DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, and 423

[CMS–4144–P]

RIN 0938–AQ00

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

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

ACTION: Proposed rule.

SUMMARY: We are proposing 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 continued experience in the administration of the Part C and D programs. These latter proposed revisions would clarify various program participation requirements; make changes to strengthen beneficiary protections; strengthen our ability to identify strong applicants for Parts C and D program participation and remove consistently poor performers; and make other clarifications and technical changes.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. Eastern Standard Time (EST) on January 21, 2011.

ADDRESSES: In commenting, please refer to file code CMS–4144–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/eRulemaking.* Click on the link "Submit electronic comments on CMS regulations with an open comment period." (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4144–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4144–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Vanessa Duran, (410) 786–8697 and Sabrina Ahmed, (410) 786–7499, General information.
Christopher McClintick, (410) 786–4682, Part C issues.
Deborah Larwood, (410) 786–9500, Part D issues.
Kristy Nishimoto, (410) 786–8517, Part C and D enrollment and appeals issues.
Deondra Moseley, (410) 786–4577, Part C payment issues.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–4144–P.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received at *http://www.cms.hhs.gov/eRulemaking.* Click on the link "Electronic Comments on CMS Regulations" on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

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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
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 Programs
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
TrOOP True Out-Of-Pocket
U&C Usual and Customary
USP U.S. Pharmacopoeia

SUPPLEMENTARY INFORMATION:

I. Background

A. Overview of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

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 D regulations to continue to improve or clarify existing policies and/or codify current guidance for both programs. For example, 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 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). In April 2010, we finalized new policies for both the MA and Part D prescription drug programs as part of our continuing efforts to protect beneficiaries from excessive out-of-pocket costs, ensure transparency in plan costs and benefits, and strengthen plan compliance with our requirements (75 FR 19678 through 19826).

B. History and Overview

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. As discussed above, the MMA, enacted on December 8, 2003, added a new "Part D" to the Medicare statute (sections 1860D–1 through 42 of the Act) creating the Medicare Prescription Drug Benefit Program, and made significant changes to the M+C program.

Also as noted previously, MIPPA, enacted on July 15, 2008, further amended provisions in Part C and D, including adding extensive new provisions governing marketing under both programs, which were implemented in a final rule that paralleled provisions in MIPPA that was published in the **Federal Register** on September 18, 2008 (73 FR 54208), and in the same issue of the **Federal Register** (73 FR 54226) we published a separate interim final rule that addressed the other provisions of MIPPA affecting the MA and Part D programs. We also clarified the MIPPA marketing provisions in a November 2008 interim final rule (73 FR 67407) and issued a separate interim final rule in January 2009 to address MIPPA provisions related to Part D plan formularies (74 FR 2881).

The proposed and final rules addressing additional policy clarifications under the Part C and 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 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 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 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.

In this new proposed rule, we are continuing 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 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 are proposing 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, our proposals are intended to strengthen the way we administer the Part C and D programs, and help beneficiaries make the best plan choices for their health care needs.

II. Provisions of the Proposed Regulations

A. Overview of Proposed Changes

In the sections that follow, we discuss the proposed changes to the 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 are proposing, we have structured the preamble narrative by topic area rather than in subpart order. Accordingly, our proposals 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 for approval stronger applicants for Parts C and D program participation and to remove consistently poor performers.
- Implementing other clarifications and technical changes.

A number of the proposed revisions and clarifications affect both the MA and prescription drug programs, while 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 would be revised.

We note that these regulations would be effective 60 days after the publication of the final rule that will finalize the proposed changes discussed in this proposed rule, except where otherwise noted in the preamble. Table 1 lists the proposed changes that have an effective date other than 60 days after the publication of the final rule. The proposed effective dates are discussed in the preamble for each of these items.

We are proposing several changes to the regulations to reflect provisions in the ACA which either are already in effect, or have an effective date that will likely be earlier than 60 days after the publication of the final rule. Table 2 lists these proposed changes. While these ACA provisions are effective on the statutory effective date, we propose that the regulations implementing these provisions be effective 60 days after the publication of the final rule.

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Table 1: Proposed Effective Date of Certain Proposed Provisions Effective on Dates other than 60 Days after the Publication of the Final Rule

Preamble Section	Section Title	Effective Date As Specified in the ACA
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	01/01/2012
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: Certain Proposed Provisions with ACA Effective Dates Earlier than 60 Days after the Publication of the Final Rule

Preamble Section	Section Title	Effective Date 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

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 Act concern the Part C and D programs and 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.

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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	§417.101 §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
Uniform Exceptions and Appeals Process for Prescription Drug Plans	N/A	N/A	Subpart C Subpart M	§423.128 §423.562

PROVISION	PART 417/422		PART 423	
	Subpart	Section	Subpart	Section
and MA-PD Plans				
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	§417.101 §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 (§ 417.101 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 services 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 at 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 final rule that appeared in the April 15, 2010 **Federal Register** (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 are proposing to amend § 422.100 by adding a new paragraph (g). 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 are proposing in a proposed new paragraph (g) in § 417.100 that the requirements in section 3202 of the ACA be extended by regulation 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.

We believe that the measures to protect beneficiaries from high out-of-pocket costs in section 3202 of the ACA complement the steps we already have taken in our April 2010 final rule to protect beneficiaries from health plans with high out-of-pocket costs, discriminatory cost sharing and benefit designs that interfere with beneficiaries' access to affordable high quality health care, and create confusion that is attributable to having too many MA plan choices in an area that are not "meaningfully different." In fact, for CY 2011, MA organizations already were expected to comply with new standards for cost sharing and to submit meaningfully different plans in order to reduce beneficiary confusion, and were strongly encouraged to provide Medicare-covered preventive services without cost sharing. Organizations also were expected to limit the number of plans offered in a service area by identifying for non-renewal plans with sustained low enrollment.

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 addition to § 422.100 and § 417.101, we would incorporate these definitions for the two service categories. We welcome comments on these proposed cost sharing standards.

We also are proposing to limit cost sharing for home health services under MA plans to that charged under Original Medicare. We note 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 would rely instead 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 believe that even with the additional restriction on cost sharing for home health services, 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. We are soliciting public comment on our proposal to limit cost sharing for home health services to that charged for those services under Original Medicare.

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 propose to amend § 422.62(a)(2) and § 423.38(b) to codify this change, which will be effective October 15, 2011 for elections effective January 1, 2012.

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 replaces the MA open enrollment period that previously occurred annually from January 1 to March 31, and eliminates the requirements in section 1851(e)(2)(c)(iii) of the previous open enrollment provision that required that Part D status be maintained when an election is made (under the previous rule, an individual disenrolling from an MA–PD plan to Original Medicare was required to enroll in a Part D plan, where it is optional under the new provision). We propose to amend § 422.62(a) to provide for this new disenrollment opportunity, and modify § 423.38(d) to allow for enrollment into a standalone PDP.

We also would amend § 422.62(a) to clarify that the open enrollment opportunities for those beneficiaries who are newly eligible for MA would continue only through the end of 2010. Additionally, we would modify § 422.68(f) to specify the effective date for disenrollment requests submitted during the new 45-day disenrollment period. Finally, in § 423.40(d), we would 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. These changes would be effective January 1, 2011.

As indicated in section II.A. of this proposed rule, we propose that the regulations implementing these provisions be effective 60 days after the publication of the final rule.

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

This section proposes a definition of a fully integrated dual-eligible special needs plan (SNP) for purposes of section 3205(b)(iv)(II) of the ACA, and regulations implementing changes made by the ACA which extend the SNP program, extend provisions permitting existing DE–SNPs that were not seeking to expand their service areas to continue operating through 2012, and establish a required NCQA 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 provides authority to apply a frailty payment under PACE payment rules for certain individuals under fully integrated dual-eligible special needs plans described in section 3205(b)(iv)(II) of the ACA. We are adding a definition of fully integrated dual-eligible SNPs to § 422.2 that would apply for these purposes. Under this definition, a plan—

- Is a SNP enrolling special needs individuals entitled to medical assistance under a State plan under Medicaid, as defined under section 1859(b)(6)(B)(ii) of the Act and § 422.2;
- Provides dually-eligible beneficiaries access to Medicare and Medicaid benefits under a single managed care organization (MCO);
- 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;
- 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
- Employs policies and procedures approved by CMS and the State to coordinate or integrate member materials, including enrollment, communications, grievance and appeals, and quality assurance.

b. Extending SNP Authority

Section 3205 of the ACA revised section 1859(f)(1) of the Act 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, with the exception of dual eligible SNPs that do not have a contract with the State in which they operate as described in section II.B.1.c. of this proposed rule. This provision is effective upon enactment of the ACA. However, as indicated in section II.A. of this proposed rule, we propose that the regulations implementing this provision be effective 60 days after the publication of the final rule.

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

Section 164 of MIPPA provided that all new dual-eligible SNPs (DE SNPs) must have contracts with the State Medicaid Agencies in the States in which the SNP plans operate. The provision also allowed existing DE 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 all other MIPPA established requirements were met. This authority was codified at § 422.107. Section 3205 of the ACA extended this provision for existing DE SNPs through December 31, 2012 such

that all new DE SNPs must have contracts with State Medicaid agencies, while all renewing DE SNPs that do not have contracts with State Medicaid agencies and are not seeking to expand their service areas may continue to offer DE SNPs through the 2012 contract. For contract year 2013, all DE SNPs—new and renewing—must have contracts with State Medicaid agencies. Accordingly, we propose revising § 422.107(d)(ii) to codify this provision. This provision is effective upon enactment of the ACA. However, as indicated in section II.A. of this proposed rule, we propose that the regulations implementing this provision be effective 60 days after the publication of the final rule.

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 SNPs be approved by the National Committee for Quality Assurance (NCQA) effective January 1, 2012 and subsequent years. Under this section, the NCQA approval process shall be based on the standards established by the Secretary.

The NCQA SNP approval process should provide a foundation for selecting Medicare Advantage organizations that comprehend the unique requirements of the SNP program and are capable of implementing these requirements. Both the overall quality improvement (QI) program 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.

New SNPs or SNPs that are expanding their service areas are already required to submit a QI Program Plan and a MOC as part of the application process. For 2012, we will also require existing SNPs to submit their QI Program and MOC during the same application timeframe. NCQA will review the QI program and the MOC elements during the application process using the standards that are currently being developed by CMS. NCQA would assume responsibility for the review and scoring of the overall QI program plan and the MOC based on the standards developed by CMS. While we will coordinate with NCQA in developing these standards, CMS will not participate in the scoring and review of the MOC and QI program plans.

Shortly, we will release specific instructions and guidance to organizations about how to submit their QI program and MOCs. This guidance will include the specific criteria that NCQA will use to evaluate the QI program and the MOC. Also included in the guidance will be information about technical assistance that will be available to the SNPs as they prepare their QI Program and MOC submissions as well as details on the frequency of the SNP approval process. We are concerned that an annual approval process could be burdensome for plans. Therefore, we are considering an approval cycle that would occur between 1 to 5 years. This approval cycle would be designed so that the plans that have a higher score on the initial approval of their QI program and MOC would be granted a longer period before being required to be re-approved. While plans that scored at the lower end of the acceptable spectrum would be granted a shorter period before the next approval was required. We are also considering using other quality improvement measures to help determine the length of time a plan may have before reapproval. For example, plans that score well during their annual quality improvement audits may be eligible for extensions to the time period for the approval process. We would like to use the public comment period to help to determine the appropriate frequency for the SNP approval process.

We are conducting a review of the MOCs from a sample of the SNPs. Data are not yet available from these audits. However, it is anticipated that the audits will be completed by the end of the calendar year. Information received from the audits will be used to assist CMS in revising and improving the MOC. In addition, we intend to use this information to modify and refine the required evaluation criteria over time to improve the QI program and the MOC.

Accordingly, we propose adding 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 overall quality QI program and MOC to CMS for NCQA evaluation and approval, per CMS guidance. We also propose codifying the new requirement at § 422.101(f), which specifies MOC requirements, by adding a new paragraph (vi). Finally we propose codifying the new requirement by revising § 422.152(g), which specifies QI program requirements.

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

Section 3206 of the ACA revised section 1876(h)(5)(C) of the Act 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) be non-renewed beginning in 2010. In addition, MIPPA specified that MA plan enrollment be assessed over a full contract year.

As a result of the ACA revision, we will evaluate enrollment of competing MA coordinated care plans beginning 2012, and affected section 1876 cost contractors will receive non-renewal notices beginning 2013. Beginning in 2014, section 1876 cost contractors will no longer be able to offer health care services in affected service areas. We propose to revise § 417.402(c) to specify the statutory change in the implementation date of the section 1876 cost plan competition requirements from 2010 to 2013.

This provision is effective upon enactment of the ACA. However, as indicated in section II.A. of this proposed rule, we propose that the regulations implementing this provision be effective 60 days after the publication of the final rule.

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

Section 3208 of the ACA establishes (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. MA senior housing facility plans must:

- Limit enrollment to residents of continuing care retirement communities as defined in section 1852(l)(4)(B) and codified at § 422.133(b)(2)—that is, an arrangement under which housing and health-related services are provided (or arranged) through an organization for the enrollee under an agreement that is effective for the life of the enrollee or for a specified period;
- Provide primary care services onsite and have a ratio of accessible physicians to beneficiaries that the Secretary determines is adequate; and
- Provide transportation services for beneficiaries to specialty providers outside of the facility.

We propose to amend the definitions section at § 422.2 to include "senior

housing facility plan" as a new coordinated care plan type. Our proposed definition of the term senior housing facility plan would be consistent with the statutory requirements for such plans at section 1859(g) of the Act—that is, that such 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 note that a senior housing facility plan must otherwise meet all requirements applicable to MA organizations under this part.

In addition, we propose 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 propose 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 propose 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. As indicated in section II.A. of this proposed rule, we propose that the regulations implementing this provision be effective 60 days after the publication of the final rule.

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 subsections (C)(i) and (ii) to provide that nothing in section 1854 of the Act shall be construed as requiring the Secretary to accept any or every bid submitted by an MA organization, and expressly provides 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 also extends these provisions 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 proposed rule, we propose that the regulations implementing this provision be effective 60 days after the publication of the final rule.

We believe that these amendments clarify the Secretary's authority to deny bids submitted by MA organizations and PDP sponsors and provide support for our current policies intended to encourage plans that are high quality, meaningfully different from each other, and nondiscriminatory with respect to cost sharing. In our final rule entitled "Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" (75 FR 19678), we established authority to impose limits on cost sharing and to deny bids submitted by plans with sustained low enrollment, and for plans not meaningfully different from other plans offered by the same MA organization or PDP sponsor in a service area. We provided further guidance related to these policies 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 "2011 Part D Plan Benefit Package (PBP) Submission and Review Instructions").

Using our authority under sections 1857(c)(2)(B) and 1860D–12(b)(3)(D) of the Act, we codified requirements in § 422.506(b)(1)(iv) and § 423.507(b)(1)(iii) for Part C and Part D, respectively, to non-renew a health plan or prescription drug plan (at the benefit-package level) if the plan does not have sufficient number of enrollees to establish that it is a viable independent plan option. Consistent with that authority, we scrutinized low-enrollment plans during the bid review period this year and encouraged sponsors to withdraw or consolidate low-enrollment plans prior to submitting bids for CY 2011. We revised § 422.256(b)(4)(i) and § 423.272(b)(3)(i) to stipulate that we would only approve a bid submitted by a MA organization or Part D sponsor if its benefit package or plan cost structure is substantially different from those of other plan offerings by the organization or sponsor in the service area with respect to key characteristics such as premiums, cost-sharing, formulary structure, or benefits offered. Related changes to § 422.254(a)(4) and § 423.265(b)(2) provide that MA organizations and Part D sponsors may submit multiple bids in the same area only if the offerings are substantially different from each other. In the above-mentioned April 16, 2010 guidance for PDP sponsors, for the CY 2011 plan year, we defined meaningful differences between health plans as a $20 per member per month difference (PMPM) in cost sharing and for PDPs as a $22 PMPM difference in cost sharing (not including premiums) as reflected in the out-of-pocket cost (OOPC) data.

We further indicated that we do not believe sponsors can demonstrate meaningful differences based on expected out-of-pocket costs between two stand-alone basic Part D benefit designs and maintain both statutory actuarial equivalence requirements and fulfill the requirement (in § 423.153(b)) to maintain cost-effective drug utilization review programs. Therefore, we indicated that PDP sponsors should submit only one basic offering (where basic offering includes defined standard, actuarial equivalent or basic alternative drug benefit types) for a stand-alone prescription drug plan in a service area. We also are increasing our scrutiny of the expected cost sharing amounts incurred by beneficiaries under coinsurance tiers, in order to more consistently compare copay and coinsurance cost sharing impacts. If a sponsor submitted coinsurance values (instead of copayment values) for its formulary tiers, we requested documentation from the sponsor on the average expected price for medications on the coinsurance tier(s) in order to better translate the coinsurance value into an average cost sharing amount for the purpose of our anti-discrimination review. These additional benefit and formulary evaluations are in addition to our formulary review and analysis of tier placement of drugs to ensure that the coverage is balanced and that the associated cost sharing does not discriminate against beneficiaries with a certain disease or diagnosis category. Therefore, we have already established, in effect, a bid review policy that evaluates the limits plans place on member benefits and cost sharing.

Under authority clarified in section 3209 of the ACA to decline to accept bids, we believe that we can choose to limit the number and/or type of plans offered in service areas to enhance our ability to achieve our goals, which are to protect beneficiaries from confusion, discriminatory cost sharing, and any but the highest performing plans. For instance, for CY 2011, we are requiring that MA organizations and PDP sponsors meet new cost sharing standards, ensure that meaningful differences exist between plan offerings,

and consolidate or terminate plans with sustained low enrollment. Although we are not now proposing to establish additional restrictive criteria for CY 2012, we considered proposing additional regulatory restrictions and assessed the expected effects of such additional restrictions on MA organizations, PDP sponsors, and beneficiaries. For example, we believe the Secretary has authority under section 3209 by regulation to set specific thresholds limiting premium increases that can be imposed without a bid being denied, limit which MA organizations and PDP sponsors may offer plans based on quality ratings, and specify caps on the number or the types of plans that may be offered in a service area.

We concluded that we would not propose such additional restrictions limiting MA organizations' or PDP sponsors' plan bids until we were able to evaluate the effectiveness of the limits in place for CY 2011. We also are aware of the many changes we required plans to make for CY 2011 and believe that allowing plans time to adjust to the most recent policies prior to implementing further restrictions may be the most advantageous and reasonable approach for CMS, Medicare beneficiaries, and the organizations and sponsors. Thus, although we believe the new authority strengthens our ability to take corrective action in the event that MA organizations and PDP sponsors do not meet the criteria in our current regulation and subsequent guidance, we realize that setting further limits before we have enough information to evaluate the effectiveness of our recent policy changes or their effects on the market may be premature.

Furthermore, with respect to Part C, we believe that the implementation of specific non-acceptance and denial policies based on comparisons of premium and cost sharing increases and benefit decreases from year to year would be especially challenging considering the number of plan types and services offered by MA organizations. There would be serious difficulties with an effective quantitative premium and cost sharing evaluation process. Such a process would need to measure and adjust for annual changes in maximum out-of-pocket limits, Original Medicare cost-sharing and premiums, medical cost inflation, MA payment policy, benefit designs, and plan service expansions and reductions. Such a process might well turn out to be too rigid to adapt to rapidly changing circumstances and market conditions.

To avoid such rigidity, and to promote the statutory goals (including protection of beneficiaries from confusion and discriminatory cost sharing), we do not propose to specify additional criteria such as thresholds (either absolute or relative to the distribution of bids received) limiting acceptable premium increases. But we do seek comment on our proposed approach and on possible alternatives, designed to balance the need to avoid rigidity while promoting clarity and predictability. We are specifically soliciting public comments from the industry and advocacy communities regarding 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. We also invite comment as to 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 provision of high quality, affordable health plans. We also solicit comments on whether we should adopt other substantive criteria for exercising our authority under section 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. For example, for contract year 2011, we identified plan outliers based on changes in premiums and cost-sharing and required some changes to plan bids in order for them to be approved. We solicit comment on this and other, similar approaches of using outlier analyses based on previous and/or current contract year bids to exercise our authority under section 3209 of the ACA. We ask the industry and advocacy communities what we should consider when limiting the acceptance of plan bids or denying plan bids (for example, comparability and access to services in certain service areas, plan performance, outlier plans with the highest bids), were we to choose to move in that direction. Finally, we solicit comment 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. Our decision not to propose additional specific criteria for CY 2012 should not be interpreted as an indication that we will not adopt specific policies in future rulemaking or that we will not perform robust and thorough reviews of bid submissions. We will continue to use our statutory and regulatory authority to ensure that only high value, non-discriminatory, and actuarially sound bid submissions are approved as we evaluate the effects of our current cost sharing, meaningful differences and low-enrollment policies and consider the timely suggestions and comments we receive from the public on this proposed rule to guide our future policy. Additionally, we note that our discretion to make determinations that MA plan bids propose significant increases in cost sharing or decreases in benefits offered on a case-by-case basis, in accordance with statutory goals, is limited to consideration of the criteria for acceptance or denial of plan bids that have been established via rulemaking and guidance.

We propose 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.

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. Section 1860D–14(b)(3)(B)(iii) of the Act, as amended by the ACA, 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. This proposed rule updates the regulations at § 423.780(b)(2)(ii)(C) to incorporate this change. As indicated in section II.A. of this proposed rule, we propose that the regulations implementing this provision be effective 60 days after the publication of the final rule.

We note that the ACA also requires us to calculate the low-income premium benchmarks before the application of the quality bonuses under section 1853(o) of the Act. The ACA section 1102(d) ties the level of rebate to a plan's star rating for quality of performance. Since the quality bonus is part of the rebate, we do not refer to this requirement in the regulation text. The quality bonus is described in more detail in the Medicare Advantage Benchmark, Quality Bonus Payments, and Rebate section (*see* section II.B.20. of this proposed rule).

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 the plan's premium was greater than the LIS benchmark premium amount, so long as amount of

the premium is *de minimis* and the plan waives it.

Section 3303(b) of the ACA modifies section 1860D–1(b)(1) of the Act 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 there is more than one plan, the statute requires that enrollees be randomly assigned among all such plans in the PDP region. We propose to amend regulations in § 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 proposed rule, we propose that the regulations implementing these provisions be effective 60 days after the publication of the final rule.

a. Reassigning LIS Individuals (§ 423.34)

Currently, § 423.34(c) specifies that CMS may reassign certain low income subsidy 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 is going to exceed the low income benchmark as calculated in § 423.780(b)(2). As noted above, 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 is *de minimis* and the plan volunteers to waive the amount by which their monthly premium exceeds the LIS benchmark. Thus, plans that would otherwise have lost enrollees because of a *de minimis* monthly beneficiary premium can retain their membership. We are proposing to amend § 423.34(c) regarding reassignment of LIS beneficiaries to reflect section 1860D–1(a)(5) of the Act.

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

Currently, § 423.34(d) specifies that CMS enroll LIS eligible individuals who fail to enroll in a PDP. The PDP into which we auto-enroll these individuals are 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 are proposing 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 the ACA. We will provide details on when we will use this discretion in forthcoming guidance, specifically operational guidance memorandums as well as in Chapter 3 on Eligibility, Enrollment, and Disenrollment of the Medicare Prescription Drug Benefit Manual. We expect that we will not auto-enroll or reassign beneficiaries into plans that volunteer to waive the *de minimis* amount. The only exception would be in cases where the reassignments would allow beneficiaries to remain within the same parent organization. Plans within the same organization usually have the same formulary, so keeping a person within the same organizations minimizes disruption. This mimics the policy in place during the *de minimis* demonstration from 2007 and 2008. The goal of that policy was to minimize reassignments, while maintaining downward pressure on Part D bids by not rewarding *de minimis* plans with new enrollees. Beneficiaries with 100 percent premium subsidy who are already enrolled in, or voluntarily elect, a PDP or MA–PD plan that waives the *de minimis* amount will not be liable for premiums. Although we do not intend to exercise this discretion by including Part D plans that waive the *de minimis* amount in the pool of Part D plans qualified to receive auto-enrollees or reassignees, we do believe that the D regulations should be modified so that the flexibility to do so can be maintained.

c. Premium Subsidy (§ 423.780)

We are also proposing to amend § 423.780(f) to reflect section 1860D–14(a)(5) of the Act. 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 propose to limit the waiver of the *de minimis* amount to the premium applicable to the basic benefit. We will determine the *de minimis* amount taking into consideration the goal of minimizing reassignments without undue cost to the program. We will announce the *de minimis* amount each August, in conjunction with our announcement of the LIS benchmarks. Plans will volunteer as part of the bid finalization process. Additional details will be provided in forthcoming guidance.

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 calendar year (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.
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.
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.
Greater than $214,000	Greater than $428,000	80.

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 income related monthly amount for Part D will be calculated using the Part D national base beneficiary premium and the premium percentages in the above chart as follows: BBP x [(P percent − 25.5 percent)/25.5 percent]. The BBP is the base beneficiary premium and P percent 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 us 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. We must also provide SSA, no later than October 15 of each year, beginning 2010, 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 will provide SSA with an initial list of all individuals enrolled in the Part D program. In accordance with section 3308 of the ACA, SSA will use 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 will occur in 2010 so that individuals identified will be 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 to SSA in the same manner that has been established for the Part B—IRMAA 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 are proposing 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 propose to revise § 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.

We also propose to add a new § 423.286(d)(4) to define the increase for the income related monthly adjustment amount for Part D. This provision would specify that, beginning, January 1, 2011, the monthly beneficiary premium amount would be increased for any individual whose modified adjusted gross income amount exceeds the minimum income threshold amounts established at 20 CFR 418.1115 for the Part B—IRMAA. Additionally, proposed § 423.286(d)(4)(i) would specify that SSA would determine the individuals that are subject to the Part D—IRMAA and the amount of the adjustment. Proposed § 423.286(d)(4)(ii) would provide the formula used to calculate the monthly adjustment amount. Finally, proposed § 423.286(d)(4)(iii)–(iv) would provide appeals rights to individual who disagree with SSA's determination that they are subject to Part D—IRMAA or the threshold amount.

b. Collection of Monthly Beneficiary Premium (§ 423.293)

We are proposing to establish a new § 423.293(d)(1) that describes how the Part D—IRMAA would be collected. First, we would address the process for collecting the Part D—IRMAA from SSA, RRB or OPM benefit payments. In cases where SSA had determined that a Part D enrollee must pay an income related monthly adjustment amount, 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 would establish 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. Although the Part D—IRMAA is paid to CMS (via benefit payment withholdings or direct billing as described above), and not to the PDP, we believe the same consequences should apply for failure to pay the Part D—IRMAA as for failure to pay plan premiums. Therefore, we are proposing, at § 423.293(d)(3), that CMS would terminate Part D coverage for any individual who fails to pay the income related monthly adjustment amount in accordance with proposed § 423.44.

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 propose to apply provisions similar to the existing Part D premium rules to terminate Part D coverage for any individual who fails to pay the Part D—IRMAA. However, prior to terminating coverage, we propose to provide the beneficiary with a grace period to pay the Part D—IRMAA. We propose to add § 423.44(e), to specify the involuntary disenrollment process by CMS when an individual fails to pay the Part D—IRMAA.

Section 1860D–13(c) of the Act provides that enrollees' Part D coverage can be terminated if they fail to pay their Part D premiums to the PDP after a grace period and adequate notice has been provided. In cases where enrollees' Part D coverage is terminated due to their failure to pay premiums, Medicare rules do not now provide reinstatement if the enrollee later pays the premium arrearages after the termination date. We note that section C.8 of this preamble addresses our proposal to amend § 423.44(d)(1) to reinstate a beneficiary's enrollment into Part D if the beneficiary demonstrates good cause for failing to pay the Part D premium. Additionally, terminated enrollees cannot re-enroll in a stand-alone Part D or MA–PD plan unless they have a valid enrollment period. Consequently, waiting for a valid enrollment period may create a period in which an individual is without coverage and, depending on the duration, the enrollee may incur a Part D late enrollment penalty. Therefore, we propose to create a grace period and an extension of the grace period for good cause and reinstatement at § 423.44(e)(2) and (3) for individuals subject to the Part D—IRMAA. Although CMS recently extended the grace period that PDPs must provide enrollees before disenrolling them for failure to pay their premium (75 FR 19816) from a minimum of 1 month to 2 months, we propose to apply a longer grace period with respect to the Part D—IRMAA. The extended grace period under this proposed provision would be similar to the grace period (and extension of the initial grace period) afforded individuals under section 1838(b) of the Act with respect to the Part B premium (including the Part B—IRMAA).

We believe that it is appropriate to provide additional beneficiary flexibility in terms of a longer grace period for the Part D—IRMAA because section 3308 of the ACA does not impact the direct subsidy amount that CMS is required to pay Part D plan sponsors. Specifically, the Part D—IRMAA is not a reduction in the direct subsidy that CMS pays to PDPs; instead, it is an income-based amount paid to CMS in addition to the premium that is paid by the enrollee to his/her Part D plan. Thus, an extended grace period would not impact PDPs negatively. Furthermore, the extended grace period would allow the beneficiary more time to pay the Part D—IRMAA arrearages and avoid an immediate disenrollment that would leave the beneficiary without Part D coverage sooner. Therefore, we are proposing to allow all enrollees a minimum grace period of 3 months following the billing month to pay any Part D—IRMAA arrearages before they are disenrolled from their Part D plan. In addition, we propose that an enrollee's Part D coverage may be reinstated without interruption if the enrollee, within 3 calendar months after the termination date, demonstrates "good cause" (as defined under § 423.44(d)(1)(iv)of this proposed rule) for failure to pay Part D—IRMAA during the initial grace period, pays all Part D—IRMAA arrearages, and does not owe any plan premiums to the PDP. CMS (or an entity acting on behalf of CMS) will determine whether the beneficiary has demonstrated "good cause."

We are also proposing at § 423.44(e)(4) to require 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. We are also proposing to add a provision at § 423.44(e)(5) that would stipulate that in cases where an enrollee has been directly billed for the Part D—IRMAA and provided with the appropriate grace period as described above, the enrollee's termination will be effective the first day following the last day of the initial grace period. That is, the enrollee's last day of Part D coverage would be the last day of the grace period.

Finally, we propose to modify the title of § 423.44 from "Involuntary disenrollment by the PDP" to "Involuntary Disenrollment from Part D Coverage." The new title would encompass disenrollments at the behest of both PDPs and CMS. In addition to disenrollments for failure to pay the Part D—IRMAA, examples of disenrollments that may be initiated by CMS include disenrollment due to death or loss of entitlement to Medicare Parts A or B.

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 also 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 propose 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 policy in 42 CFR 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 without any further regulatory changes. We will update our guidance to plans to provide additional detail on how the Best Available Evidence regulation applies to this population.

Section 3309 of the ACA provides the Secretary the discretion regarding the effective date of this provision, with the stipulation that it shall be effective no earlier than January 1, 2012. We rely on data from State Medicaid agencies, submitted to us no less frequently than monthly, to identify the individuals in the State who are full-benefit dual eligibles and are institutionalized. These data allow us to set these individuals' Part D cost-sharing to zero. To expand the population entitled to zero cost-sharing to include individuals receiving home and community-based services, states would be required to identify these additional individuals in their data to CMS.

We are proposing that this provision take effect on January 1, 2012. We believe it is important to provide this benefit at the earliest possible date, since it will provide assistance to an estimated 600,000 beneficiaries a year. In proposing an effective date, we considered the administrative impact on States, and we believe that even the earliest possible effective date will provide States with adequate time for implementation.

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

Section 3310 of the ACA provides that the Secretary shall require Part D sponsors to utilize specific, uniform dispensing techniques, as determined by the Secretary in consultation with relevant stakeholders, such as weekly, daily, or automated dose dispensing when dispensing covered Part D drugs to enrollees who reside in long-term care (LTC) facilities in order to reduce waste associated with 30-day fills. We propose to implement this requirement by adding a new regulation at § 423.154 to govern how plan sponsors handle dispensing of covered Part D drugs in LTC facilities. The provisions of this regulation will apply to all organizations and sponsors offering Part D including stand alone Part D plans, MA organizations, EGWP contracts, and PACE plans.

Consistent with section 3310 of the ACA, we consulted with a number of stakeholders about dispensing in the LTC arena and their recommendations for implementing section 3310 of the ACA. On March 19, 2010, we participated in the "Short Cycle Dispensing Focus Group for Long Term Care" program hosted by the National Council for Prescription Drug Programs (NCPDP). The well attended focus group brought together pharmacies servicing LTC facilities, LTC facilities, vendors, prescription drug plans, and pharmacy benefit managers (PBMs). The objective of the conference was to discuss the implementation of 7-day-or-less dispensing from various points of view. We announced our open-door policy in several industry forums and have also actively reached out to all industry groups we could identify. We have consulted with a wide spectrum of industry stakeholders including professional organizations and trade groups; providers of LTC pharmacy services; vendors for automated dispensing technologies, pre-pack filling equipment and software; Part D sponsors; group purchasing organizations; LTC pharmacy networks; and pharmacy benefit managers. On June 29, 2010, we hosted a meeting on long-term care waste and the implementation of section 3310 of the ACA. The meeting brought together leaders in the LTC industry including nursing and pharmacy professional organizations, LTC facilities, and LTC pharmacies. The industry has been helpful in providing recommendations for implementing Section 3310 of the ACA to reduce waste associated with 30-day dispensing.

We consider "waste" to occur when a Part D drug is dispensed to a Part D enrollee residing in a LTC facility and billed to a Part D sponsor, but is not consumed by the Part D enrollee. Waste may occur, for example, when treatment with the Part D drug has been discontinued, the Part D enrollee has been discharged to the community, the Part D enrollee has been hospitalized, or the Part D enrollee has died, leaving unused dispensed drugs.

Under § 423.154 (a)(1)(i), we propose to require all pharmacies servicing long-term care facilities, as defined in § 423.100, to dispense brand-name medications, as defined in § 423.4, to enrollees in such facilities in no greater than 7-day increments at a time. During our discussions with the industry, multiple parties reported that 75 percent to 80 percent of the cost of drug wastage arises from only 20 percent of the drugs. That 20 percent is made up exclusively of brand-name medications. 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 supplies, we propose initially limiting the requirement for 7-day-or-less dispensing to brand-name drugs as defined in § 423.4. However, nothing precludes LTC pharmacies and facilities from expanding 7-day-or-less dispensing to more than brand-name drugs, and we encourage Part D sponsors to facilitate that practice. While we considered imposing the 7-day dispensing requirement for all drugs at once, in consultation with industry representatives, we have concluded that a transitional approach would ease the initial burden on nursing facility nursing staff time and LTC pharmacy pharmacist staff time, in particular 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. Many industry participants in our consultative phone interviews and face-to-face meetings indicated that they believed it would be feasible to change quickly to 7-days-or-less dispensing for the 20 percent of total scripts (that is, those for brand-name drugs). Although other industry representatives opined that a transitional approach was not necessary and that the additional labor associated with four times as many dispensing events per month on all applicable medications was being overestimated. Nonetheless, we are not aware of any objective data which demonstrate the cost effectiveness of full versus partial implementation, and thus we believe the more prudent course is to proceed with a transitional approach. If such data does exist, we welcome comments from the public presenting such data. Therefore, our proposal would apply the 7-day-or-less supply requirement initially only to brand-name drugs and would postpone applying the requirement to generic drugs until a later date which we will determine through future rulemaking. In the meantime, we solicit comments on how soon the industry can transition to include generic drugs in the 7-day-or-less requirement.

We also propose excluding from the requirements of § 423.154(a) those drugs that are difficult to dispense in a 7-day or less supply and drugs that are dispensed for acute illnesses. We believe 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. We propose to codify these exclusions at § 423.154(b). In proposing these exclusions, we recognize that there are some medications that, for the reasons described above, do not lend themselves well to a 7-day or less supply. These include eye drops, ear drops, inhalers and inhalation drugs, nasal sprays, reconstituted antibiotics and other drugs with parenteral route of administration, drugs that must remain in their original container, and topical medications. However, in keeping with the statute's intent—that is, the reduction of drug waste in the LTC setting—our proposal aims to be limited to instances where a 7-day-or-less dispensing requirement is truly not feasible. For example, some in the industry have suggested that we exclude liquids from the requirements; however, we believe most liquids can be transferred to smaller amber prescription bottles or oral syringes to accommodate 7-day-or-less dispensing, so we decline to propose the exclusion of all liquids. In contrast, we believe antibiotics reconstituted from powder need to remain in their original container and, thus, our proposal would exclude them from the 7-day-or-less dispensing requirement. For other medications that we proposed excluding from the requirement, we encourage use of smaller size containers, when available, to reduce the potential for waste. We solicit comments on the types of dosage forms and drugs that should be excluded from the requirements under § 423.154(a).

Another solution we considered to reduce waste in LTC facilities is in the area of return for credit and reuse. Under this scenario, Part D sponsors

would have policies in place, consistent with state law, to require unused Part D drugs to be returned to the pharmacy for reuse to fill another patient's prescription. Although return for credit and reuse is not prohibited by CMS, we recognize limitations to this approach since return for credit and reuse is not permitted in all states, often excludes lower cost generic drugs, and is frequently limited to a subset of drugs in unused or specially approved packaging. Moreover, return and reuse of controlled substances is limited by the Drug Enforcement Agency (DEA). In order to reduce pharmaceutical and financial waste, pharmacies must reclaim the unused medications from the LTC facility, reverse, and re-bill the claim to reflect the unused portion of drug, and restock the drug. We understand from discussions with the industry that this places a significant burden on the pharmacies. In addition, there are safety and quality control issues regarding storage of the unused medications in the LTC facility and chain of custody of the drugs to be returned. Finally, return for credit and reuse does not address issues regarding drug diversion because unused drugs that may be returned to the pharmacy for reuse are still available for diversion prior to restocking. Upon consideration of these facts, we decided that return for credit and reuse would not be the optimal solution to address drug waste generated by LTC facilities under Part D. However, we believe that Part D sponsor contracts should not be silent on the disposition of unused drugs. 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 propose 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 will also address contractual obligations for disposal in accordance with Federal and State regulations, as well as whether return for credit and reuse is authorized where permitted under State law. Beyond these proposed requirements, we urge the industry to improve practices with respect to the tracking and inventory control of returned unused drugs, as well as electronic transactions for adjustments to previously submitted claims and other reporting on the disposition of unused drugs. We solicit comments on whether there are DEA or state technical issues that may be barriers to the implementation of this provision.

Although we are not proposing to recognize return for credit and reuse as an alternative to 7-day-or-less dispensing, we understand that return for credit and reuse may be a supplement to reduce the minimal pharmaceutical waste associated with 7-day-or-less dispensing. Through conversations with the industry, we learned that there are circumstances where a Part D drug can be safely returned to stock for reuse. For example, a LTC facility may have an onsite pharmacy that services only that facility using unit dose packaging. Under those conditions, assuming state law allows return for credit and reuse, it would be a reasonable way to reduce the minimal waste that may be generated with 7-day-or-less dispensing. We will allow return for credit and reuse in LTC pharmacies, when return for credit and reuse is permitted under the state law and is allowed under the contract between the Part D sponsor and the pharmacy. We expect that if Part D drugs are returned for credit, the Part D drugs will be reused only if the environments to which the drugs have been exposed and chain of custody of the drugs do not compromise the safety or efficacy of the medication. In addition, when permitted or required contractually, we believe pharmacy dispensing fees paid to pharmacies may take into account restocking fees consistent with the proposed modification to dispensing fees under § 423.100, "Dispensing Fees" discussed in section II.F. of this proposed rule (Other Clarifications and Technical Changes).

While we believe return for credit and reuse, where permitted, can help to reduce some drug waste after it occurs, we believe it is better to prevent the waste from occurring in the first place through the use of 7-day-or-less dispensing. It stands to reason that if fewer drugs are available to be wasted, fewer drugs will be wasted. That proposition is supported in smaller studies and analyses projecting waste based on retrospective reviews of drugs dispensed using less than 30-day dispensing methodologies.[1] Those studies not only show a reduction in pharmaceutical waste, but also show savings associated with reduction of the waste.

Seven-day-or-less dispensing has advantages besides reducing financial waste. For example, 7-day-or-less dispensing is consistent with the DEA's requirement to guard against diversion of controlled substances by limiting the quantity of drugs dispensed. (See for example 21 CFR 1301.71). We are also convinced that 7-day-or-less dispensing would be more beneficial for the environment. We note that the Environmental Protection Agency (EPA) recommends that LTC facilities reduce the amount of pharmaceutical waste generated by limiting the amount of pharmaceuticals dispensed at one time.[2]

Based on our research and discussions with stakeholders, we therefore propose to require that for the purposes of dispensing Part D drugs to Part D enrollees in LTC facilities, Part D sponsors require that their contracted pharmacies dispense no more than a 7-day supply of brand-name drugs as defined in § 423.4, except when a brand-name drug is excluded from the requirement. We understand from the industry that 7-day-or-less dispensing has been used for decades by some pharmacies servicing small facilities with as few as ten beds, as well as by some pharmacies that service large facilities with hundreds of beds. Many pharmacies are currently using 14-day or 7-day-or-less dispensing methodologies for their Medicare Part A population since the nursing facilities are responsible for Part A stay-related costs and recognize the cost-saving value of lesser amounts dispensed at a time. As a result, many pharmacies providing drugs to LTC facilities have experience with 7-day-or-less dispensing.

The requirement would generally apply to "all pharmacies," including not only closed-door exclusively LTC pharmacies, but also retail pharmacies and mail order pharmacies that dispense to LTC facilities. Under section § 423.100, a LTC facility means a skilled nursing facility as defined in section 1819(a) of the Act, or a medical institution or nursing facility for which payment is made for an institutionalized

[1] James W. Moncrief, Advanced Pharmacy, data from a seven month study of 36 LTC facilities presented at the NCPDP Short Cycle Dispensing Meeting. Sheraton Hotel BWI, March 19, 2010.

Lepinski PW, Am J Hosp Pharm 1986 Nov; 43 (11):2771–9 Cost comparison of unit dose and traditional drug distribution in a long-term-care facility.

Brown CH, Am J Hosp Pharm. 1984 Apr; 41(4):698–702 Cost of discarded medication in Indiana LTC facilities.

Parrott KA Am J Hosp Pharm 1980 Nov; 37(11);1531–4 Drug waste in LTC facilities: impact of drug distribution system.

Farmer RG Am J Hosp Pharm 1985 Nov; 42(11):2488–91 Cost of drugs wasted in the multiple-dose drug distribution system in long-term-care facilities.

[2] Environmental Protection Agency, Unused Pharmaceuticals the health care industry: Interim report, August 2008 (available at *http://epa.gov/waterscience/ppcp/hcioutreach.pdf*)

individual under section 1902(q)(1)(B) of the Act. We note that this provision does not encompass settings such as group homes or assisted living facilities that may also be serviced by these same pharmacies.

We also note that 7-day-or-less dispensing does not correspond to a change in the quantity of a prescription a prescriber writes, or the number of prescriptions. Unlike the typical 30 or 90-day prescriptions written for individuals in the community, prescribing in the LTC setting is generally done by physicians inserting standing orders for medications into the residents' medical record. Pharmacies may dispense a partial days supply in a manner consistent with the proposed requirements of § 423.154(a)(1). Partial filling of prescriptions is not inconsistent with DEA regulations and is permissible under 21 CFR 1306.23 for Schedule III, IV, and V drugs and under 21 CFR 1306.13(b) for Schedule II drugs.

Under § 423.154(a)(1)(ii), we propose to permit the use of uniform dispensing techniques defined by each of the LTC facilities being serviced. By uniform techniques, we 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. The industry currently employs a variety of single and multi-dose packaging systems such as punch cards (also known as blister packs or bingo cards), strip packaging, cassettes, pouches, and envelopes. Consistent with section 3310 of the ACA, we consulted with the LTC industry and based on industry input, we have determined that it is not possible or practical for CMS or Part D sponsors to identify the uniform dispensing techniques that must be used by all pharmacies. Rather, it is the LTC facilities that are in the best position to identify uniform dispensing techniques to be used throughout their LTC facility. We understand from the industry that there are various constraints and considerations that limit the type of dispensing systems used in a particular LTC facility. For example, we understand that there are older LTC facilities that cannot easily support automated dose dispensing technology because of the computer networking and ventilation considerations for that type of equipment. Therefore, we are proposing 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. Based on our conversations with industry, we understand that one of the greatest potential problems in implementing a 7-day-or-less dispensing approach would be any inconsistency in the dispensing methodology and/or packaging technique utilized in the same LTC facility. We believe our proposal to require that Part D sponsors must ensure that their contracted pharmacies dispense Part D drugs using techniques that are uniform throughout the facility would address this concern. We believe this proposal is consistent with the purpose of section 3310 of the ACA because it is intended to minimize waste through the use of uniform dispensing techniques that are specific to the LTCs being served.

We understand from the industry that depending on the 7-day-or-less dispensing methodology used, there may be an increase in nursing time devoted to ordering and receiving medication. We encourage LTC facilities to work with the pharmacies serving them to determine the 7-day-or-less dispensing methodology that will work best for the LTC facility, taking into account not only physical plant and labor considerations, but also overall cost effectiveness and waste reduction potential . We believe our proposed requirement will accommodate various 7-day-or-less on-demand or cycle filling methodologies in use by the LTC industry today, including (1) 7-day-supply dispensing; (2) dispensing of a drug for 2 days, followed by the dispensing of the drug for another 2 days, followed by dispensing of the drug for 3 days, referred to as "2–2–3" day dispensing; (3) dispensing of a drug for 4 days followed by the dispensing of the drug for 3 days, referred to as "4–3" day dispensing; (5) daily dispensing; and (6) automated shift or dose dispensing.

In making this proposal, we recognize that automated dose dispensing, which generally refers to medication dispensing through automated technology located at the facility on a demand basis, is likely the most efficient dispensing methodology and the most effective in reducing waste. However, we recognize there are significant limitations to the rapid adoption of automated dose dispensing systems, including capital acquisition costs, state pharmacy board restrictions, the lack of final automated medical record and interface standards, and inventory considerations. Additionally, automated dose dispensing may not be considered practical by some LTC facilities and the pharmacies servicing them due to size or physical plant limitations. Thus, we expect Part D sponsors to encourage pharmacies and LTC facilities to work together to determine the most appropriate dispensing methodology or methodologies to be used for a particular facility.

We recognize that the majority of pharmacies not already using 7-day-or-less dispensing methodologies are using 30-day dispensing for their Part D population. We understand that the most common 30-day dispensing system is the 30-day punch card. As a result, these pharmacies will have to make changes in the number of medications packed in a 30-day card or switch to 7-day card stock in order to continue dispensing brand-name drugs to Part D enrollees residing in LTC facilities. Our conversations with manufacturers of the 30-day punch card systems have indicated that there is minimal conversion involved in the transition from 30-day dispensing to 7-day dispensing.

We also do not expect a pharmacy's delivery schedule to be greatly affected since deliveries are generally made at least daily to long-term care facilities to accommodate first dose and new admission needs. However, we recognize that for some pharmacies there will be changes in the way deliveries are made. Some pharmacies may not service the number of beds to justify hiring additional delivery drivers and purchasing additional delivery vehicles. These arrangements need to be considered by the pharmacy and LTC facilities. As specified under 50.5.2 of Chapter 5 of the Medicare Prescription Drug Benefit Manual (See *http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter5.pdf*), which outlines the Long-Term Care Performance and Service Criteria, specific delivery arrangements are to be determined through an agreement between the pharmacy and the LTC facility. Accordingly and subject to any state law restrictions, pharmacies and LTC facilities may agree to use a common carrier for some deliveries of drugs to LTC facilities. We would not consider a contractual agreement to deliver a portion of Part D drugs to Part D enrollees residing in LTC facilities via a common carrier to constitute a mail order benefit, or the pharmacy making some but not all deliveries by common carrier being considered a mail order pharmacy. We solicit comments on this interpretation.

We note that options for billing to accommodate 7-day-or-less dispensing are being discussed in a National Council for Prescription Drug Programs (NCPDP) workgroup. Unless the

industry voluntarily adopts a single billing standard, we believe that Part D sponsors should generally allow pharmacies to use currently accepted transactions to minimize burden in transitioning to more frequent dispensing of smaller amounts. However, 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 also propose establishing 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 proposed § 423.154(a)(1)(i) and (ii). We expect that our data collection efforts will help us to estimate the relative efficiencies of dispensing methodologies and determine the residual waste to estimate additional savings. We cannot establish the impact of increased dispensing fees prior to the dispensing fees being renegotiated. We believe that it is critical for Part D sponsors and CMS to obtain data to identify changes in the industry and to evaluate the effect of different dispensing methodologies on the reduction of waste. We note that the NCPDP workgroup is considering the adoption and transmission of specific codes on billing transactions that would facilitate the collection of this information by Part D sponsors in an automated and cost-effective manner.

We note that if adopted, this proposal would likely lead to a change in copayment methodology. We anticipate the implementation of particular co-payment methodologies will be dependent on the billing and dispensing methodologies used, and as a result, we acknowledge that co-payment methodologies within the same plan may vary depending on the LTC facility where the beneficiary resides. We believe implementation of co-payment methodologies in this way is consistent with the uniform benefit requirement at § 423.104(b)(2) so long as the copayment methodology throughout the plan's service area is consistent for beneficiaries who receive their Part D medications using the same dispensing methodology. 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.

Despite the changes in dispensing events, billing, and co-payments, we are considering limiting the LTC claims prescription drug events (PDEs) to 1 per month for each standing order or prescription. We solicit comments on this proposal.

We realize our proposed requirements are likely to result in renegotiations of dispensing fees to reflect the costs associated with additional dispensing events in a single billing cycle for a single prescription and the costs undertaken to acquire technology aimed at reducing waste. Currently, Part D plans have the flexibility to vary the actual dispensing fees paid to pharmacies. As provided in section 1860D–11(i) of the Act, we are prohibited from intervening in negotiations between pharmacies and Part D plans; however, we do believe that it reasonable to expect that dispensing fees be adjusted based on the proposed requirements under this provision. Accordingly, we propose to modify the definition of "dispensing fee" under § 423.100 to include costs associated with the acquisition and maintenance of technology to maintain reasonable pharmacy costs. Although it is not our intent to include all activities that are "reasonable costs" in the definition of "dispensing fees," in light of statutory requirements regarding LTC pharmacy dispensing, we believe it is particularly important to highlight potential pharmacy costs aimed at reducing waste and efficiency of dispensing. We also believe dispensing fees are likely to differentiate among the costs associated with different dispensing methodologies and appropriately address costs that are incurred to offset waste. Appropriate dispensing fees that differentiate among the various dispensing methodologies could incentivize more rapid adoption of the most cost-effective technologies and align facility, plan sponsor, and public interests in minimizing costs and pharmaceutical waste.

We also solicit comments on whether the requirements should be waived for particular types of LTC pharmacies. We propose to waive the requirements under paragraph (a) for pharmacies when they dispense brand-name Part D drugs to Part D enrollees residing in an intermediate care facilities for the mentally retarded and developmentally disabled (ICFMRDD) and institutes for mental disease (IMDs) under § 423.154(c). We believe that due to specific problems with medication delivery and dispensing to closed (and often locked) facilities, it would be difficult for these pharmacies to adhere to 7-day-or-less dispensing. Waving the requirements in this instance would be consistent with the statute when done on a uniform basis (that is, all similarly situated LTCs) and when there is a demonstration that applying the dispensing requirements to that type of LTC would not serve to reduce waste. For the ICFMRDD and IMDs, there is a good rationale for not requiring 7-day dispensing, because requiring 7-day-or-less dispensing is not feasible and could increase costs rather than decrease waste associated with 30-day dispensing. We solicit comments on whether other types of similarly situated facilities (such as LTC facilities utilizing Indian Health Service (IHS) facilities to provide pharmaceuticals 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 specific reasons as to why those facilities should be waived from the requirement.

We note that we originally considered waiving the requirements for pharmacies dispensing to small LTC facilities. However, we do not believe that such a waiver is supported based on conversations with the industry which, as stated above, demonstrate that pharmacies servicing LTC facilities as small as 10 beds are using 7-day-or-less dispensing methodologies. We also considered waiving the requirements for pharmacies that dispense to LTC facilities in rural areas. Similarly, we do not believe such a waiver is supported since many of these pharmacies deliver to LTC facilities daily to accommodate first fill and new admissions. We solicit specific comments on the waiver criteria for LTC pharmacies.

Pursuant to section 3310 of the ACA, the requirements of this section go into effect January 1, 2012. However, as a result of discussions with the LTC industry, we propose a limited extension to a Part D sponsor when an independent community pharmacy (such as, not a closed door pharmacy dedicated to servicing LTC facilities only) with which the Part D sponsor has contracted is the primary provider to a small LTC facility (less than 80 beds) in rural communities, as defined by the Bureau of the Census, and the pharmacy is not already dispensing a 7-day supply to any patient population in the LTC facility. Since independent community pharmacies are frequently the only pharmacy provider to rural LTC facilities, we understand that there could be significant challenges in getting Part D drugs to beneficiaries residing in LTC facilities in rural areas. We have heard from the industry that small pharmacies dispensing to small LTC facilities in rural areas frequently only dispense in 30-day supplies. We understand that those facilities may

need extra time because of a lack of dedicated staff to adequately train and make the necessary changes to convert to 7-day-or-less dispensing by January 1, 2012. Under § 423.154(e), we propose allowing an independent community pharmacy that is the primary provider of the Part D drugs to a LTC facility located in a rural to dispense no more than a 14-day supply through December 31, 2012. We expect that these pharmacies contracted with Part D sponsors will find solutions to their significant challenges and work towards full compliance with § 423.154(a) during this extension. We propose that Part D sponsors contracted with these independent community pharmacies must come into full compliance with § 423.154(a) by January 1, 2013. We solicit comments on this proposal.

Based on the preceding, we propose to revise § 423.150 by renumbering paragraphs (b) through (g) as paragraphs (c) through (h) and adding a new paragraph (b) that would address appropriate dispensing of covered Part D drugs in LTC facilities. We also propose to add 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-name medications and use uniform dispensing methodologies as defined by each of the LTC facilities being serviced. In addition, we propose § 423.154 (a)(2) which requires Part D sponsors to collect and report, as CMS requires, the dispensing methodology used for each dispensing event described by paragraphs (a)(1)(i) and (ii) of § 423.154. We propose exceptions to this requirement at § 423.154(b)(1) and (2) relative to specific drugs and waivers of this requirements for specific pharmacies under § 423.154(c). Pursuant to section 3310 of the ACA, we propose the effective date of January 1, 2012 for § 423.154 under § 423.154(d) with a limited extension through December 31, 2012 to pharmacies meeting the requirements under § 423.154(e). We also propose to add the requirement that Part D sponsors require any unused Part D drugs originally dispensed to its 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 in § 423.154(f).

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

The Secretary has the authority under the Act to include any terms or conditions the Secretary deems necessary and appropriate in MA organization and Part D sponsor contracts, including requiring the organization to provide the Secretary with such information as the Secretary may find necessary and appropriate. (*See* section 1857(e)(1) of the Act as incorporated into Part D through section 1860D–12(b)(3)(D) of the Act.) Under this authority, we have proposed a number of contract provisions that require MA organizations and Part D sponsors to report specific information to CMS for a variety of purposes, with the overall goal of improving the Part C and D programs. For example, we relied on this authority to establish a requirement related to the reporting of prescription drug event data under Part D for purposes other than payment. One of the purposes for requiring submission of these data for nonpayment-related purposes was to enable us to conduct evaluations of the data in order to make recommendations for improving the Medicare program.

Up until now, we have not implemented specific regulatory requirements related to the tracking and resolution of complaints that we capture from the Part C and D enrollees in the CMS-established Health Plan Management System (HPMS) Complaints Tracking Module (CTM). This system was established at the start of the Part D program in order to record and track complaints received by CMS from beneficiaries, providers, and other constituents about prescription drug plans. After the start of the Part D program, the system was expanded in July 2008 to collect and capture complaints related to the Part C program.

With the establishment of the CTM system, we have routinely provided complaint-related information to Part C and D sponsoring organizations to assist sponsors in the identification of operational and plan performance issues. In addition, we have issued oversight and compliance direction to Part C and D sponsors with respect to CTM complaints, including CMS' expectations of MA organization and Part D sponsors with regard to complaint resolution. These expectations are largely contained in recommended standard operation procedures (SOPs) that CMS issued to MA organization and Part D sponsors (*see https://www.cms.gov/PrescriptionDrugCovContra/Downloads/CTMSOP_10.06.09.pdf*). As part of these procedures, CMS directed MA organizations and Part D sponsors to document when they resolve a complaint in their case notes, and to enter a resolution date and a resolution summary note in the CTM complaint tracking system, to which they have access. Since we developed the CTM system, we have focused on complaint resolution monitoring for oversight purposes but have not gone so far as requiring in regulation that MA organizations and Part D sponsors respond to complaints received by us and document the details of the complaint resolution in the CMS CTM system.

With the enactment of the Affordable Care Act, we now believe additional requirements in the area of complaint resolutions are necessary. Under section 3311 of the Affordable Care Act, we (under our delegation of authority by the Secretary of HHS) are directed to develop a complaint system that will allow for the collection and maintenance of complaints against PDPs and MA–PD plans. We are also directed to develop a model electronic complaint form that is to be maintained on *http://www.medicare.gov* and the Office of Medicare Ombudsman's Web site. Finally, we are required to report to Congress annually on the number and types of complaints reported in the system, geographic variations in such complaints, the timeliness of agency or plan responses to such complaints, and the resolution of such complaints.

We believe that the current CTM system largely fulfills the requirement by Congress that we establish a complaint system to capture complaints against Part D plans. As explained previously, the CTM system was established to record and track complaints received by us from beneficiaries, providers, and other constituents about health and drug plans. However, to ensure that the data collected and warehoused in the system provide us with sufficient information to report to Congress, we believe that enhancements to the current system are necessary, particularly with respect to the data relating to the closure of complaints. While our SOP instructs MA organizations and Part D sponsors to indicate in the system a clear and concise complaint resolution summary note when the complaint is resolved, we have determined that many sponsors do not do so and merely write the words "complaint closed" in the CTM. Absent more detailed information on how a complaint is resolved by the plan, we do not believe we will be able to meet the objectives of Congress to report on the timeliness and resolution of complaints. Therefore, to ensure that we have the appropriate information to report to Congress, and to further improve our monitoring efforts with respect to complaint closure, we are proposing a

new requirement on MA organizations and Part D sponsors, under the authority of section 3311 of the ACA and section 1857(e)(1) and 1860D–12(b)(3)(D) of the Act, to require sponsors to respond to complaints received by us. We believe it is necessary and appropriate to apply these requirements to both MA organizations and Part D sponsors to maintain a balanced and fair program for beneficiaries receiving medications under the Part D program or an enhanced benefit under the MA program. At this time, with respect to the proposed requirement to document how a complaint was resolved, we are contemplating adding a drop down checklist to CTM that MA organization and Part D sponsors would use to document closure of complaints, as opposed to requiring free text descriptions of complaint closure. We invite comments on this approach.

With respect to the model electronic complaint form to be used for reporting plan complaints, Congress has directed us to prominently display the form on the front page of the Medicare.gov Internet Web site and on the Internet Web site of the Medicare Beneficiary Ombudsman. We are in the process of developing the model electronic complaint form and plan to make this form available on the internet websites as required. Considering the importance that Congress has given to the issue of reporting complaints and the development of a standardized form for taking complaints against plans, we are also proposing to require MA organizations and Part D plans to link to the CMS-developed electronic complaint form on the Medicare.gov Internet Web site from their main Web page. We believe the importance Congress has given to the issue of complaint reporting makes it necessary and appropriate to propose to apply this requirement to both MA organizations and Part D plans.

Accordingly, based on the preceding, we propose to add a new requirement to § 422.504(a) and § 423.505(b) to require MA organization and Part D sponsors to address and resolve all complaints in the CMS complaint tracking system and to require a link to the electronic complaint form at the Medicare.gov Internet Web site on each Part C and Part D sponsor main Web page. If adopted, this requirement would be effective January 1, 2012. Following the issuance of a final rule, we will develop guidance to instruct MA organizations and Part D sponsors on how to comply with this new requirement.

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 will require, effective January 1, 2012, each PDP sponsor of a prescription drug plan 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 by enrollees through a toll-free telephone number and an Internet Web site.

Since the inception of the Part D program, we have received numerous comments, especially from beneficiary advocacy groups, suggesting the coverage determination and appeals processes are too complex and difficult for enrollees to navigate. The commenters recommended streamlining the existing coverage determination and appeals processes in order to simplify the plan appeals procedures for both enrollees and providers. The most significant concerns noted by commenters involve access to the Part D coverage determination and redetermination processes. For a variety of reasons, enrollees often have difficulty making initial requests for coverage. Over time, plan sponsors have developed plan-specific forms for requesting coverage, and often have multiple request forms that are drug-specific. As a result, enrollees often have difficulty locating or obtaining these plan-specific request forms and determining which form should be used for their particular request. Even when enrollees are able to locate and complete the appropriate request forms, they may have trouble determining where the forms should be submitted, because plan sponsors often have multiple addresses, telephone numbers, and fax numbers, and it is not clear which address or phone number should be used to submit a particular request. Commenters indicate these elements create a process that is quite overwhelming and frustrating for enrollees, and for those who try to assist them.

In accordance with the new section 1860D–4(b)(3)(H) of the Act, we propose 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 also propose to revise the regulation at § 423.128 paragraphs (b)(7) and (d) to provide 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. We believe the proposed requirements will address many of the long-standing concerns about the Part D coverage determination and appeals processes being too complex and difficult for enrollees to navigate.

At § 423.128(b)(7), we propose 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. We plan to evaluate the feasibility of developing and requiring the use of standard request forms and will determine whether a single form can reduce confusion and address the needs of beneficiaries, providers, and PDP sponsors. If it is determined that standardized forms are appropriate, the forms will be developed by us and will be used to request any type of coverage determination under Part D (including exception requests and requests for drugs that may be subject to a utilization management requirement) and redeterminations. We will evaluate existing plan and CMS forms used for requesting coverage determinations and redeterminations to determine what elements should be included in the forms. We welcome comments and suggestions regarding: (1) The specific elements that should be included in these forms; (2) whether a single request form is feasible; and (3) any other issues that should be considered and/or resolved before this requirement is operationalized.

Section 3312 of the ACA also requires plan sponsors to provide instant access to the coverage determination and appeals processes through an internet Web site. Therefore, we propose to add paragraph (ii) to § 423.128(b)(7), which would require 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. We believe that allowing requests for coverage determinations and redeterminations to be made through plan websites will further increase beneficiary access to the coverage determination and redetermination processes. We propose that the interface would be the "electronic equivalent" of the paper

coverage determination and appeals forms proposed at § 423.128(b)(7)(i). In establishing this interface, Part D sponsors must ensure that any such interface complies with the Health Insurance Portability and Accountability Act (HIPAA) of 1996, the Privacy Act, and CMS's information security requirements where appropriate. Some Part D sponsors may already have an electronic means for requesting coverage determinations and redeterminations available to their enrollees. We request comments and ideas regarding how such an electronic interface should work and any issues that need to be addressed before operationalizing this requirement.

Plan sponsors must also establish a toll-free telephone line that provides instant access to the coverage determination and appeals process pursuant to section 3312 of the ACA. Therefore, we propose to revise § 423.128(d)(1) to include a requirement that sponsors provide a toll-free telephone line for requesting coverage determinations and appeals. We currently require sponsors to offer a toll-free customer call center as part of the provision of specific information requirements at § 423.128(d), and propose requiring plan sponsors to provide enrollees with access to the coverage determination and redetermination processes through the toll-free customer call center if sponsors are not doing so already. In other words, we envision the customer service representative (CSR) accessing the on-line coverage determination and redetermination process via the plan's web-based application discussed previously, and entering the information supplied by the enrollee via telephone. We will develop model scripts for the CSRs to use for this purpose.

Consistent with the proposals to require the use of standardized forms for requesting coverage determinations and redeterminations (should this be determined feasible and to the extent that standard request forms have been approved for use by CMS), and the establishment of a toll-free telephone number and Web site for accepting requests for coverage determinations and redeterminations, we propose to amend § 423.562 by adding a new paragraph (a)(1)(ii) which cross-references the proposed 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 are proposing to require Part D sponsors to modify their electronic response transactions to pharmacies so that they can transmit codes instructing the pharmacy to provide a point-of-sale (POS) notice to enrollees when a prescription cannot be filled. Currently, when an enrollee attempts to fill a prescription at a pharmacy, the pharmacist receives certain information electronically related to the prescription from the Part D sponsor, which may include whether it is on the plan's formulary, and whether there are any conditions associated with filling the prescription. In cases where a prescription cannot be filled as written, Part D sponsors are required under § 423.562(a)(3) to arrange with their network pharmacies to either post or distribute a pharmacy notice advising the enrollee of his or her right to contact the plan to request a coverage determination. The pharmacy notice is generic and does not include plan-specific information for requesting coverage determinations. While the current pharmacy notice provides enrollees with some information about requesting coverage determinations, beneficiary advocacy groups have argued the notice is too generic to provide enrollees with all of the information they need to easily access the coverage determination process. Advocates have also expressed concern about enrollees not receiving, or not being directed to the notice. Although we have been concerned about these complaints, under the existing pharmacy billing standard agreed upon by the National Council of Prescription Drug Programs (NCPDP version 5.1), it has not been feasible for plan sponsors to systematically transmit situation-specific messaging to pharmacists because transaction coding could not easily or quickly be changed. Furthermore, the pharmacies do not have the capability to populate, print, and distribute plan-specific notices to each enrollee who is not able to obtain a prescription as written.

With the adoption of the new HIPAA pharmacy billing standard (NCPDP version D.0), we now have the opportunity to work with the NCPDP to develop and standardize use of codes that will prompt a Part D network pharmacist to print or provide a POS notice to give to enrollees when a prescription cannot be filled. Accordingly, we are proposing at § 423.128(b)(7)(iii) that Part D sponsors modify their systems so that the plan sponsors are capable of transmitting codes to their contracted 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 believe such notices should be printed and provided in the same manner as other instructions (for example, instructions for taking prescriptions). We will 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 are also proposing to revise § 423.562(a)(3) by deleting the reference to posting the pharmacy notice and 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 propose that the pharmacy notice be provided in writing, consistent with the standards established in § 423.128(b)(7)(iii), and will include instructions explaining how enrollees can request coverage determinations by calling their plan sponsor's toll free customer service line or accessing their plan sponsor's Web site.

14. 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)

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. TrOOP expenditures represent costs actually paid by the beneficiary, another person on behalf of the beneficiary, or a qualified State Pharmaceutical Assistance Program (SPAP). Most third party assistance, such as that from employers and unions, does not count toward the TrOOP threshold.

Prior to the passage of the ACA, our policy as specified in the definition of "incurred cost" at § 423.100 and as clarified in section 30.4 of Chapter 5 of the Prescription Drug Benefit Manual was that to the extent that a party paying for cost-sharing on behalf of a Part D enrollee was a group health plan, insurance program or otherwise (such as a government-funded health program), or third party payment arrangement with an obligation to pay for covered Part D drugs, that party's payment would not count toward TrOOP. Under this policy, supplemental drug coverage provided by the Indian Health Service (IHS), as defined in section 4 of the Indian Health Care Improvement Act, Indian tribes and organizations, and

urban Indian organization facilities were not considered to be TrOOP eligible because these entities fell under our definition of "government-funded health program," under § 423.100.

Similarly, Aids Drug Assistance Programs (ADAPs) co-payments, which are funded under the Ryan White CARE Act, 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 receive Federal funding. Moreover, because the law specified that costs for covered Part D drugs paid by insurance or otherwise on behalf of a Part D enrollee do not count as incurred costs, any coverage that supplements the benefits available under Part D coverage that are provided to beneficiaries by Medicaid, Medicaid Section 1115 waiver programs, the VA health care program, the IHS, ADAP programs, and local or State indigent drug programs would not count as an incurred cost for purposes of TrOOP (see 70 FR 4240 and 4241).

With the passage of the ACA, CMS requirements as they relate to IHS 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 would be treated as incurred costs for the purpose of meeting the annual out-of-pocket threshold. Based on these amendments, we propose to revise the definition of incurred cost at § 423.100(2)(ii) to include cost paid for 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 propose 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.

As indicated in section II.A. of this proposed rule, we propose that the regulations implementing this provision be effective 60 days after the publication of the final rule.

15. Cost Sharing for Medicare-Covered Preventive Services (§ 417.101 and § 422.100)

Effective January 1, 2011, sections 4103 and 4104 of the ACA revise 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. Because we agree with Congress that the utilization of preventive services should be encouraged by providing them without cost sharing, 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 propose to add a new paragraph (h) to § 422.100 to require MA organizations 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 propose requiring that all MA organizations provide Medicare-covered preventive services, as specified by CMS, without enrollee cost sharing charges. Under our authority in section 1876(i)(3)(D) of the Act to impose requirements we find "necessary and appropriate," we also propose to add a new paragraph (f) to § 417.101 to extend this proposed requirement to section 1876 cost plans.

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 propose to direct plans to go to the following Medicare Web sites: *https://www.cms.HospitalOPPS/* and *http://www.cms.gov/PhysicianFeeSched/.*

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. The Fund was also established to retain MA regional plans in regions with relatively low MA market penetration. Specifically, the MMA authorized us to make a 1-year "national bonus payment" to an organization or organizations that offered an MA Regional Plan in each MA region in a given year (if there was no such plan offered in one or more regions in the previous year). If no national bonus payment was made in a given year, we could have used the fund to increase payments to MA regional plans offered in regions that did not have any MA regional plans offered in the prior year. Finally, to encourage plans to remain in regions with

relatively low MA market penetration, we could have used the Fund to make retention payments to MA regional plans that notified us of their intent to exit a region prior to the bidding deadline. Payments from the Fund, which was initially established at $10 billion, were first available beginning January 1, 2007.

Section 301 of Division B, Title III, of the Tax Relief and Health Care Act of 2006—enacted December 20, 2006—delayed Stabilization Fund payments until January 1, 2012, and limited initial funding to $3.5 billion. Subsequent legislation, including the Medicare, Medicaid and SCHIP Extension Act of 2007, and the Medicare Improvements for Patients and Providers Act of 2008, further delayed the timeframe during which initial funding was available until 2014 and limited the amount to $1.

Section 10327(c) of the ACA repealed section 1858(e) of the Act, eliminating the Stabilization Fund. Therefore, we are proposing to delete paragraph (f) from § 422.458, since the statutory basis for the Fund no longer exists.

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

Section 1860D–4(c)(1)(C) of the Act requires Part D sponsors to 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. These requirements are codified in § 423.153(d) of the Part D regulations.

The federal regulations at § 423.153(d)(1) require each Part D sponsor to establish a MTMP that is designed to ensure that covered Part D drugs (as defined in § 423.100) prescribed to targeted beneficiaries are appropriately used to optimize therapeutic outcomes through improved medication use; designed to reduce the risk of adverse events for targeted beneficiaries; furnished by a pharmacist or other qualified provider; and allowed to distinguish between services provided in ambulatory and institutional settings. Beginning in 2011, § 423.153(d)(2) defines targeted beneficiaries as enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur annual costs for covered Part D drugs that are greater than or equal to $3,000 as adjusted by the annual percentage increase under § 423.153(d)(5)(iv) for subsequent years.

With the recent passage of the Affordable Care Act, Congress provided for specific MTMP improvements by law. 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 that 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.

Prior to the passage of the new legislation, we had already made several improvements to the MTM program via the 2010 Call Letter to Part D sponsors on the CMS Web site at *http://www.cms.gov/PrescriptionDrugCovContra/,* as well as via the 2011 final rule containing policy and technical changes under the Part C and D programs (*see* 75 FR 19772 through 19776 and 19818 and 19819). In this final rule, in accordance with our authority under sections 1860D–4(c)(1)(C) and 1860D–4(c)(2) of the Act, we revised our regulations at § 423.153(d)(1)(v) to require Part D sponsors to enroll beneficiaries in their MTMPs using only an opt-out method of enrollment; § 423.153(d)(1)(vi) to require Part D sponsors to target beneficiaries for enrollment in the MTMP at least quarterly during each plan year; and § 423.153(d)(1)(vii) to require Part D sponsors to offer a minimum level of MTM services for each beneficiary enrolled in the MTMP that includes interventions for both beneficiaries and prescribers including, an annual comprehensive medication review with a written summary, and quarterly targeted medication reviews with follow up when necessary. We also revised § 423.153(d)(2) to clarify which beneficiaries should be targeted for MTMP services.

In comparing the requirements codified in the final rule to those required by section 10328 of the ACA, we found that a number of the provisions are consistent. The final rule requires opt-out enrollment of targeted beneficiaries, 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.

Based on this review and to ensure that our policies are fully consistent with the new requirements added by section 10328 of the ACA, we have determined that it is necessary 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 accordance with sections 1860D–4(c)(1)(C) and 1860D–4(c)(2) of the Act as amended by section 10328 of the ACA, we propose 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 plan to award a contract to an outside entity 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.

We also propose 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 that cannot travel to the provider's location, or who reside in a remote location or in different time zone. Recent advancements in digitized health care and telecommunication now permit some direct provider care to be delivered to beneficiaries remotely. As promoted in the American Recovery and Reinvestment Act of 2009 (ARRA), the adoption and use of health information technology (HIT) and electronic health records (EHR) to provide patient care is encouraged by the federal government. We emphasize that when using telehealth technologies, personal health information privacy and security must be ensured.

In addition to the regulatory changes required to implement the ACA provisions, we are proposing a further revision to the MTMP requirements related specifically to MTM services furnished in LTC facilities. 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. 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. 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. Further, we are concerned 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 propose to add a requirement for Part D sponsors to coordinate their MTMP with the drug regimen reviews performed by the LTC consultant pharmacists.

Specifically, we propose to revise § 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 believe 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. We believe that requiring this coordination is the best way to ensure that residents receive the advantage of MTM services in LTC facilities. We are soliciting comments from the public on how such coordination between sponsors and LTC facilities might work best.

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

Section 1860D–2(b) of the Act, as amended by the ACA, revises 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. The new provisions not only 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), but also reduce the growth in the annual out-of-pocket threshold from 2014 to 2019.

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 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 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. 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. 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 propose codifying 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 are proposing new definitions for these terms at § 423.100.

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 accordance with the new requirements, as proposed in § 423.104(d)(5)(iii), 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. In accordance with the new requirements in sections 1860D–2(b)(4)(B)(i) and 1860D–2(b)(7) of the Act, we propose amending § 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. 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 propose to amend § 423.104(d)(5)(iii) to reflect this requirement.

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 propose codifying this new requirement in § 423.884(d) of this rule.

As indicated in section II.A. of this proposed rule, we propose that the regulations implementing these provisions be effective 60 days after the publication of the final rule.

19. Payments to Medicare Advantage Organizations (§ 422.308)

Section 1853(a)(1)(C) of the Act requires the Secretary to adjust MA payments by risk factors including age, disability status, gender, institutional status, and other factors as the Secretary determines to be appropriate, including adjustment for health status. Section 1853(a)(3) of the Act required the Secretary to establish a "risk adjustment" methodology which "accounts for variations in per capita costs based on [the] health status [of the enrollee]."

Generally, the law related to MA payments is self-implementing, and the effective dates for changes to the payment methodology are established in statute and announced in accordance with section 1853(b) of the Act. Regulations related to payment provisions thus implement requirements that are effective on the date specified in statute and as provided for 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)

Section 3205 of the ACA provides the Secretary with the authority to apply a frailty adjustment to payments to certain SNPs, 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 are interpreting this new statutory language to mean that payments to frailty-qualifying SNPs will 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 are interpreting this new statutory language to permit 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.

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 will announce any changes to the methodology used to pay for the frailty, as well as how we determine PACE program averages, and which frailty-qualifying SNPs have similar levels of frailty, in the Advance Notice and Rate Announcement for the plan year in question.

The Secretary has the authority to make an adjustment to payment to take into account the level of frailty among the enrollees of a plan if the plan meets our proposed definition of a fully integrated dual-eligible special needs plan at § 422.2 and the plan has a similar average level of frailty as the PACE program. In order to have a frailty score that can be compared to the PACE program, MA organizations sponsoring a dual eligible SNP that meets our proposed definition of a fully integrated dual-eligible SNP must fund any survey used by us to support the calculation of frailty scores; the survey must 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). Further, the survey must adhere to the methodological requirements of any such survey.

As indicated in section II.A. of this proposed rule, we propose that the regulations implementing this provision be effective 60 days after the publication of the final rule.

b. Application of Coding Adjustment (§ 422.308)

Section 1102(e) of the ACA amended section 5301(b) of the Deficit Reduction Act (DRA) of 2005. Beginning in 2006, section 1853(a)(1)(C)(ii), as added by section 5301(b) of the DRA, required the Secretary, in risk adjusting payments for health status under 1853(a)(1)(C)(i), to ensure that such adjustment reflects changes in treatment and coding practices in the FFS sector and beginning in 2008 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. The ACA adds new statutory language clarifying our existing authority to adjust risk scores for coding trends in the FFS sector, under its 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.

Adjusting risk scores for the underlying FFS trend—or normalization—is necessary to ensure accurate payments because, each time we recalibrate a risk adjustment model, the average risk score is set to 1.0 using the fixed set of coefficients appropriate to the population and data for that calibration year. When the model with fixed coefficients is used to predict expenditures for other years, predictions for prior years are lower and predictions for succeeding years are higher than for the calibration year. Because average predicted expenditures increase after the model calibration year due to coding and population changes, we apply a normalization factor to adjust beneficiaries' risk scores so that the average risk score is 1.0 in subsequent years.

Adjusting risk scores for the difference between MA and FFS coding patterns is also necessary in order for payments to be accurate because we calibrate the CMS–HCC model using FFS data, and the relative factors reflect the FFS pattern of coding. We adjust for the trend in the rate of increase of diagnoses codes submitted by FFS providers with the application of a normalization factor that is updated annually and that adjusts risk scores with the goal that the average remains 1.0 in each payment year. However, because MA coding patterns differ from those in FFS, MA risk scores generally increase more quickly and are, therefore, higher than they would be if MA plans coded in the same manner as FFS providers.

The DRA also required the Secretary to conduct an analysis of the differences in FFS and MA coding patterns in order to ensure payment accuracy. Such an 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. In conducting such analysis, the Secretary was to use data submitted with respect to 2004 and subsequent years, as available.

The ACA made four modifications to this requirement for analysis. They are—(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 indefinitely.

The ACA added two additional requirements to the DRA-mandated requirements. First, the ACA requires that the adjustment factor for 2014 be not less than the adjustment factor applied for 2010 plus 1.3 percentage points; for each of the years 2015 through 2018, not less than the 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.

As indicated in section II.A. of this proposed rule, we propose that the regulations implementing this provision be effective 60 days after the publication of the final rule.

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

The CMS–HCC risk adjustment model incorporates a set of coefficients for calculating risk scores for new enrollees that are based on demographic factors only, such as age, sex, Medicaid status, and original reason for entitlement. A new enrollee risk score is used in the payment of a beneficiary who is enrolled in an MA plan or PACE organization and who does not have enough diagnoses in the data collection period to calculate a full risk score. We classify a beneficiary as a new enrollee when they do not have 12 months of Part B in the data collection period.

Because chronic SNP enrollees must, as a condition of enrollment, have specific conditions, the average new enrollee risk score of new enrollees in chronic SNPs is likely to understate these beneficiaries' risk. For 2011 and subsequent years, for purposes of the adjustment under section 1853(a)(1)(C)(i) of the Act, the Secretary will use a risk score that reflects the known underlying risk profile and chronic health status of similar individuals. 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.

For 2011 and periodically thereafter, the Secretary will 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. The Secretary is required to 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.

As indicated in section II.A. of this proposed rule, we propose that the regulations implementing this provision be effective 60 days after the publication of the final rule.

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

a. Terminology (§ 422.252)

In order to implement new ACA provisions affecting MA payments, we propose to revise § 422.252 by adding two new terms and revising one term. We propose to add the terms "new MA plan" and "low enrollment contract." A new MA plan means, for the purpose of quality ratings under proposed § 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 propose to revise the definition of Unadjusted MA area-specific non-drug monthly benchmark amount to reflect the provision of the ACA that, 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 ratesetting 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.

b. Calculation of Benchmarks (§ 422.258)

Section 1102(b) of the ACA establishes a new blended benchmark as the MA county rate, effective 2012, and section 1102(c) of the Act establishes quality-based increases to the blended benchmark. To implement these rate-setting rules for the MA program effective 2012 onward, we propose amendments to § 422.258(a) and § 422.258(c)(3), and propose the addition of 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).

Proposed § 422.258(a) implements section 1853(j) of the Act to reflect the ACA requirement that CY 2011 MA capitation rates be set at 2010 levels. Proposed § 422.258(a) also clarifies which ratesetting rules are in effect for a particular time period by distinguishing the (c)(1) capitation rates in effect prior to 2007 from the applicable amount rates in effect from 2007 to 2011 (section 1853(k)(1) of the Act), and from the blended benchmark rates effective for 2012 (section 1853(n) of the Act).

We also propose to amend § 422.258(c)(3) to require that the MA regional plan statutory component of the region-specific benchmarks be calculated using the county rates determined under proposed § 422.258(a) for the year. This amendment ensures that the statutory component of the regional plan benchmarks reflects rate-setting rules regarding blended benchmarks for counties that are effective in 2012.

To implement sections 1853(n) and (o) of the Act, as added by sections 1102(b) and (c) of the ACA, respectively, on blended benchmarks and quality-based increases to the benchmarks, we propose to add a new paragraph § 422.258(d). Paragraphs (1) through (6), and (8) and (9), of paragraph (d) implement provisions regarding the blended benchmark, effective for 2012 onward. Paragraph (7) implements the provisions to increase the blended benchmarks for MA plans that receive quality ratings of a specified level. The quality bonus provisions in § 422.258(d)(7) are discussed following presentation of other provisions on the blended benchmarks that are implemented in this proposed paragraph.

The MMA established the concept of the "unadjusted MA area-specific non-drug monthly benchmark amount" as the service-area level benchmark for an MA plan, as specified in section 1853(j) of the Act and implemented at § 422.258(a) for MA local plans and § 422.258(b) for MA regional plans. Under rules established by the MMA, the service area-level benchmark for an MA plan is, in effect, the bidding target. Service area-level benchmarks are based on county capitation rates, and the general amendments to the rules for setting county capitation rates are as follows. The MMA eliminated the "higher of three" rate-setting rule that had been established by the Balanced Budget Act of 1997 (BBA), and mandated a transition to the ratesetting rule that a county capitation rate was

the (redefined) minimum percentage increase rate for a year (that is, the previous year's rate increased by the greater of 102 percent or the National Per Capita Medicare Advantage Growth Percentage), except in years when county average FFS expenditures were rebased (updated with more recent data); in rebasing years a county rate for a year was the greater of the FFS rate and the minimum percentage increase rate. The DRA introduced section 1853(k)(1) of the Act, which mandated that a county rate is an "applicable amount" for an area for a year, also used "for purposes of subsection (j)," that is, to determine a plan's service area-level benchmark. Effective in 2007, the applicable amount under section 1853(k)(1) of the Act for an area for a year was the (again, redefined) minimum percentage increase rate (that is, the prior year's rate increase by the National Per Capita Medicare Advantage Growth Percentage), except in a year when we rebased the FFS rates; in a rebasing year, the applicable amount was the greater of the county's rebased FFS rate and its minimum percentage increase rate. In other words, the "unadjusted MA area-specific non-drug monthly benchmark amount" was now based on applicable amounts under section 1853(k)(1) of the Act.

Section 1102(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 determined "for purposes of subsection (j)"—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). This percentage varies depending on several rules discussed below. The minimum percentage increase rate will no longer exist. Rather, we must rebase the 2012 county FFS rates, and all 2012 county capitation rates are based on the FFS rates. The rebasing rule at section 1853(c)(1)(D)(ii) of the Act remains in effect, requiring us to rebase the FFS rates at least every 3 years. In years after 2012 when the FFS rates are not rebased, the county rate is the previous year's rate increased by the National Per Capita Medicare Advantage Growth Percentage. In effect, the ACA mandates that the "unadjusted MA area-specific non-drug monthly benchmark amount" will be based on the blended benchmark rate, thus replacing the applicable amounts determined under section 1853(k)(1) of the Act.

However, section 1853(n) of the Act states that there are two components of the blended benchmark: The applicable amount determined under section 1853(k)(1) of the Act and described at proposed § 422.258(d)(1); and the "specified amount" introduced at section 1853(n)(2) of the Act and described at proposed § 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 proposed 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. In other words, when all counties have concluded their transition periods to a blended benchmark based on 100 percent of the specified amount, the "blended" aspect of the benchmark will also be concluded, because the proportion attributed to the applicable amount under section 1853(k)(1) of the Act will be zero. However, we will continue to calculate the applicable amounts under section 1853(k)(1) of the Act because section 1853(n)(4) of the Act requires that the blended benchmarks for an area for a year must be capped at what the applicable amount under section 1853(k)(1) of the Act would be for a year if the blended benchmark provisions were not in effect.

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 proposed § 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 proposed § 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. To determine the applicable percentages for a territory, we must rank such areas for a year based on the level of the area's FFS amount net of the IME amount, relative to the quartile rankings computed for the 50 States and the District of Columbia.

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 a 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 proposed § 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). For example, if we did not rebase the FFS rates for contract year 2013, but did rebase them for contract year 2014, the base payment amount for contract year 2014 would be

the 2014 rebased FFS rates, but the applicable percentage for contract year 2014 must be based on the previous year's quartile ranking, which would be the 2013 rates. Under this hypothetical scenario, because the 2013 FFS rates were not rebased, the 2013 FFS rates are the 2012 FFS rates increased by the 2013 National Per Capita Medicare Advantage Growth Percentage; further, because the 2013 growth trend would be applied as a constant to all 2012 FFS rates, in effect the applicable percentages for contract year 2014 would be based on the quartile ranking of the 2012 rebased FFS rates.

Second, section 1853(n)(2)(D) of the Act, implemented at proposed § 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. For example, if a county's ranking changed from the third quartile to the second quartile, the applicable percentage would be 103.75 percent for the year of the change—the average of 107.5 percent and 100 percent.

Third, sections 1853(n)(2) and (n)(3) of the Act, implemented at proposed § 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 proposed paragraph (d)(1) and "the projected 2010 benchmark amount" at proposed (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 paragraph § 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 proposed § 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.

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

Under the ACA, the Secretary is required to implement increases to MA plan benchmarks (which are the basis of a plan's bidding target) if they attain 4 or more stars on a 5 star quality rating system implemented by the Secretary. The effective date for this provision is January 1, 2012. For the purposes of this preamble, we will refer to these quality-based increases in MA benchmarks as quality bonus payments (QBPs) for MA plans. We propose to implement the quality payment provisions under section 1102 of the ACA at § 422.258(d)(7) and at § 422.252. Below we discuss our proposal for applying a star rating system to MA plan benchmarks.

Under the terms of proposed §§ 422.258(d)(7) and 422.252, MA organizations would be evaluated and scored on a 5-star rating system, with bonus payments made to qualifying organizations that have a star rating of 4 or higher. As specified under section 1102 of the ACA, 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.

Under the proposed regulations, the blended benchmark for 2012 and future years would reflect the level of quality rating at the organization or contract level, as determined by the Secretary pursuant to a methodology that would be set forth in a notice to MA organizations for the calendar year in question. This notice would come in the form of a memorandum to the Medicare Compliance Officers of MA organizations. As discussed in section II.B.20.b of this proposed rule, the blended benchmark has two components—the applicable amount and the specified amount. A qualifying organization that receives 4 or more stars on a 5 star rating system would, under the proposed regulations, 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 would 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 plans 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. Under the proposed regulations, a new MA plan would 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 5 star ratings system that would be used is the system currently in place, which historically has served two purposes. First, the plan ratings provide beneficiaries information on organization performance that they may consider (in addition to cost and benefit information) when choosing a plan. The second purpose is to assist us in identifying poor performing organizations for compliance actions. 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 will receive a combined Part C and D summary rating to summarize overall contract performance with respect to health and drug issues. This combined rating would, under the proposed regulations, be used to determine the new quality bonus payments (QBPs) based on quality.

We have always considered the plan rating system to be based on information consistent with section 1852(e) of the Act, which specifies that MA organizations are required to collect, analyze and report data that measure health outcomes and other quality indices. Because section 1852(e) of the Act states that "The Secretary shall not collect data on quality, outcomes and beneficiary satisfaction to facilitate consumer choice and program administration other than the types of data that were collected by the Secretary as of November 1, 2003", we clarify here the types of data included under the plan rating system are consistent with the types of data collected as of November 1, 2003. Since 1997 Medicare managed care organizations have been required to annually report quality of care performance measures through HEDIS. HEDIS is a widely used quality measures set in the managed care industry, developed and maintained by the National Committee for Quality Assurance (NCQA). HEDIS data includes clinical measures assessing the effectiveness of care, access/availability measures such as telephone customer service, and use of service measures. We have also been conducting the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey since 1997 to measure beneficiary's experiences and satisfaction with their health plans. HOS began in 1998 to capture changes in the physical and mental health of MA enrollees. Additionally, there are several measures based on performance that address telephone customer service, members' complaints, disenrollment rates, and the seriousness of problems found during a Medicare audit. All of these measures reflect structure, process, and outcomes indices of quality that form the measurement set under plan ratings.

Additionally, since 2007, we have publicly reported a number of measures related to the drug benefit as part of the plan ratings. For MA organizations that offer prescription drug coverage, we have developed a series of measures focusing on administration of the drug benefit. Similar to MA measures of quality relative to health services, the Part D measures focus on customer service and satisfaction, effectiveness, and access to care relative to the drug benefit. Because these measures focus on structure, process, and outcomes indices of quality, we believe that they too are consistent with the types of information referenced in section 1852 (e) of the Act. Therefore, we believe that the Part C and D plan ratings are consistent with the limitation expressed in section 1852(e) of the Act limiting data collection for quality to the types of data collected as of November 1, 2003.

Additionally, for 2012 and thereafter, the ACA directs the Secretary to develop definitions for new organizations that lack sufficient data to produce a star rating. Those new plans as defined by the Secretary will be considered qualifying organizations and will receive a bonus payment. The ACA requires that for 2012 the Secretary develop definitions for low enrollment plans that lack sufficient data to produce a star rating. For years after 2012, the Secretary must develop a methodology in order to rate these low enrollment plans for purposes of determining whether these plans qualify for quality bonus payments and what are the applicable beneficiary rebates percentages for these plans. We are proposing to add a new paragraph (d)(7) to § 422.258 to reflect our authority to make bonus payments based on quality. Under § 422.252, we propose definitions of a low enrollment organization and a new organization for the purpose of identifying qualifying organizations eligible to receive a bonus payment. Low enrollment plans will be qualifying plans for 2012 and in subsequent years, the Secretary is directed to develop a methodology to assign star ratings to low enrollment organizations. MA organizations that fail to report data as required by the Secretary shall be counted as having a rating of fewer than 3.5 stars at the organization or contract level, as determined by the Secretary. For the purpose of awarding 2012 quality bonus payments, we propose to define low enrollment organizations 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. New MA organizations that meet criteria specified by the Secretary are also treated as qualifying organizations for the purposes of QBPs. We propose to define a new MA organization as a MA contract offered by a parent organization that has not had another MA contract in the previous 3 years; these contracts would qualify for the QBP. Other MA contracts that open in a given year, but have had other contracts offered by the parent organization offering the new plan in the prior three 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. Also under the ACA, new MA organizations that meet criteria specified by the Secretary are treated as qualifying organizations for the purposes of QBPS. We propose to define a new MA organization as a MA contract offered by a parent organization that has not had another MA contract in the previous 3 years; these contracts would qualify for the QBP. Other MA contracts that open in a given year, but have had other contracts offered by the parent organization offering the new plan in the prior three 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.

We anticipate moving toward transformation of 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.

As we develop a longer term strategic framework for transforming the MA quality rating system, over the near term, we also will consider 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 being proposed as 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).

We invite 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), NCQA, the Agency for Healthcare Research and Quality and Research (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?

As a part of developing our long-term quality strategy, we have begun 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. We are also examining the use of alternative measurement sets (for example, ACOVE), exploring the use of data collected in other settings (for example, rural hospital quality data 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 all-cause readmission rates and ambulatory care sensitive conditions that we would look to implement as they become available. These are some of the activities that we anticipate engaging in over the next few years, and we expect to undertake further measure identification, refinement, and development as we implement the MA quality bonus payments.

Further, beyond broadening the goals of the MA quality rating system, for instance by incorporating more outcomes-based measures, we also seek to continually raise performance targets, so as to incentivize continual quality improvement across established metrics of performance and quality. We invite public comment on appropriate performance and quality benchmarks, and what approach should be used for updating these benchmarks, including frequency of updates.

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 an agency-wide Quality Working Group Advisory 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's 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 are proposing the following amendment to § 422.258 to add a new paragraph (d)(7) to reflect our authority to make bonus payments based on quality. Under § 422.252, we propose definitions of low enrollment organization and new organization for the purpose of identifying qualifying organizations eligible to receive a bonus payment.

While the regulations we are proposing in this section would implement the QBP provisions specified in the ACA on a permanent basis, for the near term we will be conducting a demonstration project under which the rules for determining QBPs set forth in the Affordable Care Act and in these proposed regulations would be waived, and QBPs would instead be determined under the terms of the demonstration. For CYs 2012 through 2014, MA payment will be determined under the terms of the national quality bonus payment demonstration project. Details on the demonstration will be provided on the CMS Web site.

d. Beneficiary Rebates (§ 422.266)

The proposed rule for calculation of beneficiary rebates implements section 1102(d) 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.

The ACA does not change the basic rules for determining whether or not an MA plan must provide a beneficiary rebate. These three basic rules are as follows. As set forth at § 422.262, we determine whether an MA plan must charge a basic beneficiary premium for coverage of Original Medicare benefits by comparing the unadjusted (standardized) Parts A/B bid amount to the unadjusted (standardized) Parts A/B benchmark amount for the plan for the year. If the bid is less than the benchmark, the basic beneficiary premium for coverage of Original Medicare benefits is zero. Second, as set forth at § 422.264(c) and (d) for local and regional plans, we calculate the amount of savings for MA plans with zero basic beneficiary premiums, which is 100 percent of the difference between

the risk-adjusted bid amount and the risk-adjusted benchmark amount. Finally, as set forth at § 422.266, the MA plan's beneficiary rebate amount is calculated as a percentage of the savings amount. Rebates must be used to reduce the costs of Part C mandatory supplemental benefits, Part D supplemental benefits, and/or to reduce the Part D basic premium and Part B premium.

Section 1102(d) 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 proposed rule would not affect the rebate percentages associated with a particular star rating, under the terms of the ACA.

We propose to revise § 422.266 by first redesignating paragraph (a) as paragraph (a)(1), and amending it to apply to years 2006 through 2011. We further propose to add paragraph (a)(2), which sets forth the rebate determination rules for 2012 and subsequent years. Proposed § 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.

Proposed § 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: 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 or contract based on the plan's star rating for the year.

Proposed § 422.266(a)(2)(iii) describes the rules for low enrollment plans. For 2012, the ACA requires that low enrollment plans shall be treated as having a rating of 4.5 stars for the purpose of determining the beneficiary rebate amount. Proposed § 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) shall 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.

For the purpose of setting a plan's rebate level for 2012 and 2013, we anticipate that MA organizations will receive adjustments to their quality ratings in a manner similar to the adjustments proposed for benchmarks, in recognition that MA organizations have limited ability to influence their summary plan ratings for purposes of the 2012 and 2013 determination of the plan rebate amount.

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

Section 1853(o) of the Act requires us to make QBPs to MA organizations that achieve performance rating scores of at least 4 stars under a five star rating system. While we have applied a star rating system to MA organizations for a number of years, these star ratings have thus far been used only to provide additional information for beneficiaries to consider in making their Part C and D plan elections. Beginning in 2012, the star ratings we assign for purposes of QBPs under section 1858(o) of the Act will directly affect the monthly payment amount MA organizations receive from us under their contracts. In effect, the bonus payment provisions of the new statute create a new category of CMS determinations related to MA organizations that affect their payments, arguably similar in terms of possible adverse impact to determinations related to contract qualification, termination, sanction, and payment reconciliation. Historically, a key aspect of the exercise of our authority to make such organization-specific determinations has been making an administrative review process available to MA organizations. Accordingly, we are proposing a review process through which MA organizations may seek review of their star rating ("QBP status") for QBP determinations.

Section 1854(b)(1)(C)(v) of the Act, as added by the ACA, also requires us to change the share of savings that MA organizations must provide to enrollees as the beneficiary rebate specified at § 422.266(a) based on the level of a sponsor's star rating for quality performance. This review process will also apply to the determinations made by us where the organization's plan rating sets its QBP status at ineligible for rebate retention.

While the statute does not specify a process for appealing low star ratings for QBP purposes, we are proposing this process pursuant to our authority to establish MA program standards by regulation at section 1856(b)(1) of the Act. We are proposing to afford the MA organization the opportunity to seek an appeal of their QBP status by a hearing officer. Prior to a request for an appeal, we will afford MA organizations the benefit of a technical report on the calculation of their QBP status, at the organization's request.

As previously discussed, for calendar years 2012 through 2014, QBP payments will be awarded under the terms of a demonstration project. Because the appeals process proposed in this proposed rule contemplates that the regulations governing QBP payments would be in effect, we are considering that these regulations not take effect until after the demonstration project has terminated. We anticipate making the appeals regulations effective when the demonstration project has terminated. In the interim, we will announce a process to appeal low star ratings for both QBP determinations under the demonstration and rebate retention allowances in separate guidance. We request comment regarding our proposal to delay the effective date of the appeals process set forth in this proposed rule until after the end of the demonstration.

Under the proposed regulations described in this section, MA organizations would be permitted to request a report on the calculation of their QBP status upon CMS' issuance of its final QBP payment determinations each year. Currently, we make plan star ratings available to MA organizations each September. As we have in prior years, we will continue to provide all organizations with a two-week preview period during which they can review their plan rating and raise questions concerning its accuracy with us before it is displayed on the CMS Web site. As noted in the discussion of the implementation of quality bonus payments earlier in this preamble, the plan ratings play a significant role in identifying MA organizations that qualify for QBPs. While we 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 will be considered made, subject to the appeal rights described in this section, when the notice of QBP status is released.

Under our proposed regulations, MA organizations would have 5 calendar days from the date of CMS' release of its QBP determinations to request from CMS a technical report explaining the development of their QBP status. The report would be produced by an independent contractor engaged by us to review the application of CMS' QBP payment methodology to the organization's performance for the most recent evaluation period. The technical report would be designed primarily to allow MA organizations to "see CMS' work" by providing the organization with a full explanation of how the values were determined for each performance area and how those values were in turn incorporated into the methodology used to calculate the QBP. This information would help MA organizations identify the ways in which their organization would need to improve to qualify for a QBP in future MA program years. The technical report contractor would provide its report in writing by electronic mail to the MA organization and CMS within 30 days of CMS' receipt of the organization's request for the report.

If, after reviewing the technical report, the MA organization believes that we were incorrect in its QBP determination, the MA organization would be able to 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. Such request would have to include a statement that describes the errors that we made in our QBP determination and how correction of those errors would result in the organization's qualification for a QBP.

We propose that the scope of the hearing 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 CMS used to make the QBP determination. We would make available and request comment from the public on the star rating calculation methodology each year. Once that process is concluded, the appeals process proposed may not be used as a means to challenge the validity of the adopted methodology.

Generally, we do not believe that the appeals process should provide a forum for MA organizations to challenge the accuracy of plan rating data as such data has often been made available to the sponsor and been subject to independent review (for example, HEDIS, CAHPS) prior to their use in QBP determinations. However, we acknowledge that while MA organizations often have access to the their raw performance data, the data sets we actually develop and use for the calculation of some of the performance measures may not be made available to the MA organization until they are released to them during the star rating preview period or through the technical report proposed here (for example, call center studies, appeals processing analysis). With respect to those data sets, we think it is appropriate to afford MA organizations the opportunity to challenge their accuracy during an appeal. Therefore, we propose to limit the scope of the hearing officer's consideration concerning the underlying data sets to those that have not been previously subject to independent validation. We are soliciting comments on whether this is an appropriate limitation on the scope of a QBP status appeal.

We expect that the appropriately limited scope of the appeal means that the relevant issues can be developed sufficiently for review by a hearing that would be conducted on the record, unless the parties requested and the hearing officer approved, a live or telephonic hearing. Also, the parties will not be permitted to conduct discovery as the only facts at issue will already have been sufficiently developed by CMS and in the QBP technical report contractor.

In determining the appropriate official to conduct a QBP appeal, we must consider issues of expertise and efficiency. We are proposing to designate a hearing officer who was not directly involved in the QBP determinations but who has sufficient understanding of the QBP methodology to promptly and effectively consider an MA organization's appeal. The designated hearing officer for the purpose of these appeals may or may not be the CMS Hearing Officer.

The hearing officer would be required to issue his or her decision on or before May 15 of the year preceding the year in which the plans for which the QBP is to be applied will be offered. This deadline is necessary to afford MA organizations time to incorporate their QBP status into their plan bids, due to us by the first Monday in June. 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 would have the right to revise, on its own initiative, an MA organization's QBP status at any time after the initial release of the QBP determinations through May 15 of each year. We may take this action on the basis of any credible information, including the technical report issued pursuant to the process proposed here, which demonstrates that the initial QBP determination was incorrect.

At this time, we are not proposing another level of administrative review beyond the hearing officer. While many of our administrative processes include the potential for review by the CMS Administrator, given the timing considerations of concern for both CMS and the MA organizations, we have opted not to propose Administrator review in these cases. We expect that the time between our notification to MA organizations of their QBP status and the date by which organizations need to have certainty concerning their QBP status to develop their MA plan bids each year may only be sufficient to accommodate the completion of the technical report and the hearing officer review. We believe that it would not benefit MA organizations to afford them an appeal right which they likely may not be able to avail themselves of in time to affect their bid calculations. However, we are soliciting comments 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 both in terms of its contribution to administrative due process and its impact on the annual MA bid submission timeline.

C. Clarify Various Program Participation Requirements

The proposed regulations in this section clarify existing regulations or implement new requirements consistent with existing policy guidance to assist sponsoring organizations with attaining the goals envisioned by the Congress when the legislation implementing the Medicare Advantage and Prescription Drug Benefit programs was first passed. These clarifications are detailed in Table 4.

TABLE 4: 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 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

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

Section 1866(a)(1)(O) of the Act and regulations at § 422.214(b) require that, when paid by an MA organization for services furnished to an MA plan enrollee, a non-contracting provider of services (for example, a hospital, skilled nursing facility or home health agency) must accept, as payment in full, the amounts that the provider could collect if the beneficiary were enrolled in Original Medicare. While this provision acts as a cap on what an MA organization is required to pay a non-contracting provider of services, if the provider of services bills the MA organization an amount that is less than the Original Medicare payment amount, the MA organization is only obligated to pay the amount billed.

Payment disputes have occurred in recent years for services provided on a non-contract basis to MA enrollees by providers of services that are paid under prospective payment (PPS) methodologies, such as hospitals and home health agencies. In several cases, MA organizations have interpreted requests for payment by such providers to be requests for amounts less than the amount that would be paid under Original Medicare. This is because, under PPS methodologies, providers are to submit estimated charges, which are then combined with diagnostic information in pricing software to determine the PPS payment rate for the service. Under Original Medicare, if these estimated charges are less than the PPS payment amount produced by the Medicare pricing software, the higher Medicare payment amount is paid. Because this is the method for requesting payment at the Original Medicare payment amount under the Original Medicare program, we believe that the same information should similarly be treated as a request for the full Medicare payment amount when submitted to an MA organization in a request for payment unless the provider has made clear that it intends to bill the MA organization less than the Original Medicare amount. Thus, if the provider of services notifies the MA organization in writing that it intends to bill less than the payment amount it would receive under Original Medicare, consistent with longstanding policy, the MA organization may pay the provider the lower amount that is billed.

In response to questions about this issue, CMS clarified its expectations for plans and out-of-network providers in its Out-of-Network Payment Guide released February 25, 2010. This guidance reflected 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. However, the guide 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 propose to reflect the policy set forth in our February 25, 2010 guidance in the regulations governing payment to non-contract providers by adding a new paragraph (c) to § 422.214 to provide that a request for payment from an MA organization by a non-contract provider paid under a 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 also think it is important to clarify in this proposed rule that MA organizations offering regional PPO MA plans must always pay non-contract providers the Original Medicare payment rate in those portions of their service area where they are meeting requirements for access to services by non-network means as described in § 422.111(b)(3)(ii). We believe this requirement is justified under 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.

We propose adding a new paragraph (d) to § 422.214 clarifying that an MA organization must always pay non-contract providers at least the Original Medicare payment rate in those portions of its service area where it is meeting access to services requirements by non-network means under § 422.111(b)(3)(ii).

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 propose 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 (D.C.) (collectively referred to as "United States authorities"). We propose adding a definition for the word "pharmacist" to § 423.4 in Subpart A to reflect this understanding.

The proposed change is prompted by recent Medicare Part D sponsor audit findings in which CMS 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. We believe that there are potential threats to beneficiary safety and access when decisions are made by clinicians who are not licensed by United States authorities. 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; make clinical decisions consistent with the Federal Drug Administration (FDA) prescribing information for products; and are knowledgeable about the range of pharmaceutical products available on the United States market, appropriate generic substitutions, and over-the-counter and behind-the-counter products. We believe that requiring pharmacists to be licensed by United States authorities will help guarantee that Part D sponsors meet these expectations.

3. Prohibition on Part C and 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 our final rule (75FR 19678) entitled "Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs." that appeared in the April 15, 2010 **Federal Register**, we modified § 423.508 by adding a paragraph (e) stating that 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 circumstances warranting special consideration. Similarly, in § 423.504(b), we added a new paragraph (b)(6) stating that as a necessary condition to contract as a Part D sponsor, an organization must not have terminated a contract by mutual consent and, as part of that consent, agreed not to apply for new contracts or service area expansions for a period of up to 2 years. Similar modifications were made for the MA regulations. Specifically, we modified § 422.508 by adding paragraph (c) and § 422.503(b) by adding a new paragraph (b)(7). 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 D programs.

In this rule we are proposing to amend the 2-year new contract prohibition in both § 422.508 and § 423.507 by adding a new subsection entitled "Prohibition of Part C and 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 propose adding similar clarifying language to the existing language at § 422.506, § 422.512, 423.508, and § 423.510. Under sections 1857(e)(1) and 1860D–12(b)(3)(D) of the Act, the Secretary may add terms to the contracts with MA and Part D sponsors including requiring the organization to provide the Secretary with such information as the Secretary may find necessary and appropriate. It is our belief that to carry out the intentions of the 2-year exclusion we 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 D programs. In order to meet this goal we want to evaluate the new organization's management and ownership to detect a situation in which "ABC, Inc." applies for a new contract as "XYZ, Inc." Therefore, we are proposing a requirement which will 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 are proposing to develop standards and benchmarks regarding the percentage of ownership or management control that we would conclude is problematic.

This proposed requirement will 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. Since the start of the Medicare Advantage and Part D programs, we have seen MA organizations and Part D entities that terminated a contract for various reasons apply as a new organization with Medicare within the 2-year exclusion period with the same ownership and management structure as the previous organization. This proposed requirement will help ensure that the provisions of the 2-year application prohibition are given full effect.

Therefore, we are proposing that the 2-year ban on new Part C or 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 D organization. Under this proposed regulation, we would then 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. For this proposal we are defining "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.

This standard for disclosure is modeled after the authority granted to the Secretary by section 1124(a) of the Act (42 U.S.C. 1320a–3) which provides for disclosure standards for, among other entities, Medicaid managed care organizations and Medicare carriers and fiscal intermediaries.

We solicit comments on whether plan sponsors, or other stakeholders consider the proposed definition of "5 percent or more" truly represents current market conditions. We are requesting comments on this section because we do not want to arbitrarily decide on the percentage of interest the above mentioned persons could have in an organization, especially if this percentage does not reflect standard business practices.

We are proposing 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 are proposing to make similar amendments to § 422.506, § 422.512, § 423.508, and § 423.510.

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 defines 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 effectuate 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 correctly place the beneficiary in the benefit and provide the catastrophic level of coverage at the appropriate time. This list is an example of various required data and is not intended to be all inclusive of the data necessary to assure a timely and smooth transition for the Medicare beneficiary when leaving the terminated plan and enrolling in a new plan.

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 are proposing 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 will 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).

Sponsors that fail to provide the necessary data directly harm beneficiaries, as these individuals will likely be charged incorrect amounts for their medications when transferring to a new Part D sponsor. Specifically, beneficiaries may be forced to re-satisfy deductible requirements under the new plan, or prevented from moving into the catastrophic phase of the benefit (where there are minimal out-of-pocket costs) when otherwise eligible. Therefore, plans that do not comply with this section may be subject to a Civil Monetary Penalty as defined by § 422.752(c) and § 423.752(c).

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)

Pursuant to our authority under sections 1852(g) and 1860D–4(g) of the Act, which incorporates by reference paragraphs (1) through (3) of section 1852(g), CMS established procedures for making organization determinations and reconsiderations regarding health services under Part C, and coverage determinations and redeterminations regarding covered drug benefits under Part D. These requirements are codified in our regulations at part 422 subpart M part 423 subpart M, respectively.

Section 1852(g)(1)(A) of the Act gives us broad authority to determine how best to establish the procedures Part C organizations must follow for processing organization determinations. Furthermore, section 1852(g)(2)(B) of the Act requires Part C plan reconsiderations related to medical necessity determinations to be made by physicians with appropriate expertise in the applicable field of medicine, and that those physicians be different from a physician involved in the initial determination. Although § 422.590(g)(2) requires physician review of adverse organization determinations that involve medical necessity, we do not specify in this provision or elsewhere in part 422 subpart M who must conduct the initial medical necessity determinations. Given the language in § 422.590(g)(2), we believe Congress expected that appropriate health care professionals would review initial determinations involving medical necessity. Further, by requiring that all organization determinations and plan reconsiderations involving medical necessity be reviewed by an appropriate health care professional with sufficient medical and other expertise, including knowledge of the Medicare program, enrolled beneficiaries would be assured of consistent and accurate decisions by Part C organizations. We propose 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 propose 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.

Consistent with the rationale for requiring 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, and pursuant to our authority under section 1857(e) of the Act to add additional terms to our contracts with MA organizations as necessary and appropriate, we also propose to revise § 422.562(a) by adding paragraph (4), which will require each MA organization to employ a medical director who is responsible for ensuring the clinical accuracy of all organization determinations and reconsiderations regarding medical necessity. Under our proposal, 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. Because the requirement to employ a medical director will enhance the coordination and accountability of plan operations and strengthen quality assurance activities across the organization, we believe that this proposal strikes the appropriate balance between our interest in ensuring that plans are properly administering the Part C benefit, and the plans' interest in minimizing their administrative burden.

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. As noted above, we are proposing a requirement that Part C organizations employ (1) physicians or other appropriate health care professionals with sufficient medical and other expertise, including knowledge of the Medicare program, to review organization determinations involving medical necessity; and (2) a medical director who is responsible for ensuring the clinical accuracy of all organization determinations and reconsiderations regarding medical necessity. Consistent with the proposed changes to the Part C organization determination process, we propose adding paragraph (d) to § 423.566, which will require Part D coverage determinations involving 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, and 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. Also, we propose revising § 423.562(a) by adding paragraph (5), which will require each Part D plan sponsor to employ a Medical Director who is responsible for ensuring the clinical accuracy of all coverage determinations and redeterminations that involve medical necessity issues, and who 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. In addition to being consistent with the proposed changes to the Part C organization determination process, we believe that the proposed changes are necessary under Part D to prevent certain issues that have been discovered while auditing plan sponsors, such as: (1) Preventing enrollees who were stable on a protected-class drug from accessing that drug; (2) applying inappropriate prior authorization and step therapy criteria when adjudicating prescriptions; (3) issuing denials based on a lack of medically accepted indications when medically accepted indications were specified in at least one of the applicable compendia; and (4) failing to provide transition supplies for existing members who experienced formulary changes across plan years. We believe the proposed changes to § 423.562(a) and § 423.566 will enhance Part D plan sponsors' ability to ensure consistent formulary administration, application of plan coverage rules, and assist in the early identification and resolution of potential quality concerns.

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

Pursuant to our authority under sections 1860D–4(c)(1)(D) and 1860D–12(b)(3)(C) of the Act which incorporates by reference section 1857(d) of the Act, we propose to clarify that MA organization and Part D sponsor compliance officers must 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 must have their compliance officers obtain training in 2012 to prepare for the upcoming contract year. We propose adding § 422.503(b)(4)(vi)(B)(1)(i) and (ii) to subpart K and § 423.504(b)(4)(vi)(B)(1)(i) and (ii) to subpart K to reflect this clarification.

Under § 422.503(b)(4)(vi)(B) and § 423.504(b)(4)(vi)(B), MA organizations and Part D sponsors (collectively referred to as plan sponsors) must designate a compliance officer to oversee the day-to-day operations of the compliance program. We are proposing 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. Compliance officers are the individuals whom we expect to be among the most familiar of any sponsor's executives with basic program requirements. 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 D contract compliance matters for them.

We believe that requiring annual training for compliance officers will help to address these deficiencies by emphasizing the critical role of the compliance officer in maintaining and ensuring program compliance. Our expectations of Medicare plan sponsor compliance officers are different from what the expectations might be for a commercial health insurance compliance officer. We expect plan sponsors' compliance officers to have, at minimum, a basic, working knowledge of the MA and/or Part D programs and an awareness of the corresponding operational activities within their organizations. Program knowledge and operational awareness are necessary skills for a compliance officer, in addition to being able to implement an effective compliance program. We rely on the compliance officer to have the authority and resources needed to foster compliance-oriented organizational processes and effectuate changes needed to ensure sustained program

compliance. We will announce our expectations regarding the content and hours of annual training required in forthcoming guidance. At this time, we expect that one to two days of annual Medicare Part C and D specific compliance training offered by an entity with expertise in MA and Part D compliance will be sufficient. We are exploring the current programs available as well as considering offering CMS-sponsored training.

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

We have delegated our authority to evaluate whether an MA organization is in compliance with certain Medicare requirements to three private accrediting organizations. This evaluation method is known as "deeming," and is conducted as a part of the audit process. Currently, an MA organization may be deemed to meet requirements in the following areas:

- Quality improvement.
- Confidentiality and accuracy of enrollee records.
- Anti-discrimination.
- Access to services.
- Information on advance directives.
- Provider participation rules.
- Access to covered drugs.
- Drug utilization management, quality assurances measures and systems, medication therapy management, and a program to control fraud, waste, and abuse.
- Confidentiality and accuracy of enrollee prescription drug records.

We require all MA organizations to submit their quality improvement projects (QIPs) and chronic care improvement programs (CCIPs) on an annual basis. We propose to exclude the QIPs and CCIPs as components of the deeming process. Removing the QIPs and CCIPs from the deeming process avoids redundancy and reduces the burden for the MA organizations. Further, this process provides for improved consistency in the evaluation and assessment of the QIPs and CCIPS. Improved consistency in the assessment of the QIPs and CCIPs is important as these elements may be incorporated into future plan ratings. The QIPs and CCIPs will be reviewed and evaluated by CMS or an appropriate CMS contractor. Therefore, we propose to amend § 422.156 to specify that the deeming process should focus on evaluating and assessing the overall quality improvement (QI) program, but that QIPs and CCIPs will be excluded from the deeming process.

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

As provided under section 1857(i) of the Act and as codified at § 422.106(d), we may waive or modify requirements that hinder the design of, the offering of, or the enrollment in, an MA plan offered by one or more employers, 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. The purpose of this authority is to facilitate the offering of MA plans under contracts between MA organizations and employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof). Following implementation of the Medicare Modernization Act (MMA), similar authority was established with respect to Part D sponsors in relation to employment-based retiree health coverage at section 1860D–22(b) of the Act. In addition, unlike the original authority established for employment-based retiree health coverage under the MA program at section 1857(i) of the Act, section 1860D–22(c) of the Act establishes definitions of terms related to this authority, including of the terms "employment-based retiree health coverage" and "group health plan." The definition of "group health plan" at section 1860D–22(c)(3) of the Act refers to the definition of such term in section 607(1) of the Employee Retirement Income Security Act of 1974 (ERISA).

Since the enactment of the MMA, we have become concerned that MA organizations have been contracting with entities providing coverage that, in some instances, cannot properly be characterized as "employment-based" group health plan coverage—for example, with professional or group associations. Examples of existing employer contracts furnished through an association include a professional trade association representing employers and its employees within the builders association; a professional trade association representing new car and heavy-duty truck dealers; and a professional trade association representing physicians and medical students. As provided in our subregulatory guidance on MA employer group/union sponsored group health plans, Chapter 9 of the Medicare Managed Care Manual (*http://www.cms.gov/manuals/downloads/mc86c09.pdf*), entitled "Employer/Union Sponsored Group Health Plans," we restrict 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. Thus, a beneficiary's enrollment in one of these MA plans must be based on receiving "employment-based" health coverage from an employer/union group health plan sponsor 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. In that guidance, we also note that coverage obtained through a professional or other type of group association would not make a beneficiary eligible for these kinds of plans, except to the extent that the coverage obtained through the association can properly be characterized as "employment-based" group health plan coverage. We are aware that some MA organizations have contracted with professional or group associations and offered coverage via EGWPs to individuals who are members, but not employees, of such associations. While there is no reference to the ERISA definition of group health plan in section 1857(i) of the Act, we believe Congress did not envision 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 ERISA.

In order to provide clarification with respect to our requirements for offering employment-based retiree health coverage via an MA plan, we propose to codify—under the general authority provided at section 1857(i) of the Act—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). These proposed definitions are consistent with those provided for Part D sponsors at § 423.454 and § 423.882. We also propose to change the reference to an MA plan at § 422.106(d) to a reference to an employer-sponsored group MA plan.

We solicit comment on our proposals to revise these definitions.

D. Strengthening Beneficiary Protections

This section includes provisions aimed at strengthening beneficiary protections under Parts C and D. Some of the proposals affecting both Parts C

and D include requiring that MA organizations and Part D sponsors must provide interpreters for all 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 Part C include our proposal to extend the mandatory maximum out-of-pocket (MOOP) amount requirements to regional PPOs, and prohibit the use of tiered cost sharing by MA organizations. Under Part D, we address the delivery of adverse coverage determinations.

In the area of Parts C and D marketing, proposals include requiring MA organizations' and Part D sponsors' agents and brokers to receive training and testing via a CMS endorsed or approved training program and extending the annual training and testing requirements to all agents and brokers marketing and selling Medicare products.

This information is detailed in Table 5.

TABLE 5: 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	Subpart F	§422.262	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)

Section 1851(h)(2) of the Act requires us to establish marketing standards for Medicare Advantage organizations. Section 1860D–1(b)(1)(B)(vi) of the Act requires that we ensure that beneficiaries are not misled or provided inaccurate information by Part D sponsors. Additionally, section 1851(j)(2)(E) of the Act provides the Secretary the authority to establish limitations with respect to agent and broker training. Section 1860D–4(l)(2) of the Act applies the same requirements with respect to sales and marketing activities to Part D sponsors.

Our current regulations at § 422.2274(b) and (c) and § 423.2264(b) and (c), require MA plans and Part D sponsors to ensure agents selling Medicare products are trained and tested annually on Medicare rules and regulations specific to the plan products they intend to sell. Since the training and testing requirements were implemented following the enactment of MIPPA, MA organizations, and Part D sponsors conducted training and testing largely on their own or through third party vendors. We have reviewed some training programs upon request by third party vendors, but we do not routinely review MA organization, Part D sponsor, or third party vendor training programs to ensure their comprehensiveness or accuracy.

To develop a uniform understanding of the Medicare program requirements and further ensure beneficiary protection, we launched a pilot online training and testing module on July 31, 2009 for the CY 2010 marketing season. Twenty-six MA organizations and Part D sponsors volunteered to participate in the pilot, and about 3,700 agents and brokers were trained and tested. About 85 percent of trained agents and brokers passed the certification exam.

Based on our experience with the pilot, we have concluded that we should move toward greater standardization of agent and broker training and testing. 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. More specifically, we believe that MA organizations' and Part D sponsors' agents and brokers not only should be annually trained and tested on Medicare rules and regulations specific to the products they intend to sell, as currently provided under § 422.2274(b) and (c) and § 423.2274(b) and (c), but that the training and testing vehicles MA organizations and Part D sponsors use meet our minimum standards.

To that end, we are proposing to revise § 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. Following implementation of this proposal, we

would review and endorse or approve one or more entities to provide Medicare agents and brokers with their annual testing and training. We would review and approve or endorse proposed training programs for comprehensiveness and consistency with marketing rules and policies. We are considering implementing this requirement through a request for proposal (RFP) competitive process; however, we seek comments and suggestions about alternatives to using the RFP competitive process. We note that these proposed new requirements would also be applicable to section 1876 cost contract plans, since in our April 15, 2010 final rule (75 FR 19784 through 19785), we extended the Part 422 requirements regarding MA marketing to section 1876 cost contract plans by cross-referencing the MA marketing requirements at § 417.428.

We believe this proposed change would ensure that agents and brokers selling Medicare products have a comprehensive and consistent base of understanding of Medicare rules and would eliminate the duplication of training and testing requirements for agents and brokers who contract with multiple plans.

b. Extending Annual Training Requirements to All Agents and Brokers (§ 422.2274 and § 423.2274)

In addition to the proposed changes specified above to require that MA organization and Part D sponsor training and testing programs be CMS endorsed or approved, we propose a correction to our current regulations at § 422.2274(b) and (c) and § 423.2264(b) and (c), which require MA plans and Part D sponsors to ensure agents selling Medicare products are trained and tested annually on Medicare rules and regulations specific to the plan products they intend to sell. In our November 2008 interim final rule implementing the MIPPA agent/broker requirements (73 FR 67413), we inadvertently made a drafting error and applied the annual agent and broker training and testing requirements only to independent (such as, non-employee) brokers or agents. Our intent, which was initially stated in our September 2008 interim final rule (73 FR 54239), was to require that all agents and brokers, whether independent or employed by a plan, be subject to our annual training and testing requirements. We believe it is critical that all agents and brokers selling Medicare products receive training and testing on Medicare rules, regulations and the plan-specific 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 are proposing to revise § 422.2274 and § 423.2274 to correctly apply these requirements to all agents and brokers marketing and selling Medicare products. We also note that these proposed new requirements would be applicable to section 1876 cost contract plans, since in our April 15, 2010 final rule (75 FR 19784 through 19785), we extended the Part 422 requirements regarding MA marketing to section 1876 cost contract plans by cross-referencing the MA marketing requirements at § 417.428.

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)

As provided in section 1852(c)(1)of the Act and as codified at § 422.111(b), MA organizations must disclose in a clear, accurate, and standardized form to each enrollee, at the time of enrollment and annually thereafter, detailed information about the MA plans they offer. Section 1860D–4(a)(1) of the Act provides similar authority for Part D sponsors, which is codified at § 423.128(b). Section 1860D–4(a)(3) of the Act provides additional authority to require that Part D sponsors provide specific plan information on a timely basis to plan enrollees upon request through a toll-free telephone number, and that they make available on timely basis through an Internet Web site information on specific formulary changes under Part D plans. This authority is codified at § 423.128(d)(1) and § 423.128(d)(2), which require that Part D sponsors operate a toll-free customer service that is open during usual business hours and provide such service in accordance with standard business practices, as well as an Internet Web site that, at a minimum, provides the information Part D sponsors are required to provide enrollees at the time of enrollment and annually thereafter under § 423.128(b).

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.

We believe it is important to clarify that current and prospective enrollees of MA plans should 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. Furthermore, as a practical matter, most MA organizations must offer MA–PD plans in order to offer MA-only plans and are therefore already operating customer service call centers and Internet Web sites consistent with our regulatory and subregulatory requirements. Therefore, under our authority at section 1852(c) of the Act to require that MA organizations disclose MA plan information upon request, as well as our authority under section 1857(e) of the Act to specify additional contractual terms and conditions the Secretary may find necessary and appropriate, we propose to extend call center and Internet Web site requirements to MA organizations. Specifically, we propose 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 also propose deleting paragraph § 422.111(f)(12), which requires 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 move these requirements to § 422.111(g)(2)(i).

b. Call Center Interpreter Requirements (§ 422.111 and § 423.128)

Pursuant to our authority under sections 1852(c)(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 propose to clarify Medicare Part C and D requirements regarding current and prospective enrollee toll-free customer call centers. Specifically, we propose clarifying that MA organizations and Part D sponsors must provide interpreters for all non-English speaking and limited English proficient (LEP) callers. We propose adding new paragraphs § 422.111(g)(1)(iii) and

§ 423.128(d)(1)(iii), respectively, to reflect this clarification.

This proposed clarification is a result of findings from our call center monitoring, which revealed that a significant percentage of Medicare Part C and D sponsors were not providing foreign language interpreters for non-English speaking callers. For example, only 65 percent of Spanish speaking callers in our monitoring study were connected with an interpreter, and only 60 percent of Mandarin or Russian speaking callers were connected with an interpreter. The results varied widely among plan sponsors of all enrollment sizes. Some plan sponsors did not provide any interpreters at all. The preamble to our January 28, 2005 final rule (70 FR 4223) stated, "Call centers must be able to accommodate non-English speaking/reading beneficiaries. Plan sponsors should have appropriate individuals or translation services available to call center personnel to answer questions that beneficiaries may have concerning aspects of the drug benefit." Subsequently, the August 15, 2005 Medicare Marketing Guidelines contained this statement from the preamble. When we followed up with sponsors and discussed the lack of interpreters for LEP callers, many indicated they were unaware of the requirement to provide interpreters to LEP callers. This clarification addresses the problem by explicitly codifying the requirement to provide interpreters for LEP callers in regulations. The origin of this requirement to serve LEP individuals is Title VI of the Civil Rights Act of 1964, which, in part, prohibits discrimination in federal programs based upon national origin. Additionally, this clarification is consistent with fulfilling the goals of Executive Order 13166, Improving Access to Services for Persons with Limited English Proficiency, and with the HHS Secretary's implementation of the Executive Order as described in the Strategic Plan for Implementing Access to HHS Programs and Activities by LEP Persons and the CMS Language Access Plan. Providing interpreters for LEP beneficiaries is a key component of the CMS Language Access Plan and helps ensure that beneficiaries have access to all of the information they need to make appropriate decisions about their health care. Our rules do not require translation of marketing materials into all languages; therefore, call center interpreters are a safety net in geographic areas where only a few beneficiaries are LEP because interpreters can help answer questions and translate marketing materials over the phone. Compliance with the Civil Rights Act is included in plan sponsors' contractual requirements in accordance with § 422.503(h)(1) and § 423.505(h)(1).

3. Require Plan Sponsors To Contact Beneficiaries To Explain Enrollment by an Unqualified Agent/Broker (§ 422.2272 and § 423.2272)

The regulations implementing section 103 of MIPPA (§ 422.2268, § 422.2272, § 422.2274, § 422.2276, § 423.2268, § 423.2272, § 423.2274, and § 423.2276), included a number of provisions that prohibited or limited certain sales and marketing activities by MA organizations and PDPs. Specifically, § 422.2272 and § 423.2272 require plan sponsors that used 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.

We have become aware through recent audits that when plan sponsors discover that an unlicensed agent has assisted with an enrollment, they are not notifying the beneficiary involved that the agent representing them was unlicensed. Beneficiaries rely heavily on information they receive from agents regarding plan benefits and costs and should have the opportunity to ask additional questions or reconsider their enrollment when they have been enrolled in a plan by an unlicensed agent. Therefore, we are proposing to revise § 422.2272(c) and § 423.2272(c) to require that MA organizations and Part D sponsors must terminate unlicensed agents upon discovery and notify any beneficiaries who were enrolled in their plans by an unlicensed agent in order to give them the option of confirming enrollment in the plan or making a plan change.

We believe that the proposed changes are consistent with the statute and with the beneficiary protections we specified in our regulations implementing MIPPA. We also note that these proposed requirements would be applicable to section 1876 cost contract plans, since in our April 15, 2010 final rule (75 FR 19784 and 19785), we extended the Part 422 requirements regarding MA marketing to section 1876 cost contract plans.

4. Customized Enrollee Data (§ 422.111 and § 423.128)

Section 1852(c) of the Act requires MA organizations to disclose a detailed plan description in a clear, accurate, and standardized form to each Medicare enrollee in a MA plan offered by the organization. The plan description is to be provided at the time of enrollment and annually thereafter and includes items such as service area, premium, benefits, plan providers and coverage. Additionally, section 1860D–1(c)(3) of the Act requires Part D sponsors to provide comparative information to beneficiaries about their qualified prescription drug benefits, premiums, cost sharing, quality and performance, and results of consumer satisfaction surveys. Specifically, the Part D plan description includes items such as service area, benefits, premium, formulary, network pharmacies, and coverage. These requirements are codified at § 422.111 and § 423.128 and are implemented through the annual notice of change (ANOC) and evidence of coverage (EOC) documents, which must be furnished to all plan enrollees at least 15 days before the annual open election period.

While the ANOC describes plan benefit and cost sharing changes for the coming year, we are concerned that this information alone may not be enough to prompt enrollees to actively evaluate their plans annually with respect to plan costs, benefits, and overall value. In addition, we have received requests from the beneficiary advocacy community 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. Therefore, in accordance with authority cited above, we propose to also 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 propose 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 annual renewal materials (currently the ANOC and EOC).

We are considering several options for implementing this data disclosure requirement, and we note that this proposal would only specify our authority to require such a disclosure. As we contemplate implementation and model designs moving forward, we seek 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 are considering running 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 receive.

One option we are considering is a customized statement of the beneficiary's estimated out-of-pocket costs in the following year based on utilization of the same health care services as in the prior year. We recognize that projecting past health care utilization as a predictor of future use would yield only an estimate of enrollee out-of-pocket costs. However, we believe that such an estimate, with appropriate caveats, would illustrate in real dollar terms how the member's costs are likely to change in the coming year, and what this means for them. Such a statement would enable plan members to better understand how the costs of their plan are changing in the upcoming contract year and what that means for them if they remain in the plan and use similar services. This customized out-of-pocket cost statement would supplement general plan information in the ANOC and EOC documents as well as enhance the currently available information through tools such as Medicare Options Compare (MOC) and the Medicare Prescription Drug Plan Finder (MPDPF), which provide general information about plan costs. For example, the MOC approximates out-of-pocket costs based on self-selected health status and a national cohort sample of information calculated using data from the Medicare Current Beneficiary Survey. MPDPF allows a beneficiary to select certain drugs and calculate annual out-of-pocket costs, based on their expected use of those drugs. We intend for any customized out-of-pocket cost statement to provide personal information to beneficiaries that would help them consider using other tools and resources, including MOC and MPDPF, to determine whether to select a new plan. Such a statement would also include information for accessing these tools.

We are considering several different designs for showing enrollees how their expenses would change in the following year, in addition to changes in the maximum out-of-pocket (MOOP) amount and network service area for the next year (see Tables 6 through 8). Options for categorizing services that we are considering include the following: (1) Premium; a summation of cost-sharing for all MA services; all prescription drug costs; and the total out-of-pocket costs for the enrollee; (2) premium; MA cost-sharing detailing inpatient care (Part A), outpatient care (Part B), and supplemental benefits; prescription drug costs; and total costs; and (3) premium; a more detailed breakdown of costs for services, including information specifying the top 5 services utilized by each individual enrollee; as well as prescription drug costs and total costs. We seek comments on the categorizations described above. We also seek comments on including mandatory and/or optional supplemental benefits in the document, given their variety for individual enrollees or plan and impact on the overall premium cost.

Since all MA organizations must currently track utilization and beneficiary responsibility related to the MOOP and, in some cases, catastrophic limits, we do not anticipate that they will have difficulty in determining at least 6 months of actual beneficiary out-of-pocket cost liability. Since this statement is intended to be distributed in conjunction with the other renewal materials each fall, we understand that MA organizations and Part D sponsors will have only partial year data on beneficiary costs. Moreover, we also understand that people tend to incur increased utilization of services during the second half of the year, adding another trending factor to a calculation of average monthly or yearly cost. Therefore, we also seek comment as to whether the customized statement of costs should include six months of actual costs for each category described, an average monthly cost for each category described, or an estimated yearly cost for each category. Regardless of the time period, we would require that any costs be represented as estimates and that the notice clearly indicate to enrollees the time period on which the estimates are based. Tables 6 through 8 describe possible types of service categorization, and each table includes a different option for representing the cost calculation (average monthly, actual 6 months, and yearly estimated costs). Dollar figures are for illustrative purposes only and do not reflect any decision on final document design or any calculation of actual beneficiary costs.

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TABLE 6:

	Average amount you have spent per month this year	If you use the very same health care services next year the amount you will spend per month
Premium Total	$50	$60
Medicare Cost Sharing Includes all Part A and B services; does not include supplemental benefits	$100	$75
Prescription Drug Costs	$25	$50
Total average per month **including** premium	$175	$185

TABLE 7:

	What you have spent between January – June 2011	If you use the very same health care services next year the amount you will spend between January-June 2012
Premium Total	$300	$250
Cost-Sharing		
Inpatient Care Includes services such as: inpatient hospital, skilled nursing facility, home health care	$0	$0
Outpatient Care Includes services such as: outpatient hospital services, physician office services, physical and occupational therapy, outpatient mental health services and durable medical equipment	$500	$700
Supplemental Services Includes services such as vision and dental services	$100	$150
Prescription Drug Costs	$200	$250
TOTAL Cost-sharing **NOT** including premium	$800	$1100

Table 8:

This table includes the services you have used most often this year	Your estimated costs this year	If you use the very same health care services next year the amount you would spend
Premium Total	$700	$800
Cost-Sharing		
Inpatient Care		
Inpatient Hospital Care	$1,600	$2,100
Home Health Care	$500	$750
Outpatient Care		
Outpatient Hospital Care	$900	$1200
Physician Office Services	$400	$300

This table includes the services you have used most often this year	Your estimated costs this year	If you use the very same health care services next year the amount you would spend
Physical, Occupational, and Speech Therapies	$200	$100
Durable Medical Equipment	$300	$300
Ambulance Services	$50	$100
Part D Drug Coverage	$1000	$2000
Total cost-sharing **NOT** including premium	$4,950	$6700*

*We estimate that if you use the same amount of services next year, the amount you pay will be capped by the maximum out-of-pocket cost limit for this plan. The $6,700 is the capped amount.

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Another, but potentially complementary, option would be to require a periodic EOB for MA plans, similar to the EOB that Part D sponsors provide to Part D enrollees. This EOB would include a specific list of services and the enrollee's utilization and out-of-pocket costs during a period of time to assist him or her in evaluating their options for the future. It would be furnished periodically throughout the contract year and could include current as well as cumulative data on utilization and costs for that period. It could also present data by service categories as a percentage of total costs. We also understand that there would be data collection and timing concerns for plans, and the frequency of the distribution of the EOB would affect the time period of the data collected. For example, an annual notice distributed at the end of the contract year would not arrive in sufficient time for a beneficiary to make determinations during an enrollment period. However, a notice furnished just prior to the open enrollment period could only contain partial year actual data, unless plans use 12 months of data over two contract years. An EOB as described above could be used in conjunction with a customized annual out-of-pocket cost statement to fine-tune an enrollee's search for another plan that might be a better fit for his or her particular health care needs. We seek comments and suggestions for implementing an EOB for MA enrollees, including suggestions for design, calculation of data and frequency of disclosure to enrollees.

We note that we are considering 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 EOB, since enrollees in these plans generally do not incur out-of-pocket costs. We seek comment on exempting D–SNPs from this proposed requirement.

In summary, we seek comments and suggestions regarding our proposal to add to the current disclosure requirements in § 422.111 and § 423.128, a new requirement that MA organizations and Part D plan sponsors 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 utilization and out-of-pocket costs for the following plan year. Such data would be disclosed to plan members periodically in conjunction with other annual plan renewal materials (currently the ANOC and EOC). In addition, we seek comments and suggestions on the topics discussed above, including the number of disclosures per year, document design models, categories of services included, calculation, and presentation of costs, and standardization of information.

5. Extending the Mandatory Maximum Out-of-Pocket (MOOP) Amount Requirements to Regional PPOs (§ 422.100 and § 422.101)

In our April 15, 2010 final rule (75 FR 19709 through 19711), we established a new 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), effective for contract year 2011, 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. All cost sharing (that is, deductibles, coinsurance, and copayments) for Parts A and B services must be included in plans' MOOPs. In our April 15, 2010 final rule (75 FR 19709 through 19711), we stated that for contract year 2011, we would implement a mandatory MOOP limit in accordance with the requirements at § 422.100(f)(4), as well as continue to allow MA organizations the option of adopting a lower, voluntary MOOP limit. MA organizations that adopt the lower voluntary MOOP are provided more flexibility in establishing cost sharing amounts for Parts A and B services than those that do not elect the voluntary MOOP. However, we did not include regional PPOs in the mandatory MOOP and catastrophic limit requirements, as discussed below.

Since implementation of the Medicare Modernization Act of 2003, RPPOs have been required under section 1858(b)(2) of the Act to establish a MOOP for in-network cost sharing and a catastrophic limit inclusive of both in- and out-of-network cost sharing for Parts A and B services; however, those amounts are currently at the discretion of MA organizations offering RPPO plans. Because the statutory MOOP requirement was already in effect with respect to RPPO plans, we applied the new mandatory MOOP requirement only to local MA plans in our final rule (75 FR 19711). We stated that for contract year 2011, RPPOs would continue to be permitted to establish their own in-network MOOP and catastrophic limits without a maximum limit set by CMS, but we encouraged them to adopt either the mandatory or voluntary MOOPs established in CMS guidance. We stated 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 proposed Parts A and B services cost sharing amounts. However, we also stated that, while we believe RPPOs should be subject to the same requirements with respect to a MOOP as local PPO plans, we would address this discrepancy in future notice-and comment rulemaking, since our proposed rule did not give MA organizations offering RPPOs an opportunity to comment on such a proposal. We have concluded that, in order to make it easier for beneficiaries to understand and compare MA plans, RPPO plans should also be subject to the mandatory maximum MOOP requirements that currently apply to

local PPO plans. Therefore, we propose to extend the mandatory MOOP and catastrophic limit requirements to RPPO 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 propose to codify this requirement by revising § 422.100(f) (CMS review and approval of MA benefits and associated cost sharing), in paragraphs (f)(4) and (5) to include regional MA plans. In addition, we propose to revise paragraphs (d)(2) and (d)(3) of § 422.101(d) (Special cost-sharing rules for MA regional plans), to specify that the catastrophic limits set by RPPOs may not be greater than the annual limit set by CMS.

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 it 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.

Program experience has demonstrated that differential, or "tiered," cost sharing is simply not transparent and can be deceptive and misleading in terms of the cost to beneficiaries. We do not believe it is consistent with the intent of the uniformity requirement in section 1854(c) of the Act for MA organizations to impose such differential benefit cost sharing, or to differentially design in-network health care benefits, network access, or cost sharing for covered benefits in a manner that is not uniform or transparent to the beneficiary. We believe that MA organizations should impose uniform plan care, cost sharing and MA benefits throughout the plan's service area. Furthermore, we believe that tiered cost sharing in certain circumstances may deter beneficiaries from seeking care, otherwise negatively affect beneficiaries who are sicker, or impose greater cost sharing on beneficiaries who utilize services infrequently.

As a consequence of MA organizations' increasing and inappropriate imposition of differential or "tiered" cost sharing, we have become increasingly concerned and believe that revisions to the regulations are warranted. Accordingly, we propose 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.

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 for unfavorable Part D standard coverage determinations in § 423.568(f). Neither § 422.568(d) nor § 423.568(f) allow an MA organization or Part D plan sponsor to make the initial notice of an adverse standard organization/coverage determination orally. However, for the reasons noted below, we propose to revise § 423.568(f) by allowing a Part D plan sponsor to first provide 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 notification.

We believe that the proposed change is necessary because the timeframe for providing notice of an adverse standard determination is much shorter under Part D than under Part C. Under § 422.568(a) and (e), MA organizations provide enrollees with written notice of adverse standard organization determinations within 14 calendar days, but pursuant to § 423.568(a) and (c), Part D plan sponsors must provide written notice of adverse standard coverage determinations within 72 hours. While MA organizations are largely able to meet the 14-calendar day timeframe for providing written notice of adverse standard organization determinations, we believe many Part D plan sponsors are having difficulty providing written notice of adverse standard coverage determinations within the 72-hour timeframe given the significant number of coverage determination requests that are auto-forwarded to the Part D Independent Review Entity (IRE) because decisions were not issued timely. Thus, we believe plan sponsors need the ability to first provide oral notice in order to meet the very short 72-hour timeframe.

We also believe the proposed change is consistent with the Part C organization determination process. An MA organization is required under § 422.572(a) to make an expedited organization determination and provide notice of its decision within 72 hours after receiving a request. Consistent with § 422.572(c), an MA organization may choose to meet the 72-hour timeframe by 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. Given that MA organizations are permitted under the regulations to meet the 72-hour timeframe by first providing oral notice and following up with written notice, we believe giving Part D plan sponsors the same option when required to provide notice within 72 hours is consistent with the Part C organization determination process and section 1860D–4(g) of the Act. Therefore, we propose to revise § 423.568(f) by allowing 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.

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 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.

Thus, 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 a period of no less than 2 months in which to resolve the delinquency. The plan must also be able to demonstrate to us that it has made reasonable efforts to collect the unpaid premium amounts.

Consistent with the provision for delinquent premium payments for Supplementary Medical Insurance (Part B of Medicare), we propose 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 had demonstrated good cause for failing to submit the premium payment timely. We propose 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. For example, if an individual failed to pay plan premiums due to an unexpected and extended hospital stay, we would encourage a plan to consider reinstatement of the individual's enrollment on the basis that he or she had good cause for failing to submit the payment timely. However, we would not expect a plan 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. We would hold the beneficiary accountable for the actions, or inactions, of his or her representative. We also propose that good cause would not exist if the only basis for requesting reinstatement was a change in the individual's circumstances subsequent to the involuntary disenrollment resulting in his or her ability to pay the premiums.

Examples of circumstances that may establish good cause include, but are not limited to, the following: (1) Serious illness, such that the illness prevented the enrollee from making payment or contacting the plan by telephone, in writing, or through a friend, relative, or other person; (2) a government employee, government contractor (for example, 1–800–MEDICARE representative), or plan representative gave the enrollee incorrect or incomplete information about when premium payments were due and how to make payments; (3) the enrollee did not receive premium billing statements and/or delinquency notices due to an error on the part of the plan or the U.S. Post Office; or (4) premium payments were sent, or requested by the enrollee to be sent, but were not received by the plan due to an error on the part of the U.S. Post Office or the enrollee's financial institution.

Since a beneficiary who is disenrolled from an MA or Part D plan for failure to pay premiums is not eligible for a special enrollment period, the beneficiary's only 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. Therefore, we are proposing to amend the regulations at § 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 would require an individual to 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), 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.

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 propose to clarify MA and Part D requirements for marketing materials in markets with a significant non-English speaking population or large percentage of limited English proficient (LEP) individuals. We propose to clarify 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 propose revising § 422.2264(e) of Subpart V and § 423.2264(e) of Subpart V to reflect this clarification.

The proposed clarification codifies existing guidance regarding translated marketing materials. We are codifying this guidance 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 translating marketing materials were required. For example, plan sponsors we talked to were confused whether the 10 percent threshold applied to a specific age group (for example, only those 65+, 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. This clarification addresses the problem by explicitly codifying the requirement to translate marketing materials for LEP individuals. The origin of the requirement to provide translated materials is derived from Title VI of the Civil Rights Act of 1964, which prohibits discrimination in federal programs based upon national origin. Compliance with the Civil Rights Act is included in plan sponsors' contractual requirements under § 422.503(h)(1)and § 423.505(h)(1). Additionally, this clarification is consistent with fulfilling the goals of Executive Order 13166, Improving Access to Services for Persons with Limited English Proficiency, and with the HHS Secretary's implementation of the Executive Order as described in the Strategic Plan for Implementing Access to HHS Programs and Activities by LEP Persons and the CMS Language Access Plan. Providing translated materials for LEP beneficiaries is a key component of the CMS Language Access Plan and helps ensure that beneficiaries have

access to all of the information they need to make appropriate decisions about their health care.

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 proposals 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 and initial implementation of the prescription drug programs 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 nonrenewals and contract terminations has evolved as well. The changes we propose below will further allow us to make these determinations more effectively. These provisions are described in detail in Table 9.

TABLE 9: 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 Additional 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	N/A	N/A	N/A	N/A
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	§422.503

1. Expand Network Adequacy Requirements to Additional MA Plan Types (§ 422.112)

In our April 15, 2010 final rule (75 FR 19678 through 19826), we established criteria that Medicare Advantage (MA) coordinated care (CCP) plans and Private Fee-for-Service (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 met. We focused on specifying benchmarks in community patterns of health care delivery that we would use to evaluate any proposed MA plan health care delivery networks. As provided under § 422.112(a)(10) these benchmarks include, but are not limited to—

- The number and geographical distribution of eligible health care providers available to potentially contract with an MA organization to furnish plan-covered services in the proposed area of the MA plans;
- The prevailing market conditions in the service area of the MA plan—specifically, the number and distribution of health care providers contracting with other health care plans (both commercial and Medicare) operating in the service area of the plan;
- Whether the service area is comprised of rural or urban areas or some combination of the two;
- Whether the MA plan's proposed provider network meets Medicare time and distance standards for member access to health care providers including specialties; and
- Other factors that we determine to be relevant in setting a standard for an acceptable health care delivery network in a particular service area.

As noted in our April 15, 2010 final rule, our operational experience has demonstrated that community patterns of health care delivery provide useful benchmarks for measuring a proposed provider network, permitting varying geographical and regional conditions to be taken into consideration when determining "reasonable" access in a given area. Our final rule provides a detailed discussion of our proposal and the response to public comments on the factors making up community patterns

of care that we established as benchmarks for evaluating proposed MA plan health care delivery networks.

We did not include MA MSAs in the regulation proposal initially because MSA plans historically have not had networks and enrollees in a MSA plan thus were able to 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 Medicare MSA network plans, we are aware of possible interest in offering such plans. As a result, we want to ensure 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). Therefore, we are proposing to apply the network adequacy standards at § 422.112(a)(10) to all MA plans that meet Medicare access and availability requirements through direct contracting network providers, including MSAs, should MSAs choose to develop contracted networks of providers. This proposed change would put all MA plans with contracted networks, and their enrollees, on a level playing field with respect to network access.

2. Maintaining a Fiscally Sound Operation (§ 422.2, § 422.504, § 423.4, and § 423.505)

Sections 1857(d)(4)(A)(i) and 1860D–12(b)(3)(C) of the Act establish requirements for MA organizations and PDP sponsors to report financial information demonstrating that the organization has a fiscally sound operation. This reporting requirement is separate from the requirement that MA organizations and PDP sponsors must be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a Medicare product.

The authority to license an MA organization or PDP sponsor and set solvency standards rests with the State licensing authority (sections 1856(b)(3) and 1860D–12(g) of the Act). Sections 1855(a)(3) and 1860D–12(e) of the Act, however, establish that licensure does not substitute for or constitute certification. Specifically, licensure does not deem the organization to meet other requirements imposed on the organization under Part C or Part D.

Furthermore, sections 1857(d)(2)(B) and 1860D–12(b)(3)(C) of the Act grant us the authority to audit and inspect any books and records of the "* * * organization that pertain (i) to the ability of the organization to bear the risk of potential financial losses, or (ii) to services performed or determinations of amounts payable under the contract."

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. We consult regularly with state insurance regulators to ensure that sponsoring organizations are meeting state reserve requirements and solvency standards required for state licensure, as this is a key component of the organization or sponsor's contract with CMS. However, we interpret the requirement for plans to report financial information demonstrating that the organization has a fiscally sound operation and CMS' authority to audit and inspect any books and records, as described above, as 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 requirements for an organization.

We are concerned that some organizations or sponsors may not have a positive net worth, may be fiscally unsound, and may be therefore unable or unwilling to expend resources necessary to continue to provide adequate care and services to their members. However, we have historically been limited in our ability to take compliance and enforcement action against an organization solely on the basis of these 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 aware 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, rather than waiting for the state to act. We believe that an organization's failure to maintain a fiscally sound operation constitutes a failure to substantially carry out the terms of its contract with CMS.

Therefore, we are proposing to modify the definitions at § 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). In addition, sections 1857(e)(1) and 1860D–12(b)(3)(D) of the Act afford the Secretary the authority to include terms and conditions in the contract that are necessary and appropriate. Thus, we are proposing to add 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).

We believe these changes will ensure that we have the authority to take the steps necessary to protect beneficiaries enrolled in organizations or sponsors that encounter financial difficulties.

3. Release of Part C and Part D Payment Data

This proposed rule would allow 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.

In keeping with the President's January 21, 2009, Memorandum on Transparency and Open Government (74 FR 26277), CMS is proposing to routinely release Part C and Part D payment data. 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 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 would release data for payment year 2010 in the fall of 2011.

This 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. If an applicable 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 other Part C and D payment data. We propose to 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.

For Part C, we are proposing the release of payment data summarized at the plan benefit package level. Specifically, we would release average per member per month (PMPM) payments for A/B (Medicare covered) benefits and average PMPM rebate amounts for each MA plan. These payments and amounts would be standardized to the 1.0 (average risk

score) beneficiary. Given that we already make Part C enrollment data publicly available, interested parties could readily calculate gross Part C payments to MA organizations and for the specific plan benefit packages offered by these organizations. As part of the annual release, we would also release the average Part C risk score for each plan benefit package for the payment year in question. In addition, we would also release aggregated Part C payment data by county. Specifically, we would release county-level average PMPM payment amounts for A/B benefits and average rebate amounts at the MA plan type level (that is, HMO, PPO, etc.) for each county in which such plan types are represented.

TABLE 10: Part C Payment Data by Plan

MA organization/Plan	Average PMPM A/B Payment	Average PMPM Rebate	Average Risk Score
H0001/Plan001	$XXX.xx	$XXX.xx	X.xxxx
H0001/Plan002	$XXX.xx	$XXX.xx	X.xxxx
H0002/Plan001	$XXX.xx	$XXX.xx	X.xxxx
H0003/Plan001	$XXX.xx	$XXX.xx	X.xxxx

TABLE 11: Part C Payment Data by MA Plan Type and County

State County	HMO A/B	HMO Rebate	PPO A/B	PPO Rebate	PFFS A/B	PFFS Rebate	RPPO A/B	RPPO Rebate
State 1 County 1	$XXX.xx	$XX.xx	$XXX.xx	$XX.xx	$XXX.xx	$XX.xx	$XXX.xx	$XX.xx
State 1 County 2	$XXX.xx	$XX.xx	$XXX.xx	$XX.xx	$XXX.xx	$XX.xx	$XXX.xx	$XX.xx
State 1 County 3	$XXX.xx	$XX.xx	$XXX.xx	$XX.xx	$XXX.xx	$XX.xx	$XXX.xx	$XX.xx
State 2 County 1	$XXX.xx	$XX.xx	NA	NA	$XXX.xx	$XX.xx	$XXX.xx	$XX.xx
State 2 County 2	$XXX.xx	$XX.xx	NA	NA	$XXX.xx	$XX.xx	$XXX.xx	$XX.xx

For Part D, we are also proposing the release of payment data summarized at the plan benefit package level. Specifically, we would release average per member per month (PMPM) payments for the direct subsidy, the low-income cost sharing subsidy, and the Federal reinsurance subsidy. Given that we already make Part D enrollment data publicly available, with these new data interested parties could readily calculate gross Part D payments to Part D sponsors and for the specific plan benefit packages offered by these sponsors. In addition, as part of the annual release, we would release the average Part D risk score for each plan benefit package for the payment year in question.

TABLE 12: Part D

PART D/Plan	Avg. PMPM Part D Payment	Avg. Risk Score
S0001/Plan001	$XXX.xx	X.xxxx
S0001/Plan002	$XXX.xx	X.xxxx
S0002/Plan001	$XXX.xx	X.xxxx
H0003/Plan001	$XXX.xx	X.xxxx

CMS makes monthly prospective payments to sponsors for providing prescription drug coverage to Medicare beneficiaries. These payments are based on estimates that sponsors provide in their approved bids prior to the beginning of the plan year. CMS makes prospective payments to sponsors for three subsidies based on sponsors' approved bids. These subsidies are: (1) The direct subsidy which, together with beneficiary premiums, is designed to cover the sponsor's cost of providing the benefit; (2) the reinsurance subsidy, which covers the Federal Government's share of drug costs for beneficiaries who have reached catastrophic coverage; and (3) the low-income cost-sharing subsidy, which covers the Federal Government's portion of the cost-sharing payments for certain low-income beneficiaries.

After the close of the plan year, CMS must reconcile these prospective payments with sponsors' actual costs to determine whether sponsors owe money to Medicare or Medicare owes money to sponsors. In 2007 and 2008 (for Part D plan years 2006 and 2007) CMS published Part D reconciliation payment data. See, for instance, *https://www.cms.gov/MCRAdvPartDEnrolData/Downloads/Part_D_2007_Reconciliation.pdf* and *https://www.cms.gov/MCRAdvPartDEnrolData/Downloads2006_Part_D_Payment_Recon.pdf* CMS is proposing to resume this disclosure in the late summer/early fall of 2011, for payment data related to Part D reconciliation payments/recoveries for CY 2010. These data are different than the Part D data discussed above since they represent final end of year adjustments to the prospective payments made to a Part D plan sponsor based on the difference between the plan's estimated revenue needs and it's actual revenue needs. The prospective Part D payment amounts we propose to

report above are different from the reconciliation data proposed to be reported here in the sense that these specific reconciliation data provide a summary of a Part D plan sponsor's ability to accurately predict Part D costs.

Finally, we are proposing to release retiree drug subsidy (RDS) data. These data will be released as a dollar amount of the gross aggregate subsidy amount paid to the eligible sponsors of qualified retiree prescription drug coverage and the total number of unduplicated Medicare eligible retirees for each sponsor.

TABLE 13: RDS

EGHP	Gross Subsidy	Number of RTs
E0001	$XX,XXX,XXX.xx	XX,XXX
E0002	$XX,XXX,XXX.xx	XX,XXX
E0003	$XX,XXX,XXX.xx	XX,XXX
E0004	$XX,XXX,XXX.xx	XX,XXX

We are not proposing to release detailed data that have been provided to CMS by MA organizations or Part D sponsors as part of their annual bids. The payment data we will release are quite different than the bid data plans submit. Furthermore, the gross payment data we are proposing to disclose cannot be disaggregated to derive the components of plan bids, nor can it be used to generate meaningful estimates of any nominally proprietary bid component such as profitability, administrative load, medical expenses, and projected utilization. By releasing payment data at an aggregate level, we believe we are protecting not only the proprietary interests of MA and Part D plan sponsors, but that we are also protecting the privacy rights of individual MA plan enrollees.

The differences between bidding data, which MA organizations and Part D sponsors submit to CMS, and payment data, which CMS computes and from which it makes payments to plan sponsors, are meaningful and significant in the context of this proposal for two basic reasons. The first is that since CMS is not releasing data provided by plan sponsors, the release of proprietary information provided by plan sponsors in the course of bidding is not implicated. The second is that we are releasing payment data in such a way that individual components of plan bids cannot be derived. We are not providing information in sufficient detail to allow others to disaggregate the information we are providing in such a way as to compromise information provided by plan sponsors in the course of bidding.

Under the Act, the Secretary has the authority to include in MA organization and Part D sponsor contracts any terms or conditions the Secretary deems necessary and appropriate. (See section 1857(e)(1) of the Act and 1860D–12(b)(3)(D) of the Act, which incorporates section 1857(e) into Part D.) Our regulations at § 422.504(j) and § 423.505(j) also 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, 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 propose to amend Part C and Part D contracts (and, in the case of RDS sponsors, agreements) to include a statement informing such sponsors that CMS payment data, as discussed in this notice, will be released as indicated above for research, analysis, and public information purposes. The purposes underlying such release include 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 addition, we believe the availability of the payment data we are proposing to release 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 of existing plan sponsors. In other words, we believe the availability of plan payment data will enhance the competitive nature of these programs. 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. As a result, we believe including a provision in our contracts with plan sponsors regarding the release of payment information is both necessary and appropriate for the effective operation of these programs.

We note that because this proposed rule 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 solicit comment generally on the public release of Part C and Part D payment data as outlined above. We also specifically solicit comment on whether any of the Part C and Part D payment data we propose to release contain proprietary information, and if they do, what safeguards might be appropriate to protect those data.

4. Required Use of Electronic Transaction Standards for Multi-Ingredient Drug Compounds; Payment for Multi-Ingredient Drug Compounds (§ 423.120)

Section 1860D–4(b)(2)(A) of the Act, as codified in § 423.120(c), requires Part D sponsors to 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. Section 1860D–4(b)(2)(B) of the Act requires CMS to 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 to consult with the NCPDP and other standard setting organizations, as appropriate. Pursuant to this authority, we recently added a new paragraph (c)(2) to § 423.120 to codify existing guidance that Part D sponsors utilize standard electronic transactions established by 45 CFR 162.1102 for processing Part D claims (75 FR 19726). We noted that we routinely work with the NCPDP and industry representatives in arriving at recommendations relating to the use of the HIPPA standard

transactions when necessary to improve administration of the Part D benefit.

The NCPDP Telecommunications Standard Version D.0 (Version D.0) is an updated version of the HIPAA standard for retail pharmacy drug claims transactions. Version D.0 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. Version D.0 includes a modification from the current version of the standard to standardize the claims processing for compounded drugs. Unlike the current version of the standard, all components of drug compounds will now be reflected on a pharmacy claim. Since under § 423.120(c)(2) Part D sponsors will be required to adhere to the new standard, we are undertaking additional rulemaking in order to provide further guidance to Part D sponsors on how to appropriately treat compounded products under the Part D program.

Historically, compounds have filled an important role in pharmacy practice by providing medically necessary drug therapies that would otherwise be unavailable to patients. We believe the main use of compounded products under Part D has been associated with home infusion therapy. The appropriate role of compounded products is less clear to us when compounds are used outside of home infusion therapy. With this proposed rule, it is not our intent to incentivize the use of compounded drug products as a substitute for FDA approved products.

Under Part D, compounded products as a whole generally do not satisfy the definition of a Part D drug. Under section 10.4 of Chapter 6 of the Medicare prescription Drug Benefit Manual (*http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter6.pdf*), CMS clarified that only those costs associated with those components of a compounded product that satisfy the definition of a Part D drug are allowable costs under Part D. Since pharmacy transactions up to this point have not captured all components of a billed compounded drug, our policy clarification has generally resulted in Part D plans' paying for the most expensive Part D drug component in a compound and submitting that component on the prescription drug event record transmitted to CMS for Part D payment reconciliation purposes. Generally, our policy guidance 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 component of the compound was a Part D drug) and to providing guidance on appropriate cost-sharing that may be charged. With respect to the latter, we have specified that in the case of a compounded product that contains all generic products, the generic cost-sharing should be applied. However, if a compounded product contains any brand name products, the Part D sponsor may apply the higher brand name cost-sharing to the entire compound. Beyond these requirements, we have not provided more explicit guidance.

As noted above, the adoption under HIPAA of Version D.0 for retail pharmacy claims transactions will require the inclusion of individual components that make up a compounded product. Because, as a result, plan sponsors will have access to more complete information regarding the components of a compound, we believe it is appropriate to provide additional clarification with respect to the treatment under Part D of compounds in general and with respect to the treatment of compounded products that include non-Part D drugs in particular.

First, we propose to codify our existing guidance—which will comprise the general rule—that only compounded products that contain at least one component that independently meets the definition of a Part D drug may be covered under Part D. Such compounded products may, for example, contain all Part D drug components or some Part D components. Consistent with our current policy, we propose to clarify that sponsors may cover the Part D components even if the compounded product as a whole does not satisfy the definition of a Part D drug (subject to the exception for Part B drug compounds described below). For purposes of this preamble, these compounds are referred to as "Part D compounds." As specified in our existing guidance, and consistent with the statute, however, components of a Part D compound that do not independently meet the definition of Part D drug are not allowable costs under Part D, so, non-Part D drug components of these compounds are not covered under Part D.

An exception to our general policy will apply to those compounds that include a drug component that is covered under Part B. If a compound includes a Part B drug component, no components of the compound may be covered under Part D, even if one or more components of the compound would meet the definition of Part D drug if the component were dispensed or administered separately. This exception to the general rule is based both on current Part B payment policy and Section 1860D–2(e)(2)(B) of the Act. Section 1860D–2(e)(2)(B) specifies that a drug prescribed to a Part D eligible individual cannot be considered a Part D drug if payment for such drug, as prescribed and dispensed or administered to the beneficiary, is available under Medicare Part A or B. In general under Part B, when a compounded product meets the definition of a drug in section 1861(t)(1) of the Act, fits within a Part B benefit category, and otherwise meets coverage requirements, then payment is available for that compounded product. Therefore, in our view, when a compound that otherwise would be a Part D compound contains a Part B component that meets the above requirements, the exclusion of section 1860D–2(e)(2)(B) of the Act applies—in other words, because payment for such a compound is available under Part B, the compound as a whole is excluded from Part D. We propose to codify this exception to the general rule for Part D compounds.

We also propose a requirement that the Part D sponsor make a determination as to which copayment or coinsurance applies to a Part D compound. In making this determination, we propose that a flat copay amount submitted and approved under § 423.104, must represent the copay of the tier for the most expensive Part D ingredient and a coinsurance amount, submitted and approved under § 423.104, must be applied to the cost of all Part D ingredients of the Part D compound. In either case, we are proposing to applying the cost sharing to the whole amount of the claim, having selected the cost sharing amount based on the tier of the most expensive ingredient. In the case of low income subsidy (LIS) beneficiaries, the cost-sharing amount (either copayment or coinsurance) is based on whether the most expensive Part D component is a generic or brand drug (as described under § 423.782). In the case of non-Part D components that could otherwise be covered under a supplemental benefit for excluded drugs as described under 423.104(f)(1)(ii)(A), we clarify that the sponsor may not apply cost-sharing for these covered excluded drug components in addition to the most expensive Part D components.

An underlying premise of our policy is that 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 components of that compound should be considered on-formulary, even if

individual Part D components would be considered nonformulary as a single drug claim. Accordingly, we propose that if a Part D compound as a whole is considered by a Part D sponsor to be on-formulary, the Part D sponsor must adjudicate the Part D components as formulary drugs. Alternatively, if a Part D compound as a whole is considered by the Part D sponsor to be non-formulary, but is later approved for a beneficiary under a coverage redetermination or appeal, we propose that the Part D sponsor must apply CMS transition rules such that all Part D components in the compound are covered in the event of a transition fill under § 423.120(b)(3) of the compound.

We note that while Part D sponsors may elect to contract with pharmacies to pay the additional ingredient costs of Part D compounds that are not Part D drugs and are not reimbursable by the government, they are not required to do so. Thus, the majority of the compounded ingredients may not be reimbursable to pharmacies in accordance with payment terms between sponsors and pharmacies. We propose to clarify that for a Part D compound otherwise determined to be payable under Part D, the sponsor may either contract with the pharmacy to pay for the non-Part D components without charging the beneficiary for these amounts or reporting these costs to CMS; deny payment to the pharmacy for any non-Part D components, but allow these components to be balance billed by the pharmacy to the beneficiary; or deny payment to the pharmacy for any non-Part D components and prohibit these components from being balance billed by the pharmacy. In proposing these requirements, we are considering whether the financial impact of unreimbursed compound components may deter pharmacies from continuing to provide compounding services, subsequently affecting beneficiary access to drugs. We invite comment on whether this policy is technically feasible at point-of-sale and/or otherwise appropriate.

We note that we will separately issue guidance on the treatment of PDEs in light of Version D.0. We expect that, consistent with the treatment of compounds under current guidance, Part D sponsors will likely continue reporting the National Drug Code (NDC) and quantity associated with the most expensive Part D ingredient on the PDE. However, we envision that the total cost will represent the sum of the individual Part D components that make up the compounded product.

Based on the preceding, we propose to add a new paragraph (d) to § 423.120 to clarify the aforesaid proposals effective 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)

Pursuant to § 422.502(b) and § 423.503(b) applicants with current or prior contracts with CMS are subject to CMS denial of their applications if they fail during the preceding 14 months to comply with the requirements of the Part D program even if their applications otherwise demonstrate that they meet all of the Part D sponsor qualifications. In the final rule, entitled "Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Programs" (75 FR 19678), that appeared in the April 15, 2010 **Federal Register**, we modified existing provisions at § 422.502(b) and § 423.503(b) concerning our ability to deny an application for a Part C or Part D contract or service area expansion based on the applicant's failure to comply with the requirements of the Part C or Part D program under any current or prior contract with CMS. The two modifications we made to the prior language concerned: (1) Revising the language to refer to "any current or prior contract" held by the organization, instead of the former language referring to a "previous year's contract;" and (2) clarifying that the period that will be examined for past performance problems will be limited to those identified by us during the 14 months prior to the date by which organizations must submit contract qualification applications to CMS.

At this time, we are proposing to further refine our intended approach to using past performance in making application determinations. Specifically, we are concerned about entities submitting applications to us where the entity has operated its contract(s) with us for less than 14 months at the time it submits a new application or service area expansion request. Practically speaking, an entity contracting with us for the first time would have merely 2 months experience before applications would be due for the following contract year. Two months is an inadequate amount of time for the entity to demonstrate its ability to comply with all Part C and/or Part D requirements.

As such, we are faced with two options—either to assume full compliance and exempt the entity from the past performance review, or to 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. The practical effect of denying applications from entities with less than 14 months experience operating a Medicare contract is that new entrants to the Part C or Part D programs would not be permitted to expand their operations (either via a new contract or a service area expansion of an existing contract) until the beginning of their third year of experience with CMS. As an example, an entity that submits an application for its first Part C or Part D contract in February 2010 is approved and begins delivering Part C or D services on January 1, 2011. Because 2012 applications would be due in February 2011, when the applicant has only two months experience with the Part C or Part D programs, its applications would be denied. The next opportunity to submit a viable application would be in February 2012 for the 2013 contract year. At that point, the entity would have exactly 14 months performance history for CMS to consider in making application determinations.

By making this change, we will ensure that new entrants to the Part C or Part D program can fully manage their current contracts and books of business before further expanding. This change will also 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 propose to modify § 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.

F. Other Clarifications and Technical Changes

We propose seven technical changes in this section, affecting as noted in Table 14 below, cost contract plans, MA plans, or Part D plans.

TABLE 14—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 propose to clarify in this section 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.

Section 1851(a)(2)(A) of the Act allows for the participation of a PSO in the MA program as a coordinated care plan. A PSO is defined in section 1855(d) of the Act and codified in § 422.350 as a public or private entity that—

- Is established or organized, and operated, by a provider or group of affiliated providers;
- Provides a substantial proportion (as defined in § 422.352) of the health care services under the MA contract directly through the provider or affiliated group of providers; and
- When it is a group, is composed of affiliated providers who share, directly or indirectly, substantial financial risk, as determined under § 422.356, for the provision of services that are the obligation of the PSO under the MA contract, and have at least a majority financial interest in the PSO.

As provided under § 422.352, an organization is considered a PSO for purposes of a MA contract if the organization—

- Has obtained a waiver of State licensure as provided for under § 422.370;
- Meets the definition of a PSO set forth in § 422.350 and other applicable requirements of this subpart; and
- Is effectively controlled by the provider or, in the case of a group, by one or more of the affiliated providers that established and operate the PSO.

Section 1855(a)(1) of the Act requires that MA organizations be licensed as risk-bearing entities under the laws of the state, but section 1855(a)(2)(A) of the Act establishes an exception to this requirement by allowing PSOs to obtain a Federal waiver of the state licensure requirement from the Secretary under certain circumstances. Accordingly, we specified in § 422.370 that CMS may waive the state licensure requirement for PSOs if the organization requests a waiver no later than November 1, 2002, and we determine there is a basis for a waiver under § 422.372.

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 are taking the opportunity to clarify this policy in this proposed rule because of questions we have received. Accordingly, we propose to revise paragraph (a) of § 422.4 to clarify that we no longer have the authority to waive the state licensure requirement for PSOs.

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 are proposing changes to § 417.430(a)(1) that would allow us to approve other enrollment mechanisms for cost plans in addition to paper forms, such as electronic enrollment.

We are also proposing 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 proposed 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).

3. Fast-Track Appeals of Service Terminations to Independent Review Entities (IREs) (§ 422.626)

To correct a typographical error in § 422.626(f)(3), we propose removing the word "to" before the word "may."

4. Part D Transition Requirements (§ 423.120)

Pursuant to our authority under section 1860D–11(d)(2)(B) of the Act, we previously codified plan transition policies at § 423.120(b)(3). For enrollees residing in a long-term care (LTC) facility, a Part D sponsor is required to provide a LTC resident enrolled in its Part D plan at least a 31 day supply of a prescription when presenting in the first 90 days of enrollment (unless the prescription is written for less) with refills provided, if needed, up to a 93 day supply. As a result of section 3310 of the ACA and the proposed rule at § 423.154 for dispensing brand-name medications in increments of 7 days or less, we are proposing to revise the existing transition policy for LTC facilities to be more consistent with 7 day or less dispensing. Consistent with our proposed rule that would require Part D sponsors to require all pharmacies servicing LTC facilities to dispense no more than a seven-day supply of brand-name medication when dispensing covered Part D drugs to enrollees who reside in LTC facilities, with certain exceptions for specific types of drugs and certain waivers of the requirement for specific types of pharmacies, we propose revising the transition fill supply from 93 days to 91 days to accommodate multiple fillings of 7 days or less in the LTC setting whenever § 423.154 (a) applies to drugs dispensed in 7-day-or-less supplies. The proposed change to a 91-day supply would permit exactly 13 weeks of 7-day transition fills. Under this revised 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 propose to amend § 423.120(b)(3)(iii) to clarify transition notice requirements that must be sent to beneficiaries within 3 business days of adjudication of a temporary fill. Upon review of the regulatory language, we believe revisions are needed in the case of multiple dispensing of 7 days or less of a single prescription. While we continue to believe that written notice must be sent to each affected enrollees, in the case of a LTC enrollee impacted by the 7-day-or-less dispensing requirement, we believe that the written notice should be sent within 3 business days after adjudication of the first transition fill. Otherwise, we are persuaded based on 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. We solicit comments on this proposed revision.

Accordingly, based on the preceding, we have proposed revisions to 423.120(b)(3)(iii)(B) and (iv) to be consistent with the proposed requirements related to dispensing brand-name medications in 7-day-or-less increments 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, with a limit on charges to enrollees for emergency department services of $50 or what an MA organization would charge an enrollee if he or she obtained the services through the MA organization, whichever is less. The limit on cost sharing at the lesser of $50 or what the plan would charge the enrollee if he or she obtained the services through the organization 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.

We are proposing to revise the regulations to remove the $50 cost sharing amount for CY 2012 because we believe that it is outdated considering the increasingly higher costs of emergency care during the past decade. The relatively low cost-sharing limit for emergency department services has constrained MA organizations' ability to control unnecessary use of emergency departments. We believe that we are in a position to evaluate the cost-sharing limit for emergency care as part of our annual benefits review process to strike a balance between reasonable cost-sharing amounts and MA organizations' ability to appropriately control utilization and costs.

Therefore, we propose revising § 422.113(b)(2)(v) to remove the $50 amount and replace it with language indicating that we will evaluate and determine the appropriate enrollee cost-sharing limit for emergency department services. We would annually evaluate the emergency department cost sharing limit and inform MA organizations of any changes to the limit in annual guidance, such as the Call Letter.

6. Clarify Language Related to Submission of a Valid Application (§ 422.502 and § 423.503)

Since the enactment of the MMA in 2005, we have adapted our processes for reviewing applications for qualification for contracts to operate as Medicare Part C or D sponsoring organizations to accommodate the timely review of large numbers of applications each year. That adaptation has included the establishment of strict deadlines for the initial submission of applications and the resubmission of materials needed to cure identified deficiencies. 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. We established the submission deadline to ensure that all organizations had the same amount of time in which to develop their materials and that the agency could provide each applicant a fair and timely review of its application. Our adoption of a policy of strict enforcement of application submission deadlines is entirely consistent with our regulatory authority, stated at § 422.501(b) and

§ 423.502(b), to require organizations to submit applications in a form and manner required by CMS. 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. As a result, in the CY 2010 Call Letter, we informed all current and potential Part C and D organizations that we would not review any application for contract qualification that amounted to a "placeholder" application. We inadvertently stated in the Call Letter that we would deny such applications pursuant to § 423.503(c), which could have been interpreted to mean that we were providing an opportunity for an administrative appeal. This was not our intent as we do not accept invalid applications, and where there is no valid application, we have no obligation to issue a notice of intent to deny or a right to appeal under § 422.660 or § 423.650.

In addition, 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. It now 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 propose 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."

7. Modifying the Definition of Dispensing Fees (§ 423.100)

As stated in our August 3, 2004 proposed rule, MMA does not define the term "dispensing fee," although the terms "dispensing fee" and "dispense" appear several times throughout the Act. Because the statute is ambiguous on the meaning of "dispensing fee," in the August 3, 2004 proposed rule we offered three options and sought comments on the proposed definitions. "Dispensing fees" as defined in our final rule, January 28, 2005, distinguished between pharmacies owned and operated by a Part D plan itself and all other pharmacies.

"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 propose to clarify that the salaries of pharmacists and other pharmacy workers may be reasonable pharmacy costs for any pharmacy. Consistent with that clarification, we simplify the definition of "dispensing fees" and remove reference to "pharmacies owned and operated by a Part D plan itself."

We propose to modify the definition of "dispensing fee" under § 423.100 to include costs associated with the acquisition and maintenance of technology to maintain reasonable pharmacy costs. We also propose to add 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. Although it is not our intent to include all activities that are "reasonable costs" in the definition of "dispensing fees," in light of the statutory requirements regarding LTC pharmacy dispensing, we believe that it is particularly important to highlight the potential pharmacy costs aimed at reducing waste and increasing efficiency of dispensing. We also believe dispensing fees should differentiate among the costs associated with different dispensing methodologies and appropriately address costs that are incurred to offset waste.

We now propose to simplify and 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 propose modifying § 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. 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.

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 (§ 417.101 and § 422.100)

Under proposed § 417.101(g) and § 422.100(g) and (h), we would clarify that MA organizations may not impose cost sharing that exceeds that required under Original Medicare. We would 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 proposed 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 proposed 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)

Proposed § 422.107(d)(ii) would extend the time allowed for the continuance of existing SNPs that do not have contracts with the State Medicaid agencies in which they operate. For new and existing dual eligible SNPs 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, we do not expect the burden to change from the existing burden estimate, as currently approved, under OCN 0938–0753, with a November 30, 2011, expiration date.

2. ICRs Regarding NCQA Approval of SNPs (§ 422.101 and § 422.152)

Proposed § 422.101 and § 422.152 provide for the approval of all SNPs, existing and new, by the National Commission for Quality Assurance (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 overall quality improvement (QI) program and the model of care (MOC) to CMS for NCQA evaluation and approval as per CMS guidance. Although the submission of the MOC and the QI program documents is already part of the application process, scrutiny of these documents by NCQA for approval is a new requirement. Additionally, in the past all SNPs were not required to complete the SNPs proposal portion of the application each year, resulting now in all SNPs, (that is, all of the SNP plans offered by an MA organization) being required to complete the SNPs proposal within the application and possibly provide documentation external to the existing electronic application process. It is estimated that it will take each SNP plan 40 hours to complete the annual application. Within those 40 hours, the SNP portion of the burden is 6 hours. For the existing 544 SNPs, the burden associated with completing the SNP section only is estimated to be 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 proposed regulatory modifications pursuant to section 3303 of the ACA ensure that our regulations reflect the new statutory prohibition on reassigning low-income subsidy (LIS) beneficiaries from Part D plans that waive a *de minimis* amount of their premium. Further, the proposed regulatory modifications reflect statutory discretion for us to autoenroll or reassign LIS beneficiaries to Part D plans that waive the *de minimis* amount of the premium. The proposed 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 proposed 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 autoenroll 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 annually, it will take an additional 10 minutes 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 (D—IRMAA) (§ 423.44)

Proposed § 423.44(e)(4) would require 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 Office of Personnel Management, or the Railroad Retirement Board, 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 proposed to amend § 423.772 and § 423.782 in accordance with section 3309 of the ACA. Specifically, the proposed 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 would require State Medicaid Agencies to submit data at least monthly identifying these individuals. There is an already established data exchange for States to identify their dual eligible individuals to CMS at least monthly. We would leverage that data exchange by adding a new value for the existing institutional field, which also prompts CMS to set a zero copayment liability for full benefit dual eligible beneficiaries. 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.

The burden associated with the requirement for States to provide CMS with the specified information is estimated to include a one-time development cost as well as 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 propose to 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 proposing a new requirement under § 423.154(a)(3) 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). We anticipate a billing standard that incorporates the collection of this information. While the requirements under this proposed section are subject to the PRA, should the rule be finalized, the reporting requirement will be proposed under currently approved OCN 0938–0992.

The proposed 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 the entity described above and the pharmacies servicing long-term care 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 requirements is $1,578,602. This is a one-time contract negotiation cost.

G. ICRs Regarding Complaint System for Medicare Advantage Organizations and PDPs (§ 422.504 and § 423.505)

Under proposed § 422.504(a) and § 423.505(b) we would require MA organization 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.

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 propose to revise § 423.128 at paragraphs (b)(7) and (d) 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.

At § 423.128(b)(7), we proposed adding paragraph (i) to require that plan sponsors make available standard forms to request coverage determinations and

redeterminations (should this be determined feasible and to the extent that standard request forms have been approved for use by CMS).

We also propose to add paragraph (ii) to § 423.128(b)(7), which would require 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 proposed at § 423.128(b)(7)(i). Similarly, we propose to revise § 423.128(d) by requiring sponsors to provide a toll-free telephone line for requesting coverage determinations and redeterminations. The burden associated with these proposed requirements involves collecting the coverage determination request information submitted through the various proposed processes.

We estimate that all 731 plan sponsors will receive a total of 484,468 coverage determination requests submitted by mail, with some using the standardized coverage determination request form if available, and 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 80,745 hours. We also estimate that all plan sponsors will receive a total of 52,086 coverage determination requests submitted through secure websites, but that this process will not create an additional burden for plan sponsors beyond that required for requests submitted by mail because enrollees will enter information into a claims processing system themselves. Finally, we estimate that all plan sponsors will receive a total of 690,064 coverage determination requests submitted by telephone, and it will 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 and information collected when conducting an administrative action is not subject to the PRA.

We also proposed to require Part D sponsors to modify their electronic transactions to pharmacies so that they can transmit codes instructing pharmacies to distribute notices at the point-of-sale (POS). That is, pharmacies and processors will be required to program their systems to relay the message at the pharmacy to distribute the appeal notice. 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. 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, for a total one-time burden of 1,600 hours. The estimated one-time cost associated with the processor 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 estimated that the average time to process a coverage determination is 10 minutes (0.167 hours) and that the average number of coverage determination requests received by mail or secure Web site processed for each respondent (n=731) was 734. Requiring plan sponsors to process the information submitted in standardized coverage determination requests forms (§ 423.128(b)(7)(i)) is, therefore, estimated to 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 $3.2 million. We estimated 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. This is estimated to result in an annual burden of 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 estimated that contacting entities (n = 731) 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(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.

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)

Our revised definition of "incurred cost" at § 423.100 to include the costs associated with IHS/ADAPs as a cost that counts towards 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)

We propose to amend § 423.153(vii) to require the Part D sponsor use a standardized format for the action plan and summary resulting from the annual comprehensive medication review, permit the use of telehealth technology in the conduct of the CMR, and require sponsors to contract with LTC facilities to utilize independent consultant pharmacists to perform the targeted medication reviews that are required at least quarterly.

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 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, no additional burden is estimated. Further, since the use of telehealth technology to conduct the CMR is permitted but not required, there is no burden associated with this change.

The proposed rule also requires Part D sponsors to coordinate MTM program quarterly medication reviews with LTC consultant pharmacist monitoring for Part D enrollees in LTC facilities. The ICR burden associated with this requirement is related to developing and

executing contracts with all the LTC facilities in which Part D enrollees reside to provide appropriate MTM services in coordination with LTC consultant pharmacist evaluation and monitoring. Although all Part D plan sponsors would need to contract with all the LTC facilities in which their enrollees reside, for purposes of determining the ICR burden, we assume that the contracts would be negotiated, drafted and executed by the sponsors' parent organization on behalf of all the parent's Part D contracts. In the absence of a parent organization, the sponsor would undertake the contracting activity directly. We expect a total of 240 parent organizations and sponsors would have a contract with an average of 802 LTC facilities.

We expect that complying with this requirement would primarily require the involvement of the parent organization's or the sponsor's general counsel to negotiate, draft and execute the contract. We estimate that complying with this requirement would require 4,812 burden hours (6 burden hours × 802 LTC facilities) for each parent organization or sponsor to execute a contract with a average of 802 LTC facilities at an estimated cost of $402,957 (4,812 burden hours × $83.74 estimated hourly cost). Thus, it would require 1,154,880 hours (4,812 burden hours per parent organization or sponsor × 240 parent organizations or sponsors with Part D LTC residents) for all Part D sponsors to comply with this requirement at an estimated cost of $96,709,680 ($402,957 estimated cost per parent organization or sponsor × 240 parent organizations or sponsors with Part D LTC residents).

After the first fiscal year, we estimate that continued compliance with this requirement would require 1,604 burden hours in each fiscal year (2 hours × 802 LTC facilities) per parent organization or sponsor general counsel to review the contract and, if necessary, execute updated contracts with the LTC facilities at an estimated cost of $134,319 per parent organization or sponsor. Thus, it would require 384,960 burden hours per fiscal year (1,604 annual burden hours per parent organization or sponsor × 240 parent organizations or sponsors with Part D LTC residents) for all Part D sponsors with Part D LTC residents to comply with this requirement at an estimated cost of $32,236,560 ($134,319 estimated cost per parent organization or sponsor × 240 parent organizations or sponsors with Part D LTC residents).

K. ICRs Regarding Changes To Close the Part D Coverage Gap (§ 423.104 and § 423.884)

Proposed § 423.104(d)(4) would require 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 propose to 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.

OCNs Associated With the 5-Star Rating System for Quality Bonus Payments

OCN	Expiration date
0938–1028	November 30, 2011.
0938–0732	November 30, 2010.
0938–0701	August 31, 2010.

We have also proposed 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 propose to 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 the time and effort of the MA organizations in developing and presenting their case to a CMS official and, ultimately, the CMS Administrator, to demonstrate that they in fact should qualify for the quality bonus payment. 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)

We propose to amend § 423.509 to state 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 Compliance Officer Training (§ 422.503 and § 423.504)

The proposed § 422.503(b)(4)(vi)(B)(1)(b) and § 423.504(b)(4)(vi)(B)(1)(b) regarding compliance officer training will clarify existing requirements by providing additional guidance with respect to the particular training requirements. The burden associated with this requirement is the time and effort put forth by the plan sponsor to train a compliance officer to meet the existing training requirements of this section. The proposed clarification is related only to the content and timing of the existing training requirement. While these requirements are subject to the PRA, the burden associated with them is currently approved under OCN 0938–1000 with an expiration date of February 28, 2010.

P. ICRs Regarding Agent and Broker Training Requirements (§ 422.2274 and § 423.2274)

Proposed § 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 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 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 for the preparer of the proposal will be $59.20 (based on hourly wages for management analysts reported by the U.S. Department of Labor Bureau of Labor Statistics). The total annual labor cost of this proposal preparation is estimated to be $71,040 ($59.20 × 1200 hours) per fiscal year.

Also at § 422.2274 and § 423.2274, we propose to 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 training annually. While this requirement is subject to the PRA, we 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 Call Center and Internet Web Site Requirements (§ 422.111 and § 423.128)

We propose in § 422.111(g)(1)(2)(3) to 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 propose in § 422.111(g)(1)(iii) and § 423.128(d)(1)(iii) to 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 limited English proficient (LEP) beneficiaries. The burden associated with this proposed 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.

R. ICRs Regarding Requiring Plan Sponsors To Contact Beneficiaries To Explain Enrollment by an Unqualified Agent/Broker (§ 422.2272 and § 423.2272)

Proposed § 422.2272(e) and § 423.2272(e) would 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, we 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.

S. ICRs Regarding Customized Enrollee Data (§ 422.111 and § 423.128)

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 ANOC and EOC).

Plan sponsors already collect enrollee utilization and cost-sharing information as part of their claims processing operations. Therefore, the burden associated with this proposed requirement is 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 anticipate that it would take 30 hours per MA organization and 20 hours per Part D sponsor to develop and submit the required information. This includes 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 beneficiary. We developed this burden estimate using our burden estimates for the ANOC/EOC documents under OCN 0928–1051 as a baseline, then expanding on that baseline, and factoring in expected programming and development costs to provide beneficiary specific information. We estimate 564 MA organizations and 85 Part D sponsors would be affected annually by this requirement. The total annual burden associated with this requirement is 18,620 hours in a fiscal

year. In subsequent years, the burden associated with this proposed requirement is the time and effort necessary for a plan sponsor to disclose (print and mail) this information to each beneficiary. We anticipate that it would take 20 hours per MA organization and 15 hours per Part D sponsor to develop and submit the required information. This includes 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 estimate 564 MA organizations and 85 Part D sponsors would be affected annually by this requirement. The total annual burden associated with this requirement is 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).

T. ICRs Regarding Extending the Mandatory Maximum Out-of-Pocket (MOOP) Amount Requirements to Regional PPOs (§ 422.100(f) and § 422.101(d))

We propose at § 422.100(f) and § 422.101(d) to extend the mandatory MOOP and catastrophic limit requirements to RPPO 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. Our proposal would 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 would be incurred by persons in the normal course of their business activities.

U. ICRs Regarding Prohibition on Use of Tiered Cost Sharing by MA Organizations (§ 422.100 and § 422.262)

Under our proposed revision to § 422.262, we would clarify 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 proposed 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.

V. ICRs Regarding Translated Marketing Materials (§ 422.2264 and § 423.2264)

This proposed 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 the Paperwork Reduction Act of 1995 (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.

W. ICRs Regarding Expanding Network Adequacy Requirements to Additional MA Plan Types (§ 422.112)

Our proposed amendment to § 422.112(a)(10) would ensure 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 did 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 proposal would 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.

X. ICRs Regarding Maintaining a Fiscally Sound Operation (§ 422.2, § 422.504, § 423.4, and § 423.505)

Proposed § 422.504(a) and § 423.505(b) would 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 proposed requirement is the time and effort necessary to submit these financial reports. While this proposed requirement is subject to the PRA, the associated burden is currently approved under OCN 0938–0469 with an expiration date of April 30, 2013.

Y. ICRs Regarding Release of Part C and Part D Payment Data (Parts 422 and 423, Subpart K)

This proposed rule would allow 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 would be routinely released on an annual basis in the year after the year for which payments were made. The data release would 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 would release data for payment year 2010 in the fall of 2011. This timeframe would 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 application 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 proposed to 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 submitted to us, but rather are compiled and derived solely from CMS internal payment files.

Z. ICRs Regarding Revision to Limitation on Charges to Enrollees for Emergency Department Services (§ 422.113)

We are proposing at § 422.113(b)(2)(v) to 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 15: 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 Reporting3 ($)	Total Labor Cost	Total Capital/ Maintenance Costs ($)	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	731 40	10 80	7,310 3,200	150.20 150.20	1,097,962 480,640	0 0	1,097,962 480,640
§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
§423.153(vii) (Start-up)	0938-New	240	802	6	1,154,880	83.74	96,709,651	0	96,709,651
§423.153(vii) (Annual)	0938-New	240	802	2	384,960	83.74	32,236,550	0	32,236,550
§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

3 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 Reporting3 ($)	Total Labor Cost	Total Capital/ Maintenance Costs ($)	Total Cost ($)
§422.2274 and §423.2274	0938-New	12	12	100	1,200	59.20	71,040	0	71,040
§422.111 and	0938-New	564	564	20	11,280	27.24	307,267	0	307,267
§423.128		85	85	15	1,275	27.24	34,731	0	34,731
Total		81,810	2,998,835		2,326,912		192,201,530		193,201,530

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V. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), 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 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

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). 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 of more than 3 to 5 percent. We do not believe that this threshold would be reached by the proposed requirements in this proposed rule because this proposed 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 proposed 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 603 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 has determined 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 2010, that threshold is approximately $135 million. This proposed rule is expected to reach this spending threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent 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 proposed 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 proposal 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.

The CMS Office of the Actuary has estimated savings and costs to the Federal government as a result of various provisions of this proposed rule. As detailed in Table 17, we expect savings to the Federal government of approximately $83.75 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.	$2.33 billion.
Elimination of the Stabilization Fund	$181 million.

In Table 16, we present Federal transfers, as well as total costs to the States, Part D sponsors, MA organizations, and other private sector entities, in the aggregate, as a result of various provisions of this proposed rule. As detailed in Table 16, we expect costs of approximately $5.57 billion for FYs 2011 through 2016 as a result of the implementation of various additional provisions of this proposed 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 proposed 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 17, 18, and 19 detail the breakdown of costs by cost-bearing entity. Specifically, Table 17 describes costs and savings to the Federal government, Table 18 describes estimated administrative costs to MA organizations and/or PDP sponsors and third party entities, and Table 19 describes costs to States.

Taking into account both costs and savings estimated in this RIA, we estimate a net savings of $78.18 billion as a result of the provisions in this proposed rule over FYs 2011 to 2016. Therefore, this proposed 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 proposed requirement. For collection of information burden associated with our proposed requirements and the bases for our estimates, refer to of the collection of information section of this proposed rule.

B. Anticipated Effects Associated With This Proposed Rule

1. Cost Sharing for Specified Services at Original Medicare Levels (§ 417.101 and § 422.100)

We estimate that our proposed implementation of section 3202 of the ACA will result in minimal additional program costs. In addition to our proposal to implement the ACA-required limits on cost sharing in MA plans for chemotherapy services, renal dialysis services, and skilled nursing facility care, we also are proposing to require the same cost sharing limits for in-network home health services provided under MA plans. We estimate that the Federal fiscal year 2012 (FY 2012) costs to Medicare of limiting cost sharing in MA plans for the three service categories specified in the ACA (that is, chemotherapy 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 reflects, or is equivalent to, 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 proposed implementation of the cost sharing limits specified in section 3202 of the ACA.

We estimate that the cost of our proposal to also limit MA plan cost sharing for in-network home health services so that it does not exceed that required under Original Medicare will not be significant. Cost sharing for home health services under Original Medicare is zero. In previous years, we have allowed increased flexibility in benefit package design for MA plans that establish a maximum out-of-pocket limit on beneficiary cost sharing for Parts A and B services (for example, $3,400 or less for contract year 2010). As a result, in contract year 2010, of the 2535 MA plans, 167 charged some beneficiary cost sharing (usually $15) for home health services. Those plans enrolled less than 4 percent of all MA enrollees. Given that, on average, home health visits account for less than 5 percent of total MA expenditures, only a small share (about 0.2 percent) of MA expenditures will be subject to the home health cost sharing prohibition.

For two reasons, we believe that the proposed home health policy will have a negligible impact on MA plans. First, as mentioned above, only a small share of expenditures will be subject to the cost sharing prohibition so that any increase in plan costs related to this provision can be absorbed through modest increases in cost sharing for other services, administrative efficiencies, and/or small increases in the plan premium. Also, as evidenced by the large proportion of plan enrollees not subject to home health cost sharing in contract year 2010, MA organizations should be able to adequately manage the use of home health services absent enrollee cost sharing.

To estimate the cost to the MA program for the loss of beneficiary cost sharing for home health services, we assumed that the enrolled beneficiaries' utilization of home health services is lower than that of the Medicare population in general due to the required copayment, and used $15 as the estimated copayment amount. Approximately 9 percent of Original Medicare beneficiaries use home health services, and the average number of visits per user is 37, resulting in 3.3 visits per beneficiary per year. We assume that utilization of home health services by enrollees in the MA plans that charge cost sharing is one-third of that for beneficiaries under Original Medicare, or 1.1 visits per MA enrollee. The resulting FY 2012 estimated cost to the MA program is $6.8 million, which is derived using the assumptions of $15 copayment for the 1.1 visits per beneficiary for the 414,000 MA enrollees subject to in-network home health cost sharing in contract year 2010. However, we estimate that the impact of having to provide home health services without cost sharing would be minimal because we expect that the costs would be reallocated across other plan benefits. We believe that the affected plans would accomplish that reallocation without affecting their actuarial equivalence relative to Original Medicare and that there would be no impact on these MA plans for FY 2012. Consequently, because we estimate that there would be only minor reallocation of the costs and zero impact on MA plans for FY 2012, we estimate zero impact for MA plans in all subsequent years.

2. 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 overall quality improvement (QI) program and the model of care (MOC) to CMS for NCQA evaluation and approval as per CMS guidance. Although the submission of the MOC and the QI program documents is already part of the application process, scrutiny of these documents by NCQA for approval is a new requirement. This requirement is for all SNPs, new and existing. We estimate that it will take each SNP plan 40 hours to complete the annual application. Within, those 40 hours, we estimate the SNP portion of the burden is 6 hours. Currently, there are 544 existing SNP plans. For the existing plans to complete the SNP sections only, the burden associated with this new requirement is 3,264 hours.

The estimated costs associated with the burden hours are summarized in Tables 16 through 18. The costs in Table 17 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 18 contains the projected administrative 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 proposed equivalent to that of one GS–13 step-10 analyst at a salary of $55.46 an hour.

3. 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 proposed rule would update 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 proposal 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 16 through 18. Table 17 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 will 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 16 does not include a projection for administrative savings.

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

The proposed new voluntary *de minimis* provisions in § 423.34(d) and § 423.780(f) would 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 would be 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 18 shows that this would result in a total cost of $30 million to PDPs during 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 proposed 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 17 and 18 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 cost plans is that Medicare's low-income cost-sharing subsidy and reinsurance payments will be greater than would have been the case if CMS reassigned these beneficiaries to lower-cost plans.

5. Increase In Part D Premiums Due to the Income Related Monthly Adjustment Amount (D—IRMAA) (§ 423.44)

Proposed § 423.44(e)(3) would require 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), and all 80,000 Part D enrollees that have a Part D—IRMAA become delinquent, 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, 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 proposed provision to be $319,960. Therefore, as shown in Table 18, we estimate this proposed provision to result in a maximum burden cost, to PDP sponsors, in the amount of $1.92 million for FYs 2011 through 2016. We believe this proposal will lead to 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 17. 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.

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

We propose amending § 423.772 and § 423.782 pursuant to section 3309 of the ACA. Specifically, the proposed 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 18, this provision will not increase administrative 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. 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.

7. Appropriate Dispensing of Prescription Drugs in Long-Term Care Facilities Under PDPs and MA–PD Plans (§ 423.154) and Dispensing Fees (§ 423.100)

In our discussions with the industry, we learned 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 7-day supplies, we propose initially limiting 7-day-or-less dispensing to brand name drugs as defined in § 423.4.

Pharmacies servicing LTC facilities may have the upfront costs associated with software upgrades, packaging and hardware changes, and ongoing costs of transaction fees, and additional deliveries. These costs are not reflected in Table 16, and we are soliciting comment 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 learned from the industry that many pharmacies already have 7-day-or-less dispensing techniques in place for their Part A population. Most pharmacies not already using a 7-day-or-less dispensing technique will generally be converting from their existing 14- or 30-day dispensing technique down to a 7-day-or-less dispensing technique. Based on discussions with the industry, we expect most pharmacies to initially convert from a 14- or 30-day punch card system to a 7-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 7-day packaging. We expect only a small number of pharmacies will convert to an automated dose dispensing system in the short-term. The industry tells us that the major barrier to adopting is automated dose dispensing technologies cost approximately $100,000 to $150,000 in capital acquisition costs per machine.

Regardless of the dispensing technique used, pharmacies will likely have to change or update software. There will be a cost associated with the change in software and training of pharmacy staff associated with the change. We are soliciting comment on these costs.

We expect some pharmacies to incur a small additional expense related to the number of deliveries required to service a facility with a 7-day-or-less dispensing technique. However, given the existing widespread agreements between pharmacies and skilled nursing facilities to dispense in 7-day-or-less packages for Part A residents and the pharmacy's responsibility to deliver at least 5 to 6 days a week to accommodate new residents, emergency supplies and changes in therapy, we expect only a small number of pharmacies to be adversely effected.

LTC facilities will need to accommodate 7-day-or-less dispensing techniques for their Part D population. We anticipate LTC facilities will be impacted by an increase in the number of medication check-ins for those facilities and pharmacies not already using automated dispensing technologies. Based on conversations with the industry, we also anticipate that the LTC facility staff will require varying amounts of additional training. Training time will vary based on the extent to which the dispensing technique changes to accommodate 7-day-or-less dispensing.

The costs associated with this proposed provision is the additional costs of dispensing fees to account for software upgrades, packaging and hardware changes, transaction fees, additional deliveries, and the time and effort of Part D sponsors to re-contract with entities (for example, pharmacy benefit managers) which contract with pharmacies servicing LTC facilities.

We anticipate that dispensing fees will be developed to take into account of 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. Part D plans have the flexibility to vary the actual dispensing fees paid to pharmacies. We project dispensing fees to pharmacies servicing LTC facilities to be between 50 percent and 100 percent higher for contract year 2012 than in previous contract years, with increases in the lower end for the large majority of the claims. For

example, 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 7-day blister pack.

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 above 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. 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 requirements is $1,578,602 ($150.20 × (3,200 + 7,310 hours) = $1,578,602) and is described in Table 18. This is a one-time contract negotiation cost.

We anticipate that the initial upfront costs to convert to a 7-day-or-less dispensing technique will eventually be more than offset by the savings to the Federal government associated with dispensing. Initial industry estimates suggest that approximately 10 percent of the total LTC drug costs could be avoided through the adoption of 7-day-or-less dispensing methodologies. One 7-month analysis using data from 36 skilled nursing facilities suggested at least a 17 percent to 25 percent savings with 7-day dispensing and almost 26 percent savings associated with automated dose dispensing when compared to 30-day dispensing for Part D drugs.[4] Given that we are not aware of additional studies to determine the cost savings, we conservatively estimate a 10 percent savings for overall costs, and therefore estimate an overall savings associated with this provision (*see* Table 16 for estimates of the year-by-year savings). We solicit comments on this estimate.

[4] James W. Moncrief, Advanced Pharmacy, data from a seven month study of 36 LTC facilities presented at the NCPDP Dispensing Meeting. Sheraton Hotel BWI, March 19, 2010.

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

The burden associated with this proposed 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.

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

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 proposal, Part D sponsors would be required to modify their electronic transactions to pharmacies so that they can transmit codes instructing pharmacies to distribute notices at the point-of-sale (POS). That is, pharmacies and PBMs will be required to program their systems to relay the message at the pharmacy to distribute the appeal notice.

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, for a total one-time burden of 1600 hours. The estimated one-time cost associated with the processor 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 $2.14 million.

10. 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)

This proposed requirement would allow Part D sponsors 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 one-time annual cost of $1,000 (50 entities (ADAPs that require VDSAs) × 5 hours × $40.00/hour = $1,000.

The burden associated with this proposed 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, which is largely funded by the Federal government, with the exception of relevant beneficiary copays. 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.

11. Cost Sharing for Medicare Covered Preventive Services (§ 417.101 and § 422.100)

We estimate that our proposed 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 (§ 417.101 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 proposal to require 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. 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.

12. 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 proposing to delete 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.

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

We estimate 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 is $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). We estimate annual costs for updating the contracts for subsequent years 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).

We expect Part D beneficiaries meeting the target criteria for MTM services will have improved access to these services both through the use of telehealth technologies and for those beneficiaries who are also LTC residents through the coordination of their MTM services with the monthly drug regimen reviews.

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

With the implementation of proposals related to closing of the Part D coverage gap, Medicare beneficiaries will have improved access to the prescription drugs in the coverage gap and enter the catastrophic phase of the benefit earlier in the benefit year as a result of our proposed changes to close the Part D coverage gap. 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 estimated 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.

15. 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 proposed 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 FY 2011 to FY 2016. The year-by-year savings in millions of dollars are shown in Table 16. We estimate that in 2017, when the MA provisions will be fully phased in, enrollment in MA plans will be lower by about 50 percent (from its projected level of 14.8 million under the prior law to 7.4 million under the new law).

16. 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 proposed 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).

17. 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 proposal to require terminated Part D plan sponsors to effectuate a smooth transition 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 proposal 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.

18. 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 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 proposed provision.

Of the 5 percent of MA organization 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 our proposed provisions to require review of medical necessity decisions by a physician or other health care professional and the employment of a medical director will help to prevent: (1) Failure to provide access to drugs for enrollees who are stable on a protected class drug; (2) application of inappropriate prior authorization and step therapy criteria when adjudicating prescriptions; (3) issuance of denials based on a lack of medically accepted indications when medically accepted indications are specified in at least one of the applicable compendia; and (4) failure to provide transition supplies for existing members who experience formulary changes across plan years.

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

Starting in 2013 for existing sponsors and 2012 for new applicants, we would require sponsors to annually pay for travel expenses and training registration fees for each compliance officer associated with a MA or Part D contract to attend compliance officer training offered by an entity with expertise in Part D. With expected travel costs of $1,000 and registration fees of $700, the increase in costs for a single contract would be $1,700. In 2012, only new applicants would have to train their compliance officers. The average number of new applicants at the parent organization level over the past 2 years has been 8. We have reason to believe there will be a similar number of new applicants for 2012; therefore, we estimate the cost for compliance officer training in 2012 would be $13,600. For 2013 and subsequent years, based on the current 316 compliance officers associated with all 2010 contracts, we estimate the annual cost associated with this requirement would be $537,200.

The anticipated effect of requiring annual compliance officer training is that compliance officers will be more knowledgeable about the MA and Part D programs which should translate into more efficient internal plan oversight. As internal plan oversight increases, we anticipate a decrease in the volume and severity of compliance issues because compliance officers will be able to identify small problems before they become large problems with significant beneficiary impact. As a result, beneficiaries will be more likely to receive benefits consistent with plan sponsors' bids and CMS requirements.

20. Agent and Broker Training Requirements (§ 422.2274 and § 423.2274)

Proposed § 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 Request for Proposal (RFP) competitive process. The burden associated with this proposed 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) × 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).

The anticipated effect of our proposed provision to require all agents and brokers to receive training and testing via a CMS-endorsed or approved training program would be beneficiary access to 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.

21. Call Center Interpreter Requirements (§ 422.111 and § 423.128)

We estimate the cost for our proposed 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.

22. Customized Enrollee Data (§ 422.111 and § 423.128)

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).

Plan sponsors already collect enrollee utilization and cost-sharing information as part of their claims processing operations and for calculating MOOP limits. Therefore, we estimate the initial year burden associated with this

proposed requirement is 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 OCN 0928–1051as a baseline, then expanding on that baseline, and factoring in expected programming and development costs to provide beneficiary specific information. We estimate 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 proposed requirement is approximately $507,208.00.

In subsequent years, the burden associated with this proposed requirement is the time and effort necessary for a plan sponsor to disclose (print and mail) this information to each beneficiary. We estimate 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 proposed requirement is approximately $342,000.

The anticipated effect of our proposed provision to require MA organizations and PDP sponsors to provide customized enrollee data would be greater access to individualized information for beneficiaries to use in making decisions about their enrollment and their health care options. While this proposed new requirement would result in cost burden for MA organizations and Part D sponsors to calculate, compile and disclose beneficiary-specific data, plans should already have the systems in place to collect the required information as part of their claims processing operations and for calculating MOOP limits; over time, therefore, 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 over time.

23. Extending the Mandatory Maximum Out-of-Pocket (MOOP) Amount Requirements to Regional PPOs (§ 422.100 and § 422.101)

Proposed § 422.100(f) and § 422.101(d) would extend the mandatory MOOP and catastrophic limit requirements to RPPO 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. In the April 15, 2010 final rule implementing policy and technical changes to the Medicare Advantage and prescription drug benefit programs (72 FR 19799 through 19800), we discussed the anticipated effects of our policy to require local MA plans to have a MOOP limit on members' out-of-pocket cost sharing. While this proposed 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 proposed change would by itself have a significant cost impact on RPPO plan participation or plan costs.

We believe any impact on enrollee premiums will be very limited for several reasons. First, since implementation of the MMA, RPPOs have been required under section 1858(b)(2) of the Act to establish a MOOP for in-network cost sharing and a catastrophic limit inclusive of both in- and out-of-network cost sharing for Parts A and B services. The MOOP 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). In guidance following publication of our April 15, 2010 final rule, we stated that, to the extent an RPPO sets its MOOP and catastrophic limits above the mandatory amounts set by us for other plan types, it may be subject to additional CMS review of its proposed Parts A and B services cost-sharing amounts. Based on data for FY 2011 submitted (but not yet approved) bids, we have found that of the 78 regional PPO plans, 25 (32 percent) met or exceeded the voluntary MOOP limits set by us and 47 (60 percent) regional PPO plans met or exceeded the mandatory maximum limits. Therefore, only five (8 percent) RPPO plans did not submit an in-network or catastrophic maximum out-of-pocket limit did not meet either the voluntary or mandatory limits for FY 2010. Based on this information, it is our expectation that the impact on RPPO plans would be very small.

Second, as we described in our April 15, 2010 final rule, 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 estimate that beneficiaries in regional PPO plans that currently offer the FY 2011 voluntary or mandatory MOOP limits (about 92 percent of RPPO plans) will experience no cost increases as a result of these provisions. In our April 15, 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 offer MOOP and catastrophic limits, so we believe any premium impact would be less than $5.

Finally, we believe that the many advantages for beneficiaries as a result of the new MOOP and cost-sharing threshold requirements will outweigh any small premium increases that may result. All regional PPO plan enrollees will be protected against high out of pocket costs, and will be better able to compare plans by focusing on differences in premium and plan quality. As we have explained previously, our goal is to set cost-sharing limits at a level that should not result in significant new costs for MA plans or beneficiaries.

24. Translated Marketing Materials (§ 422.2264 and § 423.2264)

Our proposed translated marketing materials requirements codify existing subregulatory guidance, so the impact to plan sponsors (MA organizations and PDP sponsors) depends upon whether they are currently translating marketing materials, and if so, to what extent. For 2010, there are 307 sponsors that need to provide translated marketing materials. Our translated marketing material monitoring study, which only has preliminary findings, revealed that some sponsors have produced a few materials, but we do not know the numbers of sponsors that are and are not providing all translated materials. In the event sponsors are not translating materials, our research that indicates the average translation cost is 20 cents per word. We estimate that for a sponsor to produce all of the required plan materials in one language for the first year would cost approximately $18,325 because there are approximately 17 documents containing 91,623 words for translation. In subsequent years, sponsors would 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 would 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 need to translate for the first year and what proportion would only need to update existing documents. Not all required translated marketing materials are plan benefit package (PBP) specific. Therefore, 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 assumed that all 307 sponsors would have to translate all materials for the first year at a total cost of $5,625,775. In subsequent years, sponsors would only need to edit existing translated documents, which would be a total cost of $281,212 annually for all sponsors.

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Table 16: Estimated Aggregate Costs, Savings, and Transfers by Provision for Fiscal Years 2011 Through 2016 ($ in millions)[5]

Provision(s)	Regulation Section(s)	Fiscal Year 2011	2012	2013	2014	2015	2016	Total ($ in millions) (FYs 2011-2016)
Cost Sharing for Specified Services at Original Medicare Levels	§417.101 and §422.100	0.00	6.80	0.00	0.00	0.00	0.00	6.80
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)6	§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	1.58	-300.00	-430.00	-480.00	-530.00	-590.000	-2,328.42
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	§417.101 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
Improvements to Medication Therapy Management Programs	§423.153	0.00	96.71	32.20	32.20	32.24	32.24	225.67
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

5 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.

6 Estimated total savings includes annual cost burden to all Part D sponsors (see section V.B.5. of this proposed rule).

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	-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	0.007	0.008	0.009	0.0010	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
Compliance Officer Training	§422.503 and §423.504	0.00	0.01	0.54	0.54	0.54	0.54	2.16
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	0. 51	0.34	0.34	0.34	0.34	1.88
Translated Marketing Materials	§422.2264 and §423.2264	5.63	0.28	0.28	0.28	0.28	0.28	7.03
Total		-5,225.27	-8,790.39	-12,281.36	-15,333.53	-17,310.82	-19,238.41	-78,179.78

7 Costs appear as zero due to rounding. CMS estimates actual costs of 0.003 million.
8 Costs appear as zero due to rounding. CMS estimates actual costs of 0.003 million.
9 Costs appear as zero due to rounding. CMS estimates actual costs of 0.003 million.
10 Costs appear as zero due to rounding. CMS estimates actual costs of 0.003 million.

Table 17: Estimated Costs and Savings to the Federal Government by Provision for Fiscal Years 2011 through 2016 ($ in millions)[11]

Provision(s)	Regulation Section(s)	Fiscal Year 2011	2012	2013	2014	2015	2016	Total ($ in millions) (FYs 2011-2016)
Cost Sharing for Specified Services at Original Medicare Levels	§417.101 and §422.100	0.00	6.80	0.00	0.00	0.00	0.00	6.80
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	300.00	430.00	480.00	530.00	590.00	-2,330.00
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	§417.101 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
Improvements to Medication Therapy Management Programs	§423.153	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	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

11 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	
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
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
Compliance Officer Training	§422.503 and §423.504	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	-8,915.19	-12,341.97	-15,394.14	-17,371.43	-19,299.02	-78,610.35

Table 18: Estimated Administrative Costs to MA Organizations and Part D Sponsors by Provision for Fiscal Years 2011 Through 2016 ($ in millions)[12]

Provision(s)	Regulation Section(s)	Fiscal Year 2011	2012	2013	2014	2015	2016	Total ($ in millions) (FYs 2011-2016)
Cost Sharing for Specified Services at Original Medicare Levels	§417.101 and §422.100	0.00	0.00	0.00	0.00	0.00	0.00	0.00
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	0.0013	0.0014	0.0015	0.0016	0.0017	0.0018	0.0019
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	1.58	0.00	0.00	0.00	0.00	0.00	1.58
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

12 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.

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 0.0006 million

17 Costs appear as zero due to rounding. CMS estimates actual costs of 0.0006 million

18 Costs appear as zero due to rounding. CMS estimates actual costs of 0.0006 million

19 Costs appear as zero due to rounding. CMS estimates actual costs of 0.0036 million

Provision(s)	Regulation Section(s)	Fiscal Year						Total ($ in millions) (FYs 2011-2016)
		2011	2012	2013	2014	2015	2016	
Cost Sharing for Medicare Covered Preventive Services	§417.101 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
Improvements to Medication Therapy Management Programs	§423.153	0.00	96.71	32.24	32.24	32.24	32.24	225.67
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
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
Compliance Officer Training	§422.503 and §423.504	0.00	0.01	0.54	0.54	0.54	0.54	2.16
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	0.51	0.34	0.34	0.34	0.34	1.88
Translated Marketing Materials	§422.2264 and §423.2264	5.63	0.28	0.28	0.28	0.28	0.28	7.03
Total		63.30	124.78	60.59	60.59	60.59	60.59	430.43

Table 19: Estimated Costs and Savings to States by Provision for Fiscal Years 2011 Through 2016
($ in millions)

Provision (s)	Regulation Section(s)	Fiscal Year						Total ($ in millions) (FYs 2011-2016)
		2011	2012	2013	2014	2015	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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C. Expected Benefits

1. Cost Sharing for Specified Services at Original Medicare Levels (§ 417.101 and 422.100)

We believe that the addition of home health services to the list of service categories for which MA plan cost sharing may not exceed that required under Original Medicare will provide additional transparency and predictability for beneficiaries as they evaluate their health plan options, and also will strengthen the beneficiary protections against discriminatory cost sharing and benefit designs. Even with the additional restriction on cost sharing for home health services, 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.

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

This proposed rule would 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 proposed rule would 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 would be able to remain in these PDPs and would not be reassigned to other lower-premium PDPs. Under the current framework we would expect 1.9 million reassignments. Under the proposed formula for calculating benchmarks we would expect 900,000 reassignments, or approximately one million fewer reassignments. We expect the proposed 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. This proposed rule supports pharmacy and formulary consistency for the beneficiary. Particularly in regions with high MA–PD penetration, this proposed rule would 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.

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

The proposed voluntary *de minimis* provisions would 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 reassignments will be reduced by the *de minimis* provisions in the regulation.

4. 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 coverage year 2011, we expect that implementation of the Part D—IRMAA provisions, as proposed 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.

5. 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.

6. Appropriate Dispensing of Prescription Drugs in Long-Term Care Facilities Under PDPs and MA–PD Plans (§ 423.154) and Dispensing Fees (§ 423.100)

This provision is expected to lead to a reduction in Part D program expense, pharmaceutical waste, environmental disposal costs impact, and the risk of pharmaceutical diversion associated with unused drugs in 30-day fills.

7. Complaint System for Medicare Advantage Organizations and PDPs (§ 422.504(a) and § 423.505(b))

This provision is expected 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 prescription benefit plan.

8. 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 healthcare 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. Furthermore, a standard appeals form will be utilized by all Part D sponsors.

9. 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)

This provision is expected to reduce the costs to ADAPs and IHS, since beneficiaries will be able to reach the catastrophic limit and relieve the ADAPs and IHS from incurring excessive prescription costs because beneficiaries in both programs had difficulty reaching the catastrophic phase of the Part D benefit.

10. Cost Sharing for Medicare Covered Preventive Service (§ 417.101 and § 422.100)

We believe that our proposal to require 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.

11. Elimination of the Stabilization Fund (§ 422.458)

As discussed elsewhere in this RIA, the elimination of the stabilization fund is expected to result in savings to the Federal government.

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

Under this proposed provision, beneficiaries receiving the standardized Comprehensive Medication Review documents would have a better understanding of the review findings and recommendations. The opportunity for sponsors to use telehealth technology would improve access to MTM services for beneficiaries, particularly those in remote locations or unable to travel. The proposed change requiring coordination of MTM services with LTC consultant pharmacist services would enable beneficiaries to receive the full benefits of the sponsor's MTM program and the coordinated assessments would more likely uncover evidence of adverse side effects and medication overuse.

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

Under these proposed 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.

14. Medicare Advantage Benchmark, Quality Bonus Payments, and Rebate and Application of Coding Adjustment (§ 422.252, § 422.258 and § 422.266, and § 422.308)

Our proposed revisions will result in government savings and will bring MA payments in line with FFS payments. The MA benchmarks, which are the ceiling for per member per month MA payment to a plan before risk adjustment, will now be linked to FFS costs. These provisions also provide incentives for MA organizations to maintain or increase the quality of their plans, as organizations with 4 stars or more will receive a quality bonus.

15. Quality Bonus Appeals (§ 422.260)

Our intent in implementing 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.

16. 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 do not anticipate a financial benefit to the terminated Part D sponsor.

17. 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)

By requiring that all organization determinations, coverage determinations, and plan reconsiderations and redeterminations involving medical necessity be reviewed by a medical professional with expertise in the field of medicine appropriate for the services at issue, enrolled beneficiaries would be assured of consistent and medically accurate decisions by Part C organizations and Part D sponsors. We believe that the proposal to require plans to employ a medical director to ensure the clinical accuracy of such decisions strikes the appropriate balance between our interest in ensuring that plans are properly administering the Part C and Part D benefit, and the plans' interest in minimizing their administrative burden.

18. Compliance Officer Training (§ 422.503 and § 423.503)

The benefit to requiring annual compliance officer training is that beneficiaries will be more likely to receive benefits consistent with plan sponsors' bids and CMS requirements. Compliance officers will be more knowledgeable about the MA and Part D programs which should translate into more efficient internal plan oversight. As internal plan oversight increases, CMS anticipates a decrease in the volume and severity of compliance issues because compliance officers will be able to identify small problems before they become large problems with significant beneficiary impact.

19. 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. Furthermore, this proposal would reduce or eliminate the duplication of training and testing requirements for agents and brokers who contract with multiple plans with different training and testing requirements.

20. Call Center Interpreter Requirements (§ 422.111 and § 423.128)

The expected benefit of our proposed 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.

21. Customized Enrollee Data (§ 422.111 and § 423.128)

We believe that our proposed requirement that plans provide customized enrollee data to plan enrollees at least annually after initial enrollment in conjunction with the annual renewal materials (currently the annual notice of change and evidence of coverage documents) would enable plan members to better understand their utilization and out-of-pocket costs during a period of time, as well as how the costs of their plan are changing in the upcoming contract year and what that means for them if they remain in the plan and use similar services. We intend for any EOB or customized out-of-pocket cost statement to provide personal information to beneficiaries that would help them consider using other tools and resources, including MOC and the MPDPF, to determine whether to select a new plan.

22. 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. We set the parameters for the annual mandatory MOOP limit, and this should make it easier for plans to compete on a level playing field, as well as increase transparency for beneficiaries. This proposed requirement would ensure all regional PPO 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.

23. Translated Marketing Materials (§ 422.2264 and § 423.2264)

The expected benefit of our proposed requirement to codify existing subregulatory guidance with respect to translated marketing materials is that all beneficiaries, regardless of language spoken and national origin, will have access to all the information they need to make appropriate decisions about their health care to utilize their Medicare benefits most effectively.

D. Alternatives Considered

We did not consider alternatives for the following provisions, as their implementation was mandated by the ACA:

- Approval of SNPs by NCQA (§ 422.4, § 422.101, and § 422.152)
- Determination of Part D Low-Income Benchmark Premium (§ 423.780)
- Voluntary De Minimis Policy for Subsidy Eligible Individuals (§ 423.34 and § 423.780)
- Increase in Part D Premiums Due to the Income Related Monthly Adjustment Amount (D—IRMAA) (§ 423.44, § 423.286, and § 423.293)
- Elimination of Medicare Part D Cost-Sharing for Individuals Receiving Home and Community-Based Services (§ 423.772 and § 423.782)
- Appropriate Dispensing of Prescription Drugs in Long-Term Care Facilities Under PDPs and MA–PD plans (§ 423.154) and Dispensing Fees (§ 423.100)
- Complaint System for MA Organizations and PDPs (§ 422.504(a) and § 423.505(b))
- Uniform Exceptions and Appeals Process for Prescription Drug Plans and MA–PD Plans (§ 423.128(b)(7)(i), § 423.128(d), and § 423.562(a)(3))
- Including Costs Incurred by the AIDS Drug Assistance Program (ADAP) and the IHS Toward the Annual Part D Out-of-Pocket Threshold (§ 423.100, and § 423.464)
- Elimination of the Stabilization Fund (§ 422.458)
- Improvements to Medication Therapy Management Programs (153)
- Changes To Close the Part D Coverage Gap (§ 423.104 and § 423.884)
- MA Benchmark, Quality Bonus Payments, and Rebate and Application of Coding Adjustment (§ 422.252, § 422.258, § 422.266, and § 422.308)

Alternatives considered for other proposals are summarized below.

1. Cost Sharing for Specified Services at Original Medicare Levels (§ 417.101 and § 422.100)

We considered implementing the provisions of section 3202 to limit cost sharing under MA plans to that required under Original Medicare without using our authority, granted by this same section of the ACA, to also limit cost sharing for any additional service categories. We believe it is preferable to restrict our implementation of section 3202 to the specified service categories, allowing ourselves time to evaluate the effects of those provisions, as well as other recently-established policy changes before adopting the cost sharing limits on an expanded list of service categories.

We believe that the addition of home health services to the list of service categories subject to cost sharing levels that may not exceed those required under Original Medicare was an appropriate additional service category as described in the ACA for the reasons specified elsewhere in this preamble and that adding those services would enhance beneficiary protections and would not impose a significant cost burden on the MA program.

2. Cost Sharing for Medicare-Covered Preventive Services (§ 417.101 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 propose 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 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 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 above, 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 proposal 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 proposed 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 to our proposals 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 overseeing decisions of medical necessity.

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

We considered requiring compliance officers to become certified through an existing or CMS-developed certification process. However, because training opportunities, especially the possibility

of free training opportunities offered by CMS, are available outside of a certification process, we chose only to propose requiring training. In the event that requiring annual compliance officer training does not result in the expected increase in knowledge and decrease in compliance issues, we will reevaluate whether compliance officer certification may be necessary. In contrast to training, requiring compliance officer certification would likely cost more; therefore, we chose to test the less costly option first.

7. Agent and Broker Training Requirements (§ 422.2274 and § 423.2274)

Proposed § 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. The alternative we considered to this proposal 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.

8. 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 proposed call center interpreter requirements.

9. Customized Enrollee Data (§ 422.111 and § 423.128)

The alternative considered to our proposed provision to require provision of customized enrollee data was for MA organizations and Part D sponsors to continue to provide beneficiaries with the information already required by regulation through the ANOC and EOC documents, which must be furnished to all plan enrollees at least 15 days before the annual open election period. Beneficiaries would also continue to have access to information through tools such as Medicare Options Compare (MOC) and the Medicare Prescription Drug Plan Finder (MPDPF), which provide more general information about plan costs. We did not choose this option because we are concerned that the current available options alone may not be enough to prompt enrollees to actively evaluate their plans annually with respect to plan costs, benefits, and overall value. Therefore, we expect that this customized enrollee data will be another more specific tool for beneficiaries to use, in addition to the general tools already in place, for enrollees to understand their utilization and out-of-pocket costs during a period of time, as well as how they may be affected by specific plan changes, and to assist them in evaluating their options for the future.

10. Extending the Mandatory Maximum Out-of-Pocket (MOOP) Amount Requirements to Regional PPOs (§ 422.100 and § 422.101)

The alternative we considered to this proposal 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 15, 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.

11. 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 proposed translated marketing materials requirements.

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

The legislation 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.

E. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 20, we have prepared an accounting statement showing the classification of the costs and benefits associated with the provisions of this proposed rule. The accounting statement is based on estimates provided in Tables 16, 17, 18, and 19 (our best estimate of the costs and savings as a result of the changes) and discounted at 7 percent and 3 percent for the time period of FY 2011 through FY 2016.

TABLE 20—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS AND SAVINGS, FROM FY 2011 TO FY 2016

[$ in Millions]

Category	Year dollar	Units discount rate		Period covered
		7%	3%	
Transfers				
Annualized Monetized Tranfers	2010	−$12,544.46	−$12,858.60	FYs 2011–2016
From Whom To Whom?	Federal Government to MA organizations and Part D Sponsors.			

TABLE 20—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS AND SAVINGS, FROM FY 2011 TO FY 2016—Continued

[$ in Millions]

Category	Year dollar	Units discount rate		Period covered
		7%	3%	
Costs (All other provisions)				
Annualized Costs to MA organizations and Part D Sponsors	2010	$72.88	$72.24	FYs 2011–2016
Annualized Costs to States	2010	$0.02	$0.02	FYs 2011–2016

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs—health, Medicare, 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 proposes to amend 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 B—Qualified Health Maintenance Organizations; Services

2. Section 417.101 is amended by adding new paragraphs (f) and (g) to read as follows:

§ 417.101 Health benefits plan: Basic health services.

* * * * *

(f) An HMO may not charge deductibles, copayments, or coinsurance for in-network Medicare-covered preventive services as specified by CMS annually.

(g) *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 plan's 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.

(4) Home health services provided in accordance with § 424.22.

Subpart J—Qualifying Conditions for Medicare Contracts

3. 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

4. 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.

* * * * *

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 in alphabetical order 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) Provides dual-eligible beneficiaries access to Medicare and Medicaid benefits under a single managed care organization;

(2) 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;

(3) 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

(4) Employs policies and procedures approved by CMS and the State to coordinate or integrate member materials, including enrollment, communications, grievance and appeals, and quality assurance.

* * * * *

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 by:

A. Revising paragraphs (a)(1)(iii) and (a)(1)(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 overall quality improvement (QI) program and the 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; and

(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 by:

A. Revising paragraphs (a)(2)(i), (iii), and (iv), and (a)(5).

B. Add new paragraph (a)(7).

The revisions and addition read as follows:

§ 422.62 Election of coverage under an MA plan.

(a) * * *

(2) *Annual coordinated election period.* (i) For 2002 through 2010, except for 2006, the annual coordinated election period for the following calendar year is November 15 through December 31.

(ii) * * *

(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), (a)(5)(iii), and (a)(6) of this section, an individual who is not enrolled in an MA plan but is eligible to elect an MA plan may make an election into an MA plan once during the first 3 months of the year.

(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:

A. Revising paragraph (d)(2).

B. Adding new paragraphs (j) and (k).

The revision and additions read as follows.

§ 422.100 General requirements.

* * * * *

(d) * * *

(2) At a uniform premium, with uniform benefits and level of in-network cost-sharing throughout the plan's service area, or segment of service area as provided in § 422.262(c)(2).

* * * * *

(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' 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.

(4) Home health services provided in accordance with § 424.22.

(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 specified by CMS annually.

13. Section 422.101 is amended by:

A. Revising paragraphs (d)(2) and (3).

B. Adding a new 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 provide for a catastrophic limit on beneficiary out-of-pocket expenditures for in-network benefits under the Original Medicare fee-for-service program (Part A and Part B benefits) that is no greater than the annual limit set by CMS.

(3) *Total catastrophic limit.* MA regional plans are required to provide a total catastrophic limit on beneficiary out-of-pocket expenditures for in-network and out-of-network benefits under the Original Medicare fee-for-service program. This total out-of-pocket catastrophic limit, which would apply to both in-network and out-of-network benefits under Original Medicare, may be higher than the in-network catastrophic limit in paragraph (d)(2) of this section, but may not increase the limit described in paragraph (d)(2) of this section 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 overall quality improvement (QI) program and the model of care (MOC) to CMS for NCQA evaluation and approval in accordance with CMS guidance.

14. Section 422.106 is amended by:

A. Revising paragraph (d)(1).

B. Adding paragraphs (d)(4) through (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 by:

A. Adding a new paragraph (b)(12).

B. Removing paragraph (f)(12).

C. Adding paragraph (h).

The additions read as follows.

§ 422.111 Disclosure requirements.

* * * * *

(b) * * *

(12) *Customized out-of-pocket cost statement.* CMS may require an MA organization to annually disclose to each enrollee a customized statement of the beneficiary's potential future out-of-pocket costs. This notice will be provided in each year, in which a minimum enrollment period has been met, in conjunction with the annual plan description described in paragraphs (b)(1) through (11) of this section.

* * * * *

(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 all 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) 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 overall quality improvement (QI) program and 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 by:

A. Adding in alphabetical order 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) 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 by:

A. Revising paragraphs (a)(1) and (2).

B. In paragraph (c)(3)(i), removing the phrase "county capitation rate" and adding in its place the phrase "amount determined under paragraph (a) of this section for the year".

C. Adding a new 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) 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. However, 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) 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 and the minimum percentage increase rate at § 422.306(a) for an area.

(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) 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) 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.

(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 plans.* (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 plan 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 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 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 year.

(F) For 2017 and subsequent years, the blended benchmark equals the specified amount for the area and year.

25. Add § 422.260 to read as follows:

§ 422.260 Appeals of quality bonus payment determinations.

(a) *Scope.* The provisions of this section pertain to appeals of 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 an QBP.

Quality bonus payment (QBP) status means an 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) *Technical report on QBP status.* An MA organization may request a technical report from CMS which details the performance data and performance measures that CMS relied on in applying the quality bonus payment determination methodology and how CMS applied the methodology to such performance data.

(1) The MA organization must request a technical report concerning its QBP status within 5 days of CMS' issuance of notice of the QBP status determination.

(2) The technical report must be prepared by an independent contractor engaged by CMS to review the application of CMS' QBP payment determination methodology to the organization's performance for the most recent evaluation period.

(3) Within 30 days of CMS' receipt of the MA organization request, the independent contractor must issue the technical report to the MA organization and CMS in writing and by electronic mail.

(4) The independent contractor will not accept or consider materials submitted by the MA organization in advance of the technical report.

(d) *QBP status appeal process.* (1) *Hearing request.* An MA organization may request an appeal of its QBP status.

(i) The MA organization seeking an appeal of their QBP status must do so by providing written notice to CMS within 7 days of the issuance of the QBP technical report. The notice must specify the errors the MA organization asserts that CMS made in making the QBP determination and how correction of those errors would result in the organization's qualification for a QBP.

(ii) The MA organization may not request an appeal of its QBP status unless it has already requested and received a technical report in accordance with paragraph (c) of this section.

(2) *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.

(3) *Hearing officer's review.* The hearing officer reviews the application of CMS' QBP determination methodology to the determination of the MA organization's QBP status.

(i) The hearing officer must consider whether CMS correctly applied its QBP determination methodology to the MA organization's performance, but may not consider the validity of the determination methodology itself.

(ii) The hearing officer may also consider the accuracy of the data related to individual performance measures used to arrive at a QBP determination where those performance measures have not been subject to an independent audit.

(iii) The hearing officer may not consider the accuracy of data related to individual performance measures which were subject to an independent audit prior to their use in arriving at the QBP determination.

(iv) The hearing is conducted by a CMS hearing officer on the record, unless the parties requested, subject to the hearing officer's discretion, a live or telephonic hearing.

(v) The hearing officer receives no testimony, but may accept written statements with exhibits from each party in support of their position in the matter.

(4) *Hearing officer's decision.* The hearing officer issues a decision on or

before May 15 of the year preceding the year in which the plans for which the QBP is to be applied will be offered. The hearing officer issues the decision by electronic mail to the MA organization and to CMS.

(5) *Effect of the hearing officer's decision.* The hearing officer's decision is final and binding.

(e) *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 technical report issued in accordance with paragraph (c) of this section that demonstrates that the initial QBP determination was incorrect.

26. Amend § 422.262 by revising paragraph (c)(1) to read as follows:

§ 422.262 Beneficiary premiums.

* * * * *

(c) * * *

(1) *General rule.* (i) Except as permitted for supplemental premiums under § 422.106(d), for MA contracts with employers and labor organizations, the MA monthly bid amount submitted under § 422.254, the MA monthly basic beneficiary premium, the MA monthly supplemental beneficiary premium, the MA monthly prescription drug premium, and the monthly MSA premium of an MA organization may not vary among individuals enrolled in an MA plan (or segment of the plan as provided for local MA plans under paragraph (c)(2) of this section).

(ii) The MA organization cannot vary the level of cost-sharing charged for basic benefits or supplemental benefits (if any) among individuals enrolled in an MA plan (or segment of the plan). Cost sharing cannot vary across enrollees of a plan for any reason, including that based upon primary care provider group, specialist, hospital network or an enrollee's utilization of health care services.

* * * * *

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)(6). For 2014 and subsequent years, this percentage is determined based only on the paragraph (a)(2)(ii) of this section rules.

(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 (d)(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 plans.* 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:

§ 422.308 Adjustments to capitation rates, benchmarks, bids, and payments.

* * * * *

(c) * * *

(4) *Authority to apply frailty adjustment under PACE payment rules for certain specialized MA plans for special needs individuals.* (i) 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 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.

(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 by:

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.

* * * * *

31. Amend § 422.503 by:

A. Redesignating paragraph (b)(4)(vi)(B)(*1*) as paragraph (b)(4)(vi)(B)(*1*)(*i*).

B. Adding paragraph (b)(4)(vi)(B)(*1*)(*ii*).

The addition reads as follows.

§ 422.503 General provisions.

* * * * *

(b) * * *

(4) * * *

(vi) * * *

(B) * * *

(*ii*) Beginning in 2013, the compliance officer will complete annual MA compliance training offered by an entity with expertise in MA. New applicants must complete training by the last Friday in August prior to the start of the contract year.

* * * * *

32. Amend § 422.504 by:

A. Redesignating paragraph (a)(14) as paragraph (a)(16) and revising it.

B. Adding new paragraphs (a)(14) and (a)(15).

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.

* * * * *

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—

(A) Have an ownership interest of more than 5 percent; and

(B) Acquired the ownership through public trading.

(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 assists thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(iii) An officer or 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—

(i) Have an ownership interest of more than 5 percent; and

(ii) Acquired the ownership through public trading.

(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 assists thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(3) An officer or member of the board of directors of the entity, if the organization is organized as a corporation.

35. Amend § 422.512(e) by:

A. Redesignating paragraph (e) as (e)(1).

B. Adding paragraph (e)(2) to read as follows:

§ 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—

(A) Have an ownership interest of more than 5 percent; and

(B) Acquired the ownership through public trading.

(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 assists thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(iii) An officer or 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.* When the issue involves medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the organization determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of the Medicare program. 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 § 422.626 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

39. 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 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.

40. 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 the unlicensed agent or broker of the agent's or broker's unlicensed status and of their options to confirm enrollment or make a plan change (including a special election period, as described in § 422.62(b)(3)(ii)).

41. 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 Medicare Advantage 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

42. 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

43. Amend § 423.4 by adding in alphabetical order 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

44. Amend § 423.34 by:

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. 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) MA–PDs and PDPs that voluntarily waive a *de minimis* amount as specified in § 423.780, if CMS determines that such inclusion is warranted.

* * * * *

45. Amend § 423.38 by:

A. Revising paragraph (b).

B. Adding a new paragraph (d).

The revision and addition 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.

46. 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.

47. Amend § 423.44 by revising the section heading and adding paragraphs (d)(1)(vi), (d)(1)(vii), and (e) to read as follows:

§ 423.44 Involuntary disenrollment from Part D coverage.

* * * * *

(d) * * *

(1) * * *

(iv) *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.

(v) *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 in the PDP, without interruption of coverage, if the individual shows good cause as specified in § 423.44(d)(1)(iv), pays all Part D—income related monthly adjustment amount arrearages, and any overdue premiums due the Part D plan sponsor within three 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

48. Amend § 423.100 by:

A. Adding in alphabetical order 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; and

(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.

(6) Has a claim that—

(i) Straddles the initial coverage period and the coverage gap;

(ii) Straddles the coverage gap and the annual out-of-pocket threshold; or

(iii) 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), including authorized generics (as defined in 100.5 of this guidance); 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 through an exception or appeal.

* * * * *

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 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 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 (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 § 423.464) or under an AIDS Drug Assistance Program (as defined in part B of title XXVI of the Public Health Service); or

* * * * *

49. Amend § 423.104 by:

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 (d)(5)(iii)(E).

D. Revising newly redesignated paragraph (d)(5)(iii)(F).

E. Adding a new paragraph (d)(5)(v).

The additions and revisions 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.* (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 dispensing 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.

* * * * *

50. Section 423.120 is amended by:

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) * * *

(3) * * *

(iii) * * *

(B) In the long-term care setting, the temporary supply of nonformulary 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 91 days in 7-day-or-less supply increments whenever § 423.154(a) applies and up to 93 days in 31 day supply increments whenever § 423.154(a) does not apply, 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 LTC residents dispensed multiple supplies of a Part D drug, in increments of 7 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 is considered a Part B compound, regardless of whether other ingredients in the compound are covered under Part B.

(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 section these compounds are referred to as Part D compounds.

(iii) For a Part D compound that is considered to be 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 non-formulary if it were provided separately—that is, not as part of the Part D compound).

(iv) For a 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 ingredients of the Part D compound that independently meet the definition of a Part D drug, the copayment amount submitted and approved under § 423.104(d) must equal the copayment for the tier of the most expensive of such ingredients, except in the case of low income subsidy beneficiaries where 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 drug (as described under § 423.782).

(ii) For ingredients of the Part D compound that independently meet the definition of a Part D drug, the coinsurance submitted and approved under § 423.104(d) must be applied to the cost of all such ingredients, except in the case of full subsidy eligible individuals (as defined in § 423.783(b)) where 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 drug (as described under § 423.782).

(iii) 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 may either contract with the pharmacy to—

(A) Make payment without charging the beneficiary for these amounts or reporting these costs to CMS;

(B) Deny payment, but allow the pharmacy to balance bill the beneficiary for the cost of these ingredients; or

(C) Deny payment and prohibit the pharmacy to balance bill the beneficiary for the cost of these ingredients.

51. Amend § 423.128 by:

A. Revising paragraph (b)(7).

B. Adding new paragraphs (b)(11), (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 standard form used to request a coverage determination under § 423.568 or § 423.570, and a standard form used to request a redetermination under § 423.582 or § 423.584, to the extent such standard coverage determination and redetermination request 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.

* * * * *

(11) *Customized out-of-pocket cost statement.* CMS may require a Part D sponsor to annually disclose to each enrollee a customized statement of the beneficiary's potential future out-of-pocket costs. This notice will be provided in each year in which a minimum enrollment period has been met, in conjunction with the annual plan description described in paragraphs (b)(1) through (10) of this section.

* * * * *

(d) * * *

(1) * * *

(iii) Provides interpreters for all 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

52. Amend § 423.150 by:

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 outpatient prescription drugs in long-term care facilities under PDPs and MA–PD plans.

* * * * *

53. Amending § 423.153 by:

A. Revising paragraph (d)(1)(vii)(B).

B. Adding paragraph (d)(1)(vii)(D).

C. Redesignating paragraph (d)(5) as (d)(7).

D. Adding a new paragraph (d)(5).

The revision and additions read as follows:

§ 423.153 Drug utilization management, quality assurance, and medication therapy management programs (MTMPs).

* * * * *

(d) * * *

(1) * * *

(vii) * * *

(B) *Annual comprehensive medication reviews 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.

* * * * *

(5) Coordination with long term care consultant pharmacist monitoring. Part D sponsors must contract with all long term care facilities in which their Part D enrollees reside to provide appropriate MTM services in coordination with consultant pharmacist evaluation and monitoring.

* * * * *

54. Add § 423.154 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 paragraphs (b) and (e) 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 brand-name medications, as defined in § 423.4, to enrollees in such facilities in no greater than 7-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 drugs returned to the pharmacy as required under paragraph (f) of this section.

(b) *Exclusions.* CMS excludes from the requirements under paragraph (a) of this section:

(1) Drugs difficult to dispense in supply increments of 7-day or less, such as drugs that must be dispensed in the original packaging including, but not limited to eye drops, nasal sprays, inhalational products, ear drops, reconstituted antibiotics and, in general, drugs with a parenteral route of administration, and topical preparations; or

(2) Drugs dispensed for acute illnesses including, but not limited to a 10- or 14-day course of antibiotics.

(c) *Waivers.* CMS waives the requirements under paragraph (a) of this section for pharmacies when they service intermediate care facilities for the mental retarded and developmentally disabled (ICFMRDD) and institutes for mental disease (IMDs) as defined in § 435.1010.

(d) *Effective date.* Except as provided in paragraph (e) of this section, the effective date for this section is January 1, 2012. Nothing precludes a Part D sponsor and network long-term care pharmacy from mutually agreeing to an earlier implementation date.

(e) *Extension.* A Part D sponsor may allow an independent community pharmacy that also contracts as a long-term care pharmacy to dispense up to a 14-day supply through December 31, 2012 if the following conditions are met:

(1) The independent community pharmacy is the primary provider of Part D drugs to one or more long-term care facilities with less than 80 beds; and

(2) The independent community pharmacy in its capacity as a long-term care pharmacy primarily services long-term care facilities in rural areas as defined by the Bureau of the Census.

(f) *Unused drugs returned to the pharmacy.* A Part D sponsor must include terms in its long-term care pharmacy contracts that—

(1) Require any unused drugs originally dispensed to its enrollees to be returned to the pharmacy and reported to the sponsor.

(2) Address contractual obligations for disposal 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

55. 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.

* * * * *

56. 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.

* * * * *

57. Amend § 423.286 by:

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 prescription drug 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 418.1115.

(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 § 418.1120 (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; by 25.5 percent; and the base beneficiary premium as determined under paragraph (c) of this section.

* * * * *

58. Amend § 423.293 by:

A. Redesignating paragraphs (d) and (e) as (e) and (f), respectively.

B. Adding 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 418.1115, 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

59. 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. Excluded expenditures do not include payments made by the Indian Health Service (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 § 423.464) or an AIDS Drug Assistance Program (as defined in part B of title XXVI of the Public Health Service).

(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

60. Amend § 423.503 by:

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.

* * * * *

61. Amend § 423.504 as follows:

A. Redesignating paragraph (b)(4)(vi)(B)(*1*) as paragraph (b)(4)(vi)(B)(*1*)(*i*).

B. Adding paragraph (b)(4)(vi)(B)(*1*)(*ii*).

The revisions read as follows.

§ 423.504 General provisions.

(b) * * *

(4) * * *

(vi) * * *

(B) * * *

(*ii*) Beginning in 2013, the compliance officer will complete annual Part D compliance training offered by an entity with expertise in Part D. New applicants must complete training by the last Friday in August prior to the start of the contract year.

* * * * *

62. Amend § 423.505 by adding paragraphs (b)(22) and (23) to 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).

* * * * *

63. Amend § 423.507(a) by:

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—

(A) Have an ownership interest of less than 5 percent; and

(B) Acquired the ownership through public trading.

(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) An officer or 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—

(i) Have an ownership interest of less than 5 percent; and

(ii) Acquired the ownership through public trading.

(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) An officer or 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 by:

A. Redesignating paragraph (e) as (e)(1).

B. Adding 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—

(A) Have an ownership interest of less than 5 percent; and

(B) Acquired the ownership through public trading.

(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) An officer or 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 by:

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 a new 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.* When the issue involves medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the coverage determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of the Medicare program. 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 in alphabetical order 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 by:

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. Amend § 423.782 by revising 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 by revising paragraphs (d)(1)(i), (d)(1)(ii), and (d)(5)(iii)(C) to read as follows:

§ 423.884 Requirements for qualified retiree prescription drug plans.

* * * * *

(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. Amend § 423.2264 by revising 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 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.

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 the unlicensed agent or broker of the agent's or broker's unlicensed status and 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.

* * * * *

Authority: (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program).

Dated: July 29, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: November 9, 2010.

Kathleen Sebelius,

Secretary.

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