventive services or to voluntarily adopt zero cost sharing for the specified preventive services. We determined that in light of the importance of preventive services in managed and coordinated care, and the requirements at section 1852(a)(1)(A) of the Act (except as provided in section 1859(b)(3) of the Act for MSA plans and in section 1852(a)(6) of the Act for MA regional plans) that each MA plan must provide to its members all Parts A and B benefits included under the Original Medicare fee-for-service program as defined at section 1852(a)(1)(B) of the Act, that requiring the same level of cost sharing for the specified preventive services for enrollees of Medicare health plans as required under Original Medicare would be the more appropriate policy.

3. Quality Bonus Appeals (§ 422.260)

We considered not affording bonus payment appeal rights to MA organizations. We rejected this option partly in recognition of the obligation the law generally imposes on us to afford entities affected by CMS determinations concerning contract performance or payment to have an opportunity to challenge such determinations. We also believe, as noted previously, that the appeals process promotes fairness in and enhances the credibility of the bonus payment determination process.

4. Timely Transfer of Data and Files When CMS Terminates a Contract With a Part D Sponsor (§ 423.509)

We did not consider alternatives to our provision regarding the timely transfer of data and files following the CMS termination of a Part D sponsor's contract. These data are necessary for the proper adjudication of all Part D benefits when a beneficiary changes plans, such as calculating the true out-of-pocket cost and determining whether the beneficiary has any outstanding claims for which the terminating contract is responsible. Because of these important beneficiary protections, we did not consider alternatives to these requirements.

5. Review of Medical Necessity Decisions by a Physician or Other Health Care Professional and the Employment of a Medical Director (§ 422.562, § 422.566, § 423.562, and § 423.566)

We did not consider alternatives regarding review of medical necessity decisions by a physician or other health care professional and employment of a medical director, as a majority of MA organizations and Part D sponsors already employ a medical director to oversee decisions of medical necessity. As noted previously, we are modifying our proposed rule language on the requirement for a physician or other health care professional to review initial determinations involving medical necessity. Under this final rule, if the plan expects to issue a partially or fully adverse decision based on the initial review of the request, a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, must review the request for medical necessity before the plan issues its decision.

6. Agent and Broker Training Requirements (§ 422.2274 and § 423.2274)

Sections 422.2274(b) and (c) and 423.2274(b) and (c) require MA organizations' and Part D sponsors' agents and brokers to receive training and testing via a CMS-endorsed or -approved training program. The alternative we considered was to continue to allow plans to conduct training and testing on their own or through third party vendor(s) and for CMS to continue to review some of these training programs upon request by third party vendors for comprehensiveness and accuracy. However, we believe that it is in the best interest of beneficiaries who are educated about Medicare health plan options by plan agents and brokers that those agents and brokers be consistently and thoroughly trained on the fundamentals of Medicare regulations. We believe the best method to achieve this end is to require agents and brokers to receive training and testing through one or more CMS-endorsed or -approved training programs.

7. Call Center Interpreter Requirements (§ 422.111 and § 423.128)

Compliance with Title VI of the Civil Rights Act of 1964 to serve all individuals regardless of national origin is a contractual requirement for MA and Part D sponsors; therefore, we did not consider any other alternatives to our call center interpreter requirements.

8. Customized Enrollee Data (§ 422.111 and § 423.128)

In our November 2010 proposed rule (75 FR 71249 through 71250), we considered an alternative to require MA organizations and PDP sponsors to provide each enrollee with specific data to use to compare utilization and out-of-pocket costs in the current plan year to projected utilization and out-of-pocket costs for the following plan year. We further considered requiring plans to disclose this information to plan enrollees in each year in which a minimum enrollment period has been met, in conjunction with the annual renewal materials (currently the annual notice of change/evidence of coverage, or ANOC/EOC). However, we are not finalizing this policy alternative in our final rule. Instead, as discussed in section II.D.4 of this final rule, we intend to work with MA organizations, Part D sponsors and beneficiary advocates to develop an explanation of benefits for Part C benefits modeled after the EOB currently required for Part D enrollees at § 423.128(e).

9. Extending the Mandatory Maximum Out-of-Pocket (MOOP) Amount Requirements to Regional PPOs (§ 422.100 and § 422.101)

The alternative we considered was not extending the mandatory MOOP and catastrophic limit requirements to RPPO plans, but instead to permit plans to continue to establish their own in-network MOOP and catastrophic limits without a maximum limit set by CMS while encouraging them to adopt either the mandatory or voluntary MOOPs established in CMS guidance. However, as we discussed in our April 2010 final rule, (75 FR 19711), we believe RPPOs should be subject to the same requirements with respect to a MOOP as local PPO plans. As discussed elsewhere in this preamble, we believe that the alternative chosen will make it easier for beneficiaries to understand and compare MA plans and will provide significant protection for MA enrollees from out of pocket costs.

10. Translated Marketing Materials (§ 422.2264 and § 423.2264)

Compliance with Title VI of the Civil Rights Act of 1964 to serve all individuals regardless of national origin is a contractual requirement for MA and Part D sponsors. Therefore, we did not consider any other alternatives to our translated marketing materials requirements.

Comment: One commenter was concerned that we did not consider any alternatives to codifying the existing population-based translation threshold stated in our subregulatory guidance (that is, the 10 percent translation standard).

Response: In response to numerous comments regarding the translation standard itself, we conducted several analyses using 2011 plan service area data and the most recent American Community Survey datasets. We analyzed the effect of keeping our standard at 10 percent, the effect of

moving to a 10 percent standard focusing on primary language, the effect of moving to 5 percent standard focusing on primary language, the effect of moving to a simple 5 percent standard, and the effect of using a 5 percent or 500 person standard. After reviewing the results from these sensitivity analyses, we determined that a 5 percent threshold that focuses on primary language spoken would be the most appropriate approach for beneficiaries and plans. We are therefore maintaining this 5 percent threshold in the final rule.

11. Increases to the Applicable Percentage for Quality (§ 422.258(d))

The ACA requires a 5-star rating system. We considered whether the 5-star rating system should be consistent with the current 5-star rating system in place for beneficiary choice or should be a separate system. We believe that plans should be rated the same for consumer choice and payment. There should not be two different systems to rate the quality and performance of MA plans. Thus, the plan ratings are the basis for the star rating system for quality bonus payments.

F. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 14, we have prepared an accounting statement showing the classification of the costs, benefits, and transfers associated with the provisions of this final rule. The accounting statement is based on estimates provided in Tables H10 through 13, (our best estimate of the costs, savings, and transfers as a result of the changes) and discounted at the 7 percent and 3 percent for the time period of FY 2011 through FY 2016.

TABLE 14--Accounting Statement: Classification of Estimated Costs, Savings, and Transfers from FY 2011 to FY 2016 ($ in Millions)

Category	TRANSFERS			
	Year Dollar	Units Discount Rate		Period Covered
		7%	3%	
Annualized Monetized Transfers	2011	-$12,193.50	-$12,496.54	FYs 2011-2016
From Whom To Whom?	Federal Government to MA organizations and Part D Sponsors			
	COSTS			
	Year Dollar	Units Discount Rate		Period Covered
Annualized Costs to MA organizations and Part D Sponsors		7%	3%	
	2011	$37.19	$36.63	FYs 2011-2016
Annualized Costs to States	2011	$0.02	$0.02	FYs 2011-2016

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, and Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services announces the effective date of June 6, 2011 for amendments to 42 CFR 422.564, 422.624, and 422.626 published April 4, 2003 at 68 FR 16652 and further 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: 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.

Subpart J—Qualifying Conditions for Medicare Contracts

■ 2. Section 417.402 is amended by revising paragraph (c) introductory text to read as follows:

§ 417.402 Effective date of initial regulations.

* * * * *

(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, 2013, where—

* * * * *

Subpart K—Enrollment, Entitlement, and Disenrollment Under Medicare Contract

■ 3. Section 417.430 is amended as follows:

■ A. Revising the paragraph heading for paragraph (a).

■ B. Revising paragraphs (a)(1), (b)(3), and (b)(4).

§ 417.430 Application procedures.

(a) *Application forms and other enrollment mechanisms.* (1) The application form must comply with CMS instructions regarding content and format and be approved by CMS. The application must be completed by an HMO or CMP eligible (or soon to become eligible) individual and include authorization for disclosure between the HHS and its designees and the HMO or CMP.

* * * * *

(b) * * *

(3) The HMO or CMP gives the beneficiary prompt notice of acceptance or denial in a format specified by CMS.

(4) The notice of acceptance. If the HMO or CMP is currently enrolled to capacity, explains the procedures that will be followed when vacancies occur.

* * * * *

4. Section 417.454 is amended by adding paragraphs (d) and (e) to read as follows.

§ 417.454 Charges to Medicare enrollees.

* * * * *

(d) *Limit on charges for specified preventive services.* An HMO may not charge deductibles, copayments, or coinsurance for in-network Medicare-covered preventive services (as defined in § 410.152(l)).

(e) *Services for which cost sharing may not exceed cost sharing under original Medicare.* On an annual basis, CMS will evaluate whether there are service categories for which HMOs' cost sharing may not exceed that required under original Medicare and specify in regulation which services are subject to that cost sharing limit. The following services are subject to this limit on cost sharing:

(1) Chemotherapy administration services to include chemotherapy drugs and radiation therapy integral to the treatment regimen.

(2) Renal dialysis services as defined at section 1881(b)(14)(B) of the Act.

(3) Skilled nursing care defined as services provided during a covered stay in a skilled nursing facility during the period for which cost sharing would apply under Original Medicare.

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 5. 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).

Subpart A—General Provisions

■ 6. Section 422.2 is amended by adding the definitions of "fiscally sound operation," "fully integrated dual eligible special needs plan," and "senior housing facility plan" in alphabetical order to read as follows:

§ 422.2 Definitions.

* * * * *

Fiscally sound operation means an operation which at least maintains a positive net worth (total assets exceed total liabilities).

* * * * *

Fully integrated dual eligible special needs plan means a CMS approved MA–PD dual eligible special needs plan that—

(1) Enrolls special needs individuals entitled to medical assistance under a Medicaid State plan, as defined in section 1859(b)(6)(B)(ii) of the Act and § 422.2;

(2) Provides dual eligible beneficiaries access to Medicare and Medicaid benefits under a single managed care organization;

(3) Has a capitated contract with a State Medicaid agency that includes coverage of specified primary, acute, and long-term care benefits and services, consistent with State policy;

(4) Coordinates the delivery of covered Medicare and Medicaid health and long-term care services using aligned care management and specialty care network methods for high-risk beneficiaries; and

(5) Employs policies and procedures approved by CMS and the State to coordinate or integrate member materials, enrollment, communications, grievance and appeals, and quality improvement.

* * * * *

Senior housing facility plan means an MA coordinated care plan that—

(1) Restricts enrollment to individuals who reside in a continuing care retirement community as defined in § 422.133(b)(2);

(2) Provides primary care services onsite and has a ratio of accessible physicians to beneficiaries that CMS determines is adequate consistent with prevailing patterns of community health care referenced at § 422.112(a)(10);

(3) Provides transportation services for beneficiaries to specialty providers outside of the facility; and

(4) Was participating as of December 31, 2009 in a demonstration established by CMS for not less than 1 year.

* * * * *

■ 7. Section 422.4 is amended as follows:

■ A. Revising paragraphs (a)(1)(iii) and (iv).

■ B. Adding paragraph (a)(1)(vi).

The revisions and additions read as follows:

§ 422.4 Types of MA plans.

* * * * *

(a) * * *

(1) * * *

(iii) Coordinated care plans include plans offered by any of the following:

(A) Health maintenance organizations (HMOs);

(B) Provider-sponsored organizations (PSOs), subject to paragraph (a)(1)(vi) of this section.

(C) Regional or local preferred provider organizations (PPOs) as specified in paragraph (a)(1)(v) of this section.

(D) Other network plans (except PFFS plans).

(iv) A specialized MA plan for special needs individuals (SNP) includes any type of coordinated care plan that meets CMS's SNP requirements and exclusively enrolls special needs individuals as defined by § 422.2 of this subpart. All MA plans wishing to offer a SNP will be required to be approved by the National Commission on Quality Assurance (NCQA) effective January 1, 2012. This approval process applies to existing SNPs as well as new SNPs joining the program. All SNPs must submit their model of care (MOC) to CMS for NCQA evaluation and approval as per CMS guidance.

* * * * *

(vi) In accordance with § 422.370, CMS does not waive the State licensure requirement for organizations seeking to offer a PSO.

* * * * *

Subpart B—Eligibility, Election, and Enrollment

■ 8. Add § 422.53 to read as follows:

§ 422.53 Eligibility to elect an MA plan for senior housing facility residents.

(a) *Basic eligibility requirements.* To be eligible to elect an MA senior housing facility plan, the individual must meet both of the following:

(1) Be a resident of an MA senior housing facility defined in § 422.2.

(2) Be eligible to elect an MA plan under § 422.50.

(b) *Restricting enrollment.* An MA senior housing facility plan must restrict enrollment to only those individuals who reside in a continuing care retirement community as defined at § 422.133(b)(2).

(c) *Establishing eligibility for enrollment.* An MA senior housing facility plan must verify the eligibility of each individual enrolling in its plan using a CMS approved process.

■ 9. Section 422.62 is amended as follows:

■ A. Revising paragraphs (a)(2)(i), (a)(2)(iii), and (a)(5).

■ B. Adding paragraphs (a)(2)(iv) and (a)(7).

The revisions and additions read as follows:

§ 422.62 Election of coverage under an MA plan.

(a) * * *

(2) * * **

(i) For 2002 through 2010, except for 2006, the annual coordinated election

period for the following calendar year is November 15 through December 31.

* * * * *

(iii) Beginning in 2011, the annual coordinated election period for the following calendar year is October 15 through December 7.

(iv) 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.

* * * * *

(5) *Open enrollment and disenrollment from 2007 through 2010.* (i) Open enrollment period. For 2007 through 2010, except as provided in paragraphs (a)(5)(ii), (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.

(ii) *Newly eligible MA individual.* An individual who becomes MA eligible in 2007 through 2010 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 third 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) *Single election limitation.* The limitation to one election or change in paragraphs (a)(5)(i) and (a)(5)(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.

* * * * *

(7) *Annual 45-day period for disenrollment from MA plans to Original Medicare.* For 2011 and subsequent years, at any time from January 1 through February 14, an individual who is enrolled in an MA plan may elect Original Medicare once during this 45-day period. An individual who chooses to exercise this election may also make a coordinating election to enroll in a PDP as specified in § 423.38(d).

* * * * *

■ 10. Section 422.68 is amended by adding paragraph (f) to read as follows:

§ 422.68 Effective dates of coverage and change from coverage.

* * * * *

(f) *Annual 45-day period for disenrollment from MA plans to Original Medicare.* Beginning in 2011, an election made from January 1 through February 14 to disenroll from an MA plan to Original Medicare, as described in § 422.62(a)(7), is effective the first day of the first month following the month in which the election is made.

■ 11. Section 422.74 is amended by adding paragraphs (d)(1)(v) and (vi) to read as follows:

§ 422.74 Disenrollment by the MA organization.

* * * * *

(d) * * *

(1) * * *

(v) *Extension of grace period for good cause and reinstatement.* When an individual is disenrolled for failure to pay the plan premium, CMS may reinstate enrollment in the MA plan, without interruption of coverage, if the individual shows good cause for failure to pay within the initial grace period, and pays all overdue premiums within 3 calendar months after the disenrollment date. The individual must establish by a credible statement that failure to pay premiums within the initial grace period was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

(vi) *No extension of grace period.* A beneficiary's enrollment in the MA plan may not be reinstated if the only basis for such reinstatement is a change in the individual's circumstances subsequent to the involuntary disenrollment for non-payment of premiums.

* * * * *

Subpart C—Benefits and Beneficiary Protections

■ 12. Section 422.100 is amended by adding paragraphs (j) and (k) to read as follows.

§ 422.100 General requirements.

* * * * *

(j) *Services for which cost sharing may not exceed cost sharing under Original Medicare.* On an annual basis, CMS will evaluate whether there are service categories for which MA plans' in-network cost sharing may not exceed that required under Original Medicare and specify in regulation which services are subject to that cost sharing limit. The following services are subject to this limit on cost sharing:

(1) Chemotherapy administration services to include chemotherapy drugs and radiation therapy integral to the treatment regimen.

(2) Renal dialysis services as defined at section 1881(b)(14)(B) of the Act.

(3) Skilled nursing care defined as services provided during a covered stay in a skilled nursing facility during the period for which cost sharing would apply under Original Medicare.

(k) *Cost sharing for in-network preventive services.* MA organizations may not charge deductibles, copayments, or coinsurance for in-network Medicare-covered preventive services (as defined in § 410.152(l)).

■ 13. Section 422.101 is amended as follows:

A. Revising paragraphs (d)(2) and (3).

B. Adding paragraph (f)(2)(vi).

The revisions and addition read as follows.

§ 422.101 Requirements relating to basic benefits.

* * * * *

(d) * * *

(2) *Catastrophic limit.* MA regional plans are required to establish 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) that is no greater than the annual limit set by CMS.

(3) *Total catastrophic limit.* MA regional plans are required to establish 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 and may be no greater than the annual limit set by CMS.

* * * * *

(f) * * *

(2) * * *

(vi) All MAOs wishing to offer or continue to offer a SNP will be required to be approved by the National Committee for Quality Assurance (NCQA) effective January 1, 2012 and subsequent years. All SNPs must submit their model of care (MOC) to CMS for NCQA evaluation and approval in accordance with CMS guidance.

■ 14. Section 422.106 is amended as follows:

■ A. Revising paragraph (d)(1).

■ B. Adding paragraphs (d)(4) through (d)(6).

The revision and additions read as follows.

§ 422.106 Coordination of benefits with employer or union group health plans and Medicaid.

* * * * *

(d) * * *

(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 employer-sponsored group 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.

* * * * *

(4) An employer-sponsored group MA plan means MA coverage offered to retirees who are Medicare eligible individuals under employment-based retiree health coverage, as defined in paragraph (d)(5) of this section, approved by CMS as an MA plan.

(5) Employment-based retiree coverage means coverage of health care costs under a group health plan, as defined in paragraph (d)(6) of this section, 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.

(6) 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:

(i) 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 5 U.S.C. 89 (the Federal Employee Health Benefit Plan (FEHBP)).

(ii) 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.

(iii) 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).

(iv) Any of the following plans:

(A) 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.

(B) A health Flexible Spending Arrangement (FSA) as defined in Internal Revenue Code (Code) section 106(c)(2).

(C) A health savings account (HSA) as defined in Code section 223.

(D) 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).

■ 15. Section 422.107 is amended by revising paragraph (d)(1)(ii) to read as follows:

§ 422.107 Special needs plans and dual-eligibles: Contract with State Medicaid Agency.

* * * * *

(d) * * *

(1) * * *

(ii) Existing dual-eligible SNPs that do not have a State Medicaid agency contract—

(A) May continue to operate through the 2012 contract year provided they meet all other statutory and regulatory requirements.

(B) May not expand their service areas during contract years 2010 through 2012.

* * * * *

■ 16. Amend § 422.111 as follows:

■ A. Adding paragraph (b)(12).

■ B. Removing paragraph (f)(12).

■ C. Adding paragraph (h).

The additions read as follows.

§ 422.111 Disclosure requirements.

* * * * *

(b) * * *

(12) *Claims information.* CMS may require an MA organization to 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 benefits are provided under this part.

* * * * *

(h) *Provision of specific information.* Each MA organization must have mechanisms for providing specific information on a timely basis to current and prospective enrollees upon request. These mechanisms must include all of the following:

(1) A toll-free customer service call center that meets all of the following:

(i) Is open during usual business hours.

(ii) Provides customer telephone service in accordance with standard business practices.

(iii) Provides interpreters for non-English speaking and limited English proficient (LEP) individuals.

(2) An Internet Web site that includes, at a minimum the following:

(i) The information required in paragraph (b) of this section.

(ii) Copies of its evidence of coverage, summary of benefits, and information (names, addresses, phone numbers, and specialty) on the network of contracted providers. Such posting does not relieve the MA organization of its responsibility under § 422.111(a) to provide hard copies to enrollees.

(3) The provision of information in writing, upon request.

■ 17. Section 422.112 is amended by revising paragraph (a)(10) introductory text to read as follows:

§ 422.112 Access to services.

(a) * * *

(10) *Prevailing patterns of community health care delivery.* MA plans that meet Medicare access and availability requirements through direct contracting network providers must do so consistent with the prevailing community pattern of health care delivery in the areas where the network is being offered. Factors making up community patterns of health care delivery that CMS will use as a benchmark in evaluating a proposed MA plan health care delivery network include, but are not limited to the following:

* * * * *

■ 18. Amend § 422.113 by revising paragraph (b)(2)(v) to 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 that CMS will determine annually, or what it would charge the enrollee if he or she obtained the

services through the MA organization, whichever is less.

* * * * *

Subpart D—Quality Improvement

■ 19. Amend § 422.152 by revising paragraph (g) introductory text to read as follows:

§ 422.152 Quality improvement program.

* * * * *

(g) *Special requirements for specialized MA plans for special needs individuals.* All special needs plans (SNPs) must be approved by the National Committee for Quality Assurance (NCQA) effective January 1, 2012 and subsequent years. SNPs must submit their model of care (MOC) to CMS for NCQA evaluation and approval, in accordance with CMS guidance. A SNP must conduct a quality improvement program that—

* * * * *

■ 20. Amend § 422.156 by revising paragraph (b)(1) to read as follows:

§ 422.156 Compliance deemed on the basis of accreditation.

* * * * *

(b) * * *

(1) *Quality improvement.* The deeming process should focus on evaluating and assessing the overall quality improvement (QI) program. However, the quality improvement projects (QIPs) and the chronic care improvement programs (CCIPs) will be excluded from the deeming process.

* * * * *

Subpart E—Relationships With Providers

■ 21. Amend § 422.214 by adding paragraphs (c) and (d) to read as follows:

§ 422.214 Special rules for services furnished by noncontract providers.

* * * * *

(c) *Deemed request for Medicare payment rate.* A noncontract section 1861(u) of the Act provider of services that furnishes services to MA enrollees and submits the same information that it would submit for payment under Original Medicare is deemed to be seeking to be paid the amount it would be paid under Original Medicare unless the provider expressly notifies the MA organization in writing that it is billing an amount less than such amount.

(d) *Regional PPO payments in non-network areas.* An MA Regional PPO must pay non-contract providers the Original Medicare payment rate in those portions of its service area where it is providing access to services by non-network means under § 422.111(b)(3)(ii) of this part.

Subpart F—Submission of Bids, Premiums, and Related Information and Plan Approval

■ 22. Section 422.252 is amended as follows:

■ A. Adding the definitions "low enrollment contract" and "new MA plan."

■ B. Revising the definition of "unadjusted MA area-specific non-drug monthly benchmark amount."

The additions and revision read as follows:

§ 422.252 Terminology.

* * * * *

Low enrollment contract means a contract that could not undertake Healthcare Effectiveness Data and Information Set (HEDIS) and Health Outcome Survey (HOS) data collections because of a lack of a sufficient number of enrollees to reliably measure the performance of the health plan.

* * * * *

New MA plan means a MA contract offered by a parent organization that has not had another MA contract in the previous 3 years.

* * * * *

Unadjusted MA area-specific non-drug monthly benchmark amount means, for local MA plans serving one county, the county capitation rate CMS publishes annually that reflects the nationally average risk profile for the risk factors CMS applies to payment calculations as set forth at § 422.308(c) of this part, (that is, a standardized benchmark). 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. The rules for determining county capitation rates are specific to a time period, as set forth at § 422.258(a). Effective 2012, the MA area-specific non-drug monthly benchmark amount is called the blended benchmark amount, and is determined according to the rules set forth under § 422.258(d) of this part.

* * * * *

■ 23. Section 422.254 is amended by adding paragraph (a)(5) to read as follows:

§ 422.254 Submission of bids.

(a) * * *

(5) CMS may decline to accept any or every otherwise qualified bid submitted by an MA organization or potential MA organization.

* * * * *

■ 24. Section 422.256 is amended by revising paragraph (a) introductory text to read as follows:

§ 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 and may decline to approve a bid if the plan sponsor proposes significant increases in cost sharing or decreases in benefits offered under the plan.

* * * * *

■ 25. Section 422.258 is amended as follows:

■ A. Revising paragraphs (a)(1) and (2).

■ B. In paragraph (c)(3)(i), removing the phrase "county capitation rate" and adding the phrase "amount determined under paragraph (a) of this section for the year" in its place.

■ C. Adding paragraph (d).

The revisions and additions read as follows:

§ 422.258 Calculation of benchmarks.

(a) * * *

(1) For MA local plans with service areas entirely within a single MA local area:

(i) For years before 2007, one-twelfth of the annual MA capitation rate (described at § 422.306) for the area, adjusted as appropriate for the purpose of risk adjustment.

(ii) For years 2007 through 2010, one-twelfth of the applicable amount determined under section 1853(k)(1) of the Act for the area for the year, adjusted as appropriate for the purpose of risk adjustment.

(iii) For 2011, one-twelfth of the applicable amount determined under 1853(k)(1) for the area for 2010.

(iv) Beginning with 2012, one-twelfth of the blended benchmark amount described in paragraph (d) of this section, subject to paragraph (d)(8) of this section and 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 amounts described in paragraph (a)(1) of this section for the year 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.

* * * * *

(d) *Determination of the blended benchmark amount*—(1) *General rules.* For the purpose of paragraphs (a) and (b) of this section, the term blended benchmark amount for an area for a year means the sum of two components: the applicable amount determined under section 1853(k)(1) of the Act and the specified amount determined under section 1853(n)(2) of Act. The weights for each component are based on the phase-in period assigned each area, as described in paragraphs (d)(8) and (d)(9) of this section. At the conclusion of an area's phase-in period, the blended benchmark for an area for a year equals the section 1853(n)(2) of the Act specified amount described in paragraph (d)(2) of this section. The blended benchmark amount for an area for a year (which takes into account paragraph (d)(8) of this section), cannot exceed the applicable amount described in paragraph (d)(2) of this section that would be in effect but for the application of this paragraph.

(2) *Applicable amount.* For the purpose of paragraphs (a) and (b) of this section, the applicable amount determined under section 1853(k)(1) of the Act for a year is—

(i) In a rebasing year (described at § 422.306(b)(2), an amount equal to the greater of the average FFS expenditure amount at § 422.306(b)(2) for an area for a year and the minimum percentage increase rate at § 422.306(a) for an area for a year.

(ii) In a year when the amounts at § 422.306(b)(2) are not rebased, the minimum percentage increase rate at § 422.306(a) for the area for the year.

(iii) In no case the blended benchmark amount for an area for a year, determined taking into account paragraph (d)(8) of this section, be greater than the applicable amount at paragraph (d)(2) of this section for an area for a year.

(iv) Paragraph (d) of this section does not apply to the PACE program under section 1894 of Act.

(3) *Specified amount.* For the purpose of paragraphs (a) and (b) of this section, the specified amount under section 1853(n)(2) of the Act is the product of the base payment amount for an area for a year (adjusted as required under § 422.306(c)) multiplied by the applicable percentage described in paragraph (d)(5) of this section for an area for a year.

(4) *Base payment amount.* The base payment amount is as follows:

(i) For 2012, the average FFS expenditure amount specified in § 422.306(b)(2), determined for 2012.

(ii) For subsequent years, the average FFS expenditure amount specified in § 422.306(b)(2).

(5) *Applicable percentage.* Subject to paragraph (d)(7) of this section, the applicable percentage is one of four values assigned to an area based on Secretary's determination of the quartile ranking of the area's average FFS expenditure amount (described at § 422.306(b)(2) and adjusted as required at § 422.306(c)), relative to this amount for all areas.

(i) For the 50 States or the District of Columbia, a county with an average FFS expenditure amount adjusted under § 422.306(c) that falls in the—

(A) Highest quartile of such rates for all areas for the previous year receives an applicable percentage of 95 percent;

(B) Second highest quartile of such rates for all areas for the previous year receives an applicable percentage of 100 percent;

(C) Third highest quartile of such rates for all areas for the previous year receives an applicable percentage of 107.5 percent; or

(D) Lowest quartile of such rates for all areas for the previous year receives an applicable percentage of 115 percent.

(ii) To determine the applicable percentages for a territory, the Secretary ranks such areas for a year based on the level of the area's § 422.306(b)(2) amount adjusted under § 422.306(c), relative to the quartile rankings computed under paragraph (d)(5)(i) of this section.

(6) *Additional rules for determining the applicable percentage.* (i) In a contract year when the average FFS expenditure amounts from the previous year were rebased (according to the periodic rebasing requirement at § 422.306(b)(2)), the Secretary must determine an area's applicable percentage based on a quartile ranking of the previous year's rebased FFS amounts adjusted under § 422.306(c).

(ii) If, for a year after 2012, there is a change in the quartile in which an area is ranked compared to the previous year's ranking, the applicable percentage for the area in the year must be the average of the applicable percentage for the previous year and the applicable percentage that would otherwise apply for the area for the year in the absence of this transitional provision.

(7) *Increases to the applicable percentage for quality.* Beginning with 2012, the blended benchmark under paragraphs (a) and (b) of this section will reflect the level of quality rating at the plan or contract level, as determined by the Secretary. The quality rating for a plan is determined by the Secretary according to a 5-star rating system (based on the data collected under section 1852(e) of the Act). Specifically, the applicable percentage under paragraph (d)(5) of this section must be increased according to criteria in paragraphs (d)(7)(i) through (v) of this section if the plan or contract is determined to be a qualifying plan or a qualifying plan in a qualifying county for the year.

(i) *Qualifying plan.* Beginning with 2012, a qualifying plan means a plan that had a quality rating of 4 stars or higher based on the most recent data available for such year. For a qualifying plan, the applicable percentage at paragraph (d)(5) of this section must be increased as follows:

(A) For 2012, by 1.5 percentage points.

(B) For 2013, by 3.0 percentage points.

(C) For 2014 and subsequent years, by 5.0 percentage points.

(ii) *Qualifying county.* (A) A *qualifying county* means a county that meets the following three criteria:

(*1*) Has an MA capitation rate that, in 2004, was based on the amount specified in section 1853(c)(1)(B) of the Act for a Metropolitan Statistical Area with a population of more than 250,000.

(*2*) Of the MA-eligible individuals residing in the county, at least 25 percent of such individuals were enrolled in MA plans as of December 2009.

(*3*) Has per capita fee-for-service spending that is lower than the national monthly per capita cost for expenditures for individuals enrolled under the Original Medicare fee-for-service program for the year.

(B) Beginning with 2012, for a qualifying plan serving a qualifying county, the increase to the applicable percentage described at paragraph (d)(7)(i) of this section must be doubled for the qualifying county.

(iii) MA organizations that fail to report data as required by the Secretary must be counted as having a rating of fewer than 3.5 stars at the plan or contract level, as determined by the Secretary.

(iv) *Application of applicable percentage increases to low enrollment contracts.* (A) For 2012, for an MA plan that the Secretary determines is unable to have a quality rating because of low enrollment, the Secretary treats this plan as a qualifying plan under paragraph (d)(7)(i) of this section.

(B) For 2013 and subsequent years, the Secretary develops a methodology to apply to MA plans with low enrollment

(as defined by the Secretary) to determine whether a low enrollment contract is a qualifying plan.

(v) *Application of increases in applicable percentage to new MA plans.* A new MA plan (as defined at § 422.252) that meets criteria specified by the Secretary must be treated as a qualifying plan under paragraph (d)(7)(i) of this section, except that the applicable percentage must be increased as follows:

(A) For 2012, by 1.5 percentage points.

(B) For 2013, by 2.5 percentage points.

(C) For 2014 and subsequent years, by 3.5 percentage points.

(8) *Determination of phase-in period for the blended benchmark amount.* For 2012 through 2016, the blended benchmark amount for an area for a year depends on the phase-in period assigned to that area. The Secretary assigns one of three phase-in periods to each area: 2-year, 4 year, or 6 year. The phase-in period assigned to an area is based on the size of the difference between the 2010 applicable amount at paragraph (d)(2) of this section and the projected 2010 benchmark amount defined at paragraph (d)(8)(i) of this section.

(i) The projected 2010 benchmark amount is calculated once for the purpose of determining the phase-in period for an area. It is equal to one-half of the 2010 applicable amount at paragraph (d)(2) of this section and one-half of the specified amount at paragraph (d)(3) modified to apply to 2010 (as described in (d)(8)(ii) of this section).

(ii) To assign a phase-in period to an area, the specified amount is modified as if it applies to 2010, and is the product of—

(A) The 2010 base payment amount adjusted as required under § 422.306(c) of this part; and

(B) The applicable percentage determined as if the reference to the "previous year" at paragraph (d)(5) of this section were deemed a reference to 2010 and increased as follows:

(*1*) The increase at paragraph (d)(7)(i) of this section for a qualifying plan in the area is applied as if the reference to a qualifying plan for 2012 were deemed a reference for 2010; and

(*2*) The increase at paragraph (d)(7)(ii) of this section is applied as if the determination of a qualifying county were made for 2010.

(iii) *Two-year phase-in.* An area is assigned the 2-year phase-in period if the difference between the applicable amount at paragraph (d)(2) of this section and the projected 2010 benchmark amount at paragraph (d)(8)(i) of this section is less than $30.

(iv) *Four-year phase-in.* An area is assigned the 4-year phase-in period if the difference between the applicable amount at paragraph (d)(2) of this section and the projected 2010 benchmark amount at paragraph (d)(8)(i) of this section is at least $30 but less than $50.

(v) *Six-year phase-in.* An area is assigned the 6-year phase-in period if the difference between the applicable amount at paragraph (d)(2) of this section and the projected 2010 benchmark amount at paragraph (d)(8)(i) of this section is at least $50.

(9) *Impact of phase-in period on calculation of the blended benchmark amount.* (i) *Weighting for the 2-year phase-in.* (A) For 2012, the blended benchmark is the sum of one-half of the applicable amount at paragraph (d)(2) of this section and one-half of the specified amount at paragraph (d)(3) of this section.

(B) For 2013 and subsequent years, the blended benchmark equals the specified amount.

(ii) *Weighting for the 4-year phase-in.* The blended benchmark is the sum of the applicable amount at paragraph (d)(2) of this section and the specified amount at paragraph (d)(2) of this section in the following proportions:

(A) For 2012, three-fourths of the applicable amount for the area for the year and one-fourth of the specified amount for the area and year.

(B) For 2013, one-half of the applicable amount for the area for the year and one-half of the specified amount for the area and year.

(C) For 2014, one-fourth of the applicable amount for the area for the year and three-fourths of the specified amount for the area and year.

(D) For 2015 and subsequent years, the blended benchmark equals the specified amount for the area and year.

(iii) *Weighting for the 6-year phase-in.* The blended benchmark is the sum of the applicable amount at paragraph (d)(2) and the specified amount at paragraph (d)(3) of this section in the following proportions:

(A) For 2012, five-sixths of the applicable amount for the area and year and one-sixth of the specified amount for the area and year.

(B) For 2013, two-thirds of the applicable amount for the area and year and one-third of the specified amount for the area and year.

(C) For 2014, one-half of the applicable amount for the area and year and one-half of the specified amount for the area and for year.

(D) For 2015, one-third of the applicable amount for the area and year and two-thirds of the specified amount for the area and for year.

(E) For 2016, one-sixth of the applicable amount for the area and year and five-sixths of the specified amount for the area and for year.

(F) For 2017 and subsequent years, the blended benchmark equals the specified amount for the area and year.

■ 26. Section 422.260 is added to read as follows:

§ 422.260 Appeals of quality bonus payment determinations.

(a) *Scope.* The provisions of this section pertain to the administrative review process to appeal quality bonus payment status determinations based on section 1853(o) of the Act.

(b) *Definitions.* The following definitions apply to this section:

Quality bonus payment (QBP) means—

(i) Enhanced CMS payments to MA organizations based on the organization's demonstrated quality of its Medicare contract operations; or

(ii) Increased beneficiary rebate retention allowances based on the organization's demonstrated quality of its Medicare contract operations.

Quality bonus payment (QBP) determination methodology means the formula CMS adopts for evaluating whether MA organizations qualify for a QBP.

Quality bonus payment (QBP) status means a MA organization's standing with respect to its qualification to—

(i) Receive a quality bonus payment, as determined by CMS; or

(ii) Retain a portion of its beneficiary rebates based on its quality rating, as determined by CMS.

(c) *Administrative review process for QBP status appeals.* (1) Reconsideration request. An MA organization may request reconsideration of its QBP status.

(i) The MA organization requesting reconsideration of its QBP status must do so by providing written notice to CMS within 10 business days of the release of its QBP status. The request must specify the given measure(s) in question and the basis for reconsideration such as a calculation error or incorrect data was used to determine the QBP status. The error could impact an individual measure's value or the overall star rating.

(ii) The reconsideration official's decision is final and binding unless a request for an informal hearing is filed in accordance with paragraph (2) of this section.

(2) *Informal hearing request.* An MA organization may request an informal hearing on the record following the reconsideration official's decision regarding its QBP status.

(i) The MA organization seeking an appeal of the reconsideration official's decision regarding its QBP status must do so by providing written notice to CMS within 10 business days of the issuance of the reconsideration decision. The notice must specify the errors the MA organization asserts that CMS made in making the QBP determination and how correction of those errors could result in the organization's qualification for a QBP or a higher QBP.

(ii) The MA organization may not request an informal hearing of its QBP status unless it has already requested and received a reconsideration decision in accordance with paragraph (c)(1) of this section.

(iii) The informal hearing request must pertain only to the measure(s) and value(s) in question that precipitated the request for reconsideration.

(iv) The informal hearing is conducted by a CMS hearing officer on the record. The hearing officer receives no testimony, but may accept written statements with exhibits from each party in support of their position in the matter.

(v) The MA organization must provide clear and convincing evidence that CMS' calculations of the measure(s) and value(s) in question were incorrect.

(vi) The hearing officer issues the decision by electronic mail to the MA organization.

(vii) The hearing officer's decision is final and binding.

(3) *Limits to requesting an administrative review.* (i) CMS may limit the measures or bases for which a contract may request an administrative review of its QBP status.

(ii) An administrative review cannot be requested for the following: the methodology for calculating the star ratings (including the calculation of the overall star ratings); cut-off points for determining measure thresholds; the set of measures included in the star rating system; and the methodology for determining QBP determinations for low enrollment contracts and new MA plans.

(4) *Designation of a hearing officer.* CMS designates a hearing officer to conduct the appeal of the QBP status. The officer must be an individual who did not directly participate in the initial QBP determination.

(d) *Reopening of QBP determinations.* CMS may, on its own initiative, revise an MA organization's QBP status at any time after the initial release of the QBP determinations through April 1 of each year. CMS may take this action on the basis of any credible information, including the information provided during the administrative review process that demonstrates that the initial QBP determination was incorrect.

■ 27. Amend § 422.266 by revising paragraph (a) to read as follows:

§ 422.266 Beneficiary rebates.

(a) *Calculation of rebate.* (1) For 2006 through 2011, 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.

(2) For 2012 and subsequent years, an MA organization must provide to the enrollee a monthly rebate equal to a specified percentage of the average per capita savings (if any) at § 422.264(b) for MA local plans and § 422.264(d) for MA regional plans. For 2012 and 2013, this percentage is based on a combination of the (a)(1) rule of 75 percent and the (a)(2)(ii) rules that set the percentage based on the plan's quality rating under a 5 star rating system, as determined by the Secretary under § 422.258(d)(7). For 2014 and subsequent years, this percentage is determined based only on the paragraph (a)(2)(ii) of this section.

(i) *Applicable rebate percentage for 2012 and 2013.* Subject to paragraphs (a)(2)(iii) and (iv) of this section, the transitional applicable rebate percentage is, for a year, the sum of two amounts as follows:

(A) *For 2012.* Two-thirds of the old proportion of 75 percent of the average per capita savings; and one-third of the new proportion assigned the plan under paragraph (a)(2)(ii) of this section, based on the quality rating specified in § 422.258(d)(7).

(B) *For 2013.* One-third of the old proportion of 75 percent of the average per capita savings; and two-thirds of the new proportion assigned the plan under paragraph (d)(2)(ii) of this section, based on the quality rating at § 422.258(d)(7).

(ii) *Final applicable rebate percentage.* For 2014 and subsequent years, and subject to paragraphs (a)(2)(iii) and (iv) of this section, the final applicable rebate percentage is as follows:

(A) In the case of a plan with a quality rating under such system of at least 4.5 stars, 70 percent of the average per capita savings;

(B) In the case of a plan with a quality rating under such system of at least 3.5 stars and less than 4.5 stars, 65 percent of the average per capita savings.

(C) In the case of a plan with a quality rating under such system of less than 3.5 stars, 50 percent of the average per capita savings.

(iii) *Treatment of low enrollment contracts.* For 2012, in the case of a plan described at § 422.258(d)(7)(iv), the plan must be treated as having a rating of 4.5 stars for the purpose of determining the beneficiary rebate amount.

(iv) *Treatment of new MA plans.* For 2012 or a subsequent year, a new MA plan defined at § 422.252 that meets the criteria specified by the Secretary for purposes of § 422.258(d)(7)(v) must be treated as a qualifying plan under § 422.258(d)(7)(i), except that plan must be treated as having a rating of 3.5 stars for purposes of determining the beneficiary rebate amount.

* * * * *

Subpart G—Payments to Medicare Advantage Organizations

■ 28. Amend § 422.308 by adding paragraphs (c)(4) through (6) to read as follows:

* * * * *

(c) * * *

(4) *Authority to apply frailty adjustment under PACE payment rules for certain specialized MA plans for special needs individuals.* (i) *Application of payment rules.* For plan year 2011 and subsequent plan years, in the case of a plan described in paragraph (c)(4)(ii) of this section, the Secretary may apply the payment rules under section 1894(d) of the Act (other than paragraph (3) of that section) rather than the payment rules that would otherwise apply under this part, but only to the extent necessary to reflect the costs of treating high concentrations of frail individuals.

(ii) *Plan described.* A plan described in this paragraph is a fully integrated dual-eligible special needs plan, as defined at § 422.2, and has a similar average level of frailty (as determined by the Secretary) as the PACE program.

(5) *Application of coding adjustment.* (i) In applying the adjustment under paragraph (c)(1) of this section for health status to payment amounts, the Secretary ensures that such adjustment reflects changes in treatment and coding practices in the fee-for-service sector and reflects differences in coding patterns between MA plans and providers under Part A and B to the extent that the Secretary has identified such differences.

(ii) In order to ensure payment accuracy, the Secretary annually conducts an analysis of the differences described in paragraph (c)(5)(i) of this section.

(A) The Secretary completes such analysis by a date necessary to ensure that the results of such analysis are incorporated on a timely basis into the risk scores for 2008 and subsequent years.

(B) In conducting such analysis, the Secretary uses data submitted with respect to 2004 and subsequent years, as available and updated as appropriate.

(iii) In calculating each year's adjustment, the adjustment factor is as follows:

(A) For 2014, not less than the adjustment factor applied for 2010, plus 1.3 percentage points.

(B) For each of the years 2015 through 2018, not less than the adjustment factor applied for the previous year, plus 0.25 percentage points.

(C) For 2019 and each subsequent year, not less than 5.7 percent.

(iv) Such adjustment is applied to risk scores until the Secretary implements risk adjustment using MA diagnostic, cost, and use data.

(6) *Improvements to risk adjustment for special needs individuals with chronic health conditions*—(i) *General rule.* For 2011 and subsequent years, for purposes of the adjustment under paragraph (c)(1) of this section with respect to individuals described in paragraph (c)(6)(ii) of the section, the Secretary uses a risk score that reflects the known underlying risk profile and chronic health status of similar individuals. Such risk score is used instead of the default risk score for new enrollees in MA plans that are not specialized MA plans for special needs individuals (as defined in section 1859(b)(6) of the Act).

(ii) *Individuals described.* An individual described in this clause is a special needs individual described in section 1859(b)(6)(B)(iii) of the Act who enrolls in a specialized MA plan for special needs individuals on or after January 1, 2011.

(iii) *Evaluation.* For 2011 and periodically thereafter, the Secretary evaluates and revises the risk adjustment system under this paragraph in order to, as accurately as possible, account for—

(A) Higher medical and care coordination costs associated with frailty, individuals with multiple, comorbid chronic conditions, and individuals with a diagnosis of mental illness; and

(B) Costs that may be associated with higher concentrations of beneficiaries with the conditions specified in paragraph (c)(6)(iii)(A) of this section.

(iv) *Publication of evaluation and revisions.* The Secretary publishes, as part of an announcement under section 1853(b) of the Act, a description of any evaluation conducted under paragraph (c)(6)(iii) of this section during the preceding year and any revisions made under paragraph (c)(6)(iii) of this section as a result of such evaluation.

* * * * *

Subpart J—Special Rules for MA Regional Plans

§ 422.458 [Amended]

■ 29. In § 422.458, paragraph (f) is removed.

Subpart K—Application Procedures and Contracts for Medicare Advantage Organizations

■ 30. Amend § 422.502 as follows:

■ A. Redesignating paragraph (b) as paragraph (b)(1).

■ B. Adding paragraph (b)(2).

■ C. Revising paragraph (c)(2)(i).

The revisions read as follows:

§ 422.502 Evaluation and determination procedures.

* * * * *

(b) * * *

(2) In the absence of 14 months of performance history, CMS may deny an application based on a lack of information available to determine an applicant's capacity to comply with the requirements of the MA program.

(c) * * *

(2) * * *

(i) If CMS finds that the applicant does not appear to be able to meet the requirements for an MA organization, CMS gives the applicant notice of intent to deny the application and a summary of the basis for this preliminary finding.

* * * * *

■ 32. Amend § 422.504 as follows:

■ A. Redesignating paragraph (a)(14) as paragraph (a)(16).

■ B. Adding new paragraphs (a)(14) and (a)(15).

■ C. Revising newly redesignated paragraph (a)(16).

■ D. Adding paragraph (n).

The additions and revision read as follows.

§ 422.504 Contract provisions.

* * * * *

(a) * * *

(14) Maintain a fiscally sound operation by at least maintaining a positive net worth (total assets exceed total liabilities).

(15) Address complaints received by CMS against the MAO by—

(i) Addressing and resolving complaints in the CMS complaint tracking system.

(ii) Displaying a link to the electronic complaint form on the Medicare.gov Internet Web site on the MA plan's main Web page.

(16) An MA organization's compliance with paragraphs (a)(1) through (15) and (c) of this section is material to performance of the contract.

* * * * *

(n) *Release of summary CMS payment data.* The contract must provide that the MA organization acknowledges that CMS releases to the public summary reconciled CMS payment data after the reconciliation of Part C and Part D payments for the contract year as follows:

(1) For Part C, the following data—

(i) Average per member per month CMS payment amount for A/B (original Medicare) benefits for each MA plan offered, standardized to the 1.0 (average risk score) beneficiary.

(ii) Average per member per month CMS rebate payment amount for each MA plan offered (or, in the case of MSA plans, the monthly MSA deposit amount).

(iii) Average Part C risk score for each MA plan offered.

(iv) County level average per member per month CMS payment amount for each plan type in that county, weighted by enrollment and standardized to the 1.0 (average risk score) beneficiary in that county.

(2) For Part D plan sponsors, plan payment data in accordance with § 423.505(o) of this subchapter.

■ 33. Amend § 422.506 by adding paragraph (a)(5) to read as follows:

§ 422.506 Nonrenewal of contract.

(a) * * *

(5) During the same 2-year period as specified in paragraph (a)(4) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the non-renewing sponsor. A "covered person" as used in this paragraph means one of the following:

(i) All owners of nonrenewed or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

* * * * *

■ 34. Amend § 422.508 by adding paragraph (d) to read as follows:

§ 422.508 Modification or termination of contract by mutual consent.

* * * * *

(d) *Prohibition against Part C program participation by organizations whose owners, directors, or management employees served in a similar capacity with another organization that mutually terminated its Medicare contract within the previous 2 years.* During the same 2-year period, CMS will not contract with an organization whose covered persons also served as covered persons for the mutually terminating sponsor. A "covered person" as used in this paragraph means one of the following:

(1) All owners of nonrenewal or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(2) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(3) A member of the board of directors of the entity, if the organization is organized as a corporation.

■ 35. Amend § 422.512 as follows:

A. Redesignating paragraph (e) as (e)(1).

B. Adding a new paragraph (e)(2).

§ 422.512 Termination of contract by the MA organization.

* * * * *

(e) * * *

(2) During the same 2-year period specified in paragraph (e)(1) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the terminating sponsor. A "covered person" as used in this paragraph means one of the following:

(i) All owners of nonrenewal or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the organization.

(iii) A member of the board of directors of the entity, if the organization is organized as a corporation.

Subpart M—Grievances, Organization Determinations, and Appeals

■ 36. Amend § 422.562 by adding paragraph (a)(4) to read as follows:

§ 422.562 General provisions.

* * * * *

(a) * * *

(4) An MA organization must employ a medical director who is responsible for ensuring the clinical accuracy of all organization determinations and reconsiderations involving medical necessity. The medical director must be a physician with a current and unrestricted license to practice medicine in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

* * * * *

■ 37. Amend § 422.566 by adding paragraph (d) to read as follows:

§ 422.566 Organization determinations.

* * * * *

(d) *Who must review organization determinations.* If the MA organization expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the organization determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

■ 38. Amend § 422.622 by revising paragraph (g)(1) to read as follows:

§ 422.622 Requesting immediate QIO review of the decision to discharge from the inpatient hospital.

* * * * *

(g) * * *

(1) *Right to request a reconsideration.* If the enrollee is still an inpatient in the hospital and is dissatisfied with the determination, he or she may request a reconsideration according to the procedures described in § 422.626(g).

* * * * *

■ 39. Amend § 422.626 by revising paragraph (g)(3) to read as follows:

§ 422.626 Fast-track appeals of service terminations to independent review entities (IREs).

(g) * * *

(3) If the IRE reaffirms its decision, in whole or in part, the enrollee may appeal the IRE's reconsidered determination to an ALJ, the MAC, or a Federal court, as provided for under this subpart.

* * * * *

Subpart V—Medicare Advantage Marketing Requirements

■ 40. Amend § 422.2264 by revising paragraph (e) to read as follows:

§ 422.2264 Guidelines for CMS review.

* * * * *

(e) For markets with a significant non-English speaking population, provide materials in the language of these individuals. Specifically, MA organizations must translate marketing materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.

■ 41. Amend § 422.2272 by adding paragraph (e) to read as follows:

§ 422.2272 Licensing of marketing representatives and confirmation of marketing resources.

* * * * *

(e) Terminate upon discovery any unlicensed agent or broker employed as a marketing representative and notify any beneficiaries enrolled by an unqualified agent or broker of the agent's or broker's status and, if requested, of their options to confirm enrollment or make a plan change (including a special election period, as described in § 422.62(b)(3)(ii)).

■ 42. Amend § 422.2274 by revising the introductory text and paragraphs (b) and (c) to read as follows:

§ 422.2274 Broker and agent requirements.

For purposes of this section "compensation" includes pecuniary or nonpecuniary remuneration of any kind relating to the sale or renewal of a policy including, but not limited to, commissions, bonuses, gifts, prizes, awards, and finder's fees. "Compensation" does not include the payment of fees to comply with State appointment laws, training, certification, and testing costs; reimbursement for mileage to, and from, appointments with beneficiaries; or reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials. If a MA organization markets through

independent (that is, non-employee) brokers or agents, the requirements in paragraph (a) of this section must be met. The requirements in paragraphs (b) through (e) of this section must be met if a MA organization markets through any broker or agent, whether independent (that is, non-employee) or employed.

* * * * *

(b) It must ensure that all agents selling Medicare products are trained annually through a CMS endorsed or approved training program or as specified by CMS, on Medicare rules and regulations specific to the plan products they intend to sell.

(c) It must ensure agents selling Medicare products are tested annually by CMS endorsed or approved training program or as specified by CMS.

* * * * *

PART 423—MEDICARE PROGRAM; MEDICARE PRESCRIPTION DRUG PROGRAM

■ 43. The authority citation for part 423 continues to read as follows:

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

■ 44. Amend § 423.4 by adding the definitions of "fiscally sound operation" and "pharmacist" to read as follows:

§ 423.4 Definitions.

* * * * *

Fiscally sound operation means an operation which at least maintains a positive net worth (total assets exceed total liabilities).

* * * * *

Pharmacist means any individual who holds a current valid license to practice pharmacy in a State or territory of the United States or the District of Columbia.

* * * * *

Subpart B—Eligibility and Enrollment

■ 45. Amend § 423.34 as follows:
■ A. Revising paragraphs (c) and (d)(1).
■ B. Adding paragraph (d)(4).

The revisions and addition read as follows:

§ 423.34 Enrollment of low-income subsidy eligible individuals.

* * * * *

(c) *Reassigning low income subsidy eligible individuals*—(1) *General rule.* Notwithstanding § 423.32(e) of this subpart, during the annual coordinated election period, CMS may reassign certain low income subsidy eligible individuals in another PDP if CMS determines that the further enrollment is warranted, except as specified in paragraph (c)(2) of this section.

(2) *Part D prescription drug plans that waive a de minimis premium amount.* If a Part D plan offering basic prescription drug coverage in the area where the beneficiary resides has a monthly beneficiary premium amount that exceeds the low-income subsidy amount by a de minimis amount, and the Part D plan volunteers to waive that de minimis amount in accordance with § 423.780, then CMS does not reassign low income subsidy individuals who would otherwise be enrolled under paragraph (d)(1) of this section on the basis that the monthly beneficiary premium exceeds the low-income subsidy by a de minimis amount. A Part D plan that volunteers to waive such a de minimis amount agrees to do so for each month during the contract year for which a beneficiary qualifies for 100 percent low-income premium subsidy as provided in § 423.780(f).

(d) *Automatic enrollment rules*—(1) *General rule.* Except for low income subsidy eligible individuals who are qualifying covered retirees with a group health plan sponsor, as specified in paragraph (d)(3) of this section, CMS enrolls those individuals who fail to enroll in a Part D plan into a PDP offering basic prescription drug coverage in the area where the beneficiary resides that has a monthly beneficiary premium amount that does not exceed the low income subsidy amount (as defined in § 423.780(b) of this part). 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 are enrolled in such PDPs on a random basis.

* * * * *

(4) *Enrollment in PDP plans that voluntarily waive a de minimis premium amount.* CMS may include in the process specified in paragraph (d)(1) of this section that PDPs that voluntarily waive a de minimis amount as specified in § 423.780, if CMS determines that such inclusion is warranted.

* * * * *

■ 46. Amend § 423.38 as by revising paragraph (b) and adding paragraph (d) to read as follows:

§ 423.38 Enrollment periods.

* * * * *

(b) *Annual coordinated election period*—(1) *For 2006.* This period begins on November 15, 2005 and ends on May 15, 2006.

(2) *For 2007 through 2010.* The annual coordinated election period for the following calendar year is November 15 through December 31.

(3) *For 2011 and subsequent years.* Beginning with 2011, the annual coordinated election period for the following calendar year is October 15 through December 7.

* * * * *

(d) *Enrollment period to coordinate with MA annual 45-day disenrollment period.* Beginning in 2011, an individual enrolled in an MA plan who elects Original Medicare from January 1 through February 14, as described in § 422.62(a)(7), may also elect a PDP during this time.

■ 47. Amend § 423.40 by adding paragraph (d) to read as follows:

§ 423.40 Effective dates.

* * * * *

(d) *PDP enrollment period to coordinate with the MA annual disenrollment period.* Beginning in 2011, an enrollment made from January 1 through February 14 by an individual who has disenrolled from an MA plan as described in § 422.62(a)(7) will be effective the first day of the month following the month in which the enrollment in the PDP is made.

■ 48. Amend § 423.44 by revising the section heading and adding paragraphs (d)(1)(vi), (d)(1)(vii), and (e) as follows:

§ 423.44 Involuntary disenrollment from Part D coverage.

* * * * *

(d) * * *

(1) * * *

(vi) *Extension of grace period for good cause and reinstatement.* When an individual is disenrolled for failure to pay the plan premium, CMS may reinstate enrollment in the PDP, without interruption of coverage, if the individual shows good cause for failure to pay within the initial grace period, and pays all overdue premiums within 3 calendar months after the disenrollment date. The individual must establish by a credible statement that failure to pay premiums within the initial grace period was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

(vii) *No extension of grace period.* A beneficiary's enrollment in the PDP may not be reinstated if the only basis for such reinstatement is a change in the individual's circumstances subsequent to the involuntary disenrollment for non-payment of premiums.

* * * * *

(e) *Involuntary disenrollment by CMS*—(1) *General rule.* CMS will disenroll individuals who fail to pay the Part D income related monthly adjustment amount (Part D—IRMAA) specified in § 423.286(d)(4) and § 423.293(d) of this part.

(2) *Initial grace period.* For all Part D—IRMAA amounts directly billed to an enrollee in accordance with § 423.293(d)(2), the grace period ends with the last day of the third month after the billing month.

(3) *Extension of grace period for good cause and reinstatement.* When an individual is disenrolled for failing to pay the Part D—IRMAA within the initial grace period specified in paragraph (e)(2) of this section, CMS (or an entity acting on behalf of CMS) may reinstate enrollment, without interruption of coverage, if the individual shows good cause as specified in § 423.44(d)(1)(vi), pays all Part D—IRMAA arrearages, and any overdue premiums due the Part D plan sponsor within 3 calendar months after the disenrollment date.

(4) *Notice of termination.* Where CMS has disenrolled an individual in accordance with paragraph (e)(1) of this section, the Part D plan sponsor must provide notice of termination in a form and manner determined by CMS.

(5) *Effective date of disenrollment.* After a grace period and notice of termination has been provided in accordance with paragraphs (e)(2) and (4) of this section, the effective date of disenrollment is the first day following the last day of the initial grace period.

Subpart C—Benefits and Beneficiary Protections

■ 49. Amend § 423.100 as follows:

■ A. Adding the definitions of "Applicable beneficiary," "Applicable drug under the Medicare coverage gap discount program," and "Coverage gap."

■ B. Revising paragraph (2) of the definition of "Dispensing fees" and paragraph (2)(ii) of the definition of "Incurred costs."

The additions and revisions read as follows:

§ 423.100 Definitions.

* * * * *

Applicable beneficiary means an individual who, on the date of dispensing a covered Part D drug—

(1) Is enrolled in a prescription drug plan or an MA–PD plan;

(2) Is not enrolled in a qualified retiree prescription drug plan;

(3) Is not entitled to an income-related subsidy under section 1860D–14(a) of the Act;

(4) Has reached or exceeded the initial coverage limit under section 1860D–2(b)(3) of the Act during the year;

(5) Has not incurred costs for covered part D drugs in the year equal to the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B) of the Act; and

(6) Has a claim that—

(i) Is within the coverage gap;

(ii) Straddles the initial coverage period and the coverage gap;

(iii) Straddles the coverage gap and the annual out-of-pocket threshold; or

(iv) Spans the coverage gap from the initial coverage period and exceeds the annual out-of-pocket threshold.

Applicable drug means a Part D drug that is—

(1)(i) Approved under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA); or

(ii) In the case of a biological product, licensed under section 351 of the Public Health Service Act (other than a product licensed under subsection (k) of such section 351); and

(2)(i) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in;

(ii) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in; or

(iii) Is provided to a particular applicable beneficiary through an exception or appeal for that particular applicable beneficiary.

* * * * *

Coverage gap means the period in prescription drug coverage that occurs between the initial coverage limit and the out-of-pocket threshold. For purposes of applying the initial coverage limit, Part D sponsors must apply their plan specific initial coverage limit under basic alternative, enhanced alternative or actuarially equivalent Part D benefit designs.

* * * * *

Dispensing fees * * *

(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 salaries of pharmacists and other pharmacy workers as well as the costs associated with maintaining the pharmacy facility and acquiring and maintaining technology and equipment necessary to operate the pharmacy. Dispensing fees should take into consideration the number of dispensing events in a billing cycle, the incremental costs associated with the type of dispensing methodology, and with respect to Part D drugs dispensed in LTC facilities, the techniques to minimize the dispensing of unused drugs. Dispensing fees may also take into account costs associated with data collection on unused Part D drugs and restocking fees associated with return for credit and reuse in long-term care pharmacies, when return for credit and reuse is permitted under the State in law and is allowed under the contract between the Part D sponsor and the pharmacy.

* * * * *

Incurred costs * * *

(2) * * *

(ii) Under a State Pharmaceutical Assistance Program (as defined in § 423.464); by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act) or under an AIDS Drug Assistance Program (as defined in part B of title XXVI of the Public Health Service); or

* * * * *

■ 50. Amend § 423.104 as follows:

■ A. Revising paragraphs (d)(2)(i) introductory text, (d)(2)(ii), (d)(3) introductory text, and (d)(4).

■ B. Redesignating paragraph (d)(5)(iii)(B) as (d)(5)(iii)(F).

■ C. Adding new paragraphs (d)(5)(iii)(B) through (E).

■ D. Revising newly redesignated paragraph (d)(5)(iii)(F).

■ E. Adding paragraph (d)(5)(v).

The revisions and additions read as follows:

§ 423.104 Requirements related to qualified prescription drug coverage.

* * * * *

(d) * * *

(2) * * *

(i) Subject to paragraph (d)(4) of this section, 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—

* * * * *

(ii) *Tiered copayments.* A Part D plan providing actuarially equivalent standard coverage may apply tiered copayments, provided that any tiered copayments are consistent with paragraphs (d)(2)(i)(B) and (d)(4) of this section and are approved as described in § 423.272(b)(2).

(3) *Initial coverage limit.* Except as provided in paragraphs (d)(4) and (d)(5) of this section, the initial coverage limit is equal to—

* * * * *

(4) *Cost-sharing in the coverage gap for applicable beneficiaries.* (i) Coinsurance in the coverage gap (as defined in § 423.100) for costs for covered Part D drugs that are not applicable drugs (as defined in § 423.100) under the Medicare coverage gap discount program that is—

(A) Equal to the generic gap coinsurance percentage described in paragraph (d)(4)(iii) of this section; or

(B) Actuarially equivalent to an average expected coinsurance for covered Part D drugs that are not applicable drugs under the Medicare coverage gap discount program, as determined through processes and methods established under § 423.265 (c) and (d).

(ii) Coinsurance in the coverage gap for the actual cost minus the dispensing fee and any vaccine administration fee for covered Part D drugs that are applicable drugs under the Medicare coverage gap discount program that is—

(A) Equal to the difference between the applicable gap coinsurance percentage described in paragraph (d)(4)(iv) of this section and the discount percentage determined under the Medicare coverage gap discount program; or

(B) Actuarially equivalent to an average expected coinsurance for covered Part D drugs that are applicable drugs under the Medicare coverage gap discount program, as determined through processes and methods established under § 423.265 (c) and (d).

(iii) *Generic gap coinsurance percentage.* The generic gap coinsurance percentage is equal to—

(A) For 2011, 93 percent.

(B) For years 2012 through 2019, the amount specified in this paragraph for the previous year, decreased by 7 percentage points.

(C) For 2020 and each subsequent year, 25 percent.

(iv) *Applicable gap coinsurance percentage.* The applicable gap coinsurance percentage is equal to—

(A) For 2013 and 2014, 97.5 percent.

(B) For 2015 and 2016, 95 percent.

(C) For 2017, 90 percent.

(D) For 2018, 85 percent.

(E) For 2019, 80 percent.

(F) For 2020 and subsequent years, 75 percent.

(5) * * *

(iii) * * *

(B) *For each year 2007 through 2013.* 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.

(C) *For years 2014 and 2015.* 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, minus 0.25 percentage point.

(D) *For each year 2016 through 2019.* The amount specified in this paragraph for the previous year, increased by the lesser of—

(*1*) The annual percentage increase specified in (d)(5)(v) of this section plus 2 percentage points; or

(*2*) The annual percentage increase specified in (d)(5)(iv) of this section.

(E) *For 2020.* The amount specified in this paragraph for 2013 increased by the annual percentage increases specified in paragraph (d)(5)(iv) of this section for 2014 through 2020, and rounded to the nearest $50.

(F) *For 2021 and subsequent years.* 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 $50.

* * * * *

(v) *Additional annual percentage increase.* The annual percentage increase for each year is equal to the annual percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending in July of the previous year.

* * * * *

■ 51. Section 423.120 is amended as follows:

■ A. Revising paragraphs (b)(3)(iii)(B) and (b)(3)(iv).

■ B. Adding paragraph (d).

The revisions and addition read as follows.

§ 423.120 Access to covered Part D drugs.

* * * * *

(b) * * *

(iii) * * *

(B) In the long-term care setting, the temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) must be for up to at least 91 days and may be up to at least 98 days, consistent with the dispensing increment, with refills provided, if needed, unless a lesser amount is actually prescribed by the prescriber.

(iv) Ensure written notice is provided to each affected enrollee within 3 business days after adjudication of the temporary fill. For long-term care residents dispensed multiple supplies of a Part D drug, in increments of 14-days-or-less, consistent with the requirements under § 423.154, the written notice must be provided within 3 business days after adjudication of the first temporary fill.

* * * * *

(d) *Treatment of compounded drug products.* With respect to multi-ingredient compounds, a Part D sponsor must—

(1) Make a determination as to whether the compound is covered under Part D.

(i) A compound that contains at least one ingredient covered under Part B as prescribed and dispensed or administered is considered a Part B compound, regardless of whether other ingredients in the compound are covered under Part B as prescribed and dispensed or administered.

(ii) Only compounds that contain at least one ingredient that independently meets the definition of a Part D drug, and that do not meet the criteria under paragraph (d)(1)(i) of this section, may be covered under Part D. For purposes of this paragraph (d) these compounds are referred to as Part D compounds.

(iii) For a Part D compound to be considered on-formulary, all ingredients that independently meet the definition of a Part D drug must be considered on-formulary (even if the particular Part D drug would be considered off-formulary if it were provided separately—that is, not as part of the Part D compound).

(iv) For a Part D compound that is considered off-formulary—

(A) Transition rules apply such that all ingredients in the Part D compound that independently meet the definition of a Part D drug must become payable in the event of a transition fill under § 423.120(b)(3); and

(B) All ingredients that independently meet the definition of a Part D drug must be covered if an exception under § 423.578(b) is approved for coverage of the compound.

(2) Establish consistent rules for beneficiary payment liabilities for both ingredients of the Part D compound that

independently meet the definition of a Part D drug and non-Part D ingredients.

(i) For low income subsidy beneficiaries the copayment amount is based on whether the most expensive ingredient that independently meets the definition of a Part D drug in the Part D compound is a generic or brand name drug (as described under § 423.782).

(ii) For any non-Part D ingredient of the Part D compound (including drugs described under § 423.104(f)(1)(ii)(A)), the Part D sponsor's contract with the pharmacy must prohibit balance billing the beneficiary for the cost of any such ingredients.

■ 52. Amend § 423.128 as follows:
■ A. Revising paragraph (b)(7).
■ B. Adding paragraphs (d)(1)(iii) and (d)(1)(iv).

The revision and additions read as follows:

§ 423.128 Dissemination of Part D plan information.

* * * * *

(b) * * *

(7*) Grievance, coverage determination, and appeal procedures.* All grievance, coverage determination, and appeal rights and procedures required under § 423.562 et. seq., including—

(i) Access to a uniform model form used to request a coverage determination under § 423.568 or § 423.570, and a uniform model form used to request a redetermination under § 423.582 or § 423.584, to the extent such uniform model forms have been approved for use by CMS;

(ii) Immediate access to the coverage determination and redetermination processes via an Internet Web site; and

(iii) A system that transmits codes to network pharmacies so that the network pharmacy is notified to populate and/or provide a printed notice at the point-of-sale to an enrollee explaining how the enrollee can request a coverage determination by contacting the plan sponsor's toll free customer service line or by accessing the plan sponsor's internet Web site.

* * * * *

(d) * * *

(1) * * *

(iii) Provides interpreters for non-English speaking and limited English proficient (LEP) individuals.

(iv) Provides immediate access to the coverage determination and redetermination processes.

* * * * *

Subpart D—Cost Control and Quality Improvement Requirements

■ 53. Amend § 423.150 as follows:
■ A. Redesignating paragraphs (b) through (g) as paragraphs (c) through (h).
■ B. Adding a new paragraph (b) to read as follows:

§ 423.150 Scope.

* * * * *

(b) Appropriate dispensing of prescription drugs in long-term care facilities under PDPs and MA–PD plans.

* * * * *

■ 54. Amending § 423.153 as follows:
■ A. Revising paragraph (d)(1)(vii)(B).
■ B. Adding paragraph (d)(1)(vii)(D).

The revision and addition read as follows:

§ 423.153 Drug utilization management, quality assurance, and medication therapy management programs (MTMPs).

* * * * *

(d) * * *

(1) * * *

(vii) * * *

(B) Annual comprehensive medication review with written summaries. The comprehensive medication review must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider unless the beneficiary is in a long-term care setting and may result in a recommended medication action plan.

* * * * *

(D) Standardized action plans and summaries that comply with requirements as specified by CMS for the standardized format.

* * * * *

■ 55. Section 423.154 is added to read as follows:

§ 423.154 Appropriate dispensing of prescription drugs in long-term care facilities under PDPs and MA–PD plans.

(a) *In general.* Except as provided in paragraph (b) of this section, when dispensing covered Part D drugs to enrollees who reside in long-term care facilities, a Part D sponsor must—

(1) Require all pharmacies servicing long-term care facilities, as defined in § 423.100 to—

(i) Dispense solid oral doses of brand-name drugs, as defined in § 423.4, to enrollees in such facilities in no greater than 14-day increments at a time;

(ii) Permit the use of uniform dispensing techniques for Part D drugs dispensed to enrollees in long-term care facilities under paragraph (a)(1)(i) of this section as defined by each of the long-term care facilities in which such enrollees reside; and

(2) Collect and report information, in a form and manner specified by CMS, on the dispensing methodology used for each dispensing event described by paragraph (a)(1) of this section, and on the nature and quantity of unused brand and generic drugs, as defined in § 423.4, dispensed by the pharmacy to enrollees residing in a LTC facility. Reporting on unused drugs is waived for Part D sponsors for drugs dispensed by pharmacies that dispense both brand and generic drugs, as defined in § 423.4, in no greater than 7-day increments.

(b) *Exclusions.* CMS excludes from the requirements under paragraph (a) of this section—

(1) Solid oral doses of antibiotics; or

(2) Solid oral doses that are dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance (for example, oral contraceptives).

(c) *Waivers.* CMS waives the requirements under paragraph (a) of this section for pharmacies when they service intermediate care facilities for the mentally retarded (ICFs/MR) and institutes for mental disease (IMDs) as defined in § 435.1010 and for I/T/U pharmacies (as defined in § 423.100).

(d) *Applicability date.* The applicability date for this section is January 1, 2013. Nothing precludes a Part D sponsor and pharmacy from mutually agreeing to an earlier implementation date.

(e) *Copayments.* Regardless of the number of incremental dispensing events, the total cost sharing for a Part D drug to which the dispensing requirements under this paragraph (a) apply must be no greater than the total cost sharing that would be imposed for such Part D drug if the requirements under paragraph (a) of this section did not apply.

(f) *Unused drugs returned to the pharmacy.* The terms and conditions that must be offered by a Part D sponsor under § 423.120(a)(5) must include provisions that address the disposal of drugs that have been dispensed to an enrollee in a long-term care facility but not used and which have been returned to the pharmacy, in accordance with Federal and State regulations, as well as whether return for credit and reuse is authorized where permitted under State law.

Subpart F—Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

■ 56. Amend § 423.265 by adding paragraph (b)(3) to read as follows:

§ 423.265 Submission of bids and related information.

* * * * *

(b) * * *

(3) CMS may decline to accept any or every bid submitted by a Part D sponsor or potential Part D sponsor.

* * * * *

■ 57. Amend § 423.272 by adding paragraph (b)(4) to read as follows:

§ 423.272 Review and negotiation of bid and approval of plans submitted by potential Part D sponsors.

* * * * *

(b) * * *

(4) CMS may decline to approve a bid if the Part D sponsor proposes significant increases in cost sharing or decreases in benefits offered under the plan.

* * * * *

■ 58. Amend § 423.286 as follows:

■ A. Revising paragraph (a).

■ B. Adding paragraph (d)(4).

The revision and addition read as follows:

§ 423.286 Rules regarding premiums.

(a) *General rule.* Except as provided in paragraphs (d)(3), (d)(4), 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.

* * * * *

(d) * * *

(4) *Increase for income-related monthly adjustment amount (Part D—IRMAA).* Beginning January 1, 2011, Medicare beneficiaries enrolled in a Medicare Part D plan must pay an income-related monthly adjustment amount in addition to the Part D premium as determined under paragraph (c) of this section and adjusted under paragraph (d) of this section, if the enrollee's modified adjusted gross income exceeds the threshold amounts specified in 20 CFR 418.2115.

(i) *Social Security Administration determination.* (A) SSA determines which Part D enrollees are subject to the Part D—IRMAA and the amount each enrollee will have to pay.

(B) If an individual disagrees with SSA's determination that such individual is subject to the Part D—IRMAA, or about the amount the individual must pay, an individual may file an appeal or request a new initial determination consistent with 20 CFR part 418.

(ii) *Calculating the income-related monthly adjustment amount.* The income-related monthly adjustment is equal to the product of the quotient obtained by dividing the applicable premium percentage specified in § 418.2120 (35, 50, 65, or 80 percent) that is based on the level of the Part D enrollee's modified adjusted gross income for the calendar year reduced by 25.5 percent; and the base beneficiary premium as determined under paragraph (c) of this section.

* * * * *

■ 59. Amend § 423.293 as follows:

■ A. Redesignating paragraphs (d) and (e) as (e) and (f), respectively.

■ B. Add new paragraph (d).

§ 423.293 Collection of monthly beneficiary premium.

* * * * *

(d) *Collection of the income-related monthly adjustment amount (Part D—IRMAA).* (1) *Collection through withholding.* Where the Social Security Administration has determined the income-related monthly adjustment amount for an individual whose income exceeds the income threshold amounts specified at 20 CFR 418.2115, the Part D—IRMAA must be paid through withholding from the enrollee's Social Security benefit payments, or benefit payments by the Railroad Retirement Board (RRB) or the Office of Personnel Management (OPM) in the manner that the Part B premium is withheld.

(2) *Collection through direct billing.* In cases where an enrollee's benefit payment check is not sufficient to have the Part D—IRMAA withheld, or if an enrollee is not receiving such benefits, the beneficiary must be billed directly for the Part D—IRMAA. The beneficiary will have the option of paying the amount through an electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account) or according to other means that CMS may specify.

(3) *Failure to pay the income-related monthly adjustment amount: General rule.* CMS will terminate Part D coverage for any individual who fails to pay the Part D—IRMAA as determined by the Social Security Administration. CMS will terminate an enrollee's Part D coverage as specified in § 423.44(e).

* * * * *

Subpart J—Coordination Under Part D Plan With Other Prescription Drug Coverage

■ 60. Amend § 423.464 by revising paragraph (f)(2) to read as follows:

§ 423.464 Coordination of benefits with other providers of prescription drug coverage.

* * * * *

(f) * * *

(2) *Treatment under out-of-pocket rule.* (i) 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 plan must—

(A) Include the enrollee's incurred costs (as defined in § 423.100); and

(B) 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.

(ii) A Part D enrollee must disclose all these expenditures to a Part D plan in accordance with requirements under § 423.32(b)(ii).

* * * * *

Subpart K—Application Procedures and Contracts With PDP Sponsors

■ 61. Amend § 423.503 as follows:

■ A. Redesignating paragraph (b) as paragraph (b)(1).

■ B. Adding paragraph (b)(2).

■ C. Revising paragraph (c)(2)(i).

The revisions and addition read as follows:

§ 423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.

* * * * *

(b) * * *

(2) In the absence of 14 months of performance history, CMS may deny an application based on a lack of information available to determine an applicant's capacity to comply with the requirements of the Part D program.

* * * * *

(c) * * *

(2) * * *

(i) If CMS finds that the applicant does not appear qualified to contract as a Part D sponsor, it gives the applicant notice of intent to deny the application and a summary of the basis for this preliminary finding.

* * * * *

■ 62. Amend § 423.505 as follows:

■ A. Adding paragraphs (b)(22) and (b)(23).

■ B. Adding paragraph (o).

The additions read as follows:

§ 423.505 Contract provisions.

* * * * *

(b) * * *

(22) Address complaints received by CMS against the Part D sponsor by—

(i) Addressing and resolving complaints in the CMS complaint tracking system.

(ii) Displaying a link to the electronic complaint form on the Medicare.gov Internet Web site on the Part D plan's main Web page.

(23) Maintain a fiscally sound operation by at least maintaining a positive net worth (total assets exceed total liabilities).

* * * * *

(o) *Release of summary CMS payment data.* The contract must provide that the Part D sponsor acknowledges that CMS releases to the public summary reconciled Part D payment data after the reconciliation of Part D payments for the contract year as follows:

(1) The average per member per month Part D direct subsidy standardized to the 1.0 (average risk score) beneficiary for each Part D plan offered.

(2) The average Part D risk score for each Part D plan offered.

(3) The average per member per month Part D plan low-income cost sharing subsidy for each Part D plan offered.

(4) The average per member per month Part D Federal reinsurance subsidy for each Part D plan offered.

(5) The actual Part D reconciliation payment data summarized at the Parent Organization level including breakouts of risk sharing, reinsurance, and low income cost sharing reconciliation amounts.

■ 63. Amend § 423.507 as follows:

■ A. Redesignating paragraph (a)(4) as paragraph (a)(5).

■ B. Adding a new paragraph (a)(4) to read as follows:

§ 423.507 Nonrenewal of contract.

(a) * * *

(4) During the same 2-year period specified under paragraph (a)(3) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the non-renewing sponsor. A "covered person" as used in this paragraph means one of the following:

(i) All owners of nonrenewed or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner of a whole or part interest in a mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or by any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

* * * * *

■ 64. Amend § 423.508 by adding paragraph (f) to read as follows:

§ 423.508 Modification or termination of contract by mutual consent.

* * * * *

(f) *Prohibition against Part D program participation by organizations whose owners, directors, or management employees served in a similar capacity with another organization that mutually terminated its Medicare contract within the previous 2 years.* During the 2-year period specified in paragraph (e) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the mutually terminating sponsor. A "covered person" as used in this paragraph means one of the following:

(1) All owners of nonrenewed or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(2) An owner of a whole or part interest in a mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(3) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

■ 65. Amend § 423.509 by adding paragraph (e) to read as follows:

§ 423.509 Termination of contract by CMS.

* * * * *

(e) *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.

■ 66. Amend § 423.510 as follows:

■ A. Redesignating paragraph (e) as (e)(1).

■ B. Adding a new paragraph (e)(2).

The addition reads as follows:

§ 423.510 Termination of contract by Part D sponsor.

* * * * *

(e) * * *

(2) During the same 2-year period specified in (e)(1) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the terminating sponsor. A "covered person" as used in this paragraph means one of the following:

(i) All owners of nonrenewed or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner of a whole or part interest in a mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

* * * * *

Subpart M—Grievances, Coverage Determinations, and Appeals

■ 67. Amend § 423.562 as follows:

■ A. Redesignating paragraphs (a)(1)(ii) and (iii) as paragraphs (a)(1)(iii) and (iv), respectively.

■ B. Adding new paragraph (a)(1)(ii).

■ C. Revising paragraph (a)(3).

■ D. Adding paragraph (a)(5).

The revision and additions read as follows:

§ 423.562 General provisions.

(a) * * *

(1) * * *

(ii) Use a single, uniform exceptions and appeals process which includes, procedures for accepting oral and written requests for coverage determinations and redeterminations that are in accordance with § 423.128 (b)(7) and (d)(1)(iii).

* * * * *

(3) A Part D plan sponsor must arrange with its network pharmacies to distribute notices instructing enrollees how to contact their plans to obtain a coverage determination or request an exception if they disagree with the information provided by the pharmacist. These notices must comply with the standards established in § 423.128(b)(7)(iii).

* * * * *

(5) A Part D plan sponsor must employ a medical director who is responsible for ensuring the clinical accuracy of all coverage determinations and redeterminations involving medical necessity. The medical director must be a physician with a current and unrestricted license to practice medicine in a State, Territory,

Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

* * * * *

■ 68. Amend § 423.566 by adding paragraph (d) to read as follows:

§ 423.566 Coverage determinations.

* * * * *

(d) *Who must review coverage determinations.* If the Part D plan sponsor expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the coverage determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the Part D plan sponsor issues the coverage determination decision. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

■ 69. Amend § 423.568 by revising paragraph (f) to read as follows:

§ 423.568 Standard timeframe and notice requirements for coverage determinations.

* * * * *

(f) *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. The initial notice may be provided orally, so long as a written follow-up notice is mailed to the enrollee within 3 calendar days of the oral notification.

* * * * *

Subpart P—Premium and Cost-Sharing Subsidies for Low-Income Individuals

■ 70. Section 423.772 is amended by adding the definition of "Individual receiving home and community-based services" to read as follows:

§ 423.772 Definitions.

* * * * *

Individual receiving home and community-based services means a full-benefit dual-eligible individual who is receiving services under a home and community-based program authorized for a State in accordance with one of the following:

(1) Section 1115 of the Act.

(2) Section 1915(c) or (d) of the Act.

(3) State plan amendment under section 1915(i) of the Act.

(4) Services are provided through enrollment in a Medicaid managed care organization with a contract under section 1903(m) of the Act or section 1932 of the Act.

* * * * *

■ 71. Amend § 423.780 as follows:

■ A. Revising paragraph (b)(2)(ii)(C).

■ B. Adding paragraph (f).

The revision and addition read as follows:

§ 423.780 Premium subsidy.

* * * * *

(b) * * *

(2) * * *

(ii) * * *

(C) The MA monthly prescription drug beneficiary premium (as defined under section 1854(b)(2)(B) of the Act) for a MA–PD plan and determined before the application of the monthly rebate computed under section 1854(b)(1)(C)(i) of the Act for that plan and year involved.

* * * * *

(f) *Waiver of de minimis premium amounts.* CMS will permit a Part D plan to waive a de minimis amount that is above the monthly beneficiary premium defined in § 423.780(b)(2)(ii)(A) or (B) for full subsidy individuals as defined in § 423.780(a) or § 423.780(d)(1), provided waiving the de minimis amount results in a monthly beneficiary premium that is equal to the established low income benchmark as defined in § 423.780(b)(2).

■ 72. In § 423.782, revise paragraph (a)(2)(ii) to read as follows:

§ 423.782 Cost-sharing subsidy.

* * * * *

(a) * * *

(2) * * *

(ii) Full-benefit dual-eligible individuals who are institutionalized or who are receiving home and community-based services have no cost-sharing for Part D drugs covered under their PDP or MA–PD plans.

* * * * *

Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans

■ 73. Amend § 423.884 as follows:

■ A. Redesignating paragraph (c)(3)(ii) and (c)(3)(iii) as paragraphs (c)(3)(iii) and (c)(3)(iv), respectively.

■ B. Adding a new subparagraph (c)(3)(ii).

■ C. Revising paragraphs (d) introductory text, (d)(1)(i) and (ii), and (d)(5)(iii)(C).

The addition and revisions read as follows:

§ 423.884 Requirements for qualified retiree prescription drug plans.

* * * * *

(c) * * *

(3) * * *

(ii) Acknowledge that at the same time CMS releases Part C and Part D summary payment data in accordance with § 422.504(n) and § 423.505(o) CMS will also release Part D retiree drug subsidy payment data for the most recently reconciled year including the name of the eligible sponsor, the total gross aggregate dollar amount of the CMS subsidy, and the number of eligible retirees;

* * * * *

(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 coverage (as defined at § 423.100), not taking into account the value of any discount or coverage provided during the coverage gap (as defined at § 423.100). The attestation must meet all of the following standards:

(1) * * *

(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, not taking into account the value of any discount or coverage provided during the coverage gap.

(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 that plan year in question, not taking into account the value of any discount or coverage provided during the coverage gap.

* * * * *

(5) * * *

(iii) * * *

(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, not taking into account the value of any discount or coverage provided during the coverage gap.

Subpart V—Part D Marketing Requirements

■ 74. In § 423.2264, revise paragraph (e) to read as follows:

§ 423.2264 Guidelines for CMS review.

* * * * *

(e) For markets with a significant non-English speaking population, provide materials in the language of these individuals. Specifically, Part D plan sponsors must translate marketing materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.

■ 75. Amend § 423.2272 by adding paragraph (e) to read as follows:

§ 423.2272 Licensing of marketing representatives and confirmation of marketing resources.

* * * * *

(e) Terminate upon discovery any unlicensed agent or broker employed as a marketing representative and notify any beneficiaries enrolled by an unqualified agent or broker of the agent's or broker's status and, if requested, of their options to confirm enrollment or make a plan change (including a special election period, as described in § 423.38(c)(8)(i)(C)).

■ 76. Amend § 423.2274 by revising the introductory text and paragraphs (b) and (c) to read as follows:

§ 423.2274 Broker and agent requirements.

For purposes of this section "compensation" includes pecuniary or nonpecuniary remuneration of any kind relating to the sale or renewal of a policy including, but not limited to, commissions, bonuses, gifts, prizes, awards, and finder's fees. "Compensation" does not include the payment of fees to comply with State appointment laws, training, certification, and testing costs; reimbursement for mileage to, and from, appointments with beneficiaries; or reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials. If a Part D sponsor markets through independent (that is, non-employee) brokers or agents, the requirements in paragraph (a) of this section must be met. The requirements in paragraphs (b) through (e) of this section must be met if a Part D sponsor markets through any broker or agent, whether independent (that is, non-employee) or employed.

* * * * *

(b) It must ensure that all agents selling Medicare products are trained annually, through a CMS endorsed or approved training program or as specified by CMS, on Medicare rules and regulations specific to the plan products they intend to sell.

(c) It must ensure agents selling Medicare products are tested annually by CMS endorsed or approved training program or as specified by CMS.

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Authority: (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program).

Dated: March 16, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: March 31, 2011.

Kathleen Sebelius,

Secretary.

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