DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 417, 422, 423, and 424

[CMS–4159–P]

RIN 0938–AR37

Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs

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

ACTION: Proposed rule.

SUMMARY: The proposed rule would revise the Medicare Advantage (MA) program (Part C) regulations and prescription drug benefit program (Part D) regulations to implement statutory requirements; strengthen beneficiary protections; exclude plans that perform poorly; improve program efficiencies; and clarify program requirements. The proposed rule also includes several provisions designed to improve payment accuracy.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 7, 2014.

ADDRESSES: In commenting, please refer to file code CMS–4159–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4159–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 to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4159–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period: a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey 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.) b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

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

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

FOR FURTHER INFORMATION CONTACT: Christopher McClintick, (410) 786–4682, Part C issues. Marie Manteuffel, (410) 786–3447, Part D issues. Kristy Nishimoto, (206) 615–2367, Part C and D enrollment and appeals issues. Whitney Johnson, (410) 786–0490, Part C and D payment issues. Clarisse Owens, (410) 786–0880, Part C and D compliance issues. Frank Whelan, (410) 786–1302, Part D improper prescribing issues.

SUPPLEMENTARY INFORMATION: *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: *http://www.regulations.gov*. Follow the search instructions 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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Acronyms

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
AO Accrediting Organization
AOR Appointment of Representative
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)
BLA Biologics License Application
CAHPS Consumer Assessment Health Providers Survey
CAP Corrective Action Plan
CCIP Chronic Care Improvement Program
CC/MCC Complication/Comorbidity and Major Complication/Comorbidity
CCS Certified Coding Specialist
CDC Centers for Disease Control
CHIP Children's Health Insurance Programs
CMP Civil Money Penalty
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
DAB Departmental Appeals Board
DEA Drug Enforcement Administration
DIR Direct and Indirect Remuneration
DME Durable Medical Equipment
DMEPOS Durable Medical Equipment, Prosthetic, Orthotics, and Supplies
D–SNPs Dual Eligible SNPs
DOL U.S. Department of Labor
DUM Drug Utilization Management
EAJR Expedited Access to Judicial Review
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
FEHBP Federal Employees Health Benefits Plan
FFS Fee-For-Service
FIDE Fully-integrated Dual Eligible
FIDE SNPs Fully-integrated Dual Eligible Special Needs Plans
FMV Fair Market Value
FY Fiscal year
GAO Government Accountability Office
HAC Hospital-Acquired Conditions
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
ICEP Initial Coverage Enrollment Period
ICL Initial Coverage Limit
ICR Information Collection Requirement
ID Identification
IRE Independent Review Entity
IRMAA Income-Related Monthly Adjustment Amount
IVC Initial Validation Contractor
LCD Local Coverage Determination
LEP Late Enrollment Penalty
LIS Low Income Subsidy
LPPO Local Preferred Provider Organization
LTC Long Term Care
MA Medicare Advantage
MAAA Member of the American Academy of Actuaries
MA–PD Medicare Advantage-Prescription Drug Plan
MAC Medicare Appeals Council
MIPPA Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275)
MOC Medicare Options Compare
MOOP Maximum Out-of-Pocket
MPDPF Medicare Prescription Drug Plan Finder
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)
MS–DRG Medicare Severity Diagnosis Related Group
MSA Metropolitan Statistical Area
MSAs Medical Savings Accounts
MSP Medicare Secondary Payer
MTM Medication Therapy Management
MTMP Medication Therapy Management Program
NAIC National Association Insurance Commissioners
NCD National Coverage Determination
NCPDP National Council for Prescription Drug Programs
NCQA National Committee for Quality Assurance
NDA New Drug Application
NDC National Drug Code
NGC National Guideline Clearinghouse
NIH National Institutes of Health
NOMNC Notice of Medicare Non-Coverage
NPI National Provider Identifier
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 Program
PBM Pharmacy Benefit Manager

PDE Prescription Drug Event
PDP Prescription Drug Plan
PFFS Private Fee For Service Plan
POA Present on Admission (Indicator)
POS Point-of-Sale
PPO Preferred Provider Organization
PPS Prospective Payment System
P&T Pharmacy & Therapeutics
QIC Qualified Independent Contractor
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
RPPO Regional Preferred Provider Organization
SEP Special Enrollment Period
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
T&C Terms and Conditions
TPA Third Party Administrator
TrOOP True Out-Of-Pocket
U&C Usual and Customary
UPIN Uniform Provider Identification Number
USP U.S. Pharmacopoeia

I. Executive Summary

A. Purpose

The purpose of this proposed rule is to make revisions to the Medicare Advantage (MA) program (Part C) and Prescription Drug Benefit Program (Part D) regulations based on our continued experience in the administration of the Part C and Part D programs and to implement certain provisions of the Affordable Care Act. The proposed changes are necessary to—(1) clarify various program participation requirements; (2) make changes to strengthen beneficiary protections; (3) strengthen our ability to identify strong applicants for Part C and Part D program participation and remove consistently poor performers; and (4) make other clarifications and technical changes.

B. Summary of the Major Provisions

1. Eligibility of Enrollment for Individuals Not Lawfully Present in the United States

The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 makes individuals not lawfully present in the United States ineligible to receive federal benefits (such as Medicare), even if they are otherwise entitled to benefits. While we would not pay FFS claims for unlawfully present beneficiaries, MA, and Part D enrollment rules currently do not prevent the payment of capitation rates for these individuals. We are proposing to establish U.S. citizenship and lawful presence as an eligibility requirement for enrollment in MA and Part D plans.

2. Modifying the Agent/Broker Requirements, Specifically Agent/Broker Compensation

The current compensation structure is comprised of a 6-year cycle and is scheduled to end December 31, 2013. MA organizations and PDP sponsors provide an initial compensation payment to independent agents for new enrollees (Year 1), and pay a renewal rate (equal to 50 percent of the initial year compensation) for Years 2 through 6. This structure has proved to be complicated to implement and monitor, and the current structure creates an incentive for agents to move beneficiaries as long as the fair market value (FMV) continues to increase each year. To simplify the administration of these payments and reduce incentives for agents and brokers to encourage beneficiaries to enroll in plans without regard to ensuring plan benefits would meet the beneficiaries' health care needs, we are proposing to revise the existing compensation structure. Under our proposal, MA organizations and PDP sponsors would continue to have the discretion to decide, on an annual basis, whether to pay initial and/or renewal compensation payments to their independent agents. Also, for new enrollments, MA organizations and sponsors could make an initial payment that is no greater than the FMV amount, which we would set annually in our guidance that interprets these regulations. For renewals in Year 2 and subsequent years, the MA organization or sponsor could pay up to 35 percent of the FMV amount for that year. We believe that revising the existing compensation structure to allow MA organizations or Part D sponsors to pay up to 35 percent of the FMV for year 2 and subsequent years is appropriate based on a couple of factors. First, we believe that a 2 tiered payment system (that is, initial and renewal) would be significantly less complicated than a 3-tiered system (that is, initial, 50 percent renewal for years 2 through 6, and 25 percent residual for years 7 and subsequent years), and would reduce administrative burden and confusion for plan sponsors. Second, our analysis determined that 35 percent is the renewal compensation level at which the present value of overall payments under a 2-tiered system would be relatively equal to the present value of overall payments under a 3-tiered system (taking into account the estimated life expectancy for several beneficiary age cohorts). In addition to revising the agent and broker compensation structures, we propose to amend the training and testing requirements as well as setting limits on referral fees for agents and brokers.

3. Drug Categories or Classes of Clinical Concern

This proposed provision would interpret the Affordable Care Act authority to limit protected classes to those for which access to all drugs in a category or class for a typical individual with a disease or condition treated by the drugs in the class is required within 7 days and more specific formulary requirements would not suffice to meet multitude of specific applications of the drugs within the category or class. Instead of mandating coverage of all drug products in a particular class on all Part D formularies, we can save costs by identifying more efficient formulary requirements or other beneficiary protections in most cases.

4. Improving Payment Accuracy

The proposed regulatory provisions would implement the Affordable Care Act requirement that MA organizations and Part D sponsors report and return identified Medicare overpayments. We would adopt the statutory definition of overpayment for both Part C and Part D.

5. Risk Adjustment Data Requirements

The proposed rule would strengthen existing regulations at § 422.310 on MA plan sponsors' accountability for valid risk adjustment data prior to submission.

C. Summary of Costs and Benefits

TABLE 1—SUMMARY OF COSTS AND BENEFITS

Provision description	Total costs	Transfers
Changes to Audit and Inspection	We estimate that this change would require an annual cost of $7.95 million (total cost of $39.75 million) for the time and effort for all auditing organizations to perform the program audit. Additionally, we estimate an annual cost of $950,000 (total cost of 4.75 million) for MA organizations or Part D sponsors with audit results that reveal non-compliance to hire an independent auditor to validate that correction has occurred.	
Eligibility of enrollment for individuals not lawfully present in the U.S.	N/A	We estimate that this change could save the MA program up to $5 million in 2015, increasing to $8 million in 2019 (total of $32 million over this period), and could save the Part D program (includes the Part D portion of MA-PD plans) up to $5 million in 2015, increasing to $9 million in 2019 (total of $35 million over this period).
Modifying the agent/broker requirements, specifically agent/broker compensation.	N/A.	
Drug Categories or Classes of Clinical Concern	N/A	We estimate that this change could save the Part D program (includes the Part D portion of MA–PD plans) approximately $30 million in 2016, increasing to $420 million in 2019 (total of $720* million over this period).
Improving Payment Accuracy	N/A.	
Risk Adjustment Data Requirements	N/A.	
Transfer of TrOOP Between Part D Sponsors Due to Enrollment Changes during the Coverage Year.	N/A.	
Eligibility of Enrollment for Incarcerated Individuals.		We estimate that this change could save the MA program up to $27 million in 2015, increasing to $62 million in 2019 (total of $219 million over this period), and could save the Part D program (includes the Part D portion of MA-PD plans) up to $46 million in 2015, increasing to $90 million in 2019 (total of $333 million over this period).

*Projected savings are based upon full implementation of the criteria and do not reflect that changes for the antipsychotic class of drugs are deferred at this time.

II. Background

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) created a new ''Part C'' in the Medicare statute (sections 1851 through 1859 of the Social Security Act (the Act)) which established what is now known as the Medicare Advantage (MA) program. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), enacted on December 8, 2003, added a new ''Part D'' to the Medicare statute (sections 1860D–1 through 42 of the Act) entitled the Medicare Prescription Drug Benefit Program (PDP), and made significant changes to the existing Part C program, which it named 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).

Since the inception of both Parts C and D, we have periodically revised our regulations either to implement statutory directives or to incorporate knowledge obtained through experience with both programs. For instance, on the September 18, 2008 and January 12, 2009 **Federal Register** (73 FR 54226 and 74 FR 1494, respectively), we issued Part C and D regulations to implement provisions in the Medicare Improvement for Patients and Providers Act (MIPPA) (Pub. L. 110–275). We promulgated a separate interim final rule in January 16, 2009 (74 FR 2881) to address MIPPA provisions related to Part D plan formularies. In the final rule that appeared in the April 15, 2010 **Federal Register** (75 FR 19678), we made changes to the Part C and D regulations which strengthened various program participation and exit requirements; strengthened beneficiary protections; ensured that plan offerings to beneficiaries included meaningful differences; improved plan payment rules and processes; improved data collection for oversight and quality assessment; implemented new policies; and clarified existing program policy.

In a final rule that appeared in the April 15, 2011 **Federal Register** (76 FR 21432), we continued our process of implementing improvements in policy consistent with those included in the April 2010 final rule, and also implemented 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. The Affordable Care Act included significant reforms to both the private health insurance industry and the Medicare and Medicaid programs. Provisions in the Affordable Care Act concerning the Part C and D programs largely focused on beneficiary protections, MA payments, and simplification of MA and Part D program processes. These provisions affected implementation of our policies regarding beneficiary cost-sharing, assessing bids for meaningful differences, and ensuring that cost-sharing structures in a plan are transparent to beneficiaries and not excessive. In the April 2011 final rule, we revised regulations on a variety of issues based on the Affordable Care Act and our experience in administering the MA and Part D programs. The rule covered areas such as 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.

In a final rule that appeared in the April 12, 2012 **Federal Register** (77 FR 22072 through 22175), we made several changes to the Part C and Part D programs required by statute, including the Affordable Care Act, as well as made improvements to both programs through modifications reflecting experience we have obtained administering the Part C and Part D programs. Key provisions of that final rule implemented changes closing the Part D coverage gap, or ''donut hole,'' for Medicare beneficiaries who do not already receive low-income subsidies from us by establishing the Medicare Coverage Gap Discount Program. We also included provisions providing new benefit flexibility for fully-integrated dual eligible special needs plans, clarifying coverage of durable medical equipment, and combatting possible fraudulent activity by requiring Part D sponsors to include an active and valid prescriber National Provider Identifier on prescription drug event records.

III. Provisions of the Proposed Regulations

A. Clarifying Various Program Participation Requirements

1. Closing Cost Contract Plans to New Enrollment (§ 422.2 and § 422.503(b)(5))

In implementing the original Part C requirements in our June 26, 1998 final rule, entitled, ''Medicare Program; Establishment of the Medicare+Choice Program'' (63 FR 34968 through 35116), we established a requirement in 42 CFR 422.501(b)(4) that an ''entity seeking to contract as [an Medicare Advantage (MA)] organization must not accept new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer [an MA] plan.'' We stated our reasons for the policy, specifying in the preamble of the interim final rule that, ''[o]ur reason for establishing this rule is to eliminate the potential for an organization to encourage higher-cost enrollees to enroll under its cost contract while healthy enrollees are enrolled in its risk-based [MA] plan. This [final] rule is consistent with our long-standing policy that entities not have both a risk and cost contract under section 1876 [of the Act] in the same area.'' (63 FR 35014 through 35015).

This provision was recodified at 42 CFR 422.503(b)(5) in regulations implementing the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, but the requirement, as well as the rationale for the requirement, remained intact.

Since this requirement only precludes ''the entity'' contracting as an MA organization from having a cost contract open to new enrollment, the prohibition does not apply to another separate legal entity owned by the same parent organization, such that two legal entities owned by the same parent could offer a competing cost contract and MA plan. We do not believe that this result is consistent with the original intent of the prohibition because it permits legal entities that are related to each other under a common parent organization to offer a cost contract and MA plan in the same service area, creating the same potential for the entities to move higher risk enrollees from one plan to another in order to take advantage of the differing Medicare payment rules for the two plan types or for other reasons that are not related to the enrollees' best interests.

To ensure that our original intent is realized and to eliminate the potential for organizations to move enrollees from one of their plans to another based on financial or some other interest, we propose to revise paragraph § 422.503(b)(5) so that an, ''entity seeking to contract as an MA organization must [n]ot accept, or share a corporate parent organization with an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.''

In making the proposed revision to paragraph § 422.503(b), we also propose to add the definition of ''parent organization'' to § 422.2 of the MA program definitions. We would specify that, ''Parent organization means a legal entity that owns one or more other subsidiary legal entities.'' We are requesting comments on whether a parent organization with less than a 100-percent interest in a subsidiary legal entity should trigger the prohibition we propose with the amendment at § 422.503(b)(5). Although the MA program regulations do not currently define the term ''parent organization,'' our proposed definition is consistent with the way the term is currently used in the context of the MA program, for example, when assessing an organization's business structure.

2. Two Year Limitation on Submitting a New Bid in an Area Where an MA Has Been Required To Terminate a Low Enrollment MA Plan (§ 422.504(a)(19))

Under § 422.506(b)(1)(iv), we must non-renew an MA plan that does not have a sufficient number of enrollees to establish that it is a viable independent plan option. We have currently interpreted the standard of whether the MA plan has a ''sufficient number of enrollees to establish that it is a viable independent plan option'' as meaning that the MA plan has fewer than 500 enrollees for non-SNPs and fewer than 100 enrollees for SNPs over a specified time period of 3 years. As we determine adjustments are appropriate, we will revisit this interpretation as part of annual plan guidance. In cases in which an MA plan has been non-renewed on this basis, it would defeat the intent and purpose of this rule if the MA organization could simply submit a new bid for the next year in the same area for the same type of plan that failed to attract enrollment over a number of years. Indeed, the problem addressed in § 422.506(b)(1)(iv) would be exacerbated, as the new plan would start out with no MA enrollees.

In section 3209 of the Affordable Care Act, the Congress added a new section

1854(a)(5)(C)(1) of the Act that clarified that CMS is not ''require[d] . . . to accept any or every bid submitted by an MA organization. . . .'' Section 1856(b)(1) of the Act further provides authority for CMS to establish MA standards by regulation, and section 1857(e)(1) of the Act also provides authority to impose contract requirements that CMS finds ''necessary and appropriate.'' Under the foregoing authority, we propose to revise § 422.504(a) to add a new contract requirement that stipulates that the Medicare Advantage Organization (MA organization) agrees not to submit a new bid of the same type of plan that has been non-renewed under § 422.506(b)(1)(iv) in the same service area as the non-renewed plan for 2 years after such a non-renewal.

We believe this requirement will enhance our ongoing efforts to ensure that MA organization offerings in a service area present beneficiaries with viable plans that are responsive to their needs.

3. Authority To Impose Intermediate Sanctions and Civil Money Penalties (§ 422.752, § 423.752, § 422.760 and § 423.760)

Section 1857(a) of the Social Security Act (the Act) provides the Secretary with the authority to enter into contracts with MA organizations, and section 1860D–12(b)(1) of the Act provides the Secretary with the authority to enter into contracts with Part D sponsors. Section 1857(g)(1) of the Act provides a list of contract violations for which the potential enforcement response under section 1857(g)(2) of the Act is the imposition of intermediate sanctions (sanctions) and/or civil money penalties (CMPs). Section 1860D–12(b)(3)(E) of the Act applies these provisions to Part D contracts. We codified this authority in the June 28, 2000 final rule with comment period entitled, ''Medicare Program; Medicare+Choice Program (65 FR 40170) for Part C, and the January 28, 2005 final rule entitled, ''Medicare Program; Medicare Prescription Drug Benefit'' (70 FR 4194) for Part D. The authority was codified at § 422.752 (Part C) and § 423.752 (Part D). We are proposing two changes to our existing authority to impose sanctions and CMPs.

First, section 6408 of the Affordable Care Act (Pub. L. 111–148) provided the Secretary with new authorities to impose sanctions or CMPs for violations of the Part C and D marketing and enrollment requirements. Section 6408 amended 1857(g)(1) of the Act by adding new sections (H) through (K). These provisions provide CMS with the authority to impose intermediate sanctions on an organization that enrolls an individual without prior consent (except in certain limited circumstances) or transfers an individual to a new plan without prior consent. They also specifically make it a contract violation to violate the Part C and D marketing requirements, and specify that it is a violation of the sponsor's Part C or D agreement with CMS for the sponsoring organization to employ or contract with any individual or entity who engages in the conduct described in paragraphs (A) through (J) of 1857(g)(1) of the Act.

We are proposing to revise our regulations to codify the aforementioned authorities at § 422.752 (Part C) and § 423.752 (Part D), following the statutory language with little modification.

Second, we are proposing changes to the regulations intended to clarify CMS' authority to impose CMPs for the violations contained in section 1857(g)(1) of the Act and corresponding regulations at § 422.752 (Part C) and § 423.752 (Part D). Existing regulations provide the government with authority to impose CMPs for the listed violations. The existing regulations, however, designate the Office of Inspector General (OIG) as the sole government agency with the authority to impose CMPs for the violations contained in § 422.752 and § 423.752. We are proposing to revise the language of these provisions to clarify that either CMS or the OIG may impose CMPs for the violations listed at § 422.752(a) and § 423.752(a), except § 422.752(a)(5) and § 423.752(a)(5). Only the OIG will continue to have the authority to impose CMPs for the violations at § 422.752(a)(5) and § 423.752(a)(5), regarding the misrepresentation and/or falsification of information furnished to CMS, an individual or other entity. CMS or the OIG will impose the CMPs in accordance with the amounts specified in section 1857(g)(2) of the Act and § 422.760 and § 423.760 of the corresponding regulations.

We are proposing to revise the existing regulations at § 422.752, § 423.752, § 422.760, and § 423.760 to effectuate this change.

4. Contract Termination Notification Requirements and Contract Termination Basis (§ 422.510 and § 423.509)

Sections 1857(c) and 1860D–12(b)(3)(B) of the Act provide us with the authority to terminate a Part C or D sponsoring organization's contract at any time if we make a determination that the contracting organization is substantially failing to meet contract requirements and expectations. Sections 1857(h)(1)(B) and 1860D–12(b)(3)(F) of the Act provide us with the procedures necessary to facilitate the termination of contracts held between CMS and MA organizations and Part D sponsors, respectively. The Part C contract termination authorities and procedures were codified into regulations in the June 29, 2000 final rule entitled, ''Medicare Program; Medicare+Choice Program'' (65 FR 40170) at § 422.510. Likewise, the Part D authorities and procedures were codified into regulations in the January 28, 2005 final rule entitled, ''Medicare Program; Medicare Prescription Drug Benefit'' (70 FR 4194) at § 423.509.

We are proposing three revisions to our existing regulations that relate to contract termination. First, we are proposing clarification of the scope of our authority to terminate Part C and D contracts under § 422.510(a) and § 423.509(a). Section 1857(c)(2) of the Act provides us with authority to terminate a Part C or D contract if we make a determination that the organization—

- Has failed substantially to carry out the contract;
- Is carrying out the contract in a manner inconsistent with the efficient and effective administration of this part; or
- No longer substantially meets the applicable conditions of this part.

Existing regulations at § 422.510 and § 423.509 reiterate the three bases for termination set forth in the statute, however, over time CMS has also included in regulation a number of specific violations within the scope of our statutory authority, that is, violations which meet the standard established by the statute. In the June 26, 1998 proposed rule (63 FR 34968, at 35018), we stated that ''[i]n addition to repeating the above statutory language, we are implementing this language by identifying specific circumstances that we believe constitute examples of [an MA] organization substantially failing to carry out either its contract, or carrying out its contract in a manner that is inconsistent with the effective and efficient administration.''

However, we have come to believe over time that the inclusion of our broad statutory authorities in the regulations, along with the more specific violations, has the potential to lead to confusion regarding the scope of our termination authority. Terminating a contract is the strongest action that CMS may take in response to an MA organization or Part D sponsor's noncompliance. It is imperative that both CMS and affected organization understand the standard

we apply when CMS has made a determination to end the contractual relationship. Therefore, we are proposing to modify the language at § 422.510(a) and § 423.509(a) to clarify our contract termination authority by separating the statutory bases from the examples. To effectuate this change we will need to renumber the lists of bases contained in § 422.510(a) and § 423.509. Because there are cross references using the current numbering scheme, we are also proposing to make several corresponding reference changes to reflect the renumbering of this section throughout parts 422 and 423. We believe that by making these changes, we will improve the clarity of this regulation.

Second, we are proposing revisions to our contract termination notification procedures contained at § 422.510(b)(1) and § 423.509(b)(1). Current regulations state that if CMS decides to terminate a Part C or D sponsoring organization's contract, we must notify the MA organization/Part D sponsor in writing 90 days before the intended date of the termination. We believe that the 90-day timeframe is not in the best interest of Medicare beneficiaries, in light of the fact that CMS terminates contracts in circumstances where an organization is significantly out of compliance with Part C and D requirements. We also think that the 90-day timeframe is unnecessarily long given the existing procedural protections and appeal rights provided for MA organizations and Part D sponsors.

The authorizing statute for Part C, at section 1857(h)(1)(B) of the Act (applicable to Part D pursuant to section 1860D–12(b)(3)(F) of the Act), states that the Secretary must provide reasonable notice and opportunity for hearing regarding the termination (including the right to appeal the initial determination); during this hearing process, the termination is effectively stayed pursuant to § 422.664 and § 423.652. Therefore, we believe that a 45-day timeframe better balances the need to provide contracting organizations with reasonable notice of the impending contract termination with the interests of the Medicare beneficiaries who are enrolled in a plan that is deficient enough in its adherence to Part C and/or D requirements that contract termination is necessary. We also propose to make necessary cross-reference changes in parts 422 and 423 at § 422.644(c)(1) and § 423.642(c)(1).

Additionally, in an effort to respond to changes in the media and information technology landscape, we are proposing a slight modification to the termination notification provision for the general public at § 422.510(b)(1)(iii) and § 423.509(b)(1)(iii) by proposing that contracting organizations now release a press statement to news media serving the affected community or county and posting the press statement prominently on the organization's Web site instead of publishing the notice in applicable newspapers.

Third, we are proposing minor revisions to the wording of our regulations at § 422.510 and § 423.509 to reflect the authorizing language contained in sections 1857(c)(2) and 1860D–12 of the Act. Specifically, we are proposing to replace the word ''fails'' with ''failed'' in the applicable provisions of § 422.510 and § 423.509. In current regulations both of the terms failed and fails are used when describing contract violations that may be the basis for a contract termination. We would like for this list to read consistently, therefore, we are proposing to revise the language as such. The purpose of this change is merely to ensure that consistent language is used throughout § 422.510 and § 423.509 and in no way changes the meaning or policy encompassed in these provisions.

5. Reducing the Burden of the Compliance Program Training Requirements (§ 422.503(b)(4)(vi)(C) and § 423.504(b)(4)(vi)(C))

Section 1857(a) of the Act provides the Secretary with the authority to enter into contracts with MA Organizations, and section 1860D–12(b)(1) of the Act provides the Secretary with the authority to enter into contracts with Part D sponsors. Sections 1860D–12(b)(3)(D)(i) and 1857(e)(1) of the Act, specify that these contracts shall contain other terms and conditions that the Secretary may find necessary and appropriate. When we implemented the Part C program, we determined that all Part C contracts (and subsequently Part D contracts) would require that the Part C or D organization has the necessary administrative and management arrangements to have an effective compliance program, as reflected in § 422.503(b)(4)(vi) and § 423.504(b)(4)(iv).

In the December 5, 2007 **Federal Register**, we published the ''Medicare Program; Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals and Intermediate Sanctions Process'' final rule (72 FR 68700). In that final rule, we established that compliance plans for sponsoring organizations must include training and education and effective lines of communication between the compliance officer and the sponsoring organization's employees, managers, and directors as well as their first-tier, downstream and related entities (FDRs). We reiterated the importance of this requirement in the October 22, 2009 proposed rule entitled, ''Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (74 FR 53634).

In the 2009 proposed rule, entitled, ''Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs,'' we addressed concerns about the burden on FDRs such as pharmacies, hospitals and physicians as a result of this requirement, given the likelihood that many of these entities and individuals contract with multiple contracting organizations. We were concerned that these FDRs would potentially have to participate in (largely duplicative) training for each organization with whom they contract. We requested public comments on how best to ensure that the training requirement continues to be met while not overly burdening the contracting organization or its FDRs. In response, we received numerous comments suggesting that CMS develop its own web-based trainings to lessen this burden on sponsors and FDRs (75 FR 19678 at 19688).

In response to these requests, we have created the CMS Standardized General Compliance Program Training and Education Module. Until now, we have offered this as an optional training. In this rule, we propose to require that all contracting organizations accept a certificate of completion of the CMS training as satisfaction of this general compliance program training requirement. We anticipate that this proposal will greatly reduce the burden on various sectors of the industry, including, but not limited to, insurance providers, hospitals, suppliers, pharmacists, and physicians.

Under this proposed change, Part D sponsors and Part C organizations would not be permitted to develop or implement sponsor specific training or provide supplemental training materials to fulfill the general compliance program training requirement; only CMS training would suffice.

We understand that sponsors often include sponsor specific information (such as compliance officer's contact information, compliance reporting processes and expectations, hotline number or email address for compliance questions, Web site information for accessing the sponsor's compliance policies and procedures) in the training materials provided to the FDRs and will need an appropriate mechanism for

conveying this information given that the training vehicle will no longer be available. To address this issue, a sponsor may choose to include such information in the contract held between the sponsor and the FDR. Alternatively, we would allow each sponsor to develop a one page information sheet containing this material, to be distributed by the sponsor to each of its FDRs. We seek comments concerning this portion of our proposal and suggestions on other options we could implement to accomplish the desired outcome.

We are proposing to modify the regulation text by adding a new § 422.503(b)(vi)(C)(3) and § 423.504(b)(vi)(C)(4) to permit only this CMS training for satisfaction of the requirement to train FDRs.

6. Changes to Audit and Inspection Authority (§ 422.503(d)(2) and § 423.504(d)(2))

Sections 1857(d)(2)(A) and 1860D–12(b)(3)(C) of the Act specify that each contract under these sections must state that CMS has the right to audit and inspect the facilities and records of each organization. We are proposing three changes to our audit and inspection authority. First, under section 6408 of the Affordable Care Act new authority was provided to the Secretary that now requires that each contract provide the right to ''timely'': (1) Inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the contract; (2) inspect or otherwise evaluate the facilities of the organization when there is reasonable evidence of some need for such inspection; and (3) audit and inspect any books, contracts, and records of the organization that pertain to (a) the ability of the organization or its first tier or downstream providers to bear the risk of potential financial losses; or (b) services performed or determinations of amounts payable under the contract.

Therefore, we are proposing to revise both § 422.503(d)(2) and § 423.504(d)(2) to reflect this change. Specifically, we are proposing to insert the word ''timely'' at the end of both of the introductory paragraphs for § 422.503(d)(2) and § 423.504(d)(2).

Second, we are proposing to add authority that will allow CMS to require MA organizations and Part D sponsors to hire an independent auditor to perform full or partial program audits to determine compliance with CMS requirements.

MA organizations and Part D sponsors must adhere to CMS requirements to properly administer Part C and Part D benefits. These requirements are contained in statute, regulations and in the Part C and Part D sponsor agreements themselves. CMS needs assurance that MA organizations and Part D sponsors are substantially adhering to Part C and/or D requirements, and that Medicare beneficiaries are receiving the benefits to which they are entitled. To determine the extent of MA organization and Part D sponsor compliance with program requirements, CMS uses a variety of oversight and monitoring tools including CMS-conducted program audits.

CMS conducts a program audit by examining core operational areas and functions and determining the sponsors' level of compliance with these Part C and Part D program requirements. CMS may audit any program requirement, but in recent years we have focused on Part C and Part D coverage decisions, appeals, grievances, compliance program effectiveness, and formulary administration. CMS reviews a number of targeted samples to evaluate MA organizations and Part D sponsors' processes and systems. Targeting samples is an efficient way to highlight deficiencies and ensure that they are quickly and successfully remediated. The process is primarily designed to be educational for the MA organization and/or Part D sponsor as it expands the sponsor's understanding of CMS' expectations, and how program requirements are to be applied. It also identifies areas of risk or actual non-compliance so sponsors can quickly correct the deficiency. This understanding allows the MA organization and/or Part D sponsor to develop and implement a robust internal auditing and monitoring program to identify deficiencies before they reach a level of substantial non-compliance in the future. An effective monitoring program should result in early detection of system and process failures and should lead to problems being fixed quickly and steps being implemented to prevent future failures.

Organizations that are chosen for audit fall into at least one of the five following categories: High Star rated plans; sponsors with a Low Performing Icon (LPI); high risk plans (based on a data driven risk assessment); sponsors not audited in last 3 years, and CMS Regional or Central Office referrals. Annually, CMS conducts a risk assessment to determine which high-risk organizations to audit. Many of the program audits currently being conducted are with organizations whose contract performance or data indicators demonstrate the potential risk of failing to perform core program functions that, if not complied with, may result in potential beneficiary harm. These audits are a useful tool to help identify systemic deficiencies and failures in meeting CMS requirements and they help to promote compliance with those requirements. While these types of audits are necessary because these organizations pose the most risk, not all organizations are receiving the benefit of having an independent audit of their organization on a regular basis.

CMS is constrained in the number of program audits we can conduct each year, due to limited resources. Currently, CMS has close to 300 parent organizations that perform MA and/or Part D functions. CMS is only able to audit approximately 30 parent organizations per year; or roughly 10 percent of all MA organizations and/or Part D sponsors. CMS believes that MA organizations and/or Part D sponsors, their enrollees, and the Medicare program all benefit from a regular cycle of independent auditing. Therefore, we are proposing to revise our regulations to allow CMS to require MA organizations and/or Part D sponsors to hire an independent auditor to conduct regularly scheduled program audits in accordance with CMS specifications.

We currently make all of our program audit protocols available to MA organizations and/or Part D sponsors through our Web site. Pursuant to the proposed new regulatory provision, CMS would notify the MA organization and/or Part D sponsor that it has been selected to perform a full or partial program audit. The MA organization and/or Part D sponsor would then be required to engage an independent auditor to perform a full or partial program audit as directed by CMS using the CMS published protocols, methodologies, and methods of evaluation. At the conclusion of the audit, at the direction of the MA organization and/or Part D sponsor, the independent auditor will provide a draft copy of its findings to CMS and the MA organization and/or Part D sponsor. Once the MA organization and/or Part D sponsor has had an opportunity to rebut any findings, the independent auditor will provide its final report of findings to CMS and the MA organization and/or Part D sponsor. CMS anticipates that additional instruction will be necessary to interpret and implement this audit requirement of a complete and full independent review. Therefore, we intend to develop and release sub regulatory guidance to address, among other things, language and specifications which should be included in the contract between the sponsoring

organization and the independent auditor conducting the audit. The proposed authority will allow CMS to better evaluate MA organizations' and Part D plan sponsor's performance. With the proposed approach, each MA organization and/or Part D sponsor will be required to undergo an independent program audit at least every 3 years. Under this proposal, more organizations will be audited each year, which will provide CMS with substantially more data to evaluate program-wide performance, improve industry performance and protect beneficiaries enrolled in the Medicare Advantage and Prescription Drug Benefit programs. This will enhance CMS's oversight and provide us with information that enables us to focus our time and resources in the areas most needed to ensure compliance with Part C and Part D program requirements.

CMS will continue to perform program audits in limited scenarios, such as when indicated by a risk analysis; and will perform limited ''look back'' audits to ensure the integrity of the independent audit process proposed here. The latter audits will focus on reviewing the program audit findings that we receive from the independent auditors engaged by the Part C and Part D organizations, to ensure that the independent auditor conducted the audit in accordance with CMS specifications. We think that this additional authority will significantly strengthen the Medicare Parts C and D audit and oversight program.

Therefore, we are proposing to add language to § 422.503(d)(2) and § 423.504(d)(2) that will allow us to require a MA organization or Part D sponsor to hire an independent auditor, working in accordance with CMS specifications, to perform program audits to determine compliance with CMS requirements and provide to CMS an attestation affirming that the audit has been completed as required.

Third and finally, we are proposing to revise our regulations to specifically permit CMS to require MA organizations or Part D sponsors with audit results that reveal non-compliance with CMS requirements to hire an independent auditor to validate that correction has occurred. We may invoke this authority regardless of whether an independent auditor or CMS conducted the program audit that identified the programmatic deficiencies.

When program audits are conducted, non-compliance with CMS requirements is often found. When CMS finds these deficiencies, it notifies the MA organization or Part D sponsor of its non-compliance and requires correction. We do not close out audits until we have validated that correction has occurred. While we firmly believe in the value of such validation, these efforts are also limited by resources. In order to assist us in making the determination that the deficiencies found during the audit have been corrected and are not likely to recur, we need to have greater flexibilities in performing validation activities. Therefore, we are proposing that we may require a MA organization or Part D sponsor to hire an independent auditor to provide us with additional information to determine if the deficiencies found during the course of the audit have actually been corrected and are not likely to recur. The independent auditor would be hired by the MA organization and/or Part D sponsor and work in accordance with our specifications in order to provide accurate and reliable information to CMS.

CMS often relies on self-disclosed information from the MA organization or Part D sponsor, CMS and plan data; in the alternative, we must attempt to engage in a process to independently verify that deficiencies have been corrected. Given the nature and extent of some compliance deficiencies and the level of skill and experience required to conduct an exhaustive verification of correction, we have concluded that an independent auditor hired by the MA organization or Part D sponsor would be beneficial for both the organization and CMS.

This proposal is also consistent with our regulatory authority at 42 CFR 422.756 and 423.756 which permits us to require a sanctioned organization to hire an independent auditor to help us determine if a sanction should be lifted. Program experience has demonstrated other situations when the expertise of an independent auditor would be helpful in determining correction. For example, an independent auditor who specializes in complex information technology systems and who has specialized knowledge of how those systems interact with each other, in order to be compliant with our requirements, may be helpful in ensuring timely and successful correction of complex claims processing deficiencies. This is one example of a situation where we may require the MA organization or Part D sponsor to hire an independent auditor in order to assist in making the determination that the deficiencies found during the program audit have been corrected.

Therefore, we are proposing to add language to § 422.503(d)(2) and § 423.504(d)(2) that will allow us to require that a sponsoring organization hire an independent auditor, working in accordance with CMS specifications, to provide us with additional information to determine if the deficiencies that were found during a program audit have been corrected.

7. Procedures for Imposing Intermediate Sanctions and Civil Money Penalties Under Parts C and D (§ 422.756 and § 423.756)

Sections 1857(g) and 1860D–12(b)(3)(E) of the Act provide the Secretary the ability to impose intermediate sanctions on MA organizations and PDP sponsors. Intermediate sanctions consist of suspension of enrollment, suspension of marketing and suspension of payment. Current regulations governing intermediate sanctions are contained in subparts O of part 422 and part 423. Sections 422.756 and 423.756 provide specific procedures for imposing intermediate sanctions, and include provisions which address the duration of the sanction and the standard that we apply when determining if a sanction should be lifted. As specified in the Act and regulations, when intermediate sanctions are imposed on sponsoring organizations, the sanctions remain in place until we are satisfied that the basis for the sanction determination has been corrected and is not likely to recur.

Because sanctions remain in place until the deficiencies have been corrected and we are assured that they are not likely to recur, we are unable to fully test the contracting organization's compliance with certain requirements until the sanction is lifted. Therefore, in the October 2009 proposed rule, entitled ''Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (74 FR 54634), we proposed a rule, later finalized in the April 15, 2010 ''Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (75 FR 19678), that allows us to require a plan under a marketing and/or enrollment sanction to engage in a test period of marketing or accepting enrollments or both for a limited period of time. As we explained in that proposed rule, the purpose of the test period is to assist us in making a determination as to whether the deficiencies that are the bases for the intermediate sanctions have been corrected and are not likely to recur. The test period provides us with the opportunity to observe a sanctioned plan's ability to enroll or market to Medicare beneficiaries prior to lifting

the sanction. Since finalizing that rule in April 2010 (75 FR 19678), we have further considered its utility as a result of compliance issues that we have encountered over the past 2 years. We are proposing two modifications to this existing rule. First, we are proposing to expand the potential applicability of the test period requirement to all types of all intermediate sanctions. The existing regulation would only allow CMS to require this test period in instances where CMS has imposed a marketing and/or enrollment sanction. However, the type of intermediate sanction imposed is not necessarily related to the particular violations that form the basis for the sanction. Therefore, we are proposing to modify the existing rule to clarify that CMS may require a test period for a sponsoring organization that has had any of the three types of intermediate sanctions imposed: marketing, enrollment and/or payment.

We also want to clarify that our ability to require this test period is not limited to sanctions stemming from marketing or enrollment violations. In the preamble language for the October 2009 proposed rule, (74 FR 54634), we stated that ''[t]he basis for this proposal is that we have found that there is often not a satisfactory way to determine if marketing and/or enrollment problems have been corrected while a sanction is in place and no such activities are permitted.'' Upon reflection, we are concerned that this statement may have given the impression that the test period would only be used in instances where the underlying bases for the sanction are marketing and/or enrollment deficiencies. Therefore, we are clarifying here that the purpose of the test period is to assist us in making a determination as to whether the deficiencies that are the bases for the intermediate sanction have been corrected and are not likely to recur. The aforementioned deficiencies may be in any operational area, and are not limited or restricted to enrollment and/or marketing deficiencies.

Second, we are proposing to clarify the enrollment parameters for Part D contracting organizations that are under the benchmark and would normally participate in the annual and monthly auto enrollment process for beneficiaries who receive a low income subsidy (LIS) during a test period. During a test period, sanctioned Part D plans may not be allowed to receive or process these types of enrollments.

LIS beneficiaries are a vulnerable population who are particularly sensitive to financial instability. It is critical that Part D sponsors correctly identify a beneficiary's LIS status. Our goal when enrolling this particular population is to ensure that these vulnerable beneficiaries are best able to access their drugs and services in the manner to which they are entitled under the Part D program. We believe that if we allow auto-enrollments into a plan that has recently demonstrated substantial non-compliance with our regulations as evidenced by the imposition of an intermediate sanction, these vulnerable beneficiaries may experience difficulties in accessing prescription drugs. Therefore, we are proposing to make clear that we may determine that a sanctioned plan is not available to receive automatically assigned beneficiaries for the entire duration or a portion of the testing period.

We are proposing to modify the regulation text at § 422.756 and § 423.756 to reflect these changes.

8. Timely Access to Mail Order Services (§ 423.120)

Section 1860D 12(b)(3) of the Act authorizes the Secretary to include contract terms for Part D sponsors, not inconsistent with the Part C and D statutes, as necessary and appropriate. Section 423.120(a)(3) specifies that a Part D sponsor's contracted network may include non-retail pharmacies, including mail order pharmacies, so long as the network access requirements are met. Part D plans are increasingly entering into contracts with mail order pharmacies to offer beneficiaries an alternative way to fill prescriptions under the Part D benefit, often at much lower cost sharing than is available at network retail pharmacies. While mail order pharmacies make up a relatively small percentage of total prescriptions filled under the Part D program, we are committed to ensuring consistent and reliable beneficiary access to medications, regardless of what type of pharmacy fills the prescriptions.

Section 1860D–4 of the Act describes the various beneficiary protections in place in the Part D program. It is the industry standard in retail and institutional pharmacies to fill almost all prescriptions on the same day the prescription is presented. We have established a 24 hour fulfillment standard for home infusion drugs covered under Part D (§ 423.120(a)(4)(iv)). For mail order pharmacies, the industry standard for delivery times appears to range from 7 to 10 business days from the date the prescription was received, and Part D sponsors' marketing materials often specify this time frame to beneficiaries. Beneficiaries generally choose to fill prescriptions through a mail order pharmacy, for lower cost sharing, when it is feasible to wait 7 to 10 days to receive their medications. However, if this time frame is disrupted, beneficiaries may experience gaps in therapy.

We are aware of a specific instance in which significant incentives (for example, zero cost sharing) caused increased demand for mail order prescriptions sufficient to disrupt the delivery time frame, and we are concerned about the adverse effect such incentives might have on beneficiaries. When issues with filling a prescription arise in a retail setting, the beneficiary often is notified of the problem in real time, or within hours of discovery. When issues arise in a mail order setting, the delays in finding, communicating, and making the appropriate contacts to resolve the problem may add days onto the ultimate delivery date, resulting in a potentially more significant concern for mail order beneficiaries if these delays result in gaps in therapy. For this reason, we believe it is necessary and appropriate to establish fulfillment requirements for mail order pharmacies as well as home delivery services offered by retail pharmacies, to set consistent expectations for beneficiary access to drugs in this growing segment. Many beneficiaries may be very well served by this type of pharmacy access, but only if they can rely upon efficient processing and turnaround times. Mail order pharmacies contracted by Part D sponsors can reasonably be expected to meet minimum performance standards for order fulfillment, including convenient order turnaround times, as a beneficiary protection and as a component of providing good customer service. Clearly stating in beneficiary materials the expected turnaround time for delivery allows the beneficiary to better control when they need to reorder to ensure no gaps in medication supply. Clarity in expected turnaround times also can prevent needing to address customer inquiries into the status of a pending order, setting parameters for when an order is or is not delayed and what options become available at that point. We believe that established companies that have been providing these services for years have generally been meeting these standards in practice already, and that the proposed turnaround times are in line with current practices followed by mail order pharmacies today. Establishing mail order fulfillment requirements as a contract term would require plan sponsors to require that all pharmacies in its network meet the same minimum

level of service. This would underscore the importance of consistent and reliable access to medications, protecting beneficiaries from inconsistent or unreliable practices that may otherwise jeopardize timely access to prescriptions.

Therefore, we are proposing to amend § 423.120(a)(3) to specify mail order fulfillment requirements in line with what we have observed in other markets: 5 business days (from when the pharmacy receives the prescription order to when it is shipped) for those prescriptions requiring intervention beyond filling (such as clarifying illegible orders, resolving third party rejections, and coordinating with multiple providers as part of drug utilization management); and 3 business days (from when the pharmacy receives the prescription order to when it is shipped) for those prescriptions not requiring intervention. We recognize that some prescription orders may require clarification or additional steps to be taken by the provider or beneficiary that will extend beyond the proposed period of 5 days. We believe that such cases represent a minority of mail order prescriptions, and as such we would anticipate that more than 99 percent of all mail order prescriptions processed are filled in compliance with either the 3- or 5-day standard. We believe our proposed standards are in alignment with fulfillment requirements already in place in the market and as such do not create a new burden or new standard for mail order pharmacies to meet. We are soliciting comments not only on the proposed time frames, but also on whether there are instances (in addition to those discussed previously) in which the proposed 5-day time frame should apply.

We additionally are soliciting comments on whether we should establish additional requirements for beneficiary materials relating to mail order services, such as: clear definitions of processing time and delivery time; how to access customer support; how to submit a complaint via 1 800 MEDICARE; and beneficiary options for accessing medications when a delivery is lost or delayed.

We also welcome comments on any other requirements we should consider for mail order or other home delivery options. For example, also potentially affecting consistent access to medication is the use of mail order to fill initial prescriptions of new drugs or to fill 30-day supplies of chronically used medications. The need to order a refill early, allowing sufficient time for processing and delivery, can result in refill too soon edits based upon retail 30 day standards. Resolving inappropriate or inapplicable edits increases burden on the beneficiary and the mail order pharmacy and essentially creates a disincentive for beneficiaries who are planning ahead and attempting to order early enough to ensure un-interrupted supplies of chronic medications. In general, we believe that filling initial prescriptions or routine 30-day supplies at mail order is not good practice. We recognize that there may be a small minority of beneficiaries who successfully depend solely upon mail order or other home delivery options for access to prescription drugs due to particular circumstances of geography or mobility. We have no reason to discourage their continued use of these services. However, due to the difficulties reported to CMS with consistently and effectively filling short time frame supplies through mail order, we do not believe that Medicare beneficiaries in general should be incentivized through lower cost sharing to utilize mail order pharmacies for initial prescriptions or 30-day supplies.

9. Collections of Premiums and Cost Sharing (§ 423.294)

Since the beginning of the Part D program, when asked whether Part D sponsors could waive premiums and cost sharing we have responded that reducing or waiving either of these amounts would be inconsistent with the approved bid. The bid requirements, specified in section 1860D–11(e)(2)((C) of the Act, state the bid must reasonably and equitably reflect the revenue requirements of the expected population for the benefits provided under the plan. Waiving or reducing the cost sharing and/or premiums that are reflected in the approved bid would indicate that the plan bid was overstated and the amounts were not necessary for the provision of coverage. However, recently we have received reports of sponsors reducing or waiving cost-sharing and/or premiums. As a result, we propose to codify requirements for sponsor collection of cost sharing and premiums in regulation.

In addition to violating the bid requirements, as we noted in the preamble of the October 22, 2009 proposed rule entitled, ''Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (74 FR 54690), waiving cost sharing or premiums also violates the uniform benefit requirements because doing so results in the plan's not providing the same coverage to all eligible beneficiaries within its service area. Section 1860D–2(a) of the Act defines qualified prescription drug coverage to mean access to standard or actuarially equivalent prescription drug coverage and access to negotiated prices (in accordance with section 1860D–2(d) of the Act). Thus, a Part D sponsor must offer its plan to all eligible beneficiaries residing in the plan's service area. We further interpret section 1860D–2(a) of the Act as requiring the provision of uniform premium and benefits and have codified these requirements in our regulations at § 423.104(b).

Once CMS has approved a sponsor's Part D benefit package, it cannot be varied for some or all of the plan's Part D enrollees. Thus, sponsors must commit to providing the level of benefits described in the sponsor's benefit package and cannot waive or reduce cost sharing, as that would violate the uniform benefit provisions set forth in § 423.104(b). This is true regardless of whether the Part D sponsor waives the copayment directly or indirectly through an affiliate, and regardless of whether such a waiver is prohibited by other laws. Some Part D sponsors are related to pharmacies through common ownership or control, and we note that an exception to the anti-kickback statute, set forth in section 1128B(b)(3)(G) of the Act, permits a pharmacy to waive cost sharing (that is, coinsurance and deductibles) imposed under Part D, if the conditions described in clauses (i) through (iii) of section 1128A(i)(6)(A) of the Act are met. These conditions include that the waiver is not advertised (through media outlets, telemarketing or otherwise) and is not routine, and the cost sharing is waived after a good faith determination that the individual is in financial need [1] or reasonable efforts to collect the cost sharing have failed. This exception may protect from sanctions under the anti-kickback statute the waiver of cost sharing by pharmacies owned by Part D sponsors. However, as noted in the proposed rule, entitled ''Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (74 FR 54690), sponsor failure to collect or attempt to collect cost sharing at the time the service is provided or to bill cost sharing to the appropriate party (either a beneficiary or another payer) after the fact, is a violation of the uniform benefit provisions set forth in the current regulation at § 423.104(b). The fact that cost sharing is waived by a pharmacy

[1] Under section 1128B(b)(3)(G) of the Act, an individual determination of financial need is not required for Part D beneficiaries eligible for the low-income subsidy under section 1860D–14 of the Act.

that is related to a Part D sponsor by common ownership, rather than the Part D sponsor itself, and that it may be protected from sanctions under the anti-kickback statute, does not relieve the Part D sponsor of responsibility for this violation of the uniform benefit provisions. If a pharmacy is unrelated to a Part D sponsor and waives cost sharing under the conditions previously described, the pharmacy is making an independent business decision to which the Part D sponsor is indifferent. However, if an affiliated pharmacy waives cost sharing for a beneficiary enrolled in the sponsor's Part D plan, the sponsor is not indifferent because the cost-sharing waiver is more likely to be a strategic decision by the sponsoring organization to move market share to the related-party pharmacy and increase profits to the sponsor. Thus, the sponsor is altering the level of cost sharing in the approved bid in violation of the uniform benefit provisions in § 423.104(b). To clarify this for all parties, we propose to codify the prohibition of the waiver or reduction of premiums and cost sharing by adding a new section at § 423.294. We propose to specify that Part D sponsors either directly, or indirectly through related party pharmacies, as defined in regulation at § 423.501, are prohibited from reducing or waiving collection of premiums and cost sharing. In contrast, a pharmacy affiliated with one Part D sponsor may waive Part D cost sharing for beneficiaries enrolled Part D plans offered by other sponsors without violating the uniform benefit provisions.

Additionally, we have become aware that the regulations in Part 423 do not address Part D sponsor requirements for refunding incorrect collections of premiums and cost sharing or for retroactively collecting underpayments of cost sharing. Therefore, we also propose to codify requirements at § 423.294 that mirror the language at § 422.270. We propose to apply the timeframe in § 423.466(a) to these refunds and recoveries. In other words, whenever a sponsor receives information that necessitates a retroactive refund of incorrect collections of premiums and/or cost sharing or collection of underpayments of cost sharing, the sponsor would be required to issue refunds or recovery notices within 45 days. For incorrect collections, we propose to duplicate the language at § 422.270 with one exception. That is, in the absence of authority to do so, we are not proposing to reduce Part D sponsor premiums for failure to refund amounts incorrectly collected from Part D enrollees. Instead, we propose that sponsors that fail to meet these requirements may receive compliance notices from CMS or, depending on the significance of the non-compliance, be the subject of an intermediate sanction (for example, suspension of marketing and enrollment activities) pursuant to Part 423, Subpart O.

10. Enrollment Eligibility for Individuals Not Lawfully Present in the United States (§ 417.2, § 417.420, § 417.422, § 417.460, § 422.1, § 422.50, § 422.74, § 423.1, § 423.30, and § 423.44)

a. Basic Enrollment Requirements

Sections 226 and 226A of the Act establish the conditions for Medicare Part A entitlement for individuals who have attained age 65, are disabled or have end-stage renal disease (ESRD), and are entitled to monthly Social Security benefits under section 202 of the Act. Individuals entitled to Part A under these sections do not have to pay premiums for such coverage, and they may, but are not required to, enroll in Medicare Part B. Section 1818 of the Act establishes the conditions for Medicare enrollment for individuals who are not entitled to monthly Social Security benefits under section 202 of the Act. Individuals covered under section 1818 of the Act must meet citizenship or alien status requirements, in addition to other requirements, in order to enroll in Part B. Individuals must have Part B in order to purchase Part A hospital insurance.

Sections 1851(a)(3)(B), 1860D–1(a)(3)(A), and 1876(a)(1)(A) of the Act outline the eligibility requirements to enroll in MA (Part C), Medicare prescription drug coverage (Part D), and Medicare cost plans. Under all options, individuals must have active Medicare coverage. Specifically, to enroll in MA, an individual must be entitled to benefits under Part A and be enrolled in Part B; to enroll in Part D, an individual must be entitled to Part A and/or enrolled in Part B; to enroll in a Medicare cost plan, an individual must be enrolled in Part B (Part A entitlement is not required).

b. Medicare Eligibility and Lawful Presence

Section 401 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA), amended by section 5561 of the BBA, mandates that qualified aliens not lawfully present in the United States are not eligible to receive any federal benefit. This is outlined in 8 U.S.C. 1611 (Aliens who are not qualified aliens ineligible for federal public benefits) and 8 U.S.C. 1641 (Definitions). The definition of qualified alien is codified in 8 CFR 1.3 (Lawfully present aliens for purposes of applying for Social Security benefits).

The aforementioned provisions affect eligibility to receive benefits that would otherwise be payable under provisions in the Act. For example, aliens meeting certain criteria are able to earn qualified credits towards Social Security retirement benefits as outlined in 8 U.S.C. 1631 (Federal attribution of sponsor's income and resources to alien) and 8 U.S.C. 1645 (Qualifying quarters). Such individuals may earn the total number of qualified credits to be eligible under the Act to receive retirement benefits under sections 226 and 226A of the Act. However, should such individuals be unlawfully present in the United States under the previously mentioned PRWORA provisions, they are not eligible to receive the Social Security benefits they have earned for as long as they remain unlawfully present. At such time as they are lawfully present in the United States, or live outside the United States, they would again become eligible to receive Social Security payments.

Similarly, when aliens become eligible for Medicare based on age or disability under the terms of the Act, they would also automatically be entitled to premium free Part A benefits and be eligible to enroll in Part B during a valid enrollment period. Furthermore, aliens receiving Social Security retirement benefits 4 months prior to turning 65, or are in their 21st month of receiving Social Security disability benefits, would, under the terms of the Act, also automatically be enrolled into both Part A and Part B consistent with section 1837 of the Act and the enrollment process outlined in § 407.17. Again, however, under PRWORA, these individuals are not eligible to receive payment of Medicare benefits for so long as they are unlawfully present in the United States. Only upon becoming lawfully present would they become eligible to receive the Medicare benefits to which they would otherwise be entitled by paying into Social Security for the requisite number of quarters or paying premiums.

We note that current regulations at § 406.28 and § 407.27 outline the reasons for loss of premium Part A and Part B enrollment, and do not include the absence of lawful presence or citizenship as a reason for loss of entitlement. Individuals who are entitled to Part A and enrolled in Part B based on eligibility of Social Security benefits currently may be enrolled in

Medicare even if they are not lawfully present in the United States.

When PRWORA was enacted, the Act was not amended to include the additional eligibility criteria for entitlement to either Social Security benefits or for Medicare Part A entitlement, nor were new provisions put into place regarding termination of entitlement or establishment of a special enrollment period to account for situations in which individuals reestablished lawful presence. As a result, individuals who meet the current statutory eligibility criteria have been reflected in CMS records as entitled to both Social Security benefits and Medicare coverage.

c. Alignment of MA, Part D, and Cost Plan Eligibility With Fee-For-Service (FFS) Payment Exclusion Policy

In order to implement 8 U.S.C. 1611 and ensure that individuals who are present in the United States unlawfully do not receive benefits, the Social Security Administration (SSA) established internal policies and procedures to suspend Social Security benefits during periods for which individuals are unlawfully present in the United States. Because Medicare entitlement flows from entitlement to Social Security retirement and disability benefits, Medicare also has implemented this provision through a payment exclusion process.

Under Medicare's payment exclusion process, data on lawful presence is transmitted to CMS from the Department of Homeland Security via regular data exchanges from SSA. Once the data is received by us, the lawful presence status is noted on an individual's record and is retained in the FFS claims processing systems. As a result, we deny payment of both Part A and Part B claims for non-citizens where lawful presence is not established on their record, and do so until individuals regain their lawful presence status. Although payment is being denied for claims, individuals who are ''fully insured'' per section 226 of the Act, maintain Part A entitlement and remain enrolled in Part B on CMS records as long as premiums are paid. Similarly, individuals who are enrolled in premium Part A and/or Part B, maintain their enrollment status as long as premiums are paid.

Although CMS implementation of the lawful presence criteria in the FFS program achieved the intent of PRWORA by preventing FFS payments for services rendered to individuals who are not lawfully present, this policy was not adopted in regulations for Part A and Part B eligibility in 42 CFR parts 406 and 407 or addressed in regulations or subregulatory guidance for MA, Part D, and Medicare cost plans. Thus, individuals who are not lawfully present, but are nevertheless shown on CMS records to be entitled to Medicare Part A and/or enrolled in Part B, have been able to enroll in MA, Part D, and Medicare cost plans and obtain Medicare coverage for which they should not be eligible under 8 U.S.C. 1611. By permitting these MA, Part D and cost plan enrollments to remain in place, we are allowing improper payments to be made to plans on behalf of these individuals, which in turn impacts the Medicare Trust Funds. In addition, MA organizations, PDP sponsors and cost plans are making benefit payments under the Medicare program on behalf of these enrollees that are similarly prohibited under PRWORA.

Therefore, we are proposing to align eligibility for enrollment in MA, Part D, and cost plans (and resulting Medicare payments to plans and by plans that violate PRWORA) with the FFS payment exclusion policy to ensure that Medicare is only paying for services rendered to individuals who are eligible to receive them. These steps are consistent with recommendations made by the Office of Inspector General in its January 2013 report (A–07–12–01116) regarding the need for CMS to maintain adequate controls to prevent and detect improper payments for Medicare services rendered to unlawfully present beneficiaries. Accordingly, we are proposing to revise the regulations to establish U.S. citizenship and lawful presence as eligibility requirements for enrollment in MA, Part D, and cost plans. Further, we propose that individuals who are not lawfully present in the United States would be involuntarily disenrolled from MA, Part D, and cost plans, based on the date on which they lose their lawful presence status. Disenrollments would be effective the first of the month following the loss of eligibility, and the disenrollment process would follow that currently set forth in the regulations when an individual is no longer eligible to be enrolled in a plan.

These regulatory changes would prevent an individual from enrolling in a plan and/or remaining enrolled in a plan if they are not lawfully present in the United States. Affected individuals will retain their Medicare entitlement and remain enrolled in FFS, as long as premiums continue to be paid, but MA, Part D and cost plan payments would be denied for time periods during which the individuals are not lawfully present in the United States. We must ensure that in administering the Medicare program, all programs are compliant with 8 U.S.C. 1611. Specifically, we are proposing the following to address the eligibility and disenrollment of individuals not lawfully present in the United States:

- Sections 417.420, 417.422, 422.50, and 423.30 would be amended to add lawful presence or United States citizenship as eligibility criteria for enrollment in a cost, MA, or Part D plan, respectively.
- Sections 417.460, 422.74, and 423.44 would be amended to require the involuntarily disenrollment of individuals from cost, MA or Part D plans when they lose lawful presence status.

Conforming changes would be made to § 417.2, § 422.1, and § 423.1 to outline the authority for the aforementioned requirements, in 8 U.S.C. 1611 (Aliens who are not qualified aliens ineligible for Federal public benefits).

11. Part D Notice of Changes (§ 423.128(g))

Section 1860D 4(a) of the Act requires Part D sponsors to disclose to beneficiaries information about their Part D drug plans in standardized form. The Act further directs Part D sponsors to include, as appropriate, information that MA organizations must disclose under section 1852(c)(1) of the Act, which includes a detailed description of benefits. (In guidance, we refer to the document containing this information and delivered to beneficiaries as the Evidence of Coverage (EOC).) To make informed decisions, enrollees need to understand how their benefits, including premiums and cost sharing, would change from one year to the next, should they reenroll in the same plan. (In guidance, we refer to the documents containing this information and delivered to beneficiaries as the Annual Notice of Change (ANOC).) And enrollees also need to be aware of changes that may take place during the course of the year as well. Part D regulations currently do not include language found in the Part C regulations at § 422.111(d) requiring notice of changes to the plan to be provided to CMS for review pursuant to procedures for marketing material review and to all enrollees at least 15 days prior to the annual coordinated election period. Given that guidance applicable to both programs discusses notice of changes, we propose to require, for Part D, delivery of an ANOC.

Specifically, we propose to adopt in Part D, with modifications, the language contained in § 422.111(d). As is the case with the Medicare Advantage

regulation, proposed § 423.128(g) would require that Part D sponsors submit their changes to us under the procedures contained in subpart V of part 423, and, for those changes taking effect on January 1, provide a notice of changes to all enrollees 15 days before the beginning of the annual election period. While part 422 requires a minimum of 30 days' notice before the effective date for all other changes, proposed § 423.128 would not impose that standard, but rather would state that Part D sponsors remain subject to all other notice requirements specified elsewhere in the Part D regulations. Our proposal reflects a programmatic difference between Parts C and D: Under Part D it is not unusual for access to drugs listed on a plan's formulary to change during the course of a year. Changes can include changes to formulary status, tier placement, and utilization management or other restrictions. It is vital that beneficiaries currently taking a drug receive timely notice before such changes take place in order that they can decide whether to, for instance, change drugs or request an exception to cover the drug. Accordingly, our regulations currently specify when sponsors must provide notice of these kinds of changes. Our proposal to require the delivery of an ANOC is not intended to disrupt or change those existing notice requirements.

We would also like to take this opportunity to comment on the particular importance for Part D sponsors to provide notice in the ANOC of any changes they are making that will affect the amount of cost sharing which enrollees must pay for each drug belonging to a specific tier. As has been articulated in guidance, we continue to expect that sponsors will provide notice of such changes to all enrollees, including enrollees moved to a consolidated plan. Generally, sponsors compare numbers for the same plan from one year to the next in the ANOC. However, comparing numbers for the same plan would not benefit individuals moved from one plan to another. For instance, when a sponsor crosswalks members from a non-renewing plan to a consolidated renewal plan from one year to the next, cost sharing may change at the drug-tier level. For example, an enrollee who previously had zero cost sharing for all covered Part D drugs within the preferred generic tier may find that the consolidated plan now requires copays for drugs in that tier depending on how many months' supplies he or she orders, and whether he or she obtains those drugs at a retail level pharmacy or through mail order. We continue to expect that enrollees will receive ANOCs that clearly compare the non-renewed and consolidated plans' copayments or coinsurance for all drugs within each tier.

12. Separating the Evidence of Coverage (EOC) From the Annual Notice of Change (ANOC) (§ 422.111(a)(3) and § 423.128(a)(3))

As provided in sections 1852(c)(1) and 1860D–4(a) of the Act, MA organizations and Part D sponsors must disclose detailed information about the plans they offer to their enrollees. This detailed information is specified in section 1852(c)(1) of the Act and § 422.111(b) and § 423.128(b) of the Part C and Part D program regulations, respectively.

Under § 422.111(a)(3), we require MA plans to disclose a detailed plan description to each enrollee ''at the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period.'' A similar rule for Part D sponsors is found at § 423.128(a)(3). The content of the annual plan description is provided in paragraph (b) of the respective regulations. This is commonly referred to as the EOC. In addition, under § 422.111(d), we require MA organizations to notify all enrollees ''at least 15 days before the beginning of the Annual Coordinated Election Period'' of any changes that will take effect on January 1 of the next plan year. This notification is commonly referred to as the ANOC. Although our Part D guidance calls for Part D sponsors to provide an ANOC, there currently is not a regulatory requirement that they do so. Therefore, in the previous section of this proposed rule, we have proposed to codify such a requirement.

Prior to the 2009 contract year, these regulations required the provision of the EOC at the time of enrollment and at least annually thereafter but did not specify a deadline for the annual provision of the EOC. We permitted MA organizations and Part D sponsors to provide the EOC as late as January 31 of the applicable contract year. Therefore, prior to the annual coordinated election period (AEP) for the 2009 contract year, MA organizations and Part D sponsors may have provided the EOC and ANOC at different times. In the final rule entitled, ''Medicare Program, Medicare Advantage and Prescription Drug Programs; Final Marketing Provisions'' (73 FR 54220 and 54222), we required MA organizations to send the EOC at the same time as the ANOC (that is, 15 days before the AEP), with the result that the EOC was sent about 4 months earlier. Our rationale for this requirement was to provide beneficiaries with comprehensive information prior to the AEP. In addition, the consolidated mailing reduced the number of mailings to enrollees and eliminated duplicative information. However, we have found through consumer testing that beneficiaries receive multiple documents from their plans and CMS during the AEP that address similar topics, which at times beneficiaries find confusing or overwhelming. The ANOC, which is much shorter than the EOC, is intended to convey all of the information essential to a beneficiary's decision to remain enrolled in the plan or choose another plan during the AEP. Research based on the consumer testing suggests that participants were more likely to review the ANOC if it was not included with the EOC. For example, when asked about the utility of each document, many participants stated that they would read the ANOC as soon as they received it, and use it more often than a combined ANOC/EOC because the combined document is too much to worry about, too wordy, and/or too difficult to find information in compared to just the ANOC.

We have also found that sending the EOC months earlier has led to some unintended consequences. Specifically, the earlier deadline shortens the production time and affects the MA organization's or Part D sponsor's ability to produce an EOC that provides accurate benefit information in accordance with CMS required timeframes, which results in plans sending and beneficiaries receiving additional mailings containing errata sheets. We have reviewed plan ANOC/EOC documents for errors and found that, of the total number errors found, EOCs contain significantly more errors (86 percent) than the ANOCs (14 percent), which leads us to believe that allowing plans to have additional time to prepare EOCs would allow them to produce EOCs with fewer errors. Additionally, resources are wasted when beneficiaries are sent a combined ANOC and EOC, but ultimately decide to enroll in a different plan, and have no need for the EOC.

In order to help current members make timely and informed decisions about plan choices for the next year while ensuring that they continue to receive all the post-enrollment information necessary in a timely manner, we believe it would be more effective for them to receive an ANOC before the AEP, and then receive the EOC from the plan he or she chooses for

the next year after enrollment is effective. Therefore, we propose to require MA organizations and Part D sponsors to ensure that their current members receive the ANOC 15 days prior to the AEP, and receive the EOC no later than December 31st, for the contract year taking effect the following January 1st. To accomplish this, we propose to amend § 422.111(a)(3) and § 423.128(c)(3) to remove the current deadline and insert ''by December 31 for the following contract year.'' The deadline established by § 422.111(d)(2) for provision of the ANOC would continue to be 15 days prior to the beginning of the AEP. In addition, as mentioned previously, we are proposing to amend § 423.128 to require Part D sponsors to provide a separate ANOC and to adjust the time frames for delivery accordingly.

13. Agent/Broker Compensation Requirements (§ 422.2274 and § 423.2274)

Section 103(b)(1)(B) of MIPPA revised the Act to charge the Secretary with establishing guidelines to ''ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the MA plan that is intended to best meet their health care needs.'' Section 103(b)(2) of MIPPA revised the Act to apply these same guidelines to Part D sponsors. Our program experience indicates that some agents may encourage beneficiaries to enroll in plans that offer higher commissions without regard to whether plan benefits meet the beneficiaries' health needs. In recognition that agents and brokers play a significant role in providing guidance and advice to beneficiaries and are in a unique position to influence beneficiary choice, we had proposed, prior to the enactment of MIPPA, a rule to regulate agent and broker compensation. To implement the MIPAA provisions and relying in part on comments in response to our previously proposed rule, we adopted an interim final rule on September 18, 2008, entitled ''Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Final Marketing Provisions'' (73 FR 54208, at 54226), which, among other things, established the current compensation structure for agents and brokers in connection with Parts C and D. That rule remains significantly in place at § 422.2274 and § 423.2274, and our experience since then indicates that revision of the compensation requirements is appropriate to ensure that we continue to meet our statutory mandate.

The current compensation structure is comprised of a 6-year compensation cycle that began in contract year 2009. MA organizations and Part D sponsors were to provide an initial compensation payment to independent agents for new enrollees (year 1) and pay a renewal rate (equal to 50 percent of the initial year compensation) to independent agents for years 2 through 6. These rates were to be adjusted annually based on changes to the MA payment rates or Part D parameters as established by CMS. We later amended the regulations to allow MA organizations and Part D sponsors to compensate independent agents and brokers annually using an amount at or below the fair market value. (See the final rule with comment period entitled, ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes'' (77 FR 22072) published in the April 12, 2012 **Federal Register**.)

The 6-year cycle is scheduled to end at the end of CY 2013, on December 31, 2013. The first year, 2009, was considered to be the first renewal year, effectively making 2009 the second full year of compensation. Because our regulations were silent regarding compensation amounts for Year 7 and beyond, we stated in our Final Call Letter for Contract Year 2014, issued on April 1, 2013, that MA organizations and Part D sponsors could, at their discretion, pay agents and brokers the renewal amount for Year 7 and beyond. However, this subregulatory guidance was intended to be a temporary measure, pending changes to our regulations.

Under the current structure MA organizations and Part D sponsors pay an initial rate for the first year, and then a renewal payment of 50 percent of the initial compensation paid to the agent for years 2 through 6. This structure has proven to be complicated to implement and monitor as it requires the MA organization or Part D sponsor to track the compensation paid for every enrollee's initial enrollment, and calculate the renewal rate based on that initial payment. For example, assume that the same agent enrolls three beneficiaries; one in each of the 2012, 2013, and 2014 contract years. Beneficiary A is a new, initial enrollee in MA plan XYZ for CY2012. Assume that the fair market value (FMV) cut-off amount for agent services for CY 2012 is $400. Plan XYZ has decided that its initial compensation will be equal to the full FMV, resulting in a payment to the agent of $400. Beneficiary B is a new, initial enrollee in MA plan XYZ for CY2013. In CY2013, assume the FMV has increased to $420. Plan XYZ has again decided that its initial compensation will be equal to the full FMV for Beneficiary B, resulting in a payment to the agent of $420. Also in CY2013, Plan XYZ is required to pay a renewal amount of 50 percent of initial enrollment to the agent for Beneficiary A. Since the initial payment for Beneficiary A was $400, Plan XYZ will pay a renewal amount of $200. Beneficiary C is a new, initial enrollee in MA plan XYZ for CY2014. In CY2014, assume the FMV value has again increased to $430. The Plan's initial compensation is, again, equal to the full FMV. Plan XYZ's payments to the agent would be as follows: $430 for Beneficiary C (new, initial), $210 for Beneficiary B (renewal, 50 percent of the initial payment of the CY2013 FMV of $420), and $200 for Beneficiary A (50 percent of the initial payment of the CY2012 FMV of $400). Thus, Plan XYZ has to know, at any given time, the amount of the initial compensation for each plan year—going back as far as 2009—in which the member enrolled in order to pay the correct compensation amount to the agent. Moreover, MA organizations and Part D sponsors must first review CMS' reports to determine whether an initial or renewal payment should be made, and then combine that information with the FMV, or, if applicable, the plan's compensation set at less than the FMV, for each plan year to ensure the correct payments are made to agents. When these simple examples are multiplied by tens or thousands of members, the complexity and challenges associated with implementing the current compensation requirements becomes clear.

In addition to its complexity, we are concerned that the current structure creates an incentive for agents and brokers to move enrollees from a plan of one parent organization to a plan of another parent organization, even for like plan type changes. Currently, in these cases, the new parent organization would pay the agent 50 percent of the current initial rate of the new parent organization; not 50 percent of the original initial rate paid by the other parent organization. Thus, in cases where the FMV has increased, or the other parent organization pays a higher commission, the incentive exists for the agent to move beneficiaries from one parent organization to another. (See § 422.2274(a)(3) and § 423.2274(a)(3)). So, in the example provided previously, if Beneficiary A switched to Plan ABC for CY2014, Plan ABC would pay the same agent $215 (50 percent of the 2014 initial rate of $430), instead of the $200 renewal payment the agent would have received if Beneficiary A remained in

Plan XYZ. Although the mere $15 increase in the payment to the agent may not appear to be much of an incentive to move one enrollee, an agent would receive considerably more income by moving tens of enrollees to another plan.

Since 2008, we have received inquiries from MA organizations and Part D sponsors regarding the correct calculation of agent/broker compensation, and found it necessary to take compliance actions against MA organizations and Part D sponsors for failure to comply with the compensation requirements. To the extent that there is confusion about the exact levels or timing of compensation required, there could be an un-level playing field for MA organizations and Part D sponsors operating in the same geographic area. In addition, CMS' audit findings and monitoring efforts have shown that MA organizations and Part D sponsors are having difficulty correctly administering the compensation requirements. Therefore, we believe that simpler agent/broker compensation regulations that are easier to understand will better ensure that plan payments are correct and establish a level playing field that will further limit incentives for agents and brokers to move enrollees for financial gain.

We are proposing to revise the existing compensation structure for agents and brokers so that, for new enrollments, MA organizations and Part D sponsors could make an initial payment that is no greater than the FMV amount for renewals in Year 2 and beyond, the MA organization or Part D sponsor could pay up to 35 percent of the FMV amount for the renewal year, resulting in the renewal year payment changing each year if the MA organization or Part D sponsor chooses to pay 35 percent of the current FMV (that is, the renewal year FMV threshold). As we do now, we would interpret the FMV threshold in our annual guidance to MA organizations and Part D sponsors. This flexibility would enable MA organizations and Part D sponsors to better react to changes in the marketplace and adjust their compensation structures accordingly.

Under the proposed compensation structure, the calculations would be simpler than those required under the current rule, as shown in the following example:

Assume again that Beneficiary A is a new, initial enrollee in MA plan XYZ for CY2015. Assume the FMV for CY 2015 is $400. Plan XYZ has decided to pay the full FMV, resulting in a payment to the agent of $400. In CY2016, assume the FMV is $420. Again, Plan XYZ has decided to pay the maximum FMV for initial enrollments, so it pays the agent $420 for Beneficiary B, who is an initial enrollee. Plan XYZ has also decided to pay the maximum renewal payment (35 percent of the FMV), resulting in a payment of $147 ($420 x .35) to the agent for Beneficiary A. Thus, Plan XYZ's payments to its agents are based on the FMV for the contract year in question, regardless of when the beneficiary enrolled in the plan. That is, when making the renewal payment, Plan XYZ doesn't have to determine what the FMV was in the initial year, but only looks to the FMV for the current year and pays the chosen percentage up to the maximum 35 percent of the FMV established by CMS.

In order to implement these changes in the identical Part C and Part D regulations at, § 422.2274 and § 423.2274, we first propose to designate the definition of ''compensation'' as paragraph (a)(1) and to restate the fair market value limit on compensation for the initial year as paragraph (b)(1)(i). Second, we propose to combine the current (a)(1)(i)(B), which addresses payments for renewals, and (a)(1)(iii), which addresses the length of time that renewals should be paid, and designate the revisions as a new (b)(1)(ii). Thus, the new paragraph (b)(1)(ii) would state that plans may pay up to 35 percent of the current FMV and that renewal payments may be made for the second year of enrollment and beyond.

In addition, we propose to modify paragraph (a)(3) to remove the 6-year cap on the compensation cycle. Currently, paragraph (a)(3) refers to policies that are replaced with a like plan during the first year or the subsequent 5 renewal years. Since we are proposing to eliminate the 6-year cycle, our revised paragraph (b)(2) deletes the reference to the initial year and the 5 renewal years. By tying renewal compensation to the FMV for the renewal year, rather than the initial year of enrollment, our proposal reduces the financial incentives for an agent or broker to encourage Medicare beneficiaries to change plans, especially from one parent organization to another parent organization. As with the current regulation, we propose in paragraph (b)(2)(iii) that a change in enrollment to a new plan type be payable under the same rules that apply to an initial enrollment, regardless of whether the change is to an unlike plan type in the same parent organization or an unlike plan type in another parent organization. Note that, as with the current rule, our proposal only addresses compensation paid to independent agents and does not address compensation payable by an MA organization or Part D sponsor to its employees that perform services similar to agents and brokers.

For our proposed regulations, we considered several different alternatives, including prohibiting compensation payments entirely beyond year 6, permitting MA organizations and Part D sponsors to pay a residual payment for year 7 and subsequent years, and permitting existing renewal payments to continue. We also evaluated different renewal amounts, including a 50 percent renewal payment for years 2 through 6 with a continuing 25 percent residual payment for years 7 and beyond. The evaluation took into account different ages for an initial enrollment, as well as the life expectancy of beneficiaries. In the analysis, a continual renewal payment of 35 percent was similar in payout to the combination of a 50 percent payment for years 2 through 6 and a residual payment of 25 percent for year 7 and beyond. We believe that revising the existing compensation structure to allow MA organizations or Part D sponsors to pay up to 35 percent of the FMV for year 2 and beyond is appropriate based on a couple of factors. First, we believe that a two-tiered payment system (that is, initial and renewal) would be significantly less complicated than a three-tiered system (that is, initial, 50 percent renewal for years 2 through 6, and 25 percent residual for years 7 and beyond), and would reduce administrative burden and confusion for plan sponsors. Second, our analysis determined that 35 percent is the renewal compensation level at which the present value of overall payments under a two-tiered system would be relatively equal to the present value of overall payments under a three-tiered system (taking into account the estimated mortality rates for several beneficiary age cohorts). This analysis is based on the existing commission structure basing renewal commissions on the starting year initial commission amount and not the current year FMV amount. We welcome comments on both the amount of the renewal payment as well as the proposed indefinite time frame.

Current regulations at § 422.2274(a)(4) and § 423.2274(a)(4) address the timing of plan payments, as well as recovery of payments when a beneficiary disenrolls from a plan. Specifically, (a)(4) states that compensation may only be paid for the beneficiary's months of enrollment during the year (January through December). We propose to revise (a)(4) to define more clearly a plan year for

purposes of compensation. The annual compensation amount covers January 1 through December 31 of each year. We have learned that some plans have been paying compensation based on an annual cycle, rather than a calendar year cycle. We have taken appropriate compliance actions in those instances where we have evidence that an MA organization or Part D sponsor is paying compensation incorrectly, and issued sub-regulatory guidance on August 14, 2013 reminding organizations and sponsors that compensation is to be paid based on a calendar year cycle. Along the same lines, we propose to revise the language at § 422.2274(a)(4) to clarify that the payment made to an agent must be for January 1 through December 31 of the year and may not cross calendar years. For example, a renewal payment cannot be made for the period of November 1, 2013 through October 31, 2014. Rather, the renewal payment must cover January 1, 2013through December 31, 2013.

Currently, the regulation text at § 422.2274(a)(4) (i) permit payments to be made at one time or in installments and at any time. CMS proposes to change the timing of payments to require that payments may not be made until January 1 of the compensation year, and must be paid in full by December 31 of the compensation year. CMS believes this proposal is appropriate given the ability of beneficiaries to change plans during the annual coordinated election period (AEP), which runs from October 15 through December 7. That is, beneficiaries can choose a new plan during the AEP, and then revise that choice as many times as they desire during the AEP; the last enrollment choice made is the one that becomes effective on January 1 of the following year. Under CMS' current requirements, each MA organization or Part D sponsor would have to recoup compensation, if already paid, for every beneficiary that initially enrolled in their plan but later decided to enroll in a different parent organization prior to January 1. Under the proposed rule, MA organizations and Part D sponsors would not be allowed to pay compensation until the beginning of the calendar year, when the final AEP enrollment becomes effective. Thus, the proposed rule would simplify MA organizations' and sponsors' compensation processes and enable them to make more accurate payments. We welcome comments on this proposal.

Current regulations at § 422.2274(4)(ii)(A) and § 423.2274(4)(ii)(A) require MA organizations and Part D sponsors to recover compensation paid to agents when a beneficiary disenrolls from a plan within the first three months of enrollment. However, in sub-regulatory guidance, we have recognized several circumstances (for example, death of the beneficiary, the beneficiary moves out of the service area, the beneficiary becomes eligible to receive LIS, or the beneficiary loses Medicaid benefits) in which plans should not recover compensation even though the beneficiary was enrolled in the plan for less than 3 months. In circumstances such as these, since the disenrollment decision could not be based on agent or broker behavior, we believe it to be appropriate for the agent to receive the compensation associated with the months that beneficiary was a member of the plan. While the plan would not recover the compensation for those months, it would recover any compensation paid for the months after the disenrollment. Therefore, CMS is proposing to combine paragraphs (a)(4)(ii)(A) and (a)(4)(ii)(B) into a revised paragraph (b)(3)(iii),which would include new text to clarify that plans should recover compensation for only the months that the beneficiary is not enrolled, unless the disenrollment took place within the first 3 months. Under our proposal, we would require disenrollments that are the result of agent or broker behavior to trigger recoupment of any compensation that has been paid for that period. In cases where disenrollment took place within the first 3 months and the disenrollment did not result from or could not have resulted from an agent's behavior, we would not require that compensation be recovered under our proposal. We would provide more specific information in sub-regulatory guidance, and welcome comments regarding possible examples to include in that guidance.

CMS also proposes here, in § 422.2274(h) and § 423.2274(h) to codify existing sub-regulatory guidance regarding referral (finder's) fees. CMS released a memorandum on October 19, 2011 addressing excessive referral fees, noting that referral fees should not exceed $100. CMS has long been concerned that some MA organizations or Part D sponsors can offer the entire amount of compensation an agent or broker receives through only a referral, while others must combine any compensation for referrals with other agent marketing activities while meeting the same total cap on compensation, thereby creating an un-level playing field within the marketplace and a clear financial incentive for the referring agent to steer beneficiaries to MA organizations or Part D sponsors that offer the higher amount, without regard to whether plan benefits meet the beneficiaries' health care needs. Therefore, we are proposing to limit the amount that can be paid as a referral fee to independent, captive, and employed agents and brokers, regardless of who completes the enrollment, to a reasonable amount specified by CMS, which is currently, for CY 2013, and CY 2014, $100. Furthermore, note that, under § 422.2274(a) and § 423.2274(a), CMS requires that referral fees paid to independent agents and brokers must be part of total compensation not to exceed the FMV for that calendar year.

14. Drug Categories or Classes of Clinical Concern and Exceptions (§ 423.120(b)(2)(v) and (vi))

Section 3307 of the Affordable Care Act amended section 1860D–4(b)(3)(G) of the Act by replacing the specific criteria established under MIPPA in 2008 to identify categories or classes of Part D drugs for which all Part D drugs therein shall be included on Part D sponsor formularies. The specified criteria were replaced with the requirement that the Secretary establish criteria through notice and comment rulemaking to identify drug categories or classes of clinical concern. In addition, section 3307 of the Affordable Care Act requires the Secretary to engage in rulemaking to establish any exceptions that permit a Part D sponsor to exclude from its formulary a particular Part D drug (or otherwise limit access to such drug through utilization management or prior authorization restrictions) within the drug categories or classes that meet the criteria established by the Secretary. The Affordable Care Act amendments to section 1860D–4(b)(3)(G) of the Act specified that until such time as the Secretary establishes the criteria to identify drug categories or classes of clinical concern through rulemaking, the following categories or classes shall be identified as categories or classes of clinical concern: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection. We now propose to implement the Affordable Care Act requirements set forth in section 1860D–4(b)(3)(G) of the Act by revising § 423.120(b)(2)(v) and (vi) as follows: (1) the criteria the Secretary will use to identify drug categories or classes of clinical concern; and (2) the exceptions that permit Part D sponsors to exclude certain Part D drugs from within an identified drug category or class from

their formularies (or otherwise limit access to such drugs, including through utilization management or prior authorization restrictions). We also propose to specify drug categories or classes that would meet the proposed criteria and explain the process we used for making these determinations.

a. Categories or Classes of Clinical Concern

In 2005, well before the passage of MIPPA, and before the start date of the Part D program, we directed Part D sponsors through guidance to include on their formularies all or substantially all drugs in six categories or classes (antidepressants; antipsychotics; anticonvulsants; immunosuppressants for transplant rejection; antiretrovirals; and antineoplastics). Our authority for this policy arises from section 1860D–11(e)(2)(D)(i) of the Act, which requires that in order to approve a plan, we must not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain Part D eligible individuals. We refer to this as our ''non-discrimination'' policy. This statutory directive helped to ensure a smooth transition of the approximately 6 million Medicare-Medicaid beneficiaries who were converting from Medicaid drug coverage to Medicare drug coverage at the start of the Part D program. Under the existing circumstances, any formularies that did not have all or substantially all drugs in these categories or classes potentially would have been discriminatory for the Medicare-Medicaid beneficiary population because state Medicaid program formularies were generally open compared to the Part D formularies that we were anticipating prior to the beginning of the Part D program. Thus, it stood to reason that Medicare-Medicaid beneficiaries and many of their providers were largely unaccustomed to drug utilization management techniques. That is, for the most part they had little experience dealing with the rejection of a drug claim at the point of sale because the drug was either not on formulary, or another drug needed to be tried first, or because more information was required to determine whether the drug could be covered under the plan. Moreover, since the majority of the Medicare-Medicaid beneficiaries did not make a decision to elect their new plan, but were instead auto-enrolled, these individuals may not have understood whether their current medications would continue to be covered under their new Medicare plan. Since the Part D program would be administered by private plans with extensive experience managing prescription drug costs through tighter formularies and a variety of utilization management techniques, we anticipated the need for a learning curve and delays in negotiating appeals processes that might endanger the beneficiaries who needed access to drugs in these particular categories or classes. In order to mitigate the risks and complications associated with an interruption of therapy for vulnerable beneficiaries, who would be trying to navigate a new drug benefit when they attempted to fill or refill their first prescriptions under the Part D program on or after January 1, 2006, we created the special requirements for coverage of the six drug classes. However, the circumstances that existed when this policy was originally implemented have changed dramatically in the more than seven years the program has been in operation. CMS, Part D sponsors, our partners who assist beneficiaries with making enrollment choices, and particularly our Medicare-Medicaid beneficiaries and their advocates have had a great deal of experience working with Part D plans since 2005.

Section 176 of MIPPA added a new section 1860D–4(b)(3)(G)(i) to the Act requiring, effective with plan year 2010, that the Secretary identify certain categories or classes of drugs that meet two statutory specifications: (1) Restricted access to the drugs in the category or class would have major or life-threatening clinical consequences for individuals who have a disease or condition treated by drugs in such category or class; and (2) There is a significant need for such individuals to have access to multiple drugs within a category or class due to unique chemical actions and pharmacological effects of the drugs within a category or class, such as drugs used in the treatment of cancer. In addition, MIPPA provided the Secretary with the discretion to establish exceptions permitting Part D sponsors to exclude from their formularies, or to otherwise limit access to (including utilization management or prior authorization restrictions), certain Part D drugs in the protected categories or classes.

In the January 16, 2009 **Federal Register** (74 FR 2881), we published an interim final rule with comment period (IFC) entitled, ''MIPPA Drug Formulary and Protected Classes Policies.'' This rule revised the regulations governing the Medicare Part D formularies to reflect the MIPPA requirements. We codified at § 423.120(b)(2)(v) the MIPPA provision requiring the inclusion of all Part D drugs in categories or classes that we identified as meeting the two conditions set forth in section 1860D–4(b)(3)(G)(i) of the Act. Given the limited timeframe then available for establishing and implementing a process to identify such drug categories or classes due to formulary submission deadlines, we maintained the existing six drug categories and classes of clinical concern for 2010 with the intention to propose and finalize a new process through rulemaking that would be used to identify drug categories or classes that met the MIPPA criteria for CY2011. After receiving comments in response to the January 16, 2009 IFC, entitled, ''Medicare Advantage and Prescription Drug Programs MIPPA Drug Formulary Protected Classes Policies'' that persuaded us that the further interpretative rulemaking was necessary, we published a notice of proposed rulemaking (NPRM) on October 22, 2009, entitled, ''Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (74 FR 54634) to further refine the MIPPA criteria and establish a process that met MIPPA requirements. However, between the issuance of the October 22, 2009 proposed rule and the April 15, 2010 final rule (75 FR 19766), the Affordable Care Act was enacted. Section 3307 of the Affordable Care Act amended section 1860D–4(b)(3)(G) of the Act to specify that the existing drug categories or classes of clinical concern would remain so until such time as the Secretary establishes new criteria to identify drug categories or classes of clinical concern under section 1860D–4(b)(3)(G) of the Act through notice and comment rulemaking.

We are concerned that requiring essentially open coverage of certain categories and classes of drugs presents both financial disadvantages and patient welfare concerns for the Part D program as a result of increased drug prices and overutilization. The principal disadvantage is that an open coverage policy substantially limits Part D sponsors' ability to negotiate price concessions in exchange for formulary placement of drugs in these categories or classes. Since the beginning of the Part D program we have heard from stakeholders that this policy—frequently referred to as the ''protected classes'' policy—significantly reduces any leverage the sponsor has in price negotiations and results in higher Part D costs. A report by the OIG in March 2011 documented similar assertions from selected Part D sponsors, including assertions that ''they received either no or minimal rebates for the drugs in these

six classes,'' that ''there is little incentive for drug manufacturers to offer rebates for these six classes of drugs because they do not need to compete for formulary placement,'' and that ''if [a rebate] is provided, it's probably at a lower percentage than [the rebate for the drugs] that had some competition.'' (HHS Office of Inspector General, ''Concerns with Rebates in the Medicare Part D Program'', March 2011, OEI–02–08–00050)

We are aware of other analyses that support these findings. A 2008 study conducted by the actuarial and consulting firm Milliman found that the six protected drug classes disproportionately accounted for between 16.8 percent and 33.2 percent of total drug spend among sponsors surveyed (Kipp RA, Ko C). (See ''Potential cost impacts resulting from CMS guidance on 'Special Protections for Six Protected Drug Classifications' and Section 176 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (PL 110–275)'' available at: *http://amcp.org/WorkArea/DownloadAsset.aspx?id=9279*). Milliman reported that the Part D program administrators (plan sponsors and PBMs) commented that the protected status of these drug classes limited plan sponsors' ability to effectively negotiate lower costs with manufacturers since it is known that these drugs must be included on the formulary. The Milliman report estimated that affected drug costs were on average 10 percent higher than they would be in the absence of the protected class policy and that this represented $511 million per year in excess costs to beneficiaries and the Part D program. We note that numerous brand drug patents expire between now and 2015 which might reduce future cost projections. Another 2008 study from the National Bureau of Economic Research (NBER) suggested that while Medicare Part D led to a substantial decline in average pharmaceutical prices, Medicare-intensive drugs in protected classes did not experience price declines as did their counterparts not in protected classes and may have actually experienced price increases (Duggan M, Morton FS. 2010. ''The Effect of Medicare Part D on Pharmaceutical Prices and Utilization,'' American Economic Review, American Economic Association, vol. 100(1), pages 590–607). Plan sponsors can still negotiate with manufacturers for preferred or non-preferred tier placement of protected class drugs, but CMS does not have any information on the justification for the relative magnitude of these rebates. However, it can reasonably be anticipated that such rebates would vary widely for individual manufacturers and sponsors, and anecdotal evidence would suggest the leverage these options provide sponsors may be minimal when compared to leverage available in connection with an initial decision regarding formulary inclusion, especially since tier placement has no impact on statutory LIS cost sharing levels. Consequently, we would predict future savings for both beneficiaries and the Part D program from both increased price competition as newly approved drugs come onto the market and more immediate savings if plans were able to remove some currently covered agents from their formularies.

In addition to our concerns about increased Part D costs resulting from higher drug prices, we are also concerned that the policy potentially facilitates the overutilization of drugs within the protected classes. By limiting the ability of Part D sponsors to implement utilization management tools (for example, prior authorization or step therapy requirements) for an entire category or class, we also limit their ability to prevent the misuse or abuse of drugs that are not medically necessary. Not only can this increase Part D costs, but inappropriate use can also lead to adverse effects that can harm the beneficiary and require medical treatment that would otherwise not have been necessary. We believe the profitability of products not subject to normal price negotiations as the result of protected class status is a strong incentive for the promotion of overutilization, particularly off-label overutilization, of some of these drugs.

Given the findings in these reports and our expertise with the Part D program, we believe it is appropriate to revisit our original policy for the six drug categories and classes of clinical concern—particularly to assess whether it remains appropriate to require this additional level of protection for these categories or classes of drugs in order to ensure that Part D plans offer nondiscriminatory benefit designs and sufficient beneficiary access to medically necessary therapies. In considering the balance among beneficiary access, quality assurance, cost containment, and patient welfare in light of our existing beneficiary protections, we believe that drug categories and classes should be subject to normal formulary and price competition unless we cannot ensure clinically appropriate access (and thus non-discriminatory benefit design) to our Medicare beneficiaries in any less anticompetitive way than requiring the inclusion on all Part D formularies of all drugs in that category or class. Moreover, we believe that our consideration of how to implement section 3307 of the Affordable Care Act must take into account both the purpose of the Part D benefit and the context in which it is offered. Part D does not typically involve access to medications on an emergency basis. In cases where an emergency may arise, the Part D program has some protections to address this—for example, our long term care emergency first fill requirement requires plans to cover an emergency supply of non-formulary Part D drugs for long term care residents as part of their transition process. Moreover, the Part D benefit must be considered in light of the fact that urgently needed and emergency care is generally covered by Medicare Parts A and B.

To that end, we believe that criteria for identifying drug categories and classes of clinical concern should identify only those drug categories or classes for which access cannot be adequately ensured by beneficiary protections that otherwise apply. Consequently, as we take this opportunity to propose to codify criteria for identifying categories or classes of drugs that are of clinical concern, we believe that the requirements of section 3307 of the Affordable Care Act should be implemented taking into consideration the other protections available to beneficiaries. Otherwise, section 3307 of the Affordable Care Act would establish duplicative, and thus unnecessary, protections that would serve only to increase Part D costs—without any added benefit and with the possibility of added harm from misuse. Therefore, in considering whether additional protections continue to be needed under this section, we need to take the other beneficiary access protections into account. There are five such protections and these are formulary transparency, formulary requirements, reassignment formulary coverage notices, transition supplies and notices, and the coverage determination and appeals processes.

The first protection is our requirement for full transparency to beneficiaries. Sponsors are required to provide comprehensive formulary drug listings to the public through their own Web sites and printed materials, as well as to CMS for access through the online automated drug plan comparison tool, the Medicare Plan Finder (Plan Finder). Beneficiaries or their representatives can complete a personalized search on

Plan Finder to locate and select a Part D plan that covers their drugs. With our more than 7 years of experience with the Part D program, we are not aware of any Part D drug that is not included on at least one Part D formulary. Thus, beneficiaries who review plan formularies can select plans that cover all of their current medications.

The second type of protection is the Part D formulary requirements. Our annual formulary review and approval process includes extensive checks to ensure adequate representation of all necessary Part D drug categories or classes for the Medicare population and includes the following:

- Discrimination Review (§ 423.272(b)(2)). Formularies are reviewed to ensure inclusion of drug categories and classes that are used to treat all disease states. CMS evaluates the sufficiency of a Part D sponsor's formulary drug categories and classes in conjunction with the plan's formulary drug list to ensure that the formulary provides access to an acceptable range of Part D drug choices.
- Two Drugs Requirement (§ 423.120(b)(2)(i)). Each submitted formulary is reviewed for the inclusion of at least two distinct drugs from each of the submitted categories and classes, except as provided in § 423.120(b)(2)(ii).
- Formulary Tier Review (Medicare Prescription Drug Benefit Manual, Chapter 6, 30.2.7). The tiering structure of each formulary is reviewed to ensure that each category and class has at least one drug in a preferred tier.
- Common Medicare Drugs Review (§ 423.120(b)(2)(iii)). Formularies are reviewed for inclusion of the drugs or drug classes that are most commonly utilized by the Medicare population. We use prior years' data to identify the drugs or drug classes with the highest utilization in Medicare Part D, and use these drugs and drug classes as the basis for our review in this area. We also review formularies for the alternative dosage forms of the drugs that are most commonly utilized by the long-term care (LTC) population.
- Treatment Guidelines Review (§ 423.120(b)(2)(iii)). The World Health Organization (WHO) defines a standard treatment guideline as a systematically developed statement designed to assist practitioners and patients in making decisions about appropriate health care for specific clinical circumstances (available at *http://www.who.int/medicines/technical_briefing/tbs/10-PG_Standard-Treatment-Guidelines_final-08.pdf*). We analyze formularies to determine whether appropriate access is afforded to drugs or drug classes included in widely accepted treatment guidelines. In general, although sponsors have some flexibility in determining the classification system they will use to identify categories or classes of drugs, if a treatment guideline speaks to a specific category or class of drugs, we look for representation from that drug category or class of drugs on the formulary. Moreover, if the treatment guidelines address specific drugs, we would expand this requirement to review formularies for those specific drugs, and not just the drug category or class to which they belong.
- Common Home Infusion Drugs (§ 423.120(a)(4)). We review formularies for the drugs most commonly utilized in the home infusion setting in order to help facilitate rapid access to these drugs for beneficiaries.
- Vaccines Review (§ 423.100). Each formulary submission is reviewed to ensure the formulary includes Part D vaccines.
- Insulin Supplies Review (§ 423.100). Formularies are reviewed for the supplies associated with the administration of insulin: insulin syringes, alcohol swabs, and gauze pads.
- Specialty Tier Review (§ 423.578(a)(7)). For formularies using a specialty tier, we perform an extensive review of the composition of each tier. We apply a standard outlined in the annual Call Letter to determine whether drugs placed in specialty tiers meet the relevant cost criteria.
- Quantity Limits Outlier Review (§ 423.153(b)). All formulary submissions are compared to analyze the use of quantity limit (QL) edits. Formularies that are outliers with respect to the application of QL edits are asked to remove edits or provide a reasonable justification for the applicable QL.
- Quantity Limits Amount Review (§ 423.153(b)). QL restrictions are reviewed for appropriateness. The standard for the review is generally based on the Food and Drug Administration (FDA)-approved maximum doses, when such dose limits are identified in the label.
- Restricted Access Review (§ 423.153(b)). Formularies are reviewed for use of Prior Authorization (PA) and Step Therapy (ST) edits across drug categories and classes. We decline to approve utilization management (UM) for entire drug classes, other than those considered to be best practices, for example, for erythropoietin stimulating agents (ESAs).
- Step Therapy Criteria Review (§ 423.153(b)). The ST requirements are reviewed to ensure that the algorithms are consistent with best practices.
- Prior Authorization Outlier Review (§ 423.153(b)). All formulary submissions are compared to analyze the use of PA edits. Formularies that are outliers with respect to the application of PA edits are asked to remove edits or provide a reasonable justification for such PA edits.
- Prior Authorization Criteria Review (§ 423.153(b)). We then review the criteria for focused drugs requiring PA on the initial formulary submissions. We look to existing best practices, including prerequisite drugs, current industry standards and appropriate treatment guidelines, to check that the Part D plans' use of PA is consistent with such practices. Submitted criteria are also compared to compendia and FDA-approved label indications.
- Mid-year formulary change restrictions (§ 423.120(b)(5)); Chapter 6 of the Medicare Prescription Drug Benefit Manual, 30.3.3). Except when the Food and Drug Administration deems a Part D drug unsafe or a manufacturer removes a Part D drug from the market, a Part D sponsor may not remove a covered Part D drug from its formulary, or make any adverse change in preferred or tiered cost-sharing status of a covered Part D drug, between the beginning of the annual coordinated election period described in section § 423.38(b) and 60 days after the beginning of the contract year associated with the annual coordinated election period. However, prescription drug therapies are constantly evolving, and new drug availability, medical knowledge, and opportunities for improving safety and quality in prescription drug use at a lower cost will inevitably occur over the course of the year. As recognized in regulation, these new developments may require formulary changes during the year in order to provide high-quality, affordable prescription drug coverage. To address such developments our negative formulary change policy requires that beneficiaries retain ''grandfathered'' coverage for the remainder of the coverage year if we permit an adverse change in the formulary status of any drug without a generic equivalent. Thus, in summary, our formulary rules both ensure that all Part D formularies contain sufficient drugs to treat all disease states in the Medicare population and protect beneficiaries from significant changes in formularies during the course of a coverage year.

The third type of beneficiary protection is the annual notice to reassigned enrollees required under section 3305 of the Affordable Care Act. Effective January 1, 2011, we provide LIS individuals who are reassigned to

another Part D plan with information on the differences under the new plan formulary, as well as information on the beneficiary's grievance and appeal rights in the new plan. Thus, any individual who has his or her plan selection decision made through our reassignment process (in order to maintain access to a $0 premium) receives detailed coverage status information for each drug for which he or she filled a prescription between January and August of the previous year. With regard to the new plan, this notice describes for each drug whether it is on the formulary, whether the brand or generic version is covered, and whether or not utilization management tools may be applied. Moreover, the notice also provides a list of other plans that are available to the beneficiary to enroll in with no premium if they would prefer not to remain in the plan where they were reassigned. We send notices after the individual's reassignment and in time to allow for another voluntary plan selection effective January 1. Thus, any reassigned LIS individual receives advance notice of any change in formulary coverage of their medications in plenty of time to work with their prescribers if they wish to remain in the new plan, or to select a different Part D plan.

The fourth type of beneficiary protection is our unique transition supply and notice requirements. A Part D sponsor must provide for an appropriate transition process for Part D drugs that are not on its formulary with respect to: (1) The transition of new enrollees into prescription drug plans following the annual coordinated election period; (2) the transition of newly eligible Medicare beneficiaries from other coverage; (3) the transition of individuals who switch from one plan to another after the start of the contract year; and (4) in some cases, current enrollees affected by formulary changes from one contract year to the next (see § 423.120(b)(3); Chapter 6 of the Medicare Prescription Drug Benefit Manual, 30.4). Within the first 90 days of a beneficiary's enrollment in a new plan, plans must provide a temporary fill when the beneficiary requests a refill of a non-formulary drug (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules). Since certain enrollees may join a plan at any time during the year, this requirement applies beginning on an enrollee's first effective date of coverage, regardless of whether this is within the first 90 days of the contract year.

A successful transition process is contingent not only upon providing the transitional drug supply, but also upon informing affected enrollees, their caregivers, and their providers about the beneficiary's options for ensuring that his or her medical needs are safely accommodated within a Part D sponsor's formulary. For this reason, when providing a temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules), sponsors must provide enrollees and their providers with written notice within 3 business days after adjudication of the temporary fill that they are receiving a transition supply of a non-formulary Part D drug and that they must take action. The temporary fill and notice provides beneficiaries with a reasonable amount of time during which they and their providers can address the issue (by requesting a formulary exception or transitioning to a formulary drug) and prevents them from having to abruptly change or go without their medication (see Transition notice requirements (to beneficiaries and providers) [§ 423.120(b)(3)(iv and v); Chapter 6 of the Medicare Prescription Drug Benefit Manual, 30.4.10]). Thus all beneficiaries and their prescribers have advance notice of any issue with continued coverage of a previously initiated therapy and sufficient time to resolve those issues without any lapse in appropriate therapy. The preceding formulary review and transition requirements are described in Chapter 6 of the Medicare Prescription Drug Benefit Manual (located at *http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter6.pdf*).

The fifth beneficiary protection we take into account is the requirement for a robust coverage determination and appeal process, including the right of an enrollee or his or her prescriber to request an exception to the plan's utilization management criteria, tiered cost-sharing structure, or formulary. Part D plan sponsors are required to issue a coverage decision and notify the enrollee (and the prescriber, as appropriate) in writing in accordance with strict regulatory timeframes. A plan must grant a tiering or formulary exception (for example, provide coverage for a non-formulary drug or an exception to the UM criteria) when it determines that the requested drug is medically necessary, consistent with the prescriber's supporting statement indicating that preferred alternatives(s) would not be as effective and/or would have adverse effects. We have established by regulation both an expedited adjudication timeframe if the plan or prescriber believes that applying the standard timeframe may jeopardize the enrollee's health, and a requirement that plans must issue all coverage decisions as expeditiously as the enrollee's health condition requires. Any initial coverage request that the plan expects to deny based on a lack of medical necessity must be reviewed by a physician. If the Part D sponsor makes an adverse coverage determination, the required written notice must explain the specific reason(s) for the denial and include a description of the enrollee's right to a standard or expedited redetermination by the plan, and the rest of the five-level appeals process, including the right to request independent review. We require plans to conduct all redeterminations (first level appeals) using a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare criteria, if the initial denial was based on a lack of medical necessity. If a plan fails to make a coverage decision and notify the enrollee within the required timeframe, the request must be forwarded to the independent review entity to be adjudicated.

Moreover, while we do not treat a claim transaction as a coverage determination, we do require Part D sponsors to arrange with network pharmacies to provide enrollees with a written copy of the Office of Management and Budget (OMB)-approved standardized pharmacy notice (''Notice of Denial of Medicare Prescription Drug Coverage,'' CMS–10146) when the enrollee's prescription cannot be filled under the Part D benefit and the issue cannot be resolved at the POS. The notice instructs the enrollee on how to contact his or her plan and explains the enrollee's right to request a coverage determination. Thus, all beneficiaries immediately receive clear concise instructions on how to pursue their appeal rights whenever a prescription cannot be filled. For additional information on the coverage determination, appeals and grievance process, including information about the pharmacy notice, see 42 CFR Part 423, subparts M and U, and Chapter 18 of the Medicare Prescription Drug Benefit Manual.

As the preceding discussion demonstrates, we have implemented extensive beneficiary protections in the

form of formulary review checks, reassignment formulary coverage notices, drug therapy transition policies and notices for both new enrollees and continuously enrolled members experiencing changes in formulary benefits between coverage years, and robust exceptions and appeals processes that generally will assure appropriate access without having to guarantee formulary placement. Additionally, the formulary exceptions and appeals requirements facilitate obtaining any medically necessary Part D drug that is not on the formulary or that is otherwise subject to utilization management requirements. Taken together, we believe these requirements are comprehensive enough that additional access safeguards are needed only in those situations where a Part D beneficiary's clinical needs cannot be more efficiently met.

b. Criteria Necessary To Identify Categories and Classes of Clinical Concern

In developing our proposed criteria to identify drug classes of clinical concern, we considered all of the existing beneficiary protections described previously in section III.A.14.a. of this proposed rule, particularly our coverage determination and appeals process, which requires plans and other adjudicators to make all coverage decisions as expeditiously as the enrollee's health condition requires. Given our existing protections, we believe clinical concern would arise only if access to drugs within a category or class for the typical individual who is initiating therapy must be obtained in less than 7 days because the coverage determination and appeals process generally does not provide for independent review and determination, when necessary, within such timeframe. We believe this would be the case only when failure to initiate the therapy within that time period would be likely to lead to hospitalization, incapacity, disability or death as a result of the exacerbation of the disease or condition to be treated. We do not believe it is necessary to require all Part D drugs within a drug category or class to be included on the formulary if access within 7 days is likely sufficient to allow for initiation of therapy without putting beneficiaries at risk of hospitalization, incapacity, disability, or death. In other words, we believe that inconvenience associated with a delay that is unlikely to pose these serious consequences for the typical individual initiating a new therapy does not warrant requiring all Part D drugs from within the category or class to be included on the formulary because in such an instance, the beneficiary would have other protections to ensure that he or she has appropriate access to the drug. Moreover, we do not believe it is necessary to require all Part D drugs within a drug category or class to be included on the formulary when, for a typical individual who already is taking the drug, interruption in existing drug therapy might have adverse health consequences. Specifically, we believe that existing protections such as the Part D formulary change restrictions (for example, prohibition on midyear implementation of new PA, ST, or QL restrictions on existing therapies) and the transition requirements under § 423.120, which provide for temporary fills and require beneficiary notification of the need to request a coverage determination (including an exception or prior authorization approval) for future fills ensure sufficient protection for beneficiaries who may face an interruption in their ongoing therapies as a result of a change in their plan or formulary. Thus, our transition and negative formulary change requirements afford strong protections to individuals with ongoing therapy. However, this is in contrast to individuals who are initiating therapy. These individuals do not get an initial fill to try a medication while they petition for an exception, and thus the transition protections do not apply. Finally, we note that when we refer to a beneficiary's having ''access'' to a drug within 7 days, we mean that the beneficiary must need to ingest or otherwise use or consume the drug within that time period in order to avoid the adverse consequences. Thus, ''access'' means administration, which may include self-administration, of drugs. To illustrate this last point, initiation of therapy with drugs used to treat HIV/AIDS generally should not be delayed because initiation of therapy has rapid effects on viral load. Conversely, a minor delay with the initiation of therapy with HMG-CoA reductase inhibitors (also known as ''statins'') for patients with hyperlipidemia, even when transitioning among medications in the category or class in response to lipid profiles, liver or kidney function, or adverse events, is not as critical because it usually takes several weeks to detect measurable effects on serum lipid concentrations.

Thus, for all of these reasons, we propose to specify at § 423.120(b)(2)(v)(A) a first criterion under section 1860D–4(b)(1)(G)(ii)(II) of the Act as follows: In the case of a typical beneficiary who has a disease or condition treated by drugs in the following category or class, hospitalization, persistent or significant incapacity or disability, or death likely will result if initial administration (including self-administration) of a drug in the category or class does not occur within 7 days of the date the prescription for the drug was presented to the pharmacy to be filled. By typical beneficiary, we mean, for a given disease or condition, an individual who has the average clinical presentation of the relevant disease or condition.

While this first criterion would establish the critical need to promptly initiate drug therapy with a drug from an identified drug category or class, we believe that, standing alone, it may be overly inclusive and, as such, would fail to appropriately balance the need for beneficiary protection with the need to allow plans to take appropriate steps to control costs and overutilization. If the drug category or class consists of many similar drugs that are often considered to be therapeutically interchangeable with one another when initiating drug therapy, a requirement to include on the formulary all drugs in that category or class would undermine the important place that formularies, due to their ability to control costs, hold within the Part D program without providing any additional beneficiary protection. According to the Academy of Managed Care Pharmacy (AMCP), therapeutic interchange is the practice of replacing, with the prescribing provider's approval, a prescription medication originally prescribed for a patient with a chemically different medication; medications used in therapeutic interchange programs are expected to produce similar levels of clinical effectiveness and sound medical outcomes, based on available scientific evidence. Moreover, in the absence of any specific treatment guidelines to the contrary, inclusion of all drugs in that category or class would be unnecessary. For example, some drugs in the nitrate class of drugs likely would meet our first proposed criterion, but because there are many therapeutically interchangeable options among nitrates, it is not necessary to require that all nitrate products be included on every Part D formulary. Indeed, under our current formulary treatment guideline reviews, while we require that sublingual nitroglycerin be included on all formularies because beneficiaries often need it on an urgent basis, we do not require inclusion of *all* other nitrates (for example, isosorbide dinitrate, isosorbide mononitrate, and transdermal nitroglycerin) because these dosage

forms are long-acting and typically are not needed on an urgent basis. (However, current treatment guidelines require the inclusion of isosorbide dinitrate for congestive heart failure.) Similarly, the typical diabetic patient who needs insulin could reasonably be anticipated to require two insulin products as part of his or her treatment regimen: Specifically, one shorter-acting, and one longer-acting insulin. Among the insulins, there are four sub-classes: Rapid acting, short acting, intermediate acting, and long acting. Within each of the sub-classes, there are alternatives from which to choose. In accordance with treatment guidelines, in most cases a patient's regimen is comprised of one selection from either the rapid acting or short acting sub-classes, and one selection from either the intermediate acting or long acting sub-classes. While the beneficiary would require access to multiple drugs within the class (insulins), which at times could certainly be considered urgent enough to risk dire consequences as discussed in the first criterion, they would not need access to all of the options within that class because there are many alternative products on the market within those sub-classes that are largely therapeutically interchangeable, and any one of these products will generally meet the patient's needs. Thus, our formulary checks for insulin require some products in each sub-class to ensure that access through each plan is clinically appropriate.

These examples illustrate the principle that it is both feasible and appropriate to permit plan sponsors to develop formularies that exclude certain products when adequate access to an appropriate alternative is assured by way of our existing formulary requirements and review process. Moreover, the transition and coverage determination and appeal processes are available in those situations when a non-formulary drug is medically necessary for a specific individual.

For these reasons, we believe it is important to include a second criterion that must be met in order for us to consider a drug category or class to be one of clinical concern for the purposes of section 3307 of the Affordable Care Act. Specifically, we believe a drug category or class would be of clinical concern if CMS cannot establish that a formulary that includes fewer than all Part D drugs from within that category or class would include sufficient drugs needed to treat the diseases or conditions generally treated by such drugs. In other words, CMS cannot reasonably establish more specific CMS formulary requirements because there are too many potential drug-and-disease-specific scenarios that require specific drugs from within a category or class, even within sub-classes. This would be the case when the different drugs within a category or class are uniquely associated with specific clinical applications because of the unique effects of such drugs or the variable nature of the disease or condition treated by such drugs. For example, a cancer patient whose clinical picture is rapidly changing must immediately initiate very specific changes in antineoplastic therapy when the new disease target is identified. While perhaps possible, it would not be practical to establish a multitude of more class-specific formulary requirements for every current or future combination or sequence of such drugs simply to possibly exclude a few drugs. Thus, we propose to add § 423.120(b)(2)(v)(B) specifying a second criterion to identify a clinical concern as follows: More specific CMS formulary requirements will not suffice to meet the universe of clinical drug-and-disease-specific applications due to the diversity of disease or condition manifestations and associated specificity or variability of drug therapies necessary to treat such manifestations.

In summary, we propose to modify § 423.120(b)(2)(v) to require that (unless an exception applies) all Part D drugs within a drug category or class be included on the formulary if a the drug category or class of drugs for a typical individual with a disease or condition treated by the drugs in the category or class meets both of the following criteria (as determined by CMS):

- Hospitalization, persistent or significant disability or incapacity, or death likely will result if initial administration (including self-administration) of a drug in the category or class does not occur within 7 days of the date the prescription for the drug was presented to the pharmacy to be filled; and
- More specific CMS formulary requirements will not suffice to meet the universe of clinical drug-and-disease-specific applications due to the diversity of disease or condition manifestations and associated specificity or variability of drug therapies necessary to treat such manifestations.

c. Exceptions

Section 1860D–4(b)(3)(G)(i)(II) of the Act provides us with the authority to establish exceptions to the requirement that a Part D sponsor must include all Part D drugs on its formulary in the drug categories or classes identified by us as drug categories or classes of clinical concern under section1860D–4(b)(3)(G)(ii)(I) of the Act. Despite the narrow scope of applicability defined by the proposed criteria, we believe it is necessary to identify exceptions to help ensure Part D coverage is limited to Part D drugs, minimize duplicative protections within a drug category or class of clinical concern, and assure beneficiary safety while curbing potential abuse and misuse as a result of the added protection.

First, we propose to retain § 423.120(b)(2)(vi)(A) as currently codified. This provision makes an exception for drug products that are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' also known as the Orange Book). Thus, two drug products that are determined to be therapeutic equivalents by the FDA and identified in the FDA's Orange Book are considered to be the same Part D ''drug'' solely for purposes of this requirement, and sponsors would not be required to include all therapeutic equivalents on their formularies. Rather, the inclusion of one such drug product would satisfy the formulary requirement with respect to all therapeutically equivalent products.

We also propose to amend and renumber (as paragraph (F)) existing § 423.120(b)(2)(vi)(B) to make an exception for point-of-sale utilization management safety edits that are based on maximum daily doses and black-box warnings specified on the FDA-approved label, potential drug interactions, or duplication of therapy. In fact, we believe that this exception is consistent with the requirement under section 1860D–4(c)(1)(B) of the Act that requires Part D sponsors to have in place quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use. As noted previously, although we believe that section 3307 of the Affordable Care Act is intended to provide additional beneficiary protections, we also believe that it would be imprudent to interpret these protections in such a way that they interfere with existing protections intended to promote safety and efficacy. We believe that it is appropriate for Part D sponsors to establish edits for safety and that our policies should not interfere with basic drug utilization management edits that sponsors apply at point of sale to ensure that adverse events do not occur. For example, we

would expect that a claim for a 90 days supply of Atripla® for 180 tablets, when the drug is only approved for use once a day, would trigger a point-of-sale safety edit. Such edits must be consistent with FDA labeling to ensure that they are based on scientific evidence and medical standards of practice. However, the use of safety edits should not create a significant opening for plans to establish restrictive policies, because safety edits need to conform to FDA labeling.

Next, we propose to add new language at § 423.120(b)(2)(vi)(B) to make an exception for drug products that are almost always covered under Medicare Parts A or B. In order to minimize confusion about the scope of the protections under section 3307 of the Affordable Care Act, we specify that the formulary requirements set forth in section 1860D–4(b)(3)(G)(i) of the Act do not apply to drugs almost always covered by Medicare Part A or B. We do not currently require, and would not require under the authority of section 3307 of the Affordable Care Act, the inclusion of drugs that have been historically paid for under Part B (for example, ''incident to'' drugs supplied and administered by physicians during a patient visit and paid for under Part B). Given the fact that these drugs are generally covered under Medicare Part B and are not required under our existing policy, we believe their absence from plan formularies would not disrupt access. We further believe that requiring the inclusion of these drugs on the formulary would lead to beneficiary confusion. For these reasons, we are proposing to exclude drug products almost always covered under Medicare Part A or B.

We also propose to add an exception at § 423.120(b)(2)(vi)(G) to permit prior authorization for purposes of determining whether a drug is a Part D drug being used for a medically-accepted indication as defined in section 1860D–2(e)(4) of the Act or to verify a drug is not covered under Medicare Parts A or B as prescribed and dispensed or administered. Coverage under Part D is not available for drugs that are not used for a medically-accepted indication, and section 3307 of the Affordable Care Act does not change any Part D coverage rules. Moreover, we believe that this exception, like the exception for Medicare Part A or B drugs described in proposed paragraph (B), would not cause disruption because it merely reflects existing limits on Part D coverage.

Thus, we also propose that prior authorization in the drug categories or classes of clinical concern is appropriate when used to confirm the presence of a medically-accepted indication or that coverage is not available under Medicare Parts A or B as prescribed and dispensed or administered. Prior authorization requirements to determine medically-accepted indications should be limited to those drugs for which it is reasonably foreseeable that use for non-medically-accepted indications are likely to occur. For example, when only narrow indications are supported (for example, pain medications indicated only for cancer pain, supported by the FDA label or compendia), we would expect Part D sponsors to use prior authorizations to ensure that such agents are being used for the narrowly-supported indications only. Similarly, sponsors must apply prior authorizations for Medicare Parts A/B versus D determinations in a manner consistent how those determinations are made in all other categories or classes (that is, based upon likelihood of coverage under Medicare Part A or B), and thus, we would not expect to see a disproportionate amount of prior authorization requirements for the categories or classes of clinical concern compared to other formulary categories or classes. We expect that the plan sponsor's medical director is involved in establishment and oversight of plan policies related to prior authorization requirements. As with all PA requirements, these would require CMS review and approval. Consistent with current guidance, in Parts A or B versus D situations, CMS expects Part D sponsors will work aggressively to eliminate any interruptions of current therapy.

In addition, we propose to amend § 423.120(b)(2)(vi)(C) to make an exception for Part D compounds. As noted in previous rulemaking, Part D only covers those ingredients in a compound that independently meet the definition of a Part D drug (see § 423.120(d)). Since the Part D compound as a whole is not FDA approved, we do not believe that such compounded products reasonably can be classified as being included in a specific category or class that meets the criteria proposed in new § 423.120(2)(v)(A). Currently, Part D compounds that include ingredients that fall within a protected category or class are not required to be included on formularies, and we do not interpret section 3307 of the Affordable Care Act as requiring their inclusion now. Thus, we believe their continued absence from plan formularies would not disrupt access.

We also propose to add § 423.120(b)(2)(vi)(D) to make an exception for drugs (other than antiretrovirals) that are FDA approved and that are fixed-combination dosage form prescription drug products as defined in 21 CFR 300.50, that contain at least one Part D drug in the category or class of clinical concern. Because all drugs in the category or class of clinical concern would be on the formulary as single entity products, we do not believe it is necessary, in most cases, to require inclusion of the fixed dose combination or co-packaged products. However, we would propose to carve out from this exception fixed dose combinations and co-packaged antiretrovirals, as discussed in FDA guidance found here: *http://www.fda.gov/downloads/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/ucm079742.pdf*) because avoiding excessive pill burden and simplifying dosage regimens is of utmost importance with this class of drugs. This is because the risk associated with non-adherence when beneficiaries have to take the single-entity products has far more severe consequences, such as viral resistance, than in most other instances, where occasional non-adherence does not present such dire complications. Consequently, although we believe this exception is generally appropriate for the categories and classes of clinical concern that receive added protections under section 3307 of the Affordable Care Act, we propose that it not be available for antiretrovirals. This means that, under our proposed criteria, which, as discussed further in the following paragraphs, apply to antiretrovirals, all Part D formularies would need to include not only all single-entity antiretrovirals, but also all FDA-approved fixed-dose combination and co-packaged antiretrovirals.

Additionally, consistent with current guidance, we propose an exception at § 423.120(b)(2)(vi)(E) for certain types of Part D drugs, including multi-source brands of the identical molecular structure, extended-release products when the immediate-release product is included, products that have the same active ingredient or moiety, and dosage forms that do not provide a unique route of administration (for example, tablets and capsules versus tablets and transdermal products). Although such products may contribute to improvements in beneficiary adherence to their medication regimens, other interventions such as Medication Therapy Management Programs and special compliance packaging can also improve adherence. Therefore, the added costs of required formulary inclusion of such products may not

provide added value since they do not provide a clinically different therapeutic alternative. Such products currently are not required to be included on formularies, and we do not interpret section 3307 of the Affordable Care Act as requiring their inclusion now. Thus, we do not believe this exception would disrupt access.

Finally, we considered proposing an exception at § 423.120(b)(2)(vi)(H), to allow Part D sponsors to implement prior authorization, including PA used to implement step therapy requirements, to convert beneficiaries to preferred alternatives within these drug categories or classes for enrollees who are initiating therapy (new starts). This is consistent with current guidance that Part D sponsors may not implement prior authorization, including PA used to implement step therapy requirements that are intended to steer beneficiaries to preferred alternatives within these drug categories or classes for enrollees who are currently taking a drug, unless they are trying to establish appropriate coverage under Parts A, B, or D. This prohibition applies to those beneficiaries already enrolled in the plan, as well as to new enrollees who were actively taking drugs in any of the drug categories or classes of clinical concern prior to enrollment in the plan. If a sponsor cannot determine at the point of sale that an enrollee is not currently taking a drug (for example, new enrollee filling a prescription for the first time), the sponsor treats such enrollee as currently taking the drug. Additionally, step therapy and prior authorization for HIV/AIDS drugs are generally not employed in widely-used best-practice formulary models and are not permitted under the current policy. Although this has been our policy since the start of the Part D program, and we are not aware of any problems with it to date, we recognize that this raises the potential for a delay in access to initial therapy to occur and could be in conflict with our first proposed criterion. However, we must balance this with incentives for efficient formularies and do not want to eliminate a tool that may be useful for Part D sponsors. Consequently, we solicit comment on the continued need and utility of this policy and whether it should be included in the exceptions at 423.120(b)(2)(vi). These exceptions would supersede any previous guidance relative to PAs and UM for the categories and classes of clinical concern.

d. Analysis and Identification of the Categories or Classes of Clinical Concern

We convened a consensus panel of CMS pharmacists and the Chief Medical Officer for the Center for Medicare to identify which drug categories or classes met our proposed criteria for clinical concern. The panel was supported by a contractor that performed background research and provided specific information on Part D utilization by drug category or class and associated widely-accepted treatment guidelines for each drug category or class, when available. The panel reviewed all Part D drugs with utilization in 2012 using the American Hospital Formulary Service (AHFS)–6 classification system. We chose the AHFS–6 classification system as a framework because it provided us with a tool to logically, and in stepwise fashion, apply the criteria to all Part D drugs. A detailed synopsis of the panel's findings is posted at *http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_FormularyGuidance.html*. The consensus panel determined that of the current six drug categories or classes of clinical concern, three (anticonvulsants, antineoplastics, and antiretrovirals) meet both of the proposed criteria, and three do not (antidepressants, antipsychotics, immunosuppressants). The panel also determined that while other drug categories and classes met one of the criteria, no other drug categories or classes met both criteria.

With respect to the first criterion, the panel concluded that initiation of therapy with drugs from the antiretroviral, antineoplastic, and anticonvulsant categories and classes for the typical individual prescribed these drugs in a Part D setting generally cannot be delayed for 7 days because of the risk of hospitalization, incapacity, disability, or death. For antiretrovirals, the risk associated with the failure to immediately initiate recommended concurrent therapies could significantly increase the risk of developing drug resistance and the potential for re-exacerbation of the disease. For antineoplastics, prompt initiation of therapy is also critical. Given that the antineoplastic drug therapy often is but one part of a complex cancer treatment protocol that includes non-drug therapies, such as radiation or surgery, initiation of the antineoplastic drug therapy is usually integrated with the entire treatment protocol. Thus, delaying initiation of antineoplastic drugs can delay a beneficiary's entire course of treatment. For anticonvulsants, the risk of seizure associated with a delay in drug therapy for 7 days can lead to hospitalization and significant incapacity.

With respect to the second criterion, the panel concluded that the antiretroviral, antineoplastic and anticonvulsant categories and classes meet the criterion because different drugs within those categories and classes are used in so many patient-, drug-, or disease-specific clinical applications that an alternative formulary requirement is not feasible. For antiretrovirals, the panel based this conclusion on the number of multiple drug combinations and adjunctive therapies involved, frequency with which recommended drug protocols change, and the role that changing drug resistance plays in determining the selection of among the different antiretroviral drugs. The need to adjust specific combination antiretroviral therapy in real time is complex and must consider, among other things, viral sensitivity to the drugs, drug interactions, pregnancy status (if applicable), and potentially the patient's pharmacogenomic profile of the cytochrome P450 system. Similarly, for antineoplastic drug therapies, the panel based its conclusion on the diversity of treatment protocols, the specificity of such treatment protocols, including the role that specific genetic variations can play in the selection of the appropriate drug therapy, and the frequency with which disease-specific treatment protocols recognized in the official Part D compendia change and get updated. A cancer patient whose clinical picture is rapidly changing must immediately initiate very specific changes in antineoplastic therapy when the new disease target is identified. Finally, for anticonvulsants the panel concluded that the class met the criterion based on the number of unique types of seizures, the multiple drug combinations indicated for them, and the potential for altered drug effects based on drug-drug interactions that occur via the cytochrome P450 system. For all three of the classes (anticonvulsants, antineoplastics, and antiretrovirals), the panel concluded that CMS would be unable to address them more efficiently through formulary requirements that would allow for some restrictions at this time based upon the number and specificity of the different treatment protocols.

After a detailed analysis of existing therapies and widely-accepted treatment guidelines, the panel concluded that immunosuppressants for transplant rejection, antidepressants, and antipsychotics do not meet both of

the proposed criteria and thus would not be eligible for the additional protections intended by section 3307 of the Affordable Care Act.

With respect to immunosuppressants for transplant rejection, the panel concluded that the first criterion was met. Due to the immune system's ability to mount progressively faster and stronger attacks against a beneficiary's new organ, and to maintain a memory relative to those attacks, initiation of therapy in a Part D setting generally cannot be delayed for up to 7 days because of the risk of hospitalization, incapacity, disability, or death, and thus meets the first criterion. Because widely-accepted treatment guidelines recommend sub-classes of drugs rather than specific, individual drugs, the panel did not believe that every drug product should be required for inclusion on Part D sponsors' formularies. Moreover, relative to the reasonably small number of transplant options available to beneficiaries (for example, stem cell, liver, lung, kidney, pancreas, heart and intestine), the consistency and specificity of treatment guidelines, and the amount of therapeutic drug monitoring required for these drugs, provide us with sufficient clinical information necessary to establish additional, specific formulary requirements without needing to continue to identify it as a drug category or class of clinical concern.

For antidepressants, the panel concluded that a 7-day delay in initiation of therapy would generally not put the typical individual at risk of hospitalization, incapacity, disability or death, and thus did not meet the first criterion. The panel also concluded that antidepressants did not meet the second criterion. This determination was based upon the similarities of drugs within sub-classes and the lack of unique effects for distinguishing individual drug products when initiating drug therapy for the typical individual in a Part D setting. For example, for a patient initiating antidepressant therapy for depression, when the treatment guidelines indicate that a drug within the selective serotonin reuptake inhibitor (SSRI) sub-class of antidepressants should be used, there are multiple options from which to choose, such as fluoxetine, paroxetine, sertraline, citalopram, and escitalopram. While treatment guidelines may indicate the choice of an SSRI over the tri-cyclic antidepressant (TCA) or serotonin-norepinephrine reuptake inhibitor (SNRI) sub-classes, assuming a patient is dosed correctly, they generally do not advocate a preference of one SSRI drug over another for initiation of therapy, nor do they provide a hierarchical inventory for these drugs' place in therapy relative to each other. In fact, the American Psychiatric Association's 2010 treatment guideline (available at *http://www.guideline.gov/content.aspx?id=24158*) states that ''the effectiveness of antidepressant medications is generally comparable between classes and within classes of medications.''

With respect to antipsychotics, many of these take weeks to reach their full effect (steady state). In addition, with regard to the Medicare population, particularly in long term care settings, current treatment guidelines indicate that the use of antipsychotics in the elderly is, in many cases, unwarranted and in others, possibly dangerous. However, due to the potential that, untreated, beneficiaries with active psychotic symptoms may be dangerous to themselves or others, the panel concluded that a 7-day delay in initiation of therapy met the threshold to put a typical individual with psychotic symptoms at risk of hospitalization, incapacity, disability or death, and thus met the first criterion.

However, the panel concluded that antipsychotics did not have unique effects that distinguished one drug from another for the purposes of choosing the appropriate drug to initiate therapy. For example, for a patient initiating antipsychotic therapy for schizophrenia or schizoaffective, or schizophreniform disorder, when the treatment guidelines may indicate that a drug within the second generation (atypical) antipsychotic sub-class should be used, there are multiple options from which to choose such as aripiprazole, risperidone, olanzapine, quetiapine, ziprasidone, and clozapine. While the treatment guidelines may indicate the choice of a second generation antipsychotic over the neuroleptics or first generation antipsychotic sub-classes, assuming a patient is dosed correctly, they generally do not advocate a preference of one atypical antipsychotic over another for initiation of therapy, nor do they provide a hierarchical inventory for these drugs' place in therapy relative to each other. Moreover, the 2009 update to the American Psychiatric Association's treatment guideline for the management of patients with schizophrenia (available at *http://psychiatryonline.org/data/Books/prac/Schizophrenia_Guideline%20Watch.pdf*) states ''the distinction between first- and second-generation antipsychotics appears to have limited clinical utility.'' Thus the panel concluded that these agents are considered to be generally therapeutically interchangeable when initiating therapy, and based on treatment guidelines, our formulary requirements could efficiently ensure appropriate access to antipsychotics without requiring inclusion on the formulary of every drug in the class.

In addition to any cost savings that would result from the proposed change for the antipsychotic drug class, it is important to emphasize that the change also would provide Part D sponsors with an improved capability to address widespread inappropriate overuse of antipsychotic drugs through better utilization management. A recent study published in Psychiatric Services analyzing 2009 claims data from private insurance claims found that 58 percent of individuals prescribed psychotropic medication in 2009 had no psychiatric diagnosis during the year (*Psychiatric Services 2013;* doi: 10.1176/appi.ps.201200557). Moreover, on September 20, 2013, the American Psychiatric Association released a ''list of specific uses of antipsychotic medications that are common, but potentially unnecessary and sometimes harmful'', including a recommendation not to prescribe these drugs ''as a first-line intervention to treat behavioral and psychological symptoms of dementia'' (*http://www.psychiatry.org/choosingwisely*). CMS has been particularly concerned with unnecessary use of antipsychotic drugs in nursing homes, which might be exacerbated by our current policy, which significantly limits Part D sponsors' options for ensuring appropriate use of these drugs. While this change in formulary requirements generally would not impede appropriate access to antipsychotic drug therapy for the mentally ill given the other formulary protections discussed previously, it would allow Part D sponsors to better align utilization management with CMS efforts to prevent inappropriate use of these drugs and the potential harmful effects associated with such inappropriate use.

While proposing to remove the previous level of formulary coverage from these particular classes, it is worth noting that the requirement to include on plan formularies all drugs in certain categories and classes is unique to the Part D program. We are not aware of any other U.S. government programs (such as the Veteran's Administration (VA), Tricare, the Federal Employees Health Benefits Program (FEBHP), and, most recently, the Affordable Care Act Essential Health Benefits (EHB) Benchmark Plans), or commercial private health plans having a similar

requirement. Similar to the Part D program, these plans also operate in the outpatient setting where access to medications is not typically needed on an emergency basis. Even though Part D formularies are more restrictive than Federal Employees Health Benefits Plans (FEHBP) and EHB plans, when CMS compared Part D formulary requirements with those of the VA National and Department of Defense (DoD) Basic Core formularies, out of 26 distinct antidepressant drugs required on all Part D formularies, the VA included 17, and the DoD included 10. Similarly, out of 19 distinct antipsychotic drugs required on all Part D formularies, the VA included 15, and the DoD included 2.

Supporting this analysis that our formulary checks could efficiently require adequate access to the antidepressant and antipsychotic drug categories and classes without requiring that every drug be included on all Part D formularies, we compared a Part D formulary to other formularies. We took an approved CY 2014 formulary containing the average number of RxNorm Concept Unique Identifiers (RxCUIs). This formulary includes the following: 23 generic (ANDA) antidepressant drugs, 7 brand (NDA) antidepressant drugs, 18 generic antipsychotic drugs, and 9 brand antipsychotic drugs. We then reviewed the drugs comprising the aforementioned list against our formulary review requirements standards for treatment guidelines, common Medicare drugs, and the discrimination review. We found that the formulary could have passed these checks with 9 generic antidepressant drugs, and 6 generic antipsychotic drugs. No brands were necessary to meet the formulary review requirements. Thus, this formulary includes an excess of 16 brand drugs and 26 generic drugs within these two classes of medications.

While the immunosuppressant, antidepressant and antipsychotic classes all fail to meet the second criterion, we are deferring any change in formulary requirements for the antipsychotic class at this time and will continue to require all drugs from within this class to be on Part D formularies in 2015, subject to the exceptions that get finalized in § 423.120(b)(2)(vi). Section 1860D–4(b)(3)(G)(I) of the Act requires that the Secretary identify classes and categories of clinical concern ''as appropriate,'' using criteria specified in notice and comment rulemaking. We interpret this provision as permitting us to postpone applying our proposed criteria to antipsychotics at this time, and as we are not applying the criteria to antipsychotics at this time, we believe it is appropriate to continue to treat antipsychotics as a class of clinical concern, in light of section 1860D–4(b)(3)(G)(iv) of the Act, because we wish to make certain we have not overlooked a need for any transitional considerations. This is because the risks associated with untreated psychotic illness, as differentiated from the broad category of mental illness, have the potential to be so severe. Therefore, although we previously explained why we do not believe the antipsychotic drug class would meet the new proposed criteria, at this time, we are proposing not to subject the antipsychotic class to the new criteria and therefore are proposing not to change the current requirement that all drugs from within this class must be included on all formularies, except as permitted under our proposed exceptions.

In general, our existing beneficiary protections should suffice to ensure appropriate access to antipsychotic drug therapies. However, we are not changing the requirement for antipsychotics at this time because we need to determine if additional transitional consideration is necessary for any individuals taking these medications. While we are not convinced that our existing transition requirements are insufficient, we seek comment on whether there are additional considerations for transitioning some patients taking these drugs to alternative drug therapies and if so, why our current requirements are not adequate. In addition, we seek comments on what specific patient population(s) or individual patient characteristics would require such additional transition protections and how such population(s) can be consistently identified. Conversely, we also seek comments on whether it might be in the best interest of beneficiaries to have their existing antipsychotic therapies reevaluated through utilization management, given our concern with the inappropriate use of these drugs especially in nursing homes and the limited clinical utility of distinctions among agents in this class of drugs. If so, we would also appreciate comments on whether the benefits of such a periodic reevaluation that would arise from routine utilization management might outweigh other transitional risks. While we do not believe the risks associated with illnesses treated by antidepressants are as severe as those treated by antipsychotics, we are also seeking comment on whether any transitional policies specific to antidepressants would be appropriate.

We are concerned about overutilization and inappropriate prescribing of antipsychotic medications in individuals with dementia for whom these medications may be prescribed as a mechanism for behavioral control; persons for whom antipsychotics are being used as sleeping aids or anxiolytics; and children who have not been diagnosed with a disorder for which an antipsychotic medication has been FDA-approved. Our concerns about overutilization are not aimed at individuals with a current mental illness or those who are or have recently or previously been stabilized on antipsychotic medications. We do not want to limit access to effective medications, or to limit a return to those effective medications for adults with a psychotic illness who need them. Finally, we seek comment on the timing necessary to address any additional transitional considerations, and remove the temporary protections for antipsychotics, if necessary.

Therefore, the initial drug categories and classes of clinical concern that meet the proposed criteria for coverage year 2015 are anticonvulsants, antiretrovirals, and antineoplastics. In addition, the antipsychotic drug class will continue to be treated as a class of clinical concern in 2015 and until CMS determines that it is appropriate to apply the criteria with respect to the antipsychotics. These categories and classes will be read narrowly and are not inclusive of every related drug product that an individual who has a disease treated by one of these categories or classes of drugs would need to take. For example, conjugated or esterified estrogens used for the palliative treatment of carcinoma of the prostate or metastatic breast cancer are not considered antineoplastics and would not be included in the antineoplastic class of clinical concern. We will provide more detailed guidance on the specific formulary checks that will be in place relative to antidepressant and immunosuppressant categories and classes of drugs at a later date. Additionally, we plan to work with stakeholders to provide outreach to beneficiaries around the proposed modification of the categories and classes of drugs of clinical concern that receive additional protections under section 3307 of the Affordable Care Act so that beneficiaries can select the most appropriate drug plan for their needs based on drug choice as well as cost. Finally, CMS plans to periodically review the drug categories and classes

as the clinical landscape changes to determine whether these classes continue to meet both criteria and/or if other categories/classes meet both criteria. We would propose any changes to the categories and classes of clinical concern through a public notice and comment process such as the annual Call Letter.

15. Medication Therapy Management Program (MTM) Under Part D (§ 423.153(d))

Section 1860D–4(c)(2) of the Act, provides that Part D sponsors, in offering Medication Therapy Management (MTM) programs, must target individuals who: (1) Have multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure); (2) are taking multiple covered Part D drugs; and (3) are identified as likely to incur annual costs for covered Part D drugs that exceed a level specified by the Secretary. At the start of the Part D program, we believed that 25 percent of enrollees would qualify for MTM services. However, analysis revealed that MTM program enrollment was well below that level. In the 2010 Call Letter and subsequent regulation, we modified the criteria to reduce the variability in eligibility and level of service and to improve access to MTM services, again targeting 25 percent of enrollees. Despite these changes, MTM program participation remains very low. Moreover, additional evidence that the program improves quality and generates medical savings supports the idea that more than 25 percent of enrollees will benefit from MTM services.

Section 1860D–4(c)(2)(C) of the Act, as implemented in § 423.153(d)(vii), specifies that sponsors shall offer a minimum level of MTM services to targeted beneficiaries to increase adherence to prescription medications or other goals deemed necessary by the Secretary. Additionally, section 1860D–4(c)(2)(E [2]) of the Act, as implemented in § 423.153(d)(1)(v), provides that Part D sponsors must automatically enroll targeted beneficiaries in the MTM program, allowing beneficiaries the option to opt out. Under that authority, we also issued sub-regulatory guidance (found at *http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter7.pdf*) and an annual memo with MTM Program Guidance and Submission instructions notifying Part D sponsors that we expect them to promote continuity of care by performing an end-of-year analysis that identifies current MTM program participants who will continue to meet the eligibility criteria for the next program year for the same plan. We indicated that this targeting could be done to auto-enroll beneficiaries in the plan's MTM program early in the next program year in order to provide MTM interventions with less interruption. Although beneficiaries who are new to Part D or who may have changed plans may be captured during the quarterly, or more frequent, targeting throughout the year, there is a time lag at the start of the year before these beneficiaries can be enrolled in MTM. This concern is particularly relevant for LIS enrollees who may have been reassigned to a new Part D plan if their existing plan terminated or no longer qualified as a benchmark plan. Moreover, we believe that there are other special populations of beneficiaries for whom simply increasing the frequency of targeting will not adequately address barriers they face to receiving MTM services. There are also situations in which a beneficiary is unable to accept the offer to participate in a CMR, but offering to perform the CMR with the beneficiary's prescriber, caregiver, or other authorized individual, as provided at § 423.153(d)(1)(vii)(B)(2), may not be effectively addressed by the sponsor. For example, sponsors may not effectively take steps to identify the beneficiary's authorized representative or coordinate with the beneficiary's LTC facility when appropriate. Consequently, to improve access to this beneficial service, we are exploring new ways to improve access to MTM services for Part D enrollees.

Although we initially estimated that 25 percent of the Part D eligible population would meet the three criteria for MTM services at the start of the Part D program, we provided minimal detail on how sponsors should implement the criteria. For example, we did not initially provide in regulation any detail on the number of chronic diseases or covered Part D drugs, or an annual cost threshold that would be required to establish a beneficiary's eligibility for MTM services, although we established an annual cost threshold of $4,000 in subregulatory guidance. We did this to allow maximum flexibility for the industry to develop best practices in the provision of MTM services.

After an analysis of common practices revealed wide ranges in eligibility and the levels of services provided, we announced in the 2010 Call Letter (available at *http://www.cms.gov/PrescriptionDrugCovContra/Downloads/2010CallLetter.pdf*) that the MTM requirements would be revised beginning in 2010 to provide greater consistency among the MTM programs and to raise the level of MTM interventions offered to positively impact medication use by Medicare Part D beneficiaries. We clarified that in defining multiple chronic diseases, sponsors could not require more than three chronic diseases as the minimum number of chronic diseases and that sponsors must target at least four of seven core chronic diseases (hypertension, heart failure, diabetes, dyslipidemia, respiratory disease (such as asthma, chronic obstructive pulmonary disease (COPD), or chronic lung disorders), bone disease—arthritis (such as osteoporosis, osteoarthritis, or rheumatoid arthritis), and mental health (such as depression, schizophrenia, bipolar disorder, or chronic and disabling disorders)). We further clarified that in defining multiple Part D drugs, sponsors could not require more than eight Part D drugs as the minimum number of multiple covered Part D drugs. We also lowered the cost threshold to $3,000 and instructed sponsors to adjust their targeting criteria accordingly. These requirements were subsequently codified in the regulations at § 423.153(d)(1) and (2).

Despite the expanded criteria, we continue to see restrictive criteria, such as plan sponsors specifying a narrow list of chronic diseases or Part D drugs coupled with requiring a higher minimum number of covered drugs (for example, eight drugs versus two) for eligibility. As a result, access to MTM services remains very low with MTM program eligibility rates at less than 8 percent in 2011. Even more concerning, there may be racial disparities in meeting the eligibility criteria. In the 2012 Call Letter (available at *http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2012.pdf*), we reviewed a 2010 study published in *Health Services Research* (HSR) by Wang and colleagues (Wang, et al. 2010. ''Disparity Implications of Medicare Eligibility Criteria for Medication Therapy Management Services.'' *Health Services Research.* 45 (4): 1061–1082.). This study was based on data from the Medical Expenditure Panel Survey (MEPS) collected prior to the implementation of the Part D program and used the original 2006 and the revised 2010 MTM eligibility thresholds. The study suggested that Hispanic and African American beneficiaries could be less likely to meet MTM eligibility criteria where utilization was a criterion for program

[2] Two subparts (E) have been enacted in section 1860D–4(c)(2). Here, we refer to the first one.

participation. The study findings had important implications for the Part D program because utilization based upon drug costs is a critical part of MTM eligibility. In 2012, Wang and colleagues repeated the study (Wang, et al. 2012. ''Historical trend of disparity implications of Medicare MTM eligibility criteria.'' *Research in Social and Administrative Pharmacy (2012):* 1–12) using 2007–2008 data along with both the 2006 and 2010 MTM eligibility thresholds. They found that disparity patterns did not change from the first study. Their findings that ''racial and ethnic disparities in meeting the MTM eligibility criteria may not decrease over time unless the eligibility criteria are changed'' have led us to conclude that the current MTM eligibility criteria are overly restrictive.

A 2011 report from the United States Public Health Service (PHS) Pharmacist Professional Advisory Committee (PharmPAC report) (available at *http://www.usphs.gov/corpslinks/pharmacy/sc_comms_sg_report.aspx*) supports the conclusion that the current eligibility criteria are restricting access to MTM services. The PharmPAC report, which was based on the experiences of PHS clinical pharmacists who attempted to provide services to Part D beneficiaries, indicated that the Part D MTM eligibility criteria, and variability in the application of these criteria among Part D sponsors, constituted a policy constraint which limited patient participation in the program, despite the 2010 enhancements. The authors of the PharmPAC report expressed concern that, at the time, the criteria permitted sponsors to define eligibility parameters. The PharmPAC report went on to say that as a result of the overly restrictive targeting criteria, patients who may need MTM services but did not meet the plan's criteria were not able to participate, unless the plan offered MTM services to a wider group than the targeted population.

Further supporting this conclusion, a recent study conducted in conjunction with the Center for Medicare and Medicaid Innovation called Medication Therapy Management in Chronically Ill Population: Final Report (August 2013) (''CMMI MTM study'') (available at *http://innovation.cms.gov/Data-and-Reports/index.html*) explored the variations in MTM eligibility criteria. This CMMI MTM study identified patients with equivalent MTM eligibility characteristics who were in different plans with different eligibility criteria. The enrollees were ineligible for MTM in their own plan, but would have been eligible for MTM if they were enrolled in another plan which targets a particular chronic disease that is not targeted for MTM services by their own plan or which targets beneficiaries for MTM services based on a lower number of chronic diseases or Part D drugs for eligibility. We are concerned with such variability, especially in cases where a beneficiary meets the minimum number of chronic diseases for eligibility, but may not qualify for MTM because his or her chronic condition is not targeted by the plan, he or she does not take enough medications for the plan's program (even though medication management issues are present), or because high utilization of lower cost generics places prescription drug costs for the beneficiary below the cost threshold. Restrictive application of MTM eligibility criteria may limit MTM enrollment to beneficiaries with spending well above the $3,000 threshold, and the CMMI MTM study indicates that drug spending for MTM enrollees varied from $4,452 to $7,477. The CMMI MTM study's final report was published in August, 2013 and is available at: *http://innovation.cms.gov/Files/reports/MTM-FINAL-Report.pdf*.

As discussed in the 2014 Call Letter (available at *http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcements2014.pdf*), the CMMI MTM study found that MTM programs effectively targeted high risk individuals who had problems with their drug-therapy regimens and had high rates of hospital and emergency room visits before enrollment as well as those that experienced a recent visit to the hospital or emergency room. The study also found that individuals with diabetes, CHF, and COPD who were enrolled in MTM programs—particularly those who received annual comprehensive medication reviews (CMRs)—experienced significant improvements in drug therapy outcomes when compared to beneficiaries who did not receive any MTM services, thus supporting the hypothesis that the annual CMR may be one of the more crucial elements of MTM. Significant cost savings associated with all-cause hospitalizations at the overall PDP and MA–PD levels were found, which may be due to MTM's comprehensive, rather than disease specific approach. This research supports statements in a recent Congressional Budget Office report that programs and services that manage the prescription drug benefit well or improve prescription drug use might result in medical savings (Congressional Budget Office, Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services, November 2012, available at *http://www.cbo.gov/publication/43741*).

Consistent with the findings of this research, we believe that the CMS-established eligibility criteria should be considered as the threshold for MTM eligibility, but not the driver of interventions by the plan. However, because plans target beneficiaries with specific diseases for MTM services, some plans, in turn, have designed interventions only focused on these diseases, in contrast to a more comprehensive approach to improving medication management and adherence. For example, one plan targeted beneficiaries with CHF and diabetes and designed interventions for these conditions. Beneficiaries who also had COPD qualified for MTM services, but the plan did not address their COPD medication issues, a practice that is inconsistent with the intent of comprehensive MTM. Nonetheless, the best-performing plans were able to improve medication adherence and quality of prescribing while maintaining or reducing overall health care costs (including drug costs), despite the costs associated with delivering a high number of CMRs. Moreover, the study's findings suggested that other conditions associated with cardiovascular disease, such as acute myocardial infarction (AMI), stroke, and vascular disorders, in addition to those already targeted under the eligibility criteria adopted in 2010, disproportionately appeared among the top cost savers.

Overall, the CMMI MTM study identified practices that typified high-performing MTM programs, including three that concern beneficiary targeting. They are:

- Establishing proactive and persistent CMR recruitment efforts;
- Targeting and aggressively recruiting patients to complete a CMR based on information on medical events such as a recent hospital discharge in addition to scanning for the usual MTM eligibility criteria; and
- Coordinating care by utilizing trusted community relationships, including networks of community pharmacists, to recruit MTM eligible candidates, and utilizing existing working relationships between MTM providers (pharmacists) and prescribers to make recommendations and discuss identified problems for patients.

Potential additional requirements, related to the first and third practices, are discussed elsewhere in this proposed rule. However, the second practice leads us to reconsider our current MTM targeting requirements. We believe that the results of the aforementioned studies indicate the

necessity to reduce variability in eligibility criteria among plans and as a result improve access to MTM services.

a. Multiple Chronic Diseases

The statute identifies targeted beneficiaries as those Part D beneficiaries who have multiple chronic diseases such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure. We previously interpreted this language to allow sponsors to define ''multiple chronic diseases'' with three chronic diseases being the maximum number a plan sponsor may require for targeted enrollment. Further, sponsors are allowed to target beneficiaries with select chronic diseases, but must include at least five of the nine core chronic diseases in their criteria. This list of core chronic diseases, as updated in the 2013 Call Letter (available at *http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads//Announcement2013.pdf*), includes hypertension, congestive heart failure, diabetes, dyslipidemia, respiratory disease, bone disease—arthritis, mental health, Alzheimer's disease, and end stage renal disease. We propose to revise our interpretation of ''multiple chronic diseases'' to require that sponsors must target enrollees having two or more chronic diseases for MTM services. We believe this is a reasonable interpretation of the statute because ''multiple'' is commonly understood to mean more than one.

In addition, we believe that the statute specifically named the diseases that are most prevalent within the Medicare Part D beneficiary population and that present a likelihood of having medication use issues that impact therapeutic outcomes. Therefore, we propose to require that at least one of the chronic diseases that a beneficiary has in order to satisfy the eligibility criteria must be one of the list of core chronic diseases. This list has been updated since 2010 to encompass common targeting practices among plan sponsors and diseases prevalent among beneficiaries. We also believe that this interpretation is consistent with other literature concerning the relative risk of the combination of multiple disease states and medications and ensures that Medicare Part D beneficiaries with prevalent health conditions receive access to MTM. In addition, to be more consistent with the findings of the CMMI MTM study and the current drug hierarchical condition categories (RxHCCs) used in the Part D risk adjuster, we propose to redefine the core diseases by combining hypertension and congestive heart failure under the umbrella of ''cardiovascular disease,'' which would also encompass congestive heart failure, acute myocardial infarction, cerebral hemorrhage and effects of stroke, vascular disease, specified heart arrhythmias, and hypertensive heart disease. The list of core chronic diseases would thus become cardiovascular disease, diabetes, dyslipidemia, respiratory disease, bone disease—arthritis, mental health, Alzheimer's disease, and end stage renal disease. However, in future rulemaking, we may consider further revising the regulation to establish standards by which these core chronic diseases are selected, and therefore establish the list of core chronic diseases annually in subregulatory guidance based on those factors. We solicit comment on what specific patient population(s) or individual patient characteristics should be considered in establishing such standards.

b. Multiple Part D Drugs

The statute identifies targeted beneficiaries as those Part D beneficiaries who are taking multiple covered Part D drugs. Although we initially had no requirements in this area, as early as contract year 2006, we asked plan sponsors to report to us the number of covered Part D drugs that a beneficiary must have filled to meet their targeting criteria for MTM, and if applicable, to list the type of Part D drugs that would apply. While still allowing a great deal of flexibility in the design of MTM programs, for contract year 2007 forward, we requested more detailed information in this area in MTM Program Submission materials for a March 15, 2006 User Group Call which were distributed through HPMS. We asked plan sponsors to identify the number of covered Part D drugs that a beneficiary must have filled to meet their criteria for MTM programs, and to provide information on the type of covered Part D drugs that would apply. Specifically, we asked if any Part D drug would apply, only chronic/maintenance drugs, only disease-specific drugs related to chronic diseases, or if specific Part D drug classes would apply (and what those drug classes were), or what other types of categories the plan sponsor intended to use. For coverage year 2013, we consolidated this list of types of covered Part D drugs that could apply and no longer specifically collected information on disease-specific drugs related to chronic diseases. (MTM Program Submission Process Guidance for CY 2013 is available at: *http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Memo-Contract-Year-2013-Medication-Therapy-Management-MTM-Program-Submission-v041012.pdf*)

Because our analyses continued to reveal such wide ranges in eligibility under this criterion, we issued guidance in 2009, which we subsequently codified in our April 2010 final rule entitled, ''Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (75 FR 19678), to establish specific requirements regarding the minimum number of covered Part D drugs that plan sponsors should consider in order to satisfy the statutory requirement. Specifically, we instructed that Part D sponsors should define ''multiple'' for purposes of satisfying this requirement as no more than eight Part D covered drugs. (75 FR 19772) Although we tried to maintain maximum flexibility for plan sponsors by permitting this broad range, the authors of the PharmPAC report specifically cite the options available to plan sponsors in determining enrollee eligibility criteria for multiple Part D drugs as a limitation of the MTM programs required under Part D. We now believe that allowing plans this flexibility has contributed to beneficiary confusion, decreased access to MTM services, and even led to racial disparities in access to services.

We propose to revise our interpretation of ''multiple Part D drugs'' to require that sponsors must target enrollees taking two or more Part D covered drugs for MTM services. While we are expanding this criterion, we are also proposing to restrict the flexibility previously available to sponsors by requiring that they consider any Part D covered drug. Literature supports the idea that patients with multiple diseases and taking at least two drugs are more likely to have drug therapy problems.

The importance of MTM services for patients taking two or more medications was demonstrated in a 2007 evaluation which validated the Risk Based Relative Value Scale (RBRVS) for MTM Services by Isetts and colleagues on behalf of the state of Minnesota (available at *http://www.dhs.state.mn.us/main/groups/business_partners/documents/pub/dhs16_140283.pdf*). This study shows that when a patient has a single indication treated by at least two medications, there is likely to be at least one drug therapy problem. When the patient moves to two indications, he or she is more likely to be treated by at least three to five medications, and will likely have at least two drug therapy problems. It should be noted that this

evaluation considered not only prescription drugs, but also over the counter medications and dietary supplements.

TABLE 2—PHARMACEUTICAL CARE RBRVS *—AT A GLIMPSE

Level **	Number of medical indications	Number of medications	Number of drug therapy problems (DTP)
Level 1	At least 1	At least 1	None observed.
Level 1	At least 1	At least 2	1 DTP.
Level 2	At least 2	At least 3–5	2 DTPs.
Level 3	At least 3	At least 6–8	3 DTPs.
Level 4	4 or more	9 or more	4 or more DTPs.

* Summarized from the Minnesota DHS Web site Program Guide for Delivery of Medication Therapy Management Services (MTMS).
** The level of care reported is the lowest of patient needs met by all criteria in each level.

Section 3503 of the Affordable Care Act establishes a program under the Public Health Service Act under which the Secretary is authorized to provide grants or contracts to eligible entities to implement MTM services and provides that MTM programs shall target individuals who take four or more prescribed medications, including over-the-counter (OTC) medications and dietary supplements, and take any high-risk medications. Although this provision does not directly pertain to the Part D program, we believe that an examination of the criteria used to target individuals under that provision is helpful in considering what changes could be made to improve the effectiveness of MTM programs offered under Part D. Unlike section 3503 of the Affordable Care Act, which expressly requires that services be targeted based on the use of either prescription or non-prescription drugs, the Part D statute expressly requires that Part D plans target beneficiaries taking multiple covered Part D drugs for MTM services. OTC medications or dietary supplements are not covered Part D drugs, and we cannot require Part D sponsors to consider them in targeting beneficiaries for MTM services. Nevertheless, as evidenced by the RBRVS approach discussed previously, we believe that these OTC medications and supplements may contribute to drug therapy problems. Therefore, we believe that it is reasonable to propose that ''multiple Part D drugs'' should be construed to mean two or more Part D drugs in order to ensure that beneficiaries that are at risk of drug therapy problems, including problems associated with taking multiple prescription medications in conjunction with over-the-counter medications, are appropriately targeted for MTM services. A literature review (Hajjar ER, Cafiero AC, Hanlon JT. Polypharmacy in elderly patients. *Am J Geriatric Pharmacother.* 2007; 5:345–351) cited a study that found that almost 90 percent of elderly, rural community-dwelling patients took one or more OTC products and almost 50 percent took two to four. Another study of noninstitutionalized patients found that 47 to 59 percent of older patients took a vitamin or mineral and 11 to 14 percent took herbal supplements. The review found that polypharmacy among the elderly may be increasing. (Stoehr GP, Ganguli M, Seaberg EC, et al. Over the counter medication use in an older rural community: The MOVIES Project. *J Am Geriatr Soc.* 1997; 45:158–165). Therefore, it is reasonable to conclude that the Part D MTM population with multiple chronic diseases would also be taking OTC medications. Furthermore, we expect that sponsors will perform outreach to beneficiaries to acquire additional information regarding OTC medication use by their enrollees, consistent with our current guidance for CMRs, which explains that the medication review as part of the CMR should include prescriptions, OTC medications, herbal therapies, and dietary supplements (available at *http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Memo-Contract-Year-2013-Medication-Therapy-Management-MTM-Program-Submission-v041012.pdf*).

Although we are proposing this option, we also considered alternatives such as duplication of the section 3503 of the Affordable Care Act criteria for four or more prescribed medications which could include OTC medications and dietary supplements, provided the beneficiary was taking at least 2 covered Part D drugs. However, we recognized that Part D sponsors would not have the ability to assess an enrollee's use of OTC medications or dietary supplements in order to determine MTM eligibility despite the RBRVS approach which suggests that beneficiaries may still experience drug therapy problems when they have only one chronic disease but take at least two medications, which could include OTC medications or dietary supplements. As a result, we solicit comments on alternative definitions for ''multiple Part D drugs,'' including what minimum number of medications is appropriate for MTM targeting.

c. Annual Cost Threshold

The Congress did not impose any specific requirements with respect to the cost threshold at the time the MTM criteria were passed in to law, nor has it addressed this threshold in any of the subsequent amendments to section 1860D–4(c)(2) of the Act. When we first established the requirements regarding MTM programs, we recognized that cost alone was not the best indicator of those that could benefit most from MTM. Indeed, in our January 2005 final rule entitled, ''Medicare Prescription Drug Benefit'' (70 FR 4282), we stated that cost might not be the best proxy for identifying patients that could benefit most from MTM. Nevertheless, in an attempt to identify a manageable population at the start of the program, we believed that individuals with the highest costs were more likely to be suffering from more chronic conditions and taking more Part D medications. Therefore, we believed that setting a cost threshold that would limit MTM programs to the individuals with the highest costs would increase the likelihood that MTM services would be provided to those individuals that could benefit most (because those individuals were likely to be at greater risk for improper medication use and adverse drug events). Thus, although it was set in subregulatory guidance, we established the initial $4000 cost threshold at the inception of the Part D program.

As discussed in our April 2010 final rule entitled, ''Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs'' (75 FR 19776), following an analysis of plan reported data, we found

that only 10 percent of beneficiaries enrolled in a Part D plan with an approved MTM program were eligible for MTM services in 2006 and only 13.1 percent were eligible for MTM services in 2007. In 2008, we conducted an analysis of beneficiary drug costs using Prescription Drug Event (PDE) data from contract years 2006 and 2007 obtained from the Integrated Data Repository (IDR) system. As part of this analysis, the total gross drug cost and number of beneficiaries that incurred annual drug costs (below) or (greater or equal to) the $4000 cost threshold was determined. The average number of PDEs and average costs per beneficiary were also calculated. Further analysis examined cost breakouts in $500 increments to determine the distribution of beneficiaries, as well as the number of fills, and gross drug cost for beneficiaries with annual drug costs in each of these categories. We determined that close to 25 percent of Part D enrolled beneficiaries with drug utilization (beneficiaries with at least one PDE during the study period) during 2006 and 2007 had annual gross drug costs of at least $3,000. Therefore, we lowered the cost threshold to $3,000 in the 2010 Call Letter. Based upon our analysis of the more recent data in 2010, we concluded that this threshold would ensure that approximately 25 percent of the beneficiaries using the Part D benefit would receive MTM services, and we codified the $3,000 threshold, as updated annually by the annual percentage increase in the average per capita aggregate expenditures for Part D drugs for Part D eligible individuals under § 423.104(d)(5)(iv) in the April 2010 final rule entitled, ''Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs'' (75 FR 19818). The threshold is currently $3,144 in 2013.

However, the use of lower cost generics has been increasing since the Part D program began, so the application of this threshold may exclude many beneficiaries who are in need of MTM services. We believe this increase in the use of lower cost generics may contribute to low MTM program enrollment rates which currently hover around 8 percent, and may also be a driver in racial disparity in MTM program enrollment. Additionally, prior work, including the RBRVS approach described previously, assigns relative risk of needing MTM services using the number of indications that an individual has and the number of medications that he or she is taking, but does not address a cost threshold. Consequently, we are concerned that there are a number of beneficiaries who need MTM, but are not currently eligible because they do not meet the current cost threshold of $3,144, despite the increased likelihood of having drug therapy problems as a result of having multiple chronic diseases and taking multiple medications. Moreover, the current cost threshold may have the unintended consequence of causing beneficiaries to no longer qualify for MTM services in the next plan year (whether remaining in the same plan or enrolling into a new plan) if they fall below the cost threshold as a result of their enrollment in plans that employ cost avoidant strategies, such as aggressive use of generics, or in MTM programs that center on therapeutic interchange.

Consistent with our proposal that sponsors must target enrollees taking two or more Part D covered drugs for MTM services and taking into account that one or more of these Part D drugs are likely to be generics, we propose setting the annual amount in Part D drug costs at an amount that represents the intersection of multiple conditions and multiple drugs. Based on an analysis of PDE data, the average cost of a generic prescription is $25.85. Because a very small percentage of prescriptions are for more than 30 days, we assume that this amount is the average cost for a 30-day generic prescription. Thus, the annual total drug cost for a beneficiary filling two generic prescriptions is $620.40. Accordingly, consistent with our proposal to determine a cost threshold that is commensurate with the drug spending of beneficiaries that meet the first two criteria regarding multiple conditions and use of multiple covered Part D drugs, we would set the cost threshold at $620, which is the approximate cost of filling two generic prescriptions. We propose to revise this number periodically to reflect more up-to-date information regarding the drug spending of beneficiaries that have two or more chronic conditions and use two covered Part D drugs. We remind sponsors that the drug costs used to determine if the total annual cost of a beneficiary's covered Part D drugs is likely to equal or exceed the specified annual cost threshold for MTM program eligibility includes the ingredient cost, dispensing fee, sales tax, and vaccine administration fee, if applicable. Because the statute requires that plans target beneficiaries who ''are identified as likely to incur annual costs for covered Part D drugs that exceed a level specified by the Secretary,'' we encourage sponsors, as most do now, to project annual costs for a beneficiary based on costs from the preceding month or quarter.

We took a number of factors into consideration in deciding to propose lowering the annual threshold to a level commensurate with the drug spending of beneficiaries with multiple chronic diseases taking two covered Part D drugs. Doing so promotes consistency among Part D plans relative to the three eligibility criteria set forth in the statute by factoring multiple conditions and multiple Part D drugs into how the cost threshold is set. We know now that patients with multiple conditions and taking multiple drugs have a higher probability of having at least two drug therapy problems and could benefit from MTM. More beneficiaries are using lower cost generic alternatives and no longer meet the current cost threshold, which is over $3,000, and studies have found that the current cost threshold may promote racial disparities in MTM eligibility.

Based on an analysis of 2011 PDE data and 2011 RxHCCs from the Risk Adjustment system, approximately 60 percent of Part D enrollees have two or more chronic diseases were taking two or more Part D drugs and incurred drug costs greater than or equal to $500. We found that 50 percent of Part D enrollees have two or more chronic diseases, were taking two or more Part D drugs, and had drug costs of greater than or equal to $1000. Therefore, we estimate that approximately 55 percent of Part D beneficiaries will be eligible for MTM based on the proposed criteria (two or more chronic diseases, two or more Part D drugs, and likely to incur $620 in annual Part D drug costs).

The CMMI MTM study found that high-performing MTM programs not only improved drug therapy outcomes but also maintained or lowered rates of hospitalizations, ER visits, and associated costs. Therefore, more of the Part D population can benefit from MTM services and these programs can potentially positively impact the Medicare program as a whole through improved medication use and lower healthcare costs. As a result of this, we no longer believe that it is appropriate to target only 25 percent of the Part D populations, and only those beneficiaries with high drug costs. This is consistent with our view in our January 2005 final rule where we stated that we believe that MTM must evolve and become a cornerstone of the Medicare Prescription Drug Benefit. We also intend that the Medicare Prescription Drug Benefit will serve as a model for achieving quality

improvement in prescription drug therapy.

Although we are proposing to set the annual threshold at a level that is commensurate with the drug spending of beneficiaries with two or more chronic diseases that use two covered Part D drugs, we considered other alternatives. For example, we considered setting the threshold at $900 or $1200, which roughly coincide with cost thresholds achieved by taking three or four generic drugs. We solicit comment, based on industry and MTM provider experience, on where this threshold might be alternatively set.

Although we are proposing to broaden MTM eligibility, we also believe there are special populations of beneficiaries for whom broader targeting criteria will not adequately address barriers they may face to receiving MTM services. The CMMI MTM study found that effective MTM programs establish proactive and persistent CMR recruitment efforts. These programs also utilize trusted community relationships, including networks of community pharmacists, to recruit MTM eligible candidates as well as existing working relationships between MTM providers (pharmacists) and prescribers to make recommendations and discuss identified problems for patients. Trusted community relationships are an important tool that can be leveraged to reduce disparities in access to MTM services, and other health disparities in general, faced by some special populations of beneficiaries.

For example, LIS-enrollees are a diverse group and are more likely than other Medicare enrollees to have a high burden of disability and chronic disease, to have limited English proficiency, and to belong to a racial or ethnic minority group. Although LIS-eligibility is not a perfect indicator for the social determinants of health faced by those with limited English proficiency or belonging to racial or ethnic minorities, it is true that those with limited English proficiency, and those belonging to racial and ethnic minorities are more likely than other Medicare enrollees to be poor. Because this financial status is frequently compounded by a variety of barriers to accessing health insurance and care, these beneficiaries generally have a higher burden of disability and chronic disease. As discussed previously, the use of utilization-based criteria to target at-risk individuals who may not, as a result of cultural norms or preferences, be high utilizers of health care services is particularly troubling. This comes in spite of evidence in treatment guidelines which suggests that they may need targeted outreach. Such criteria may also miss other high-risk individuals who use multiple low-cost generic drugs that present a safety risk without reaching a cost threshold. More of these beneficiaries will be eligible for MTM services due to the revised criteria that we are proposing in this rule. However, there are currently no requirements under our regulations that Part D plans ensure that beneficiaries in these special populations receive focused outreach or engagement to increase their participation in MTM.

Chronic disease and disability are common in the LIS population. More than 80 percent of Part D enrollees who had spending high enough to reach catastrophic coverage were LIS enrollees. Additionally, the reassignment process can present additional challenges for LIS enrollees such as new formularies, requirements for prior authorizations, step therapy, or quantity limits, processes for exceptions, appeals, and grievances, and contacting their plan. This makes it more challenging for LIS enrollees to maintain access to their drugs. Further, pharmacists at the point of sale frequently spend a great deal of time with and on behalf of these enrollees as they face formulary changes. This, in turn often generates high levels of frustration for the enrollee, as he or she waits for the pharmacist to resolve the issues, as well as for the pharmacist, as the effort required to assist the customer approaches the level of service furnished in MTM, but remains uncompensated.

Challenges faced by LIS enrollees in the Part D program are exacerbated for those with limited English proficiency or who belong to a racial or ethnic minority. For example, translators and multi-language inserts currently required may not be adequate to address the cumulative effects of race and ethnicity, lower levels of education, and poverty that are frequently associated with individuals with limited English proficiency. Moreover, messages conveyed by such approaches may not be consistent with an individual's underlying cultural beliefs and attitudes about medicine and therapy.

Another example involves the Indian Health Service, which is staffed by many health care providers in the United States Public Health Service and bears primary responsibility for caring for American Indians and Alaska Natives. The Indian Health Service is comprised of facilities operated by the Indian Health Service, tribes or tribal organizations pursuant to the Indian Self-Determination and Education Assistance Act, and urban Indian organizations pursuant to title V of the Indian Health Care Improvement Act. When the majority of American Indians and Alaska Natives live outside reservation land, where most IHS/tribal facilities are located, barriers in access to care are seen in both rural and urban landscapes, where there is limited availability of providers or limited offering of services, respectively. Transportation to IHS/tribal facilities may be a barrier and, the PharmPAC report also indicates that the patient-perceived benefit of paying monthly premiums, in light of 100 percent coverage of health care expenses for eligible patients, may also reduce participation in MTM services. The PharmPAC report goes on to state that the Public Health Service Pharmacy program has apprehension about contracting with Part D plans offering MTM programs because limited compensation by Part D plans for MTM services is not cost-effective to implement on a national scale.

We believe that the difficulties faced by special populations of beneficiaries represent important opportunities for robust MTM services that, when associated with early completion of CMRs, will help beneficiaries navigate the reassignment process, better reward pharmacists for the level of effort needed to serve these beneficiaries, and provide another option for sponsors to manage high cost beneficiaries. We have previously discussed the impact of one-to-one counseling by State Health Insurance Assistance Programs, and a growing body of evidence indicates that the person-to-person aspect of MTM (including through the use of telehealth technologies) has the potential to yield multiple benefits that warrant more effective outreach by sponsors to LIS beneficiaries and those with limited English proficiency or who belong to a racial or ethnic minority. As we see with the proportion of LIS-eligible-but-unenrolled beneficiaries who have to apply to qualify for subsidies, generalized attempts at outreach are not sufficient to increase enrollment. Because of the wide variety in social determinants that contribute to barriers in access to coverage and care, individualized approaches to target populations such as LIS-eligible, limited English proficiency, racial and ethnic minorities, including American Indians and Alaska Natives, within the larger MTM-eligible population will likely require a multi-faceted approach. Thus, the opt-out method of enrolling targeted beneficiaries into MTM at § 423.153(d)(1)(v) may only partly

address the increased barriers to care faced by this group.

We are concerned that such social determinants contribute to persistently low MTM enrollment and participation despite attempts to broaden the criteria. As we have gained more experience with the MTM programs, we have become concerned with the number of simplistic, generalized strategies that have been implemented for delivering MTM services. We believe that Part D sponsors' strategies for outreach and service provision cannot be ''one size fits all'' and must be appropriately geared to social and demographic subpopulations within the overall targeted population in order to be effective. As discussed previously, the CMMI MTM study identified that high-performing MTM programs engage in multi-pronged, persistent efforts to recruit Medicare beneficiaries to CMRs and often use effective and diverse communication modalities such as person-to-person interactions, phone calls, or community contacts (through networks of trusted community pharmacists), if needed. Moreover, as illustrated in the example of the Indian Health Service, this may also include negotiating rates more acceptable to MTM providers that beneficiaries perceive as more accessible and trustworthy.

Consequently, we are interpreting section 1860D–4(c)(2)(D) of the Act, which requires plans to have in place a process to assess medication use of individuals who are at-risk but not enrolled in MTM, to require Part D sponsors to establish effective strategies that ensure access to MTM services for all eligible beneficiaries. The statutory requirement to assess the medication use of at risk beneficiaries should encompass the requirement that plan sponsors better address barriers in access to MTM services and improve participation rates, particularly at the start of enrollment in the plan, faced by those with limited English proficiency, those who belong to racial and ethnic minorities, or who are LIS enrollees. Without being prescriptive about what strategies must be employed, we are proposing that sponsors develop an effective strategy to ensure access to services for all MTM-eligible beneficiaries, including those who have disabilities or who have limited English proficiency. Specifically, we propose to revise § 423.153(d)(1)(v) to include the requirement that a Part D sponsor must ''have an outreach strategy designed to effectively engage all at-risk beneficiaries enrolled in the plan.''

Sponsors have previously commented to us that they have difficulty reaching many individuals in these special populations because of inconsistent or incorrect contact information. While this certainly presents an added challenge, plan sponsors could, for example, analyze fill data, and partner with pharmacies they know that a particular beneficiary or populations of beneficiaries frequent. Incorporating the pharmacies that targeted individuals utilize into the MTM program may be a particularly effective strategy for successful outreach that will lead to enrollment in MTM programs that is more broadly representative of the breadth of demographic segments in the targeted population. We believe that current plan reporting requirements, along with other CMS data sources, will be sufficient for us to evaluate the impact of such strategies. We solicit stakeholder comment on other important strategies that might prove successful in improving access to MTM services which could be considered at a later time. This proposed rule may be of interest to, and affect, American Indians/Alaska Natives. Therefore, we plan to consult with Tribes during the comment period and prior to publishing a final rule. We also intend to monitor best practices as sponsors implement more effective strategies and may consider imposing additional requirements in future rulemaking.

In summary, we are proposing revisions to the MTM eligibility criteria to target beneficiaries who have two or more chronic conditions, with at least one being a core chronic disease, who are taking two or more covered Part D drugs, and who have annual Part D drug costs commensurate with the drug spending of beneficiaries with two or more chronic diseases that use two covered Part D drugs. By decreasing the number of chronic diseases and medications and lowering the cost threshold for MTM eligibility, we anticipate that more beneficiaries will have access to MTM services which have been shown to improve drug therapy outcomes and decrease healthcare costs. We believe that these changes will simplify the MTM criteria and minimize beneficiary confusion when choosing or transitioning between plans. We believe these changes will also reduce disparities within the Part D beneficiary population and allow more beneficiaries with drug therapy problems to receive MTM. Additionally, broadened criteria, when paired with more effective strategies for outreach and access to MTM services, will more appropriately reach those individuals in need of these services. We remind sponsors that these proposed changes represent the minimum requirements, and that they may target additional beneficiaries. Effective MTM programs strengthen the Part D program and improve its overall value and, we note, our 5-star plans have consistently made significant investments in MTM.

16. Business Continuity for MA Organizations and Part D Sponsors (§ 422.504(o) and § 423.505(p))

A variety of events ranging from power outages to disasters and warnings of disasters can disrupt normal business operations, and when these events occur it is important to ensure beneficiary access to health care services and drugs. Sections 1852(d) and 1860D–4(b) of the Act, respectively applicable to Parts C and D, establish access to services and covered Part D drugs as a core beneficiary protection. After Hurricane Sandy it became apparent that a few entities, particularly those with operational centers and/or information technology (IT) resources physically located in the affected areas, did not have consistent continuity plans or back-up systems and processes to ensure ongoing coordinated deployment of critical staff to alternate locations.

Sections 1857(e)(1) and 1860D–12(b)(3)(D) of the Act authorize the Secretary to adopt additional contract terms for, respectively, MA organizations and Part D sponsors, including section 1876 cost contracts and Program for the All-Inclusive Care for the Elderly (PACE) organizations that provide qualified prescription drug coverage, that are not inconsistent with Parts C and D, respectively, of Title XVIII of the Act, when the Secretary finds it necessary and appropriate. Hereafter, all proposed requirements described in this section as applicable to Part D sponsors, also apply to section 1876 cost contract and PACE organizations that provide qualified prescription drug coverage. While a limited number of beneficiaries were affected by problems on the part of a small number of entities as a result of Hurricane Sandy, the goal of consistent disaster response remains: All MA organizations and Part D sponsors must limit the beneficiary impact of unavoidable disruptions and must ensure rapid restoration of operations. Accordingly, we propose to add contract provisions to require that MA organizations and Part D sponsors develop and maintain business continuity plans in order to better anticipate the types of disruptions that could occur and then implement policies and procedures to reduce interference with business operations. We believe this is appropriate to ensure

that Medicare beneficiaries have access to the care and coverage contemplated by the statute.

The proposed provision would, in § 422.504(o)(1) and § 423.505(p)(1), require that every MA organization and Part D sponsor develop, maintain, and implement a business continuity plan that meets certain minimum standards. In § 422.504(o)(1)(i) and § 423.505(p)(1)(i), we propose that the business continuity plan must assess risks posed to critical business operations by disasters and other disruptions to business as usual, be they natural, human, or environmental. Proposed § 422.504(o)(1)(ii) and § 423.505(p)(1)(ii) would impose a requirement that the business continuity plan contain a mitigation strategy to lessen hazards, identify essential functions, and prioritize the order in which functions are restored to normal operations; proposed paragraphs (1)(iii) through (v) contain other minimum requirements for the business continuity plan, discussed in more detail in the following paragraphs. In paragraphs (o)(2) of § 422.504 and (p)(2) of § 423.505, we propose essential functions that must be restored within 24 hours of a failure, disaster, emergency, or other disruption.

In paragraph (1)(ii) of § 422.504(o) and § 423.505(p), we would require MA organizations and Part D sponsors to mitigate those risks through a variety of strategies, specifically, by: (A) Identifying events (triggers) that would activate the business continuity plan; (B) developing plans to maintain the availability and, as applicable, the confidentiality of hard copy and electronic essential records, including a disaster recovery plan for IT and beneficiary communication systems; (C) establishing a chain of command, which would ensure that employees know the rules of succession; (D) creating a communications plan that includes emergency capabilities and means to communicate with employees and third parties; (E) establishing procedures to address management of space and transfer of employee functions; and (F) establishing a restoration plan with procedures to transition back to normal operations. Finally, we also propose, at (1)(ii)(G) in § 422.504(o) and § 423.505(p), that the business continuity plan comply with all applicable federal, state, and local laws. In light of the nature of the records an MA organization and Part D sponsor would have in its possession, we propose to emphasize continuing compliance with the contingency plan requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security Rule (45 CFR Parts 160 and 164, Subparts A and C) by including a cross-reference to those requirements in paragraph (1)(ii)(B)(*2*). These areas of responsibility are essential to continuing the business operations that allow beneficiaries to access health care services and covered Part D drugs.

To better ensure that a business continuity plan works as a practical matter, we next propose in § 422.504(o)(1)(iii) and (iv) and § 423.505(p)(1)(iii) and (iv) to require that on an annual basis, each MA organization and Part D sponsor test and revise the plan as necessary, and train employees on their responsibilities under the plan. Sections 422.504(o)(1)(v) and 423.505(p)(1)(v) would require that MA organizations and Part D sponsors keep records of their business continuity plans that would be available to CMS upon request.

We do not believe the broad list of areas that we propose be covered by business continuity plans are new to MA organizations and Part D sponsors. Rather, these topics typically appear in standard business continuity plans. And we are also building on some requirements that already exist under federal and state laws. For instance, with respect to electronic protected health information, health plans have long had to comply with the contingency plan requirements found in the HIPAA Security Rule. Indeed, our goal is to provide a list broad enough to align with the business contingency plans that we believe most, if not the vast majority, of MA organizations and Part D sponsors already have in place.

In contrast to the aforementioned list of broad content requirements, we believe the need to protect beneficiary access requires a prescriptive approach for some functions. In paragraphs (o)(2) and (p)(2), as part of the proposal that essential functions must be restored within 24 hours of failure (whether due to disaster, emergency, or other disruption), we identify what we believe are the minimum essential functions for each MA plan and Part D plan: Benefit authorization, if authorization requirements have not been waived, and claims adjudication and processing; an exceptions and appeals process; and call center operations. Given the mandate of the Act to ensure beneficiary access to health care and covered Part D drugs and the inability of many beneficiaries to pay for services or drugs without the Medicare benefit, we believe that the operations listed in the proposed regulations are the most essential operations because they directly support the provision of Part C and D benefits. They ensure immediate electronic communication on the availability and extent of Part C and D benefits and also provide support that makes it more likely that Medicare benefits will be appropriately and timely provided (for example, by providing telephone assistance to beneficiaries with questions on how to obtain benefits and maintaining a forum in which beneficiaries can challenge benefit denials). Without real time provision of Medicare benefits, beneficiaries might not pay for the entire cost of the services or drugs and therefore go without necessary treatment.

We believe the operations listed here are the essential operations which must be restored in a rapid time frame. We intend our proposed deadline of 24 hours to be the outside limit and would expect MA organizations and Part D sponsors to restore operation of essential functions as soon as possible but not later than 24 hours after they fail or otherwise stop functioning as usual. The clock would begin running in cases of total failure (for example, a computer or telecommunications system crashes or stops working after disruption of the power supply) and also when significant problems occur (for example, a central database is corrupted).

The need to ensure correct claims adjudication and benefit administration of health care services and drugs is no less acute during emergencies. A disaster or other disruption in one part of the country may disable computer systems that service areas across the country that have not otherwise been disrupted. Beneficiaries in those unaffected areas who were denied health care or drug benefits (that is, access to drugs or reimbursement for claims paid out of pocket) before the disruption took place should not be denied the right to immediately challenge those denials or to learn timely the resolution of earlier challenges. As proposed, § 422.504(o)(2)(i) and § 423.505(p)(2)(i) identify benefit authorization (if authorization requirements have not been waived) and claim adjudication and processing as essential functions which must be operational within 24 hours. We intend that this proposed regulation would require restoration of those operations for services rendered at a hospital, clinic or provider office or at the point of sale for Part D covered drugs. This function is essential for both Medicare Advantage and Part D plans.

In addition, we also propose standards specific to Part D sponsors in § 423.505(p)(2)(ii) and (iii) to ensure that a beneficiary who presents at a

pharmacy with an appropriate prescription for a covered Part D drug during a disruption will be more likely to walk away with the drug in hand. The first three prongs under proposed § 423.505(p)(2) would classify as essential the following functions: (i) Authorization, adjudication and processing of pharmacy claims at the point of sale; (ii) administration and tracking of enrollee's drug benefits in real time, including automated coordination of benefits with other payers; and (iii) provision of pharmacy technical assistance. These essential tasks entail numerous sub-functions. For instance, Part D sponsors would need to restore within the 24 hour return to operations (RTO) all computer and other systems that meet all privacy and security requirements in order to communicate to pharmacies information about topics including: Coverage under Part D and the specific plan; cost-sharing and deductibles; any restrictions such as prior authorization, step therapy, or quantity limit edits; and coordination of benefits from other insurers and any low income subsidies. Additionally, the sponsor would need to undertake a concurrent drug utilization review (DUR) to address, for instance, safety issues, as well as restore its pharmacy help desk to provide prompt answers to any questions pharmacies might have. (For more detail on some of these functions and sub-functions, as related to Part D, please see the preamble to section III. A. 17 of this proposed rule entitled, ''Requirement for Applicants or their Contracted First Tier, Downstream, or Related Entities to Have Experience in the Part D Program Providing Key Part D Functions''.)

Proposed § 422.504(o)(2)(ii) and § 423.505(p)(2)(iv) would classify as an essential operation an enrollee exceptions and appeals process including coverage determinations. Under this provision, within 24 hours of failure, MA organizations and Part D sponsors would need to restore all IT and workforce support necessary to maintain the ''safety net'' that ensures beneficiaries the right to appeal or to seek a formulary exception.

Finally, for both MA organizations and Part D sponsors, we propose that the operation of the call center be an essential function which must be restored within 24 hours. By classifying operation of the call center as essential, proposed § 422.504(o)(2)(iii) and § 423.505(p)(2)(v) would ensure that beneficiaries can receive the information necessary to find out where they need to go to access benefits and learn about any special rules that might apply (for example, whether pre-authorization requirements are waived or beneficiaries can obtain benefits at out-of-network providers or pharmacies) by requiring MA organizations and Part D sponsors to restore operation of call center services within 24 hours. Enabling a beneficiary who has just been denied Part D coverage at his or her usual pharmacy to call immediately and speak to a customer service representative while still standing in that pharmacy can ensure that he or she obtains drugs appropriately covered by his or her Part D plan before returning home or moving to a safer area.

Furthermore, because it may be difficult during a disaster to get to a provider's office or a pharmacy, we believe it is also important that benefit authorization, claims adjudication, and call center operations be restored within 24 hours after failure. While our proposed provision would require MA organizations and Part D sponsors to coordinate their workforce, facilities, and IT and other systems support to meet the 24 hour RTO, we believe that the vast majority of MA organizations and Part D sponsors already meet, or if not, would be able to meet this requirement with their current resources, based upon our knowledge of the industry and as evidenced by the lack of widespread problems with MAO and Part D operations that resulted after recent natural disasters in different parts of the country. MA organizations and Part D sponsors would not be required to take any prescribed actions (for example, there is no requirement for redundant systems located at certain distances apart). Rather, the 24 hour RTO would allow MA organizations and Part D sponsors the flexibility to continue to seek their own disaster preparedness solutions (for instance, vendor sites or functions spread across facilities).

Our goal in proposing a contractual requirement for business continuity plans is to ensure beneficiary access to health care services and Part D drugs during disasters and other interruptions to regular business operations. We view prior planning as essential to achieving this goal. We specifically solicit comments regarding which functions should be identified as essential operations and the 24-hour timeframe for RTO and would appreciate any information unique to the role of MA organizations and Part D sponsors.

17. Requirement for Applicants or Their Contracted First Tier, Downstream, or Related Entities To Have Experience in the Part D Program Providing Key Part D Functions (§ 423.504(b))

Since its establishment in 2006, the Medicare Part D program has matured into a generally stable, well functioning program, and the Part D sponsors (as well as their first tier, downstream, and related entities (FDRs)) with which CMS contracts have developed vast expertise in the operational complexities of the program. While we will continue to fine tune the program through rulemaking, guidance, and additional oversight procedures, we believe the program has largely entered a mature stage. Despite this progress, we still find ourselves spending a disproportionate amount of resources and attention on the operations of new Part D sponsors where neither the new sponsor nor its supporting FDRs have experience with Part D. In an environment where there is an abundance of Part D industry expertise, we are committed to establishing an approach to contracting with new Part D sponsors that ensures that they take advantage of that expertise and experience in the development of their Part D program operations.

To address this problem, pursuant to our authority at section 1860D 12(b)(3)(D) of the Act to adopt additional contract terms, not inconsistent with the Part C and D statutes, that are necessary and appropriate to administer the Part D program, we are proposing to adopt provisions that would require any entity seeking to contract as a Part D plan sponsor (as a stand alone prescription drug plan sponsor or as a Medicare Advantage organization offering Part D benefits) to have arrangements in place such that either the applicant or one of its contracted FDRs has one full benefit year serving as a Part D plan sponsor, or at least one full benefit year of experience performing key Part D functions for another Part D plan sponsor. The applicant or a contracted FDR will be required to have obtained that experience within the two years preceding the Part D sponsor qualification application submission. Under this proposal, the experience requirement would be met by an entity seeking to contract as a Part D plan sponsor if its parent or another subsidiary of that parent already holds a Part D sponsor contract that has been in effect for at least one year at the time of the application submission.

Of course, all applicants and their FDRs were new to the Part D program

in 2006, so we necessarily went forward with partners that may have had significant drug benefit administration experience, but no experience with the unique features of Part D. In 2014, there will be approximately 310 parent organizations that own 578 legal entities offering 881 contracts for Part D. In addition, more than 300 organizations (including Part D sponsors and their FDRs) perform key Part D functions on behalf of the Part D sponsors. Given this large number of organizations with Part D experience available to serve beneficiaries, we believe it is in the Part D program's best interest to be more discriminating about the entities with which we partner to deliver the Part D benefit.

New, inexperienced entities may be more likely to fail in all or some key Part D functions, causing harm to beneficiaries and requiring us to devote significant resources providing technical support to the new Part D sponsor in order to protect the Medicare beneficiaries enrolled in the sponsor's plan(s). Given the wealth of available Part D expertise that now exists, it is justifiable for us to require that new applicants to the program bring with them Part D experience so that we can better protect Part D enrollees and minimize unnecessary expenditures of resources by us in correcting avoidable problems.

We have determined that prior experience offering drug benefits in the commercial insurance or Medicaid markets is no longer a sufficient substitute for experience operating the Part D benefit. The Medicare drug benefit is fundamentally different from other drug benefits, with unique and operationally complex provisions, including transition fill requirements, protected class medication formulary requirements, low income subsidy administration, Part A and B versus Part D coverage determinations, requirements related to the tracking of true out of pocket costs, and requirements related to the coordination of benefits with other payers in real time. When neither a Part D sponsor, nor its FDRs providing key Part D functions, has any experience delivering Part D benefits, the consequences can be disastrous for beneficiaries and highly disruptive for the program and CMS. In a recent plan year, we placed a new PDP sponsor, where neither it nor its FDR had PDP experience, under an immediate enrollment and marketing sanction just months after the organization began its PDP operations. The sponsor had experienced widespread failures across all of the most important PDP operational areas and was unable to fix its problems without hiring additional staff and contractors with PDP experience. In this case, among other deficiencies, this sponsor had inappropriately rejected drug claims at the point of sale; failed to properly process coverage determinations (that is, requests for drug coverage or payment and reimbursement); denied enrollees the chance to appeal rejected claims and failed to ensure that denied coverage determinations were reviewed by an independent third party; and failed to process enrollment and disenrollment requests, or failed to properly process enrollment transactions. In short, the PDP sponsor was not providing the PDP benefit to its members. This became obvious when the rate at which we received beneficiary complaints about the sponsor for the first 4 months of operation was more than 225 percent higher than the average rate at which we received complaints about all other PDP sponsors for the same period. We were forced to dedicate significant resources and personnel to addressing the sponsor's systemic failures.

We believe that these failures would not occur, or would be less catastrophic, if either the Part D sponsor or its supporting FDRs have had experience actually performing key Part D functions. When both the new sponsor and its FDRs lack experience in Part D, there is no source of Part D expertise associated with the operation of a Medicare contract that could be counted on not only to establish and maintain systems that would ensure the effective delivery of the drug benefit, but also to identify emerging operational problems and promptly develop and implement necessary corrective action plans. Thus, we have found that the marriage of Part D novices under a single contract has proven to be a particularly risky and disruptive combination.

At the heart of the Part D benefit is the sponsor's ability to process claims for prescription drugs in real time because, unlike health benefits, where claims payment normally follows the delivery of services, pharmacies require confirmation of claims payment at point of sale either from an insurer or payment from the individual. While there are many operational functions that must run smoothly for a Part D plan to be successful (for example, pharmacy network development/maintenance, enrollment processing, prescription drug discount negotiation, and provision of customer service), we are proposing to require Part D experience in only three critical areas in which beneficiaries are particularly vulnerable should the sponsor demonstrate significant non compliance. We believe limiting our new requirement proposal to just three targeted areas offers a balanced approach which protects beneficiaries while at the same time provides needed flexibility to new sponsors to structure their business arrangements to address the dozens of other Part D functions. The three areas for which we are proposing to require prior experience in Part D at the time of application to become a new Part D sponsor are

- (1) Authorization, adjudication and processing of pharmacy claims at the point of sale;
- (2) Administration and tracking of enrollees' drug benefits in real time, including automated coordination of benefits with other payers; and
- (3) Operation of an enrollee appeals and grievance process.

It is in these three areas where—in our view, based on our experience with Part D enrollee health is placed at the most significant risk by Part D sponsor compliance failures. Further, our audit work has indicated that these are the operational areas where sponsors are most likely to have significant failures that require immediate corrective action. While other areas, like enrollment processing, also present risks of direct beneficiary harm, our experience has shown that organizations usually can overcome enrollment problems in a manner that minimizes direct beneficiary harm fairly quickly. Also, our audit findings have shown far fewer serious problems in the enrollment area compared to the three selected areas (see *http://www.cms.gov/Medicare/ComplianceandAudits/PartCandPartDComplianceandAudits/Downloads/2012PartCPartDProgramAuditAnnualReport.pdf*).

Authorization, adjudication and processing of pharmacy claims at the point of sale are the most basic features of the Part D program, allowing Part D plan enrollees to have their prescriptions filled at the pharmacy counter. When presented with a prescription by a beneficiary, the pharmacy communicates electronically with the Part D sponsor to determine eligibility, coverage, and cost sharing for the item according to the formulary and benefit structure of the plan in which the beneficiary is enrolled. Aspects of eligibility and coverage unique to Part D include eligibility for the Low Income Subsidy and transition benefits. Assuming that the sponsor informs the pharmacy that the prescribed drug is covered under the beneficiary's plan, the pharmacy charges the beneficiary the appropriate cost share or deductible amount, as determined by the plan

sponsor. The Part D sponsor also uses the online, real time system to conduct concurrent drug utilization review (DUR), a process through which pharmacists receive a message warning of potential safety issues given the drug requested and the patient's drug history. If any of the cost sharing information is incorrect, or if the claim fails to adjudicate electronically for any reason, the beneficiary may be forced to pay out of his own pocket costs that are not his responsibility or leave the pharmacy without his prescription drugs. If concurrent DUR is not performed correctly, the beneficiary's health and safety is at risk.

Administration and tracking of enrollees' drug benefits in real time refers to a Part D sponsor correctly adjudicating the formulary it had submitted to CMS and that had been approved by CMS, along with accurately tracking an enrollee's drug spend within the Part D benefit, and coordinating benefits in real time with other payers. Sponsors must insure that the drug dispensed meets the definition of a covered Part D drug, including a medically accepted indication that is not otherwise covered under Part A or B of Medicare. Sponsors must also insure that any approved prior authorization, step therapy, and quantity limit edits are processed consistent with those approved by us, so that drugs are not denied inappropriately at the point of sale. Sponsors are also required to insure that enrollees are charged correct cost sharing, as amounts vary depending on the drug's tier placement, the enrollee's drug spend to date, contributions from other payers, and other factors such as whether the beneficiary receives a low income subsidy. Critically, compliance also includes correct application of our transition requirements, which is a beneficiary protection that is unique to Part D, and ensures beneficiaries facing a situation where their drugs are not on the plan's formulary have access to a temporary fill of the prescription, giving beneficiaries time to switch to another drug or seek a formulary exception. Failures in this area can have significant negative health consequences for enrollees because they are likely to be denied access to Part D drugs or face incorrect charges at the point of sale.

The third key function we selected as part of the experience requirement is operation of an enrollee appeals process (including coverage determinations). A sponsor's appeals operations serve as a ''safety net'' for improper benefits administration. Medicare enrollees have the right to contact their sponsor to make a complaint about the denial of coverage for drugs or services to which the enrollee believes he or she is entitled. Generally, sponsors are required to classify and process complaints about coverage for drugs or payment as a request for a coverage determination or appeal. Improper processing of a coverage determination denies an enrollee their due process and appeal rights and may delay an enrollee's access to medically necessary, even life sustaining services or drugs. There are different decision making timeframes for the review of coverage determinations and appeals. We have a beneficiary protection in place that requires plans to forward coverage determinations and redeterminations to an Independent Review Entity (IRE) when the plan has missed the applicable adjudication timeframe. If the plan sponsor reverses its initial adverse coverage determination or the IRE reverses the plan sponsor's adverse decision, the plan sponsor must correctly authorize or provide the benefit under dispute within the timeframes set forth in regulation. If the plan sponsor does not effectuate the decision timely and correctly, this can result in delays to an enrollee's access to medically necessary or even life sustaining drugs. Thus, the appeals process is a vital beneficiary protection that serves as the beneficiary's safety net when something goes wrong with claims adjudication or benefit administration, and once again, directly affects a beneficiary's access to prescription drugs.

Under our proposal, multiple separate organizations could together combine their experience to meet the prior qualification requirements for the three key Part D functions. That is, no one single entity would need to have prior experience in all three areas. Rather, the requirement would be for the Part D applicant in combination with its FDRs, if any, to have Part D experience covering the three key functions.

We believe there will be minimal impact on the prescription drug benefit administration market stemming from our proposal, particularly since large numbers of experienced organizations currently perform this Part D work. Fifty nine entities currently perform authorization, adjudication and processing of pharmacy claims at the point of sale; 66 entities perform administration and tracking of enrollees' drug benefits in real time; and 203 entities operate an enrollee appeals and grievance process. The ready availability of entities that would meet the criteria we establish here is demonstrated by the fact that the vast majority of new Part D sponsors each year choose to contract with experienced Part D FDRs. For example, as of late May 2013, there are 21 new organizations (at the parent level) with active Part D contract qualification applications for 2014, and each applicant has contracted with an FDR having at least one year of recent Part D experience. Some of the applicants for 2014 that attempted to apply with inexperienced entities performing the selected key functions withdrew their applications upon learning that they contained significant deficiencies.

Our proposal also does not prohibit additional organizations from gaining Part D experience in the selected key functional areas. Should an organization wish to become a new Part D FDR for one or more of the key functions, this ''novice'' entity could provide the service for just one of the hundreds of existing Part D sponsors. After a period of one year, the novice entity would then be qualified to provide its services to existing Part D sponsors as well as partner with new Part D applicants. We are comfortable with this scenario because during the novice entity's first year gaining Part D experience the existing Part D sponsor would apply its knowledge of how to oversee its FDRs, have institutional knowledge of the functional area, understand the complexity of the program, and know the risks of failing to implement the program successfully.

In the somewhat the opposite scenario, a new Part D sponsor contracting with experienced FDRs will have the opportunity to gain its experience in the key Part D functions by working closely with its FDRs, developing in house expertise, and providing oversight. After a period of one or more years, if desired, the Part D sponsor itself could conceivably take responsibility for carrying out one or more of the key Part D functions. We fully believe that our proposed approach allows for new organizations to develop Part D expertise, yet minimizes the significant risk to beneficiaries that would be caused by the types of widespread failures we have seen in the selected key Part D functions performed by inexperienced entities.

While our proposal does not require the Part D experience to be current at the time of an application to become a Part D sponsor, we are proposing that the experience be recent (that is, within the past 2 years) and have lasted for at least one full benefit year. As stated previously, the Part D program is complex, and program policies evolve each year, requiring organizations working in Part D to adapt and adjust

their operations. We believe that any experience older than 2 years would be out of date and would not represent experience with the current state of the Part D program. As for our proposed requirement that the experience be for at least a term of one full benefit year, this approach is appropriate because operating the benefit involves cyclical activities, some of which take place only one time per year, and thus an organization can only gain full experience by operating its Part D functional area for an entire benefit year.

We intend to implement this proposal through our existing Part D contract qualification application process, and we have proposed to amend § 423.504(b) accordingly. Today, at the time of application, an entity seeking a Part D sponsor contract must provide evidence that it has contractual arrangements in place for any key Part D function that the applicant itself will not be performing. For the three key functions identified under this proposal, new application procedures will require the applicant to submit evidence that the entity to perform such functions (whether itself or an FDR) has provided the same function for another Part D sponsor within the past 2 years, for at least one full benefit year. Applicants with existing Part D contracts or whose parents or other subsidiaries of the same parent hold Part D contracts will not be required to submit evidence of their Part D experience.

18. Requirement for Applicants for Stand-Alone Part D Plan Sponsor Contracts To Be Actively Engaged in the Business of the Administration of Health Insurance Benefits (§ 423.504(b)(9))

The Medicare prescription drug benefit program has matured into a generally stable, well-functioning program, and the Part D sponsors with which CMS contracts have developed vast expertise in the operational complexities of the program. The market for stand-alone Part D Prescription Drug Plans (PDPs) has also matured significantly since the program's inception and what was once a novel product is now available to residents of every state from multiple sponsors who offer several plan options. Over the same period, we have noticed that the Part D program has in some cases attracted sponsors wishing to offer stand-alone PDPs who have no prior experience in the delivery of health or prescription drug insurance benefits, often to the detriment of the Part D program and the Medicare beneficiaries who elect plans offered by these sponsors. We are committed to establishing an approach to contracting with organizations new to the stand-alone PDP program that ensures that their first experience in the health insurance and health benefits market is not as the sponsor of a stand-alone PDP.

To address this problem, we are proposing, pursuant to our authority at section 1860D–12(b)(3)(D) of the Act to adopt additional contract terms that are necessary and appropriate to administer the Part D program, regulatory provisions that would require any entity seeking to contract as a stand-alone PDP sponsor, to have either actively provided health insurance or health benefits coverage for 2 continuous years immediately prior to submitting a contract qualification application, or provided certain prescription drug benefit management services to a company providing health insurance or health benefits coverage for 5 continuous years immediately prior to submitting an application. This requirement would not apply to an entity seeking to contract as the sponsor of a stand-alone PDP if its parent or another subsidiary of itself or its parent possesses the requisite experience.

This proposal may appear similar to the immediately-preceding proposal (section III.A.17) of this proposed rule requiring, at § 423.504(b)(8), that new Part D sponsors engage first tier, downstream, and related entities with prior Part D experience. However, the proposed change we are discussing in this section, which we propose to codify at § 423.504(b)(8), would apply only to entities seeking to contract as a Part D sponsor of a stand-alone PDP, whereas the proposed requirement at § 423.504(b)(8) would apply to all new Part D sponsors, including those seeking to contract as Medicare Advantage organizations offering Part D through an MA–PD plan. We are proposing both requirements because the problems encountered by new PDP sponsors with no experience in the health insurance market are distinct from those encountered by new PDP sponsors and MA organizations who use PBMs with no experience in the Part D market. New PDPs with no prior health insurance or health benefits experience have demonstrated significant problems even when using experienced PBMs.

The Part D program has matured to the point where beneficiaries in every state now have access to several options for basic and enhanced stand-alone Part D coverage. In 2013, there is an average of 15 enhanced stand-alone plans and 16 basic plans per PDP Region and no region had fewer than 23 plans from which beneficiaries may choose. These numbers are consistent with the quantity of available PDPs in recent benefit years and are well above the minimum of two plans per region required by section 1860D–(a)(1) of the Act. Also, a total of 57 parent organizations that own 72 legal entities hold 75 Part D contracts for stand-alone PDPs, numbers that indicate that CMS has kept the PDP marketplace open to a significant number of entities that compete to serve beneficiaries.

Among the patterns we have identified during our implementation and administration of the Part D program is the extent to which the program has attracted organizations with no experience in the delivery of health or prescription drug benefits prior to their entry into the Part D program. These organizations often have experience in other lines of business, such as information technology, or are formed by investment groups with no other health care business for the sole or primary purpose of entering the Part D market. The Part D program is effectively used by these organizations as a means to finance their first (and often only) foray into the health insurance or health benefits industry. It appears to CMS that these sponsors view the Part D program as simply another line of business to which they can profitably apply their information management expertise, especially if they believe they can sell these new contracts to a larger participant at a substantial profit after several years. While relatively few sponsors fit this profile each year, they have caused disproportionate problems for beneficiaries and CMS, as described in the following paragraphs. The proper administration of the Part D benefit involves much more than claims adjudication. Our interaction with these novice sponsors leads us to believe that they underestimate the value of clinical expertise in administering Part D benefits, particularly in conducting effective coverage determination and appeals processes. Also, we believe they often do not recognize the critical role that relationships, particularly those among beneficiaries, physicians, pharmacists, other health care professionals, and insurers, play in the successful delivery of a healthcare or prescription drug benefit. Yet, the stakes involved in administering a Part D plan are likely higher than those associated with any other line of business in the novice sponsor's portfolio. Operational failures in Part D can cause improper denials at the pharmacy counter of beneficiaries' valid claims for prescriptions or improper denial of

appeals, leading to interruptions in their therapies, which can have life-threatening implications. In short, we have found that these types of applicants have been unable to administer a Part D benefit.

The compliance record of PDP sponsors with no healthcare-related experience confirms our assessment of the risks they pose to the Part D program. Time and again, these sponsors fail our past Medicare contract performance and audit tests or receive low quality scores (that is, star ratings) because they lack the ability to administer even the most basic elements of a health or drug benefit program, let alone one as complex as Medicare Part D. For example, we recently sanctioned a new stand-alone PDP sponsor (a situation we describe in section III.A.17 of this rulemaking where we propose to establish the requirement that all new Part D sponsors engage subcontractors with Part D experience). The sponsor had no recent experience providing or administering health benefits. It only began offering healthcare-related benefits when it became a Part D plan sponsor. We believe the sponsor's inexperience administering health insurance and health benefits, as well as its apparent reliance on Medicare as its sole source of revenue, compounded the problems it experienced, as the sponsor was unable to independently and expeditiously identify and resolve problems with benefits administration.

Another, more dramatic case, involved a CMS decision in 2010 to immediately terminate a PDP sponsor's contract under urgent circumstances in which beneficiaries were being significantly harmed. Prior to contracting with CMS, the PDP sponsor involved had no experience providing or administering health insurance or health benefits coverage. We terminated the sponsor's contract when an audit (prompted by urgent complaints from providers) revealed that the sponsor's compliance failures resulted in improperly denied access to Part D drugs and put the health of enrollees in the sponsor's PDP at imminent and serious risk. Numerous compliance failures resulted in beneficiaries being denied drugs that they were entitled to, including those needed to treat HIV, cancer, and seizures, or receiving delayed access to these drugs, sometimes after being required to undergo medically unnecessary and invasive procedures. The problems were so egregious and widespread that we were compelled to terminate the contract less than a month after we were first alerted to the problems and less than a week after an onsite audit of the sponsor. This termination created massive disruption for beneficiaries and to the program and required significant resources from CMS to resolve. As discussed previously, we believe that these failures would not have occurred, or would not have been as catastrophic, if the sponsors had prior, recent experience providing health insurance, health benefits coverage, or key services related to health benefits coverage.

When the sponsor is a novice not only to Medicare Part D, but also to virtually every aspect of health benefits administration, there is no assurance that the entity will be able to administer or oversee the most basic elements of health benefits coverage, such as processing claims, administering a coverage determination and appeals process, enrolling beneficiaries, or administering the benefit as approved. Its systems and procedures for doing so are by definition new and unproven. We do not believe that health care is a commodity that can be reduced to a programmable data set, or that administering the Part D benefit involves little more than having the right software package. To entrust inexperienced applicants with responsibility for correctly operating a program for which even experienced health insurers have had to develop new expertise has proven to be unacceptably risky. Part D sponsors are charged with both ensuring that beneficiaries get the drugs they need and applying clinically appropriate utilization management protocols to control costs and protect beneficiary safety. In this capacity, they have a role in clinical decision making that is usually reserved for physicians and health care providers with years of academic training and clinical practice. Permitting an organization with prior experience limited to, for example, developing payroll software, to design and broker individuals' access to prescription drugs for potentially life-threatening conditions is an unacceptable mismatch between a set of tasks and the expertise applied to it.

We propose that new applicants have two years of experience providing health insurance or health benefits coverage (that is, operating as risk-bearing entities licensed in the states where they offer benefits) prior to applying as stand-alone Part D Sponsors because we believe that this provides sufficient time to demonstrate the applicant's ability to operate a health plan. A risk-bearing entity with significant problems administering health benefits would be unlikely to remain in good standing with its licensing authority for two years. While a longer record of successful operations would likely provide better evidence of the organization's competence, we are also sensitive to the need to promote innovation and competition that can come from new PDP sponsors. We believe that requiring two years of experience as a risk bearing entity offering health insurance or health benefits coverage ensures that new sponsors of stand-alone PDPs have minimal experience operating a health benefits program without unduly limiting new entrants to the marketplace.

We recognize that a number of PBMs and Third Party Administrators with experience administering prescription drug benefits have entered the stand-alone PDP market and have adapted to providing the Part D benefit despite their lack of previous experience as health insurers. We believe this success is the result, at least in part, of their substantial experience operating key functions that form the core of PDP benefits on behalf of insurers. This experience is not sufficient in and of itself to administering a Part D plan, but it is certainly necessary. Therefore, we are proposing elsewhere in this proposed rule that organizations applying to contract as stand-alone PDP sponsors that do not have experience as a risk-bearing entity providing health insurance or health benefits coverage would, in the alternative, be eligible to hold a PDP contract if they had experience performing services on behalf of an insurer in the delivery of benefits in any health insurance market in the three key areas indicated in this section III.A.17 of this proposed rule. The three areas that we are proposing as meeting the experience requirements are: (1) Adjudication and processing of pharmacy claims at the point of sale; (2) administration and tracking of enrollees' drug benefits in real time, including automated coordination of benefits with other payers; and (3) operation of an enrollee appeals and grievance process. Our reasons for selecting these three areas as meeting the experience requirements are described in more detail in the section of this rulemaking notice relating to the proposed requirement at § 423.504(b)(8) that new Part D sponsors employ experienced FDRs for these functions.

We are proposing that entities without two years of experience as a risk bearing entity offering health insurance or health benefits coverage have five continuous years' experience providing services in the three key areas listed previously. We are proposing a longer experience requirement for these entities because entities offering these services face fewer barriers to entry in

the marketplace and are not as tightly regulated as risk bearing entities. An entity seeking to become a risk bearing entity must qualify for a state license, which requires the entity to demonstrate on a continuous basis that it meets extensive financial, capitalization, and administrative requirements. By contrast, an entity seeking to become a PBM or Third Party administrator faces little or no regulatory oversight for the services it offers. The investment required to start a PBM or Third Party Administrator may be significantly lower than that required of risk bearing entities operating health insurance programs. While a PBM that performs poorly may lose contracts, it is unlikely to be subject to regulatory action that would become part of the publicly available record that CMS could use to evaluate its application to operate a stand-alone PDP. However, we do believe that over a longer period of time, a PBM or Third Party Administrator's poor reputation would become known among participants in the health and prescription drug insurance markets, making it difficult for that organization to retain current contracts or obtain new ones with insurers and remain in business. We therefore believe that entities that seek to qualify on the basis of their experience as PBMs or Third Party Administrators should be required to have provided services in these key areas for five continuous years, rather than merely two.

We believe our proposal will not have significant impact on the availability of stand-alone PDP plans in the marketplace, but that it will simply function to keep out a small number of inexperienced organizations who are likely to perform poorly as stand-alone PDPs. Fortunately, the vast majority of new sponsors of stand-alone PDPs each year have the requisite experience. For example, eight organizations filed initial applications during 2013 to qualify to offer stand-alone PDPs in 2014 and 6 of them had at least two years' experience as a health insurer or 5 years' experience managing prescription drug benefits for health insurers. Of the six new stand-alone Part D plans in 2013, five had the level of experience we are proposing to require. Thousands of entities nationally possess the requisite experience providing health insurance, health benefits coverage, or PBM services.

If this proposed change is finalized, we intend to incorporate it into our existing Part D application process. At the time of application, an entity seeking a Part D sponsor contract must provide evidence that it is currently licensed or is in the process of being licensed in a state and provide certain information about its organizational experience and history. New application procedures would require an applicant for a stand-alone PDP contract to submit evidence that the entity, its parent, or a subsidiary of the same parent has actively provided health insurance or health benefits coverage for the prior 2 years, or has engaged in the three key functions identified here continuously for the prior 5 years.

19. Limit Parent Organizations to One Prescription Drug Plan (PDP) Sponsor Contract per PDP Region (§ 423.503)

Each year, we accept and review applications from organizations seeking to qualify to offer stand-alone prescription drug plans in one or more PDP regions. With limited exceptions (for example, poor past contract performance, limited Part D experience), we approve all applications submitted by organizations that demonstrate that they meet all Part D application requirements. CMS proposes, under our authority at section 1860D–12(b)(3)(D) of the Act to adopt additional contract terms, not inconsistent with the Part C and D statutes, that are necessary and appropriate to administer the Part D program, to add as a basis upon which we may deny a PDP sponsor application the fact that the applicant is applying for qualification in a PDP Region where another subsidiary of the applicant's parent organization already holds a PDP sponsor contract. In our description of this proposal, the term ''parent organization'' refers to an entity that controls a subsidiary through ownership of more than 50 percent of the subsidiary's shares.

During the 2013 contract year, there are 72 unique contracting entities (that is, entities licensed as risk bearing entities) holding 75 PDP sponsor contracts. There are 57 parent organizations that hold more than one PDP sponsor contract through a subsidiary contracting organization over which they maintain a controlling interest.

To promote the effective administration of a Part D program that involves so many parent organizations and contracting entities, we have consistently taken steps to ensure that the numbers of PDP sponsors, PDP sponsor contracts, and plan offerings are kept at a level that allows sponsors to fully exercise their rights as PDP sponsors but avoids the duplication and confusion that can result when reasonable limits are not placed on sponsors' requests for contracting arrangements that serve only their internal business operations. During the initial Part D contracting conducted during 2005, we approved a handful of contracts that were held by subsidiaries of a common parent organization. Since then, we have worked with the affected parent organizations to consolidate almost all of those ''duplicate'' contracts down to one PDP contract per participating parent organization per PDP region. The remaining duplicate contracts accommodate parent organizations that made binding business arrangements while acting in reliance on our previous allowance of multiple PDP sponsor contracts in the same PDP region. We expect to continue to work with those parent organizations to explore options for discontinuing their reliance on the second PDP sponsor contract in the immediate future.

Section 1860D–12(b)(1) of the Act provides that PDP sponsors may offer multiple plan benefit packages (referred to as PBPs or plans) under one PDP sponsor contract. Therefore, parent organizations need only one PDP sponsor contract to offer the full range of the possible plan options in a particular PDP Region. We recognize that many parent organizations that offer plans in multiple PDP regions must use more than one subsidiary to administer their full array of plans throughout the United States and the territories. For example, parent organizations may adopt these arrangements to accommodate unique state licensure requirements or the terms of trademark licensing agreements. However, none of these justifications, which are based on a parent organization's need to serve more than one PDP Region, would support a request, like several we have received during the CY 2014 contract qualification application cycle, by a parent organization to be granted a second PDP sponsor contract in a PDP Region it already serves. As discussed more fully in the following paragraphs, there are significant inefficiencies to the program of having duplicate contracts that do not provide more benefit plan options than could be offered under a single contract. Additionally, informal communications made by past requestors of duplicate contracts indicated that the purpose has been to either (a) segregate low income beneficiaries into their own contract, or (b) corral the experience of a particular low-performing plan into its own CMS contract so as not to taint the performance rating of the better performing plan offering, as performance ratings are calculated at the contract level. CMS opposes the

inefficiencies of duplicate contracts and the gaming duplicate contracts can support. That said, we welcome comments from industry, advocates, and others as to circumstances for our consideration under which duplicate contracts may be beneficial.

One of the fundamental principles of the Part D program is that the selection of plans made available to beneficiaries is the product of true competition among PDP sponsors. Two subsidiaries of the same parent organizations offering plans in the same PDP region are not truly competitors as decisions concerning their operations are ultimately controlled by a single entity, or parent organization. Also, we only approve those PDP offerings that meet the meaningful differences test stated at § 423.265(b)(2), and we apply that test at the parent organization level. A parent organization would not gain an opportunity to offer more plan benefit packages under two or more contracts it controlled through its subsidiaries than it would under one contract because we would, as part of our bid review, evaluate whether all the plans proposed by the same parent organization met the meaningful differences test.

The proposed limitation on the number of PDP sponsor contracts a parent may control in a PDP Region is also necessary to preserve the integrity of CMS' star ratings. CMS assigns star ratings at the contract level, and they are intended to reflect all aspects of the PDP operations controlled by a unique contracting entity. However, that principle is compromised when a parent organization to one of the contracting entities is permitted to control, through other subsidiaries, more than one PDP contract. While the contracting entities (that is, PDP sponsors) are legally accountable for the delivery of benefits under a PDP sponsor contract, when those sponsors are subsidiaries to a parent organization, it is the parent that, in reality, controls the quality of the sponsor's contract performance. The parent does this by using its controlling interest in the subsidiaries to establish the budget priorities and operational policies of those entities. As a result, allowing a parent organization to effectively administer two or more PDP sponsor contracts would allow it potentially to artificially inflate the star ratings on one contract by excluding the poor performance under its other contract from the rating calculation. In that instance, some beneficiaries could make a plan election without complete information about the performance of the organization ultimately responsible for the quality of services they would receive by enrolling in that plan. A beneficiary for whom quality ratings are an important factor in choosing a plan is best served by contracting arrangements and rating systems that provide the most transparency about the performance of all the PDP products offered under the authority of the single parent organization. This goal is best served by limiting parent organizations to one PDP sponsor contract per PDP Region.

Based on our experience in administering the Part D prescription drug benefit program we do not believe that there is a compelling justification for parent organizations to administer two PDP sponsor contracts in the same PDP region. Moreover, such arrangements impede our ability to efficiently administer the PDP and provide a means by which the integrity and reliability of our star ratings system can be compromised. Therefore, we propose to amend § 423.503(a) by adding a paragraph (3) stating that CMS will not approve an application when it would result in the applicant's parent organization holding more than one PDP sponsor contract in the PDP region for which the applicant is seeking qualification as a PDP sponsor. We anticipate that we would most frequently use this authority to deny an application in instances where the applicant's parent organization already controls a PDP sponsor contract, either directly by acting as a PDP sponsor itself (in instances when the parent is licensed as a risk-bearing entity) or through its ownership of a subsidiary that qualifies as a PDP sponsor and is a party to a stand-alone PDP sponsor contract. In the less likely situation where two or more subsidiaries of the same parent organization each submit applications in the same year for PDP regions where the parent organization controls no PDP sponsor contracts, we would request that the parent withdraw all but one of the applications. In the absence of a withdrawal election, CMS will deny all of the parent organization's applications.

20. Limit Stand-Alone Prescription Drug Plan Sponsors To Offering No More Than Two Plans per PDP Region (§ 423.265)

Under our authority at section 1860D–11(d) of the Act, we conduct negotiations with stand-alone prescription drug plan (PDP) sponsors concerning our approval of the bids they submit each year. As the Part D program has evolved, we have adopted regulations designed to authorize us to use that negotiating authority to ensure that the number of plans offered in a given PDP region reflects a balance between sponsors' interest in providing options tailored to meet the needs of a diverse Medicare population and the need to avoid creating undue confusion for beneficiaries as they consider various plan offerings. We continue here our process of updating our bid review authority to reflect the evolution of the Part D program by proposing to limit to two the number of plans stand-alone PDP sponsors may offer in each PDP region.

PDP sponsors must offer throughout a PDP region at least one basic plan that consists of: Standard deductible and cost sharing amounts (or actuarial equivalents); an initial coverage limit based on a set dollar amount of claims paid on the beneficiary's behalf during the plan year; a coverage gap during which a beneficiary pays more of his drug costs; and finally, catastrophic coverage that applies once a beneficiary's out-of-pocket expenditures for the year have reached a certain threshold. Prior to our adopting regulations requiring meaningful differences among each PDP sponsor's plan offerings in a PDP Region, CMS guidance allowed sponsors that offered a basic plan to offer in the same region additional basic plans, as long as they were actuarially equivalent to the basic plan structure described in the statute. These sponsors could also offer enhanced alternative plans which provide additional value to beneficiaries in the form of reduced deductibles, reduced copays, coverage of some or all drugs while the beneficiary is in the gap portion of the benefit, or some combination of those features.

As we have gained experience with the Part D program, we have made consistent efforts to ensure that the number and type of plan benefit packages PDP sponsors may market to beneficiaries are no more numerous than necessary to afford beneficiaries choices from among meaningfully different plan options. In addition to setting differential out-of-pocket-cost (OOPC) targets each year to ensure contracting organizations submit bids that clearly offer differences in value to beneficiaries, we issued regulations in 2010 that established at § 423.265(b)(2) our authority to deny bids that are not meaningfully different from other bids submitted by the same organization in the same service area. Our application of this authority has effectively eliminated PDP sponsors' ability to offer more than one basic plan in a PDP region since all basic plan benefit packages must be actuarially equivalent to the standard benefit structure discussed in the statute. That regulation also effectively limited to two the

number of enhanced alternative plans that we can approve for a single PDP sponsor in a PDP region. As part of the same 2010 rulemaking, we also established at § 423.507(b)(1)(iii) our authority to terminate existing plan benefit packages that do not attract a number of enrollees sufficient to demonstrate their value in the Medicare marketplace. Both of these authorities have been effective tools in encouraging the development of a variety of plan offerings that provide meaningful choices to beneficiaries without creating undue confusion for beneficiaries.

We believe that the progressive closure of the coverage gap provided for in the Affordable Care Act affords us another opportunity to promote even greater clarity in the set of stand-alone PDP plan options from which beneficiaries may make an election. Under the statute, beginning in 2011, applicable beneficiaries enjoy discounts of 50 percent off negotiated prices on brand name drugs when purchased while in the coverage gap portion of the benefit. Also, since 2011, the required coverage in the gap has increased and will continue to do so gradually until 2020, when the combination of required coverage and manufacturer discounts covers 75 percent on average for both brand-name and generic drugs. This ''closing'' of the coverage gap effectively will leave the beneficiary with only a 25 percent cost share on average across the entire benefit (or its actuarial equivalent) before the catastrophic threshold.

Our experience in applying the meaningful differences standard indicates that, as the Part D coverage gap is closed, it will become increasingly difficult for a PDP sponsor to qualify to offer more than two plans in the same service area and still meet the meaningful differences test. Since we began applying the meaningful differences standard to our bid reviews, we have generally approved two types of enhanced alternative plans. The first type of plan offers beneficiaries, in exchange for a higher premium than that charged for basic plan coverage, significant reductions in the cost sharing and deductible amounts associated with the basic Part D benefit. The second type offers even greater cost sharing and deductible reductions as well as coverage for many drugs in the gap. Since coverage of Part D drugs in the gap is the distinguishing feature between the two types of enhanced alternative plans currently available, closing the coverage gap also means that sponsors can no longer rely on it to establish that their proposed second enhanced alternative plan is meaningfully different than their first.

Our enrollment data indicate that beneficiaries are already making plan choices based on their recognition of the shrinking significance of the coverage gap and with it, the value of PDP sponsors' second enhanced plans. Since the start of the coverage gap discount program in 2011, enrollment levels in the second enhanced alternative plans offered by PDP sponsors that offer two enhanced alternative plans have declined from approximately 12 percent of those sponsors' total enhanced alternative plan enrollment in 2010 to between 7 percent and 8 percent in the 2011, 2012, and 2013 benefit years. This finding suggests that the proportion of beneficiaries for whom the additional supplemental coverage offered by these plans is worth the supplemental premium continues to decline, and we expect this trend to continue as the coverage gap closes.

Despite these developments, many sponsors continue to submit three bids per region each year, at least in part, we believe (based on conversations with various stakeholders), to ensure that they are not perceived as a weaker participant in the Part D market by offering a smaller set of plans than their PDP competitors. CMS believes that plan sponsors and beneficiaries, as well as the taxpayers, would be better served by a more streamlined bid submission process that limited sponsors to submitting two PDP bids (one basic and one enhanced) per PDP region each year. This limitation would provide a consistent bidding framework for all sponsors, allowing them to focus on quality, rather than quantity, in development of their bids. It would also reduce some of the sponsors' administrative costs associated with preparing, marketing, and administering a third benefit package. It may also help ensure that beneficiaries can choose from a less confusing number of plans that represent the best value each sponsor can offer.

For CY 2013, there are seven parent organizations that offer two enhanced plans (that is, three plans total, one basic and two enhanced alternative) within a given PDP region. This amounts to 264 enhanced alternative plans in total (two for each affected PDP region) among the seven parent organizations. The application of this proposed regulation, if finalized, would result in the elimination of 132 enhanced alternative plans, representing 13 percent of the total number of stand-alone PDP plans, and 25 percent of all enhanced alternative plans in 2013. If implemented today, these proposed reductions would affect a combined 522,742 beneficiaries, approximately 2 percent of the overall stand-alone PDP enrollment of 22,529,197 (based on April 2013 enrollment data). We expect that most sponsors would attempt to consolidate their current beneficiaries in one of their two remaining plan options, so we believe adoption of this proposal would result in minimal disruption to beneficiaries currently enrolled in a sponsor's second enhanced plan.

While the incremental closure of the coverage gap continues until 2020, CMS believes that the observed enrollment trends in these plans demonstrate the reduction in beneficiaries' coverage gap costs that has occurred already has moved the stand alone PDP plan market in a way that warrants the imposition of the two plan limit as soon as possible. The list of plan options today is cluttered with those that the record shows appeal to only approximately 2 percent of the overall stand alone PDP-plan-enrolled beneficiaries of which 522,742 are enrolled in second enhanced plans). In addition, in many cases one of the two enhanced plans offers the minimum level of supplemental coverage required to meet our meaningful differences tests. We refer to these as ''low value enhanced plans'' to distinguish them from second enhanced plans with substantially more supplemental coverage. In some cases, the premiums for these low value enhanced plans have been less than the premiums for the sponsors' basic plans due to favorable risk selection. This occurs because many of the beneficiaries with more serious health issues and higher utilization of prescription drugs are in the low-income subsidy (LIS) eligible population which will not receive the full LIS subsidies in plans with supplemental coverage. For this reason we neither auto-assign the LIS eligible population into such plans, nor will this population generally voluntarily enroll in such plans. Thus, continuing to permit multiple enhanced plans, particularly low value enhanced plans, facilitates risk segmentation. This can increase costs for the Part D program and the taxpayers overall. During the most recently completed CY 2014 bid review cycle, we continued to encounter bids submitted by sponsors for low value enhanced plans with premiums lower than the premiums for their basic plans. We believe it is urgent that we adopt this proposed policy as soon as possible so that we can bring an end to this bidding practice. However, because such a change would entail substantial changes to bidding processes for both

Part D sponsors and CMS that could not realistically be undertaken until the proposal was final, we propose to adopt this policy for the 2016 Part D contracting cycle. We believe that beneficiaries and the Part D program would be better served by sponsors that are focused on developing plans with broad beneficiary appeal rather than those intended to enable the sponsor to either pursue a diminishing niche in the Part D market or segment favorable risk into low value enhanced plans. We solicit comments on whether there is any real need for more than two standalone plan options per PDP sponsor.

Therefore, we propose to amend the Part D regulations at § 423.265 to add a revised subsection (b)(3), which states that ''CMS shall not accept more than one basic bid and one enhanced bid for a coverage year from a single PDP sponsor in the same PDP region.'' We would adopt this provision under our authority at section 1860D–11(d) of the Act. In instances where a parent organization owns a controlling interest in more than one subsidiary that operates as a PDP sponsor in a single PDP region, we would apply subsection (b)(3) at the parent organization level. That is, in the same way that we currently apply the meaningful differences test, a parent organization with two subsidiary PDP sponsors could offer no more than one plan under each sponsors' contract. We anticipate that the need to use this interpretation will be infrequent as existing multi-contract arrangements are phased out through plan consolidation and the creation of new ones would be prohibited by the implementation of the provision described elsewhere in this proposal (if finalized) authorizing CMS to deny applications from organizations owned by a parent that already has a subsidiary operating a PDP sponsor contract in the same PDP region.

In a proposed rule we published in October 10, 2010, announcing our intent to codify the Affordable Care Act provision in the Part D regulations, we solicited comments on whether we should use the Affordable Care Act authority to impose limits on the number of plans in a PDP region. In the preamble to the final rule that followed on April 15, 2011, we noted that among the comments we received were those stating that we should not consider imposing limits on plan offerings until the impact of previous statutory and regulatory changes governing our bid review process could be fully evaluated. At the time we declined to codify such limits. Now, we believe that the record in support of the adoption of a two-plan limit has had time to fully develop, including, as discussed previously, the dwindling popularity of the second enhanced option, the shrinking differences between the first and second enhanced options, and the role the second enhanced option plays in enabling risk segmentation, and therefore we make the proposal described here and seek comment from the public.

In addition to proposing to limit PDP sponsors to submitting one basic and one enhanced bid per coverage year, we are also considering several regulatory proposals for limiting the type of coverage offered in those two plans to reduce or eliminate the risk segmentation described previously. We believe that risk segmentation is not consistent with the Congressional design for the Part D program, or with the policy goal of obtaining the best value for the government and the taxpayer. We believe the Congress intended sponsors to compete in the Part D market by offering their best bids for basic plans, in order to attract the greatest enrollment through the lowest premiums, and that this competition would maintain downward pressure on Part D bids and government subsidies. We do not believe that the Congress intended that instead sponsors would offer their best bids for a segment of the market that represents individuals who are low utilizers of prescription drugs due to better health and who can afford unsubsidized supplemental premiums due to better socioeconomic status. When many healthy individuals are not included in the basic plans, the cost of the basic plans is increased, and this in turn increases low-income premium subsidies. Therefore, permitting risk segmentation does not generate the best value for the Part D program as a whole. To reduce or eliminate risk segmentation, we are considering three options. We solicit comments on our conclusions with respect to risk segmentation and on the effectiveness of the following options.

The first option we are considering would be to continue to allow separate basic and enhanced plans, but require that enhanced plans offer a substantial minimum level of supplemental coverage defined in regulation. This would differ from current practice in that we currently set meaningful differences requirements by observing the distribution of benefits submitted independently by sponsors and using statistical techniques to identify outlier thresholds. The problem with the current approach is that, when all or most sponsors reduce their supplemental coverage over time—the trend that we have observed—the outlier thresholds will decline as well. When this occurs the supplemental coverage will again tend to converge on the value of basic coverage. Instead, for instance, we could require that the enhanced plan offering had to cover a minimum of 50 percent (or another higher percentage) of the remaining actuarial value of the Part D benefit not included in the standard benefit for any coverage year. The additional coverage would be in the form of reduced deductibles and cost sharing and the inclusion of excluded drugs, consistent with the statutory definition of supplemental coverage. We solicit comment on whether such an approach would be sufficient to accomplish our goal of eliminating risk segmentation.

In the second option we are considering, instead of setting minimum supplemental coverage requirements for a sponsor's enhanced plan offering, we would propose to use the authority provided in section 3209 of the Affordable Care Act which amends section 1860D–11(d)(3) of the Act to deny any enhanced plan bid with a premium equal to or lower than the sponsor's basic plan premium. Alternatively we might require the enhanced premium to be no less than a specified multiple of the basic premium, such as 115 percent or another multiple. Again, the additional coverage in the enhanced plan would be in the form of reduced deductibles and cost sharing and the inclusion of excluded drugs. We solicit comments on this approach, and on the appropriate multiple of the basic premium necessary to eliminate risk segmentation. We also solicit comment on whether there is a possibility that this approach might effectively eliminate the offering of supplemental coverage if favorable risk selection were to continue and the actuarial value of such coverage could not generate sufficient premiums to pass these sorts of tests.

The third option we are considering would be to reinterpret the provisions of section 1860D–11(b) and (c) of the Act governing the submission of bids that include supplemental benefits. We would propose that enhanced alternative coverage would be redefined to consist of supplemental coverage added to the sponsor's one basic benefits offering (for an additional premium). This could be thought of as basic benefits plus a supplemental benefit rider. This would mean that all Part D enrollees in a sponsor's Part D plans would be enrolled in the sponsor's one basic plan with the same formulary and pharmacy network, and some portion of those enrollees would

also elect the optional supplemental coverage in the form of the second plan that would be the combination of the basic plan and the supplemental benefits. Thus, the risk of the basic benefits would be estimated at the PDP Regional level and the risk of the supplemental benefits would be estimated in accordance with that of the projected enrollees in the second plans. This means that the supplemental benefits would have to constitute actual enhancements to the basic benefit and that the notion of actuarial equivalence would not apply to the combination of the basic and supplemental benefits. This change would bring standalone PDP coverage more in line with both commercial coverage designs and with the offering of Part C optional supplemental benefits. We believe this option would eliminate the possibility of risk segmentation because every enrollee participating in a sponsor's Part D line of business would be enrolled in the one basic plan and beneficiaries that elect supplemental benefits will be charged the additional premium for the extra coverage. The sponsor's Part D offerings would consist of two plan benefit packages, one comprised solely of basic coverage and the other (if offered) consisting of the combination of the basic coverage with the supplemental coverage.

We solicit comments on this approach and on our belief that this approach would be the most effective strategy for eliminating risk segmentation and providing the best value for the government and the taxpayer.

21. Efficient Dispensing in Long-Term Care Facilities and Other Changes (§ 423.154)

We are proposing changes to the rule requiring efficient dispensing to Medicare Part D enrollees in Long Term Care (LTC) facilities. For background, section 3310 of the Affordable Care Act amended the Act to add a new paragraph (3) to section 1860D–4(c) of the Act. Section 1860D–4(c)(3) of the Act provides that the Secretary shall require Medicare Part D sponsors of prescription drug plans to utilize specific, uniform dispensing techniques, such as weekly, daily, or automated dose dispensing, when dispensing covered Part D drugs to enrollees who reside in a LTC facility in order to reduce waste associated with 30-day fills. The section states that the techniques shall be determined by the Secretary in consultation with relevant stakeholders.

After extensive consultation with stakeholders, in the April 15, 2011 **Federal Register** entitled ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes'' (''April 15, 2011 Final Rule''), we published a final rule at 76 FR 21432 which governs the appropriate dispensing of prescription drugs in LTC facilities under Part D plans. Pursuant to this regulation, Part D sponsors generally must require their network pharmacies to dispense certain solid oral brand covered Part D drugs in quantities of 14 days or less, unless an exemption applies. The regulation is found at § 423.154.

We are proposing the following specific changes to the LTC short cycle dispensing requirements:

- Add a prohibition on payment arrangements that penalize the offering and adoption of more efficient LTC dispensing techniques.
- Eliminate language that has been misinterpreted as requiring the proration of dispensing fees.
- Incorporate an additional waiver for LTC pharmacies using restock and reuse dispensing methodologies under certain conditions.
- Make a technical change to eliminate the requirement that Part D sponsors report on the nature and quantity of unused brand and generic drugs.

After providing a summary of the current LTC short cycle dispensing rule, we will address each proposed change in more detail.

Section 423.154 requires that all Part D sponsors require all pharmacies servicing LTC facilities to dispense solid oral doses of covered Part D brand name drugs to enrollees in such facilities in no greater than 14 day increments at a time. Part D sponsors must also require such pharmacies to permit the use of uniform dispensing techniques, as defined by the LTC facility. The regulation refers to definitions in existence at the time of its promulgation. Brand name and generic drugs are defined in § 423.4, and the definition specifically refers to a brand name drug as being one approved under an NDA.

In order to quantify waste more precisely, the regulation requires Part D sponsors to collect and report information to CMS on the dispensing methodology used for each dispensing event, and on the nature and quantity of unused brand and generic drugs dispensed to enrollees in LTC facilities. Reporting on unused drugs is waived for Part D sponsors when both brand and generic drugs are dispensed in no greater than 7-day increments.

The regulation excludes: (1) Solid oral doses of antibiotics; and (2) solid oral doses that are dispensed in their original container as indicated in the Food and Drug Administration (FDA) prescribing information or that are customarily dispensed in their original packaging to assist patients with compliance. Thus, the regulation does not apply to drugs that are not typically dispensed in greater than 14-day supplies (for example: inhalers, eye drops, ear drops, steroid dose packs).

LTC facilities are defined in § 423.100, which definition excludes assisted living facilities. Intermediate care facilities for the mentally retarded and institutes for mental disease are specifically waived from the requirement in the regulation, as are I/T/U pharmacies, due to specific problems with delivery and dispensing to closed (often locked) facilities.

With respect to copayments, the regulation states that regardless of the number of incremental dispensing events, the total cost sharing must be no greater than the total cost sharing that would be imposed if the regulation did not apply.

When permitted under applicable law, the regulation requires Part D sponsors to include provisions that address the disposal of drugs that have been dispensed to an enrollee in an LTC but not used, and then returned to the pharmacy, in the terms and conditions that they must offer to pharmacies, including whether return for credit and reuse is authorized.

a. Prohibition on Payment Arrangements That Penalize the Offering and Adoption of More Efficient LTC Dispensing Techniques (§ 423.154)

Our first proposed change is to add a clause to § 423.154 prohibiting payment arrangements that penalize the offering and adoption of more efficient LTC dispensing techniques. It is our understanding that for 2013, some of the largest PBMs have prorated LTC pharmacy dispensing fees for medications subject to the LTC short cycle requirements. Under such dispensing fee payment arrangements, if a medication is discontinued before a month's supply has been dispensed, a pharmacy that dispenses the maximum amount of medication at a time permitted under § 423.154 collects more in dispensing fees than a pharmacy that utilizes dispensing techniques that result in less than maximum quantities being dispensed at a time.

We provide the following example of two pharmacies—one more efficient at dispensing than the other— to illustrate our concern: A $4.00 dispensing fee for

a 30-days' supply is prorated, and a medication is discontinued after 21 days. The first pharmacy dispenses 14-days' supply at a time and receives approximately $3.73 in total dispensing fees for a 28-days' supply, which results in 7 days' worth of medication waste. The second pharmacy dispenses 3-days' supply at a time and receives approximately $2.80 in dispensing fees for a 21-days' supply in total, which results no medication waste.

We believe this example is contrary to the Congress' intent in enacting section 3310 of the Affordable Care Act. In this example, the second pharmacy's more efficient dispensing techniques save facility, sponsor, and Part D program costs associated with reducing the amount of medication waste, but the pharmacy itself receives less in dispensing fees than it would if it had dispensed in 14-day increments. This approach creates a perverse incentive for LTC pharmacies to adopt less efficient dispensing techniques, if available. Rational self- interest on the part of any LTC pharmacy with the flexibility to dispense greater quantities encourages wasteful dispensing and additional costs to the Part D program, in direct opposition to the intent of the law.

During the extensive industry consultation conducted prior to the rulemaking required to implement section 3310 of the Affordable Care Act, CMS was repeatedly informed by multiple stakeholders that dispensing costs did not vary on the basis of the quantity of medication dispensed, but only by the number of dispensing events and the type of dispensing technique utilized. Therefore, there is no justifiable rationale for proration, since the cost of dispensing is not directly related to the quantity dispensed. In order to align incentives, we encouraged Part D sponsors to do quite the opposite to prorating dispensing fees, and offer differentially higher dispensing fees to promote the adoption of the most efficient dispensing methodologies.

Starting in the fall of 2012, we have received numerous complaints about proration of dispensing fees from multiple LTC pharmacy organizations, LTC pharmacies, and LTC facilities that represent, offer, or have contracted to utilize more efficient dispensing methodologies. Some smaller LTC pharmacies, which rely upon their relative greater efficiency in reducing waste from unused drugs for competitive advantage, have complained that they were unable to negotiate appropriate terms through their intermediary group purchasing and contracting organizations and could not negotiate directly with Part D sponsors. Small LTC pharmacies have also reported that they risked losing their LTC facility contracts to larger LTC pharmacies if they did not accept the payment terms that, in effect, penalize their efficiency. These pharmacies have indicated that prorated dispensing fees are not mutually agreeable terms, and that this fee structure threatens the survivability of the most efficient dispensing techniques.

It is unclear why Part D sponsors and their agents would choose to reimburse LTC pharmacies in a manner that does not promote more efficient dispensing methodologies. One possibility is that the smaller LTC pharmacies lack the leverage to negotiate differential fees due to the market power of the largest LTC pharmacies, which control more than 60 percent of the market. This would be the case only if the largest LTC pharmacies had the market power over the largest PBMs to not only set their own dispensing fees, but also the dispensing fees of their competitors. However, we have not heard any evidence or testimony that would support that conclusion.

Another possibility is that Part D sponsors are not motivated to promote efficiencies in long-term care prescription drug utilization. This could be the case because their liability for these costs is substantially less than that of the federal government. Since most LTC residents are LIS-entitled individuals or likely to incur costs subject to catastrophic coverage, or both, sponsor liabilities are actually minimized when the LTC resident beneficiary reaches the TrOOP threshold as quickly as possible. Thus, sponsors' interests may actually be aligned with those LTC pharmacies with the least efficient dispensing methodologies, since both parties' interests may be served by higher costs.

A final possibility is that Part D sponsors believe the § 423.154 and/or the upcoming daily cost-sharing rate requirement at § 423.153(b)(4)(i) (which becomes effective January 1, 2014) mandate the proration of dispensing fees when less than 30 days is dispensed. This is not accurate, and we discuss this misunderstanding both further in this section and in the section entitled, ''Application and Calculation of Daily Cost-Sharing Rates'' of this proposed rule.

Given the clear intent of the Affordable Care Act to reduce wasteful dispensing in the LTC setting, CMS is proposing to prohibit payment arrangements that penalize the offering and adoption of more efficient LTC dispensing techniques. This would be accomplished by adding a new clause (f) in § 423.154 that would state that a Part D sponsor must not, or must require its intermediary contracting organizations not to, penalize long-term care facilities' choice of more efficient uniform dispensing techniques by prorating dispensing fees based on days' supply or quantity dispensed. This clause would also state that a sponsor or its intermediary contracting organizations must ensure that any difference in payment methodology among LTC pharmacies incentivizes more efficient dispensing techniques.

b. Misinterpretation of Language as Requiring the Proration of Dispensing Fees (§ 423.154)

Our second proposed change to § 423.154 is to eliminate paragraph (e), which we believe has caused confusion. Section 423.154(e) currently states: ''Regardless of the number of incremental dispensing events, the total cost sharing for a Part D drug to which the dispensing requirements, under this paragraph (a) apply must be no greater than the total cost sharing that would be imposed for such Part D drug if the requirements under paragraph (a) of this section did not apply.'' The purpose of this language was to ensure that sponsors did not assess multiple monthly copayments for each incremental dispensing event. We believe misinterpretation of paragraph (e) may have prompted some sponsors to prorate dispensing fees, even though the regulation does not address dispensing fees.

Moreover, effective January 1, 2014, the daily cost-sharing rate requirement will apply whenever a prescription is dispensed by a network pharmacy for less than a 30 days' supply, unless the drug is excepted pursuant to § 423.153(b)(4)(i), regardless of the setting in which the applicable drugs are dispensed. In other words, the daily cost-sharing rate requirement will apply to brand drugs dispensed in LTC facilities to the extent they must be dispensed in supplies less than 30 days pursuant to § 423.154, and to generic drugs, to the extent a sponsor voluntarily dispenses generic drugs in LTC facilities in supplies less than 30 days. Consequently, the requirement of § 423.153(b)(4)(i) will make § 423.154(e) unnecessary, and we believe retaining both provisions could cause further confusion. (Note that we propose some technical changes to the daily cost-sharing rate requirement in the section, entitled ''Application and Calculation of Daily Cost-Sharing Rates'' of this proposed rule) For these reasons, we propose to delete § 423.154(e).

c. Additional Waiver for LTC Pharmacies Using Restock and Reuse Dispensing Methodologies Under Certain Conditions (§ 423.154)

Our third proposed change to § 423.154 is to waive the short-cycle dispensing requirements for LTC pharmacies meeting certain conditions. Currently, § 423.154(c) waives the requirements for pharmacies when they dispense brand name Part D drugs to enrollees residing in intermediate care facilities for the mentally retarded and institutes for mental disease, as well as for I/T/U pharmacies. We have learned that some institutional pharmacies maintain custody of medications within the LTC facilities through operating a closed pharmacy within the facility, and as a result can ensure sufficient quality control over these medications to return all unused medications to stock for reuse that are eligible for return and reuse under applicable law. This has led us to believe there is another category of pharmacies, such as some on site pharmacies in veterans' homes, for which a waiver from the LTC short cycle dispensing requirement may be appropriate, if they meet certain conditions that demonstrate that applying the 14-day dispensing requirements in these instances would not serve to reduce waste.

We are proposing to waive the requirements of § 423.154(a) for an LTC pharmacy that exclusively uses the dispensing technique of returning all unused medications to stock that can be restocked under applicable law for reuse and rebating full credit for the ingredient costs of the unused medication to the PDP sponsor. The proposed waiver would also require that for those drugs that cannot be returned for full credit and reuse under applicable law, such as controlled substances, the pharmacy uses a dispensing methodology that results in the delivery of no more than 14 days of a drug at a time. We would propose that the waiver would apply on a uniform basis to all similarly situated LTC pharmacies, but not to a pharmacy organization that is contracted to use this technique at some, but not all, of its pharmacies. Rather, the waiver would only apply to the qualifying pharmacies themselves. We would not require the pharmacy to credit back any amount of the dispensing fee when drugs are returned for reuse, since the level of effort for the pharmacies would not be expected to be decreased in any way. If anything, the level of effort would be increased to implement the appropriate internal controls for inspection and return to inventory of the unused medication.

We solicit comments on whether there are any variations in operations that may exist among LTC pharmacies that we need to consider in determining whether to implement this waiver. We also solicit comments on how such pharmacies could be identified in industry standard transaction coding, as well as in network contracting and auditing protocols. We believe that such pharmacies would be expected to have documentation of relevant protocols approved by Pharmacy and Therapeutics (P&T) committees of the LTC facility, as well as records supporting the returns to inventory that could be compared with billing credits. We solicit comments on this understanding as well.

We further solicit comments on our proposal that to qualify for the waiver, a pharmacy would have to dispense any drugs that cannot be restocked under applicable law, such as controlled substances, in no greater than 14-day supply increments. Our rationale in proposing this condition to the waiver is that we do not want the waiver to inadvertently result in large quantities of medications being dispensed to Part D enrollees serviced by the pharmacies that would qualify for the waiver because they cannot be restocked under applicable law. Therefore, we are proposing that such drugs should still effectively be subject to the short-cycle dispensing requirement. In this regard we wish to understand the extent of waste in pharmacies that would qualify for the waiver we are proposing, if we did not impose the requirement that drugs that cannot be restocked would be subject to a dispensing increment of 14-day supply or less if they cannot be restocked under applicable law. If persuaded that the waste would be insignificant, we may be persuaded to eliminate this condition to the waiver.

We acknowledge that in the aforementioned April 15, 2011 Final Rule, we responded to some comments requesting that we exempt from the short-cycle dispensing requirement those pharmacies that already utilize low waste practices or ''return for credit and reuse.'' In response, we stated that although ''return for credit and reuse'' could reduce unused drugs in LTC facilities, there are limitations to this approach, especially because not all states allow ''return for credit and reuse,'' and reuse of controlled substances is limited by the Drug Enforcement Administration. Because of these limitations, we stated that we believe financial waste is more effectively reduced by preventing the accumulation of unused drugs in the first place, rather than addressing handling of unused drugs after they have accumulated in the LTC facilities.

This proposal means that we have reconsidered our decision not to waive the short-cycle dispensing requirement for LTC pharmacies that use ''return for credit and reuse'' dispensing practices, because we did not fully consider such a waiver previously in the context of comments received about return and reuse being a universal alternative approach to short-cycle dispensing. In addition, we continue to receive persuasive arguments that such pharmacies should be exempt; for example, from some veterans' homes with on-site pharmacies. However, as we explained previously, we are still concerned about waste associated with drugs that are not permitted to be returned for reuse and credit under applicable law in such LTC pharmacies in considering this additional exemption, and for this reason have specifically solicited comments on the extent of waste in such pharmacies that would qualify for the proposed additional waiver.

d. Technical Change To Eliminate the Requirement That PDP Sponsors Report on the Nature and Quantity of Unused Brand and Generic Drugs (§ 423.154)

Finally, we are proposing to make a technical change to § 423.154(a)(2), which requires Part D sponsors to collect and report information, in a form and manner specified by CMS, on the dispensing methodology used for each dispensing event described by paragraph (a)(1) of this section, as well as on the nature and quantity of unused brand and generic drugs dispensed by the pharmacy to enrollees residing in a LTC facility. This latter reporting requirement is waived for sponsors for drugs dispensed by pharmacies that dispense both brand and generic drugs in no greater than 7-day increments.

In a memorandum titled, ''Modifications to the Drug Data Processing System (DDPS) in Relation to Appropriate Dispensing of Prescription Drugs in Long Term Care Facilities,'' issued by CMS on August 3, 2012, we explained that we planned to use the PDE data in conjunction with other CMS data (such as MDS) to determine the extent to which 14 day or less dispensing to enrollees in LTC facilities reduces the amount of unused drugs in LTC. We did this to lessen the burden on sponsors that would be created by a separate reporting requirement. Therefore, it is no longer necessary to waive the reporting requirement for any Part D sponsor, because Part D sponsors

comply with the requirement (in the form and manner we specified in the previously-referenced memorandum) via PDE submission. Thus, we are deleting the first sentence of § 423.154(a)(2) to eliminate any confusion that there is a separate reporting requirement. 22. Applicable Cost-Sharing for Transition Supplies. Transition Process Under Part D § 423.120(b)(3)

We established transition requirements under § 423.120(b)(3) for Part D sponsors to address the needs of new Part D plan enrollees who are transitioning from other prescription drug coverage (Part D or otherwise), and whose current drug therapies may not be included on their Part D plan's formulary (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under the plan's utilization management requirements). While § 423.120(b)(3)(iii) specifies that PDP plans must provide a temporary fill when an enrollee requests a fill of a non-formulary drug during the transition time period (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules), it does not currently specify the cost sharing that should apply to such fills. Current guidance (at § 30.4.9 of Chapter 6 of the Medicare Drug Benefit Manual, found at *http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter6.pdf*) states that a Part D sponsor may charge cost sharing for a temporary supply of drugs provided under its transition process. Further, cost sharing for transition supplies for low-income subsidy (LIS) eligible beneficiaries cannot exceed the statutory maximum copayment amounts. However, for non-LIS enrollees, we stated that a sponsor must charge cost sharing based on one of its approved drug cost sharing tiers (if the sponsor has a tiered benefit design), and this cost sharing must be consistent with cost sharing that the sponsor would charge for non-formulary drugs approved under a coverage exception. This guidance created a great deal of confusion on the part of sponsors and beneficiaries. Charging the same cost sharing for non-formulary drugs, which are approved during transition, as for formulary drugs subject to utilization management edits (such as prior authorization or step therapy), that are overridden during transition while waiting for the utilization management requirement to be satisfied, is likely to be inconsistent with a tiered benefit design. It is possible that beneficiaries may pay more during transition than for his or her drug's normal designated formulary tier. Conversely, it is also possible that the beneficiary may pay more once the utilization management edit had been satisfied than he or she did under the transition fill. The following examples will illustrate these scenarios, assuming that the beneficiary is eligible for a transition fill, using the following hypothetical formulary structure:

TABLE 3—HYPOTHETICAL FORMULARY STRUCTURE

Tier	Tier description	Beneficiary cost sharing
1	Generics	$5 copay/30-days' supply.
2	Preferred Brands	$10 copay/30-days' supply.
3*	Non-preferred Brands	$15 copay/30-days' supply.
4	Specialty drugs (includes both generics & brands)	25% coinsurance/30-days' supply.

*Tier 3 is the designated formulary exception tier.

Each of the following examples shows the fill date, quantity filled, the associated days' supply, whether a transition fill was applied, and as a result, if either formulary tiering or exception tiering was applied to the enrollee's cost sharing. In all cases, if a transition fill was applied, the enrollee's cost sharing used exception tiering.

TABLE 4—EXAMPLE 1—THE BENEFICIARY'S DRUG IS ON TIER 2 WITH A PRIOR AUTHORIZATION REQUIREMENT

Date of fill	Quantity	Days' supply	Transition fill applied	Cost share used formulary tiering (FT) or exception tiering (ET)
1/1/13	30	30	Y	$15.00—ET.
The beneficiary obtains the PA, and the drug is no long considered a transition fill.				
2/1/13	30	30	N	$10.00—FT.

In this example, if the exception tier is used on the transition fill, the beneficiary's cost sharing amount is reduced once he or she obtains the prior authorization approval. However, if the drug's designated formulary cost sharing amount had been used, the cost sharing amount would have stayed the same, and would have been the same cost as the cost sharing amount shown on the formulary.

TABLE 5—EXAMPLE 2—THE BENEFICIARY'S DRUG IS ON TIER 4 WITH A PRIOR AUTHORIZATION

Date of fill	Quantity	Days' supply	Transition fill applied	Cost share used formulary tiering (FT) or exception tiering (ET)
1/1/13	30	30	Y	$15.00—ET.
The beneficiary obtains the PA, and the drug is no long considered a transition fill.				
2/1/13	30	30	N	25%—FT.

In this example, if the exception tier is used on the transition fill, the beneficiary's cost sharing amount will increase once he or she obtains the PA since the designated formulary tier has a higher cost sharing amount than the exception tier. If instead, the drug's designated formulary cost sharing had been used, the cost sharing amount would have remained the same for both fills. This scenario is particularly confusing for enrollees, since they pay more after receiving the required approval than they did under transition.

TABLE 6—EXAMPLE 3—THE BENEFICIARY'S DRUG IS NOT ON FORMULARY WITH A FORMULARY EXCEPTION

Date of fill	Quantity	Days' supply	Transition fill applied	Cost share used formulary tiering (FT) or exception tiering (ET)
1/1/13	30	30	Y	$15.00—ET.
The beneficiary obtains the FE, and the sponsor continues to treat the drug as non-formulary.				
2/1/13	30	30	N	$15.00—ET.

Plan sponsors are currently required to designate to which tier a non-formulary drug will apply once a formulary exception is granted. Sponsors can continue to treat the drug as non-formulary and continue the exception for the remainder of the coverage year, in which case, cost sharing at the exception tiering continues.

We believe that more consistent treatment of formulary and non-formulary drugs, respectively, will simplify the benefit and reduce sponsor and beneficiary confusion. Consequently, we propose to add a paragraph at § 423.120(b)(3)(vi) clarifying that when providing a transition supply, the cost sharing is determined as follows: A Part D sponsor must charge cost sharing for a temporary supply of drugs provided under its transition process such that the following conditions are met:

- For low-income subsidy (LIS) enrollees, a sponsor must not charge higher cost sharing for transition supplies than the statutory maximum copayment amounts.
- For non-LIS enrollees, a sponsor must charge—
  - ++ The same cost sharing for non-formulary Part D drugs provided during the transition that would apply for non-formulary drugs approved through a formulary exception in accordance with § 423.578(b); and
  - ++ The same cost sharing for formulary drugs subject to utilization management edits provided during the transition that would apply once the utilization management criteria are met.

23. Medicare Coverage Gap Discount Program and Employer Group Waiver Plans (§ 423.2325)

Section 3301 of the Affordable Care Act, codified in section 1860D–43 and 1860D–14A of the Act, established the Medicare Coverage Gap Discount Program (Discount Program), beginning in 2011. Under the Discount Program, manufacturer discounts are made available to applicable Medicare beneficiaries receiving applicable covered Part D drugs while in the coverage gap. Section 1860D–14A(c)(1)(A)(ii) of the Act requires the manufacturer discount to be provided to beneficiaries at the point-of-sale.

Employer Group Waiver Plans (EGWPs) are customized employer-offered plans available exclusively to employer/union health plan Part D eligible retirees and/or their Part D eligible spouse and dependents. Section 423.458(c)(4) requires sponsors offering EGWPs to comply with all Part D requirements unless those requirements have been specifically waived or modified by us using our authority under section 1860D–22(b) of the Act. We do not regulate any supplemental benefits that EGWPs offer outside of Part D prescription coverage. Employers/Unions offering EGWPs must ensure that any supplemental benefits comply with any applicable requirements for issuance under state insurance laws and/or ERISA rules (see January 25, 2013 Insurance Bulletin from the Center for Consumer Information and Insurance Oversight: *http://www.cms.gov/cciio/resources/Regulations-and-Guidance/index.html#Health* Market Reforms).

EGWP benefits are generally structured to provide additional coverage so that their enrollees do not actually experience a coverage gap. However, the Affordable Care Act did not exclude EGWP enrollees from the Discount Program. Therefore, in order for an applicable drug to be covered by EGWPs, it must be covered under a manufacturer agreement, and the manufacturer must pay applicable discounts as invoiced. Beginning in 2014, all EGWP benefits beyond the parameters of the defined standard benefit will be treated as non-Medicare Other Health Insurance (OHI) that wraps around Part D. We specifically excluded supplemental coverage offered through EGWPs from the definition of Part D supplemental benefits in § 423.100. We made this a requirement with respect to EGWPs so that the discount amount could be consistently and reliably determined. This was necessary to ensure that we can determine that the discount is always calculated accurately since we do not collect information on all EGWP retiree benefit arrangements to determine actual supplemental benefits. Not only would collecting such information be impractical, but we also believe instituting a requirement to collect the specific information on all such benefits would be so burdensome as to hinder the design of, the offering of, or the enrollment in employer plans. Consequently, the discount calculation will be based upon the Part D Defined Standard benefit for all EGWPs beginning in 2014. While we believed that our justification for excluding any supplemental benefits offered through EGWPs from Part D benefits clearly indicated that the basic EGWP Part D benefits would be limited to Defined Standard benefit because that is the only way we can determine that the discount is calculated accurately, we are taking the opportunity now to propose this specific requirement in § 423.2325(h)(1) to remove any ambiguity.

Treating EGWP supplemental benefits as OHI and always calculating the manufacturer discount based on the Defined Standard benefit means that discount payments likely will increase for some applicable beneficiaries enrolled in EGWPs over the amounts that would have been calculated when these benefits were considered as supplemental benefits for purposes of the coverage gap discount program. As noted previously, EGWPs' benefits are generally structured to provide additional coverage so that their

enrollees do not actually experience a coverage gap. Now that the Part D portion of the EGWP plan is based on the Defined Standard benefit, the coverage gap discount pays before the EGWP supplemental benefits (that is, OHI) are applied. Consequently, Part D sponsors that administer EGWP plans will receive discount amounts that may not offset the enrollees' final out-of-pocket cost-sharing, as the discounts do in individual market Part D plans when it is applied after Part D supplemental benefits. Nevertheless, we think it is important that these discounts that are calculated and paid prior to the application of OHI are apparent to the employer and union group clients of our Part D sponsors. This transparency ensures that the parties who are ultimately responsible for the both the EGWPs' plan design and the financial integrity of the plans are aware of the discount amounts received. We anticipate that the employer and union group administrators will take the additional funds into account when negotiating and designing retiree prescription drug benefits. We believe that his will ultimately benefit the beneficiaries enrolled in these plans.

We considered several approaches for ensuring that all manufacturer payments accrue to the benefit of beneficiaries enrolled in EGWPs. The most obvious approach would have been to require EGWPs to use manufacturer payments to reduce beneficiary premiums or cost-sharing in the non-Part D portion of benefit. While this approach would have offered the most straightforward benefit for beneficiaries, it has several serious obstacles. First, we do not believe that we have the authority to require any specific application of the coverage gap discount payments to OHI benefits that are by definition non-Medicare private market benefits outside our regulatory purview. In addition, since we do not collect premium or benefit information for EGWPs, monitoring compliance with such requirements would not be feasible. Moreover, establishing an affirmative requirement would necessitate establishing standards for how the discount amounts should be applied to the retiree benefits. We frankly do not have the depth of knowledge of private and public sector retiree benefits necessary to establish such standards. We can envision that more prescriptive requirements about how discount amounts can be used might interfere with critical utilization management and cost control features of these benefits, conflict with employment or bargaining agreements particulars, or have other unintended consequences. We also considered not taking any action since anecdotal evidence suggests that some employer groups are already using the discounts to reduce premiums, and we have no reason to believe that this is not generally the case. However, we cannot be sure that all employer groups are aware of how Discount Program payments are calculated or the value of the payments attributable to their enrollees. After consideration, we believe that our best course is to pursue full disclosure and transparency so that employer groups have the information they need to take full advantage of these discounts to strengthen and safeguard their enrollees' retiree benefits. Through the proposed regulation we are seeking to ensure that employer groups are fully aware of Discount Program payments attributable to their enrollees so that the payments can be accurately anticipated and incorporated into EGWP benefit designs. Equipped with projected and actual payments received, each employer group can design a benefit package that best meets the needs of its retirees.

To ensure that Discount Program payments are communicated to employer groups in a uniform fashion, we propose to codify notification requirements by amending § 423.2325 to add a new paragraph (h) requiring Part D sponsors of EGWPs to disclose to each employer group the projected and actual manufacturer discount payments under the Discount Program attributable to the employer group's enrollees. We further propose that such disclosures happen at least annually or upon request. Part D sponsors must also be prepared to demonstrate to CMS that such notifications have been made upon request.

24. Interpreting the Non-Interference Provision (§ 423.10)

Since the MMA created the Part D benefit in 2003, we have never formally interpreted section 1860D–11(i) of the Act, which is known as the noninterference provision. In practice we have generally invoked the spirit of this provision in declining to intervene in negotiations or disputes involving payment-related contractual terms between participants in the drug distribution channel. However, it is increasingly clear from the many questions that continue to arise when working with stakeholders on matters ranging from lawsuits to policy clearance to complaint resolution that the agency and all Part D stakeholders would benefit from a clear, formal interpretation of these limits on our authority. Some stakeholders appear to believe the prohibition on interference in negotiations extends far beyond the boundaries that we consider relevant, while others insist our authority extends into arbitrating matters that seem to us to clearly fall within the intended prohibition. Therefore, we are proposing an interpretation through rulemaking in order to clarify and codify the extent of these limits on our authority.

The noninterference provision at section 1860D–11(i) of the Act provides that, ''In order to promote competition under this part and in carrying out this part, the Secretary: (1) May not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs.'' In beginning with the words ''In order to promote competition under this part and in carrying out this part . . .'' we believe that the Congress intended that the activities addressed in the rest of the provision should take place through private market competition. We interpret this to mean two separate but related goals. The first goal is that the Secretary through CMS should promote private market competition in the selection of Part D drugs for Part D sponsor formularies. The second goal is that CMS should not create any policies that would be expected to interfere with competitive market negotiations leading to the selection of drug products to be covered under Part D formularies. Therefore, in light of these two goals we believe there is both a duty to act—to promote competition in the private market for Part D drugs—and a duty to refrain from acting—to avoid intervention in private market negotiations that take place in the context of that competitive market.

Economic theory on competitive markets suggests that the duty to ensure a competitive market means that within the limits of our authority we should seek to encourage certain features of the market that promote more perfect competition. This would include such goals as decreasing the transaction cost of acquiring information on products offered in the market, increasing the transparency of prices, ensuring a large number of buyers and sellers, and minimizing barriers to entry to the extent possible while still ensuring quality. We have pursued these types of goals since the start of Part D program implementation through such efforts as the Medicare Prescription Drug Plan Finder, the development of the Medicare star ratings, our extensive efforts to provide technical assistance to

new and existing sponsors, and our meaningful differences policies that improve the comparability of Part D formularies and benefit packages. We will continue to seek opportunities to improve competition. As an initial matter, in light of our interpretation of the general purpose of section 1860D–11(i) of the Act, we propose a general rule at § 423.10(a) that CMS promotes fair private market competition in the market for Part D drugs.

There is also a duty to avoid intervention in private market negotiations that take place in the context of that competitive market. We believe the intent of 1860D–11(i) is to ensure that we do not create any policies or become a participant in any discussions that could be expected to interfere with negotiations leading to the selection of drug products to be covered under Part D formularies. By this we mean selection by Part D sponsors (or other intermediary contracting organizations) of specific manufacturers' products for inclusion on formularies, formulary tier placement, and negotiations of acquisition costs, rebates, and any other price concessions. We believe this interpretation is consistent with a textual reading of 1860D–11(i) and with how private market transactions determine which prescription drug products are covered under Part D plans.

Private market competition for prescription drugs is a complex process that has been described in detail elsewhere, such as in the 2007 CBO report entitled ''Prescription Drug Pricing in the Private Sector'' at: *http://www.cbo.gov/publication/18275*. This process involves specific transactions between manufacturers and distribution channel participants (generally wholesale distributors and dispensing pharmacies) that are different than the transactions that take place between manufacturers and ultimate purchasers (primarily health plans or self-insured employers and/or their intermediate contracting organizations, such as pharmacy benefit managers (PBMs)). Pharmacies will stock most commonly used brand medications but will selectively stock generic products to leverage volume in return for the best prices from competing generic manufacturers. Thus, generally speaking, the price negotiations between manufacturers and pharmacies differentially determine which generic products are stocked and dispensed by pharmacies. These price negotiations are generally based on discounts off manufacturer list prices. Health plans and PBMs, in contrast, will base decisions on which multiple-source or therapeutically equivalent brand drug products will be covered under a plan in part on the evaluation of the relative cost effectiveness of the competing drug products. This will be determined by comparing both the list prices of the drug products and the level of rebates negotiated between the sponsor and the manufacturers of the brand products. Thus the price negotiations between manufacturers and health plans determine which brand products are placed on the plan's formulary and available to enrollees. These additional price negotiations are generally around the level of rebates for both formulary and tier placement. These distinct sets of negotiations in the private market between manufacturers and pharmacies on the one hand, and between manufacturers and plan sponsors on the other hand, support our textual reading of section 1860D–11(i)(1) of the Act to prohibit CMS involvement in negotiations between manufacturers and pharmacies, and between manufacturers and plan sponsors. There are also separate price negotiations between plan sponsors (or their intermediary contracting organizations) and pharmacies around the negotiated prices required for network participation. However, as will be discussed in more detail in this section, since the statute establishes numerous requirements that CMS must regulate concerning access to network pharmacies and negotiated prices, we believe that a CMS role in negotiations between plan sponsors and pharmacies is not prohibited under section 1860D–11(i)(1) of the Act.

We note that in The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Conference Agreement (Conference Agreement), in addition to the statutory language, MMA drafters included the following sentence: ''Conferees expect PDPs to negotiate price concessions directly with manufacturers.'' We believe this statement supports our understanding that the primary focus of section 1860D–11(i) of the Act is on the negotiations between plan sponsors (or their intermediary contracting organizations) and manufacturers for rebates and other price concessions that ultimately determine which multiple source products will be placed on a sponsor's formulary. The outcome of these negotiations also determine tier placement, or the level of cost sharing that will be charged for the drug, whether the drug will be subject to certain utilization management controls, and may even influence the list prices that manufacturers submit to the commercial databases and that form the basis of most purchasing contracts in the drug distribution channel.

Section 1860D–11(i)(1) of the Act states that we ''may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors''. We believe that the term ''interference'' in this context should be interpreted as prohibiting our involvement in discussions between manufacturers and their distribution channel customers (such as wholesalers and pharmacies) or the ultimate purchasers of prescription drugs (such as plan sponsors and PBMs) leading to signed contracts. We believe that the negotiations addressed by the first clause should be read to apply to discussions manufacturers have with their customers because, as discussed previously, this textual reading comports with the nature of the transactions that occur in the private market that determine which drug products will be covered under Part D plans. We also believe section 1860D–11(i)(1) of the Act should be interpreted as prohibiting our involvement in arbitration of agreements already executed between any of these parties. It would not make sense to prohibit CMS involvement in discussions leading up to an executed agreement only to allow involvement in arbitrating the terms of the agreement afterwards. Thus we interpret the word ''negotiations'' to mean not only the initial discussions leading to executed agreements, but also any subsequent discussions between the parties as to what those agreements require. We are periodically asked to become involved in both initial negotiations and in disputes and renegotiations by parties trying to get CMS to weigh in on one side or another on the premise that failure to do so will lead to access issues for Medicare beneficiaries. We also periodically are asked to address terms and conditions of executed agreements that one of the parties believes is unfair. We believe that our involvement in these sorts of issues is precisely what the statute prohibits in section 1860D–11(i)(1) of the Act—our weighing in on a contract negotiation or dispute could influence the outcome. In other words, government involvement could affect market forces around prescription drugs in ways that change the value that would otherwise be assigned to these products in a competitive market. We believe we should not pick winners and losers in formulary selection negotiations, and that the remedies for disputes should be determined in accordance with the terms of the

contracts or in the courts having jurisdiction over the contracts.

Therefore we interpret the prohibition in section 1860D–11(i)(1) of the Act on interference in negotiations to pertain to discussions either between prescription drug manufacturers and pharmacies, or between prescription drug manufacturers and Part D sponsors (or their intermediary contracting organizations, hereafter included by association whenever we refer to Part D sponsors). Our interpretation is based on the sequential phrasing of the clause ''negotiations between drug manufacturers and pharmacies and PDP sponsors.'' Because in general these negotiations are not among all three parties at once, and because manufacturers separately contract with pharmacies for the purchase of inventory and with sponsors for formulary placement, we believe the quoted phrase can be interpreted as recognizing these distinct types of negotiations. Under such a reading, the prohibition on interference in negotiations, as described in section 1860D–11(i)(1) of the Act, would not pertain to negotiations between Part D sponsors and pharmacies.

This does not mean, however, that we would be free to interfere in sponsor-pharmacy negotiations. Indeed, we believe section 1860D–11(i)(2) of the Act sets forth specific limits on our ability to involve ourselves in Part D sponsors' arrangements with their network pharmacies, as discussed in more detail later in this section. However, we believe that our proposed interpretation of section 1860D–11(i)(1) of the Act as not applying to the sponsor-pharmacy negotiations is supported by the provision's context. There are numerous statutory provisions that require us to directly intervene in the contractual relationship between Part D sponsors and network pharmacies, and these provisions clearly signal that the Congress expected CMS involvement in at least some of these negotiations. The Congress has provided many contractual requirements for CMS to enforce between sponsors and pharmacies; just the drug-cost-related of these include: Interpretation of what ''access to negotiated prices'' means, any-willing-pharmacy standard terms and conditions, prohibition on any requirement to accept insurance risk, prompt payment, and payment standard update requirements. So it is clear that Part D sponsors and pharmacies do not have sole discretion to interpret these specific matters. We would be obligated to intervene in disputes over whether proposed or finalized contractual arrangements violated our rules in any area where our oversight is directed under the statute. Therefore, it is clear that such involvement could not be what the Congress intended to prohibit. Moreover, we observe a growth in related-party relationships between Part D sponsors and network pharmacies, where the distinction between the sponsor and the pharmacy is increasingly unclear, and there is no reason to believe that the Congress intended that we are prohibited from oversight of the sponsor's dealings with itself. In addition, we believe the goals of the non-interference provision generally support CMS avoidance of being an arbiter of private disputes. Thus, we would also decline to intervene in contractual disputes between sponsors and network pharmacies except in matters implicating CMS requirements, because to do so might distort private market outcomes in unpredictable ways. Therefore, we propose at § 423.10(b) that CMS may not be a party to discussions between prescription drug manufacturers and pharmacies, or between drug manufacturers and Part D sponsors, and may not arbitrate the meaning of or compliance with the terms and conditions of agreements reached between these parties, except as necessary to enforce CMS requirements applicable to those agreements. Thus, we could only be involved in such discussions in order to explain CMS requirements and to ensure compliance with Part D rules and regulations. We also add that nothing in this prohibition limits our authority to require documentation of and access to all such agreements, or to require the inclusion of terms and conditions in agreements when necessary to implement requirements under the Act.

The first part of the section 1860D–11(i)(2) of the Act states that CMS ''may not require a particular formulary''. The noninterference clause must be read in context of the other provisions that give CMS authority with respect to formularies, so we propose to interpret the term ''particular formulary'' to mean the selection of specific manufacturer licensed drug products to be on formulary, or on any particular tier of a formulary, assuming the product meets the definition of a Part D drug. We interpret the first part of section 1860D–11(i)(2) of the Act to prohibit us from developing formulary guidelines that prefer one manufacturer's product over another's in Part D formularies, leading to more limited formularies such as provided by the Department of Defense and the Veteran's Administration. The most efficient formularies will make formulary selections and then exclude all or most competing multi-source and therapeutically equivalent brand products in order to concentrate volume and maximize rebates. Given the size of the Part D market, if CMS were able to similarly limit access to Part D formularies to certain products, this would bestow significant competitive advantage on the manufacturers of selected products and significant competitive disadvantage on manufacturers of competing products. Such limits would be expected to fundamentally alter supply and demand in the marketplace. This prohibited sort of selection would be distinguished from CMS formulary requirements that may require particular types of drug entities to be on all formularies, or on preferred tiers, in order to provide non-discriminatory access to drugs necessary to treat conditions in all Medicare beneficiaries, or to address drug classes of clinical concern (see section III.A.14 of this proposed rule). Therefore, we propose a provision prohibiting establishment of formulary drug product selection at § 423.10(c) that specifies that CMS does not determine the specific drug products to be included on Part D sponsor formularies or any tier placement of such products, except as required to comply with § 423.120(b)(1)(v) or § 423.272(b)(2).

The second part of section 1860D–11(i)(2) of the Act states that CMS ''may not institute a price structure for the reimbursement of covered Part D drugs''. Again, the noninterference clause must be read in context of the other provisions that give CMS responsibilities in a number of areas that pertain to pricing, so we interpret the phrase ''price structure'' to refer to establishing either absolute or relative indices of price for Part D drugs. Specifically, we believe the intent of this provision is to prohibit two types of intervention by CMS. The first prohibited activity is that CMS may not require Part D drug acquisition costs or sales prices to be a function of (be defined relative to) any particular published or unpublished pricing standard, either existing or future. Thus, we could not require that Part D prices be based on, or be any particular mathematical function (such as a percentage or multiple) of established pricing standards such as Average Wholesale Price, Wholesale Average Cost, Average Manufacturer Price, Average Sales Price, Federal Supply Schedule, 340b pricing, etc. The second prohibited activity is that CMS cannot require price concessions (from any

standard or basis) to be at any specific (absolute) dollar amount or equal to a level specified in other legislative requirements for other federal programs. Thus, we could not, for example, set minimum or maximum dollar prices for a drug product or require that Part D prices be offered at acquisition cost, or at the 'best price' applicable under the Medicaid program. However, since the statute requires us to regulate many aspects of how drug costs are made available and displayed to beneficiaries and treated in Part D bidding and payment processes, it is clear that we have an important role to play in establishing rules for consistent treatment of drug costs in the program. Consequently, we may establish definitions of what constitutes a pricing standard, a price concession, a cost, etc. We may also establish rules concerning how drug costs are treated under Part D, including, but not limited to, how such amounts are disclosed in the marketplace, projected in Part D bids, made available to beneficiaries at point of sale, reported in Explanation of Benefits (EOBs), submitted to CMS, and treated in CMS payments to Part D sponsors. Therefore, we propose a provision prohibiting establishment of drug price reimbursement methodologies at § 423.10(d) that specifies that CMS does not establish drug product pricing standards or the dollar level of price concessions at any stage in the drug distribution channel for Part D drugs. Nothing in this prohibition limits our authority to require full disclosure or uniform treatment and reporting of drug costs and prices.

25. Pharmacy Price Concessions in Negotiated Prices (§ 423.100)

We have learned that some Part D sponsors have been reporting costs and price concessions to CMS in different ways. This reporting differential matters because this variation in the treatment of costs and price concessions affects beneficiary cost sharing, CMS payments to plans, federal reinsurance and low-income cost-sharing (LICS) subsidies, and manufacturer coverage gap discount payments. Differential treatment of costs would also be expected to affect plan bids. We do not collect sufficient detail in price concession data reported to CMS to quantify this impact, but this conclusion follows from the admitted reporting of some pharmacy price concessions in the annual aggregate price concession reporting (that is, the DIR reporting) during the coverage year payment reconciliation process, rather than as part of the negotiated price. (This issue, and its financial effect, have been discussed in the Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (2014 Call Letter), [at *http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2014.pdf*] and will be discussed in more detail in the discussion which follows.) If the projected net costs a sponsor is liable for in its bid are understated because the sponsor has been reporting certain types of price concessions as direct or indirect remuneration (DIR) rather than as price concessions that affect the negotiated price, it follows that the sponsor may be able to offer a lower bid than its competitors and may achieve a competitive advantage stemming not from greater efficiency, but rather from a technical difference in how costs are reported to CMS. When this happens, such differential reporting could result in bids that are no longer comparable, and in premiums that are no longer valid indicators of relative plan efficiency. We are therefore proposing changes to rectify this concern.

The MMA established Part D as a voluntary, private-market-based program that would rely on private plans to provide coverage and to bear some of the financial risk for drug costs. These private plans would determine premiums through a bid process and would compete with other plans based on premiums and negotiated prices. [The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Conference Agreement (Conference Agreement), page 4] Premiums are set through a statutory formula that ensures that premium levels are commensurate with bid levels. Therefore, all other things being equal, the lowest premium for a given level of benefits should signal the most efficient plan. Premiums are established through a prospective bidding process in which costs are projected and evaluated in accordance with actuarial guidelines set by the CMS Office of the Actuary.

Negotiated prices are the payment amounts pharmacies receive from plans for covered Part D drugs dispensed to plan enrollees. CMS payments to plans are based on the reporting of negotiated prices (through PDE reporting) that are actually paid and are then offset by any other price concessions (submitted in aggregate through the separate annual DIR reporting process). CMS establishes rules for cost and price concession reporting through both PDE and DIR guidance and other payment reconciliation rules, and has regulated the definition of negotiated price and how it is to be treated in Part D benefit administration and in payment reconciliation. Since 2010, the regulatory definition has been: ''Negotiated prices means prices for covered Part D drugs that: (1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug; (2) Are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and DIR that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale; and (3) Include any dispensing fees.''

We intended clause 2 to primarily refer to price concessions from parties other than pharmacies, since these would be price concessions that were not based on the sale of the drug by the pharmacy and calculated when the claim adjudicated and, in fact, could not be calculated until a later date. In particular, we expected these other non-claim-based price concessions to be in the form of rebates offered by prescription drug manufacturers. Since prescription drugs are dispensed by pharmacies and purchased through transactions between Part D sponsors (or their intermediary contracting organizations) and pharmacies, manufacturers are never in a position to apply price concessions to negotiated prices at point of sale. We now understand that clause 2 is ambiguous and permits sponsors and their intermediaries to elect to take some price concessions from pharmacies in forms other than the negotiated price and report them outside the PDE. When this occurs, the increased negotiated prices generally shift costs to the beneficiary, the government and taxpayer, and when applicable to certain brand name drugs, to prescription drug manufacturers. (The mechanism of this sort of cost shift was discussed at length in the analogous context of lock-in pricing in our 2008 proposed rule entitled ''Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs'' which as published on May 16, 2008 in the **Federal Register**,—FR 28563 through 28566.)

In addition, when price concessions from pharmacies are reflected in forms other than the negotiated price, the degree of price concession that the pharmacy has agreed to is no longer reflected in the negotiated prices available at point of sale or reflected on the Medicare Prescription Drug Plan

Finder (Plan Finder) tool. Thus, the true price of drugs at individual pharmacies is no longer transparent to the market. Consequently, consumers cannot efficiently minimize both their costs (cost sharing) and costs to the taxpayers by seeking and finding the lowest-cost drug/pharmacy combination. Moreover, as the coverage gap closes, there are fewer and fewer beneficiaries who are exposed to the full cost of drug products, either at the point of sale or as reflected in Plan Finder estimates. When this occurs, the basis of competition shifts from prices to cost sharing, and the pricing signals available to the market can be distorted when lower cost sharing is not aligned with lower prices. Thus, we believe the exclusion of pharmacy price concessions from the negotiated price thwarts the very price competition that the Congress intended when it said that private plans would compete with other plans on both premiums and negotiated prices.

We are aware that certain pharmacy price concessions are being excluded from the determination of the negotiated price because they are being characterized as ''network access fees'', ''administrative fees,'' ''technical fees'' or ''service fees'' that are frequently imposed through PBM-issued manuals rather than explicit contractual terms. Pharmacies and pharmacy organizations report that they do not receive anything of value for those fees other than the ability to participate in the Part D network. The itemized types of services for which their payments are offset reportedly include things such as transaction fees for submission of claims, help desk support, information technology and telecommunication systems connectivity, electronic funds transfers, and other expenses associated with credentialing, maintaining, and auditing pharmacy networks. These fees take the form of deductions from payments to pharmacies for drugs dispensed, but in our view clearly represent charges that offset sponsor/PBM operating costs. We believe that if the sponsor or its intermediary contracting organization wishes to be compensated for these services and have those costs treated as administrative costs, such costs should be accounted for in the administrative costs of the Part D bid. If instead these costs are deducted from payments made to pharmacies for purchases of Part D drugs, such costs are price concessions and must be treated as such in Part D cost reporting. This is the case regardless of whether the deductions are calculated on a per-claim basis or not. In our view, the decision on how such network management costs are funded between the PBM and the sponsor is not governed by our rules, but our rules do require that price concessions be fully disclosed and net against drug costs in reconciliation.

We have also heard from pharmacies that some sponsors apply dispensing fees to claims when they are adjudicated at point of sale, but require that these fees later be rebated back to the sponsor and deducted from payment remittances. Such practices again misstate the negotiated price. Our proposal would require that dispensing fees could only be applied at point of sale if they are received and retained by the pharmacy in the negotiated price.

In comments on our related discussion in the 2014 Call Letter, one commenter argued that these other amounts charged to pharmacies are actually valid administrative costs. In contrast, all other sponsors and PBMs that commented on that section acknowledged these amounts to be price concessions. More significantly, all pharmacies and pharmacy organizations we have heard from assert that these are price concessions. When reported as DIR, these price concessions have the effect of offsetting price concessions disproportionally against just the costs the plan is most liable for, as discussed in the 2014 Call Letter. If not reported at all, these amounts would result in another form of so-called PBM spread in which inflated prices contain a portion of costs that should be treated as administrative costs. That is, even if these costs did represent services rendered by the PBM or other intermediary organization for the sponsor, then these costs would be administrative service costs, not drug costs, and should be treated as such. Failure to report these costs as administrative costs in the bid would allow a sponsor to misrepresent the actual costs necessary to provide the benefit and thus to submit a lower bid than necessary to reflect its revenue requirements (as required at section 1860D–11(e)(2)(C) of the Act and at § 423.272(b)(1)) relative to another sponsor that accurately reported administrative costs consistent with CMS instructions. Therefore, we agree with the pharmacy position that an amount deducted from the negotiated price otherwise payable to the pharmacy for these sorts of administrative fees is a price concession that should be reflected in the negotiated price. Consequently, we believe that the best interpretation of statutory intent is that all pharmacy price concessions must be reflected in the negotiated price. This would preclude the differential reporting that is taking place today, and put all plans on a level playing field in reporting drug costs and price concessions from network pharmacies. Consistent and transparent pricing would also promote increased price competition among network pharmacies and will align beneficiary and taxpayer interests in minimizing costs. Therefore, we do not believe that other pricing arrangements that cannot be calculated at the point of sale, such as risk sharing or conditional payments based on volume, are compatible with the price competition envisioned under the statute. Such arrangements will tend to overstate negotiated prices at point of sale, and require the subsequent adjustments through DIR reporting that may increase beneficiary and government costs if specified targets are met. We believe that the advantages of any such incentive arrangement could be achieved without the cost shifting by adjusting future negotiated prices. For instance, if specified volume targets were met in one quarter, rather than retroactively adjusting that quarter's prices down through DIR reporting, the negotiated prices for the next quarter could be reduced, and so on. Therefore we propose to reinterpret section 1860D–2(d)(1)(B) of the Act such that negotiated prices are the amounts that a network pharmacy receives in total for covered Part D drugs, and that these prices must reflect all price concessions from network pharmacies. Therefore, any other negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and (DIR) referenced in the statute would be those price concessions offered by sources other than network pharmacies (or their intermediary contracting organizations). In practice, this means prescription drug manufacturers.

Some stakeholders have recommended that certain incentive payments to pharmacies, such as generic dispensing incentive fees, should not be included in negotiated prices. If these payments are included, they explain, the negotiated prices appear higher at the more efficient pharmacy as the result of the additional incentive payment. This higher price then proportionally increases costs borne by beneficiaries, the government, and manufacturers. These incentives really represent amounts that the sponsor is willing to bear in order to encourage the most efficient drug choices, which will drive down total costs overall, and thus the sponsor is willing to bear a disproportionate share of such expense. We agree with this

argument and we believe that this sort of arrangement would not conflict with our proposed requirement that all price concessions be reflected in the negotiated price since such additional payments are the opposite of price concessions. Instead such incentive fees represent contingent price increases that cannot be predicted in advance, and cannot therefore be programmed to be applied at point of sale or reflected in the price posted on Plan Finder. We believe it would be appropriate to treat this particular sort of price increase differently than price decreases because including such amounts in the negotiated price (incentive fee component) at point of sale could disguise the relative competitiveness of the underlying pharmacy prices. Incentive fees also primarily benefit the plan sponsor who benefits from the lower costs associated with the incentivized behavior, rather than the beneficiary. Therefore, in this case, we agree that it would be more appropriate for such incentive payments to be excluded from the negotiated price, and reported later in reconciliation as negative DIR. When reported as negative DIR, these amounts disproportionately affect (increase) the amounts the sponsor is liable for in risk sharing, which is appropriate given the intent of the incentives to promote least-cost drug product selection at point of sale. Least-cost drug product selection will directly reduce the sponsor's allowable risk corridor costs, so any incentive paid to encourage this behavior would be expected to be more than offset by the ingredient costs savings achieved through avoidance of higher-cost drug selection. This is so because, as we learned from numerous commenters to the 2014 draft Call Letter, the incentive payments are generally in the range of a dollar or two and the difference between preferred and non-preferred drug products is generally much greater.

Therefore, we propose to revise the definition of negotiated prices at § 423.100 to require that all price concessions from pharmacies are reflected in these prices. Specifically we propose to redefine negotiated prices to mean prices for covered Part D drugs that: (1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug; and (2) are inclusive of all price concessions and any other fees charged to network pharmacies; and (3) include any dispensing fees; but (4) exclude additional contingent amounts, such as incentive fees, only if these amounts increase prices and cannot be predicted in advance; and (5) may not be rebated back to the Part D sponsor (or other intermediary contracting organization) in whole or in part.

26. Payments to PDP Plan Sponsors for Qualified Prescription Drug Coverage (§ 423.308)) and Payments to Sponsors of Retiree Prescription Drug Plans (§ 423.882)

We propose to revise the definition of the term actually paid at both § 423.308 for the Part D program and § 423.882 for the Retiree Drug Subsidy program in order to reconcile this definition with the changes proposed to the definition of negotiated prices in this regulation. Since our proposal would require that all price concessions from network pharmacies must be reflected in the negotiated price, it would no longer be correct to include pharmacies in the list of sources from which price concessions could be received without qualification. Therefore, we propose to revise the definition of actually paid at § 423.308 to include references to incentive payments, and to clarify that DIR may include additional payments to pharmacies, such as for incentive payments, but may not include any other price concessions from pharmacies as these must be in the form of the negotiated price as proposed in § 423.100. We similarly propose to change the reference to ''from any source'' in the definition of actually paid at § 423.882 to ''from any manufacturer or similar entity'' to align these definitions.

We also propose to remove any reference to coupons in the list of price concession types. The definition of ''actually paid'' relates to costs incurred by Part D sponsors, and coupons would not affect those costs. Similarly, we are considering whether any or all of the surrounding terms ''cash discounts, free goods contingent on a purchase agreement, up-front payments . . . goods in kind, free or reduced-price services, [or] grants'' in both of those paragraphs would affect costs paid by Part D sponsors. We solicit comments on this question. We similarly propose to remove any reference to coupons in the definition of actually paid at § 423.882 to align these definitions. We also solicit comments on whether the surrounding terms ''cash discounts, free goods contingent on a purchase agreement, up-front payments . . . goods in kind, free or reduced-price services, [or] grants'' in both of those paragraphs would affect costs paid by sponsors of qualified retiree prescription drug plans.

Our reason for striking any such term is that we are not aware of any form of coupons (or the other forms of remuneration listed previously) that would affect the amount a Part D sponsor pays to the pharmacy on a claim. Therefore, the terms should be deleted to accurately reflect the types of price concessions a Part D sponsor might receive that would affect its financial obligation to pharmacies. Moreover, we do not want to signal any ambivalence with regard to the permissibility of copayment coupons to eliminate or reduce the cost-sharing obligations of Part D beneficiaries. The anti-kickback statute prohibits the knowing and willful payment of remuneration, directly or indirectly, in cash or in kind, to induce the recipient to purchase any item for which payment may be made in whole or in part under a federal health care program. (42 U.S.C. 1320a–7b(b)(2)). The statute also prohibits the knowing and willful receipt of remuneration in return for such a purchase. (42 U.S.C. 1320a–7b(b)(1)). Because copayment coupons are provided to consumers for the purpose of inducing them to purchase specific prescription drugs, knowing and willful use of such coupons to reduce the cost-sharing obligations of federal health care program beneficiaries is prohibited by the anti-kickback statute. Pharmaceutical manufacturers are aware of this prohibition and typically include language on copayment coupons stating that persons whose prescriptions are paid for by federal programs are not eligible to use them.

27. Preferred Cost Sharing (§ 423.100 and § 423.120)

In our original rule implementing the Part D Program, we codified an interpretation of section 1860D–4(b)(1)(B) of the Act at § 423.120(a)(9) that permitted Part D sponsors to offer lower cost sharing at a subset of network pharmacies, dubbed ''preferred pharmacies,'' than at other in-network pharmacies. This lower cost sharing was subject to certain conditions that seemed straightforward to us at the time, but which have proven to need clarification. We have recently discussed this concern in the Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (2014 Call Letter) on pages 175–176 [at *http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2014.pdf*]

Section 1860D–4(b)(1)(B) of the Act contemplates the possibility of sponsors offering lower cost sharing at some network pharmacies than is offered in conjunction with the any willing pharmacy terms and conditions mandated in the immediately preceding paragraph (A). However, a plan's ability to reduce cost sharing is contingent upon one condition: ''In no case shall such a reduction result in an increase in payments made by the Secretary under section 1860D–15 of the Act to a plan.'' In our original proposed rule entitled ''Medicare Program; Medicare Prescription Drug Benefit; Proposed Rule,'' published on August 3, 2004 in the **Federal Register**, 69 FR 46658 through 46659, we did not offer an interpretation of this language but implied that any assessment of whether the condition was met would be a matter of actuarial equivalence analysis. We proposed to codify the requirements in regulation with the following two conditions: ''. . . the plan must still meet the requirements under § 423.104(e)(2) and (5); and [a]ny cost sharing reduction must not increase CMS payments under § 423.329.'' In the final regulation entitled ''Medicare Program; Medicare Prescription Drug Benefit; Final Rule'', published on January 28, 2005 in the **Federal Register**, 70 FR 4247 through 4255, we reiterated the language from the aforementioned proposed rule (69 FR 46658). ''However, we note that while these within-network distinctions are allowed, the statute also requires that such tiered cost-sharing arrangements in no way increase our payments to Part D sponsors. Therefore, tiered cost-sharing arrangements based on within-network distinctions could be included in Part D plans' benefits subject to the same actuarial tests that apply to formulary-based tiered cost-sharing structures. Thus, a reduction in cost sharing for preferred pharmacies in a Part D plan network could be offered through higher cost sharing for non-preferred pharmacies (or as alternative prescription drug coverage).'' (70 FR 4254, January 28, 2005). This statement was immediately followed by an expression of our intent to ensure that such network benefit designs were non-discriminatory: ''We recognize the possibility that Part D plans could effectively limit access in portions of their service areas by using the flexibility provided in § 423.120(a)(9) of our final rule to create a within-network subset of preferred pharmacies. In other words, in designing its network, a Part D plan could establish a differential between cost-sharing at preferred versus non-preferred pharmacies—while still meeting the access standards in § 423.120(a)(1) of our proposed rule—that is so significant as to discourage enrollees in certain areas (rural areas or inner cities, for example) from enrolling in that Part D plan. We emphasize that such a network design has the potential to substantially discourage enrollment by certain Part D enrollees, and that we have the authority under section 1860D–11(e)(2)(D) of the Act to disallow benefit designs that are discriminatory.''

And in fact, once sponsors began to submit preferred cost sharing benefit designs, we imposed limits on non-preferred cost sharing in such plans (through plan benefit package (PBP) bid review) to ensure that non-preferred cost sharing in these designs did not represent a cost sharing outlier in comparison to Part D plans without preferred cost sharing. If we were to allow cost sharing in pharmacies not offering preferred cost sharing to rise above this outlier level, beneficiaries with significant utilization due to severe or chronic illness would clearly see that such plans were disadvantageous, and would avoid them. Thus, we would find any such designs to be discriminatory and would not approve the plan benefit package. However, what we failed to sufficiently explain in 2005 was that if cost sharing cannot rise beyond a certain level, then in return for lower cost sharing, preferred networks must reduce drug costs paid by the plan in order to prevent an increase in CMS payments to the plan. In part this omission may have been because we presumed that Part D sponsors would motivate enrollees to go to a subset of pharmacies through lower cost sharing only if those pharmacies offered significantly lower negotiated prices, and thus would provide a competitive advantage for the sponsor in lowering costs. As the concerns expressed in the 2014 Call Letter indicate, this does not seem to have been the case for some sponsors. However, if drug costs (negotiated prices) are not lower in return for lower cost sharing, and the lower cost sharing cannot be completely offset by higher cost sharing on other beneficiaries due to our cost-sharing-outlier limits, then the amount that must be subsidized by the government and the taxpayer will increase.

As noted in the Call Letter, we conducted an analysis of 2011 Part D drug costs in standalone PDPs with preferred networks, and compared these to costs in their non-preferred networks, as well as to costs in other PDPs without preferred networks. (The April 2013 analysis by CMS, ''Negotiated Pricing between Preferred and Non-Preferred Pharmacy Networks'', is posted at: *http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/PharmacyNetwork.pdf*). We expected to find that costs were consistently lower, although we had no preconceived estimate of how much lower. Instead we found that aggregate unit costs weighted by utilization (for the top 25 brand and top 25 generic drugs) were slightly higher in a few preferred networks than in non-preferred networks in some plans. The majority of sponsors offering preferred networks did not have these higher costs, although the range of cost savings in their preferred networks ranged from a high of 24.2 percent to as little as 0.1 percent when measured in this particular way. Surprisingly, the most significant driver of excess costs in the outlier sponsor preferred networks appeared in mail-order claims. In these cases the retail pharmacies in the non-preferred network were actually offering savings through discounted generics at prices below those offered by pharmacies with preferred cost sharing. This is a primary reason we have proposed to interpret the any willing pharmacy requirements (see section III.A.29 of this proposed rule) to require plan sponsors to offer preferred cost sharing for any pharmacy that can offer sufficient discounts to qualify. Even assuming that preferred pharmacies were to offer lower negotiated prices than those available in the rest of the network, failure to allow access to any pharmacy willing to meet the pricing terms necessary to be included in the preferred network could mean that fewer beneficiaries would have convenient access to both lower cost sharing and lower negotiated prices than would otherwise obtain. We seek to not only ensure that preferred cost sharing is aligned with lower drug costs, but also to maximize the number of beneficiaries who can take advantage of such savings. We note that most PBMs own their mail order pharmacies, and we believe their business strategy is to move as much volume as possible to these related-party pharmacies to maximize profits from their ability to buy low and sell as high as the market will bear.

Our findings—that a few sponsors have actually offered little or no savings in aggregate in their preferred pharmacy pricing, particularly in mail-order claims for generic drugs—are troubling. Instead of passing through lower costs available through economies of scale or steeper discounts, a few sponsors are actually charging the program higher negotiated prices. When these higher

prices are combined with significantly lower cost sharing offered in preferred pharmacy pricing, such pricing increases the proportion of costs borne by the plan and the government. All other things being equal, this increases payments to plans in violation of section 1860D–4(b)(1)(B) of the Act. Moreover, the lower cost sharing provides a defective price signal that distorts market behavior. As the coverage gap closes, there are fewer and fewer beneficiaries who are exposed to the full cost of drug products, either at the point of sale or in Medicare Plan Finder estimates. When sponsors compete on cost sharing unrelated to the underlying negotiated prices of drugs, beneficiaries may make choices that are rational and aligned with plan interests, but not in the best interests of the Medicare program and the taxpayer. In these cases, the lower cost sharing does not motivate enrollees to select pharmacies with lower prices and thus make more efficient choices in the market, but rather, motivates enrollees to do the opposite. This results in higher costs to the Part D program overall.

Therefore, we propose to clarify that preferred cost sharing should signal consistently lower costs. When lower cost sharing correctly signals the best prices on drugs, then choosing pharmacies on the basis of that lower cost sharing lowers not only beneficiary out-of-pocket costs, but also Part D plan and other government subsidy costs. Lower plan and government subsidies translate into lower CMS payments to plans, consistent with the statutory requirements at section 1860D–4(b)(1)(B) of the Act. Therefore, we propose to revise § 423.120(a)(9) to state: ''Preferred cost-sharing in network pharmacies. A Part D sponsor offering a Part D plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs obtained through a subset of network pharmacies, as long as such preferred cost sharing is offered in accordance with the requirements of § 423.120(a)(8) and for Part D drugs with consistently lower negotiated prices than the same drugs when obtained in the rest of the pharmacy network.'' We propose that by 'consistently lower' we mean that sponsors must offer beneficiaries and the Part D program better (lower) negotiated prices on all drugs in return for the lower cost sharing. In practice we believe this would mean that whatever pricing standard is used to reimburse drugs purchased from network pharmacies in general, a lower pricing standard must be applied to drugs offered at the preferred level of cost sharing. For instance, if drugs offered at the standard retail level of cost sharing were reimbursed at 20 percent off the average wholesale price (AWP) pricing standard, then any drugs offered at the preferred level of cost sharing must be reimbursed at deeper discount than AWP minus 20 percent. If generic drugs offered at the standard retail level of cost sharing were reimbursed according to a sponsor's proprietary maximum allowable cost (MAC) pricing standard, then generic drugs offered at the preferred level of cost sharing must be reimbursed at deeper discount than the MAC pricing rates. We believe this is not only consistent with the statutory intent, but also reasonable since the mail-order operations and other large pharmacies where preferred cost sharing is currently offered have significantly more purchasing leverage with manufacturers and wholesalers than do smaller pharmacies. Our analysis shows that some sponsors are already achieving these levels of savings, and our proposed policy would apply a consistent standard across all sponsors to compete on negotiated prices, including in related-party pharmacy operations. We would welcome comments on alternative approaches to ensuring that the offering of preferred cost sharing does not increase our payments. We believe that any alternative methodology must be based solely on the level of negotiated prices and thus consistent with our proposal to amend that definition (section III.A.25 of this proposed rule). As discussed in that section, we proposed to revise the definition to specify that all price concessions from pharmacies must be reflected in the negotiated price in order to promote transparent price competition, as well as to eliminate differential cost reporting and cost shifting that interfere with a fair and transparent competitive bidding process. We request that any alternative methodology suggestions be accompanied by specific proposals for how we could objectively validate compliance through data we already collect.

In addition, we solicit comments on whether we should also establish standards on how much lower drug costs should be in return for preferred cost sharing. We are aware that there is a wide range of savings projections associated with the use of limited networks. For instance, a January 2013 study prepared for the Pharmaceutical Care Management Association (PCMA) provides various estimates ranging from 5 percent to 18 percent [at *http://www.pcmanet.org/images/stories/uploads/2013/visante-pcma%20pharmacy%20networks%20study%201-24-13%20final.pdf*]. We solicit comment on whether Medicare should require a minimum level of savings, such as 10 percent or 15 percent, over the costs available at retail cost-sharing rates. We believe that substantial discounts in this range would be necessary to balance the extremely low preferred cost sharing rates offered by many sponsors in 2013. We also solicit comments on how broadly preferred cost sharing should be applied to drugs on a sponsor's formulary. For instance, is it reasonable to offer cost sharing as low as $0 for only the least expensive generics on formulary? Or should preferred cost sharing have to apply to a minimum percentage of formulary products to be a meaningful benefit instead? Or should preferred cost sharing have to apply to all drugs available at pharmacies offering preferred cost sharing? This would require that the prices of all drugs at those pharmacies could be no higher than the prices at the other network pharmacies. Such a policy would prevent sponsors from offering lower prices on drugs with preferred cost sharing while offering higher prices on other drugs not subject to preferred cost sharing. Our concern is that without such rules, it is possible that the beneficiary is motivated to change pharmacies in order to pay very low copays on some drugs, but the program may end up paying higher costs on other drugs the beneficiary purchases at the same pharmacy out of convenience.

We also propose a clarification in terminology to better describe the application of the policy to a sponsor's approved Part D pharmacy network. As illustrated in the proposed revision to § 423.120(a)(9), we would like to change the point of reference in our guidance away from ''preferred pharmacies'' to ''preferred cost sharing''. This is not only a more accurate interpretation of the statute, but it also avoids the use of the corollary term ''non-preferred''. We regret the unintended connotation that some network pharmacies are ''non-preferred pharmacies'' when, in most cases, these pharmacies have had no opportunity to meet the terms and conditions for qualifying for preferred cost sharing. The use of the term non-preferred also has caused confusion for some stakeholders since non-preferred is also a term of art referring to non-contracted and, therefore, non-network pharmacies. In addition, we believe it is generally misleading for our sponsors to refer to preferred pharmacies, when

only a limited number of tiers (for instance, generics) may be available at the lower preferred cost sharing rates at these pharmacies. Consequently, we are proposing to delete the definitions of ''preferred pharmacy'' and ''non-preferred pharmacy'' from § 423.100 and to add a new definition of preferred cost sharing. ''Preferred cost sharing'' would mean lower cost sharing for certain covered Part D drugs at certain network pharmacies offered in accordance with the requirements of § 423.120(a)(9). We would then require that Part D sponsors would revise any marketing materials to reflect the revised nomenclature, and eliminate any references to preferred or non-preferred network pharmacies. We solicit comment on whether any further clarifications of terminology are needed for this policy proposal.

28. Prescription Drug Pricing Standards and Maximum Allowable Cost (§ 423.505(b)(21))

We are proposing a change to the regulations governing the disclosure and updating of prescription drug pricing standards used by Part D sponsors to reimburse network pharmacies to make clear that drug pricing based on maximum allowable cost (MAC) is subject to these regulations. Section 173 of MIPPA amended sections 1860D–12(b) and 1857(f)(3) of the Act to add a provision requiring the regular updating of prescription drug pricing standards. Thus, for plan years beginning on or after January 1, 2009, CMS's contracts with Part D sponsors must include a provision requiring sponsors to update any standard they use to reimburse network pharmacies based on the cost of the drug to accurately reflect the market price of acquiring the drug. These updates must occur not less frequently than once every 7 days, beginning with an initial update on January 1 of each year.

We codified this requirement in § 423.505(b)(21). We also amended § 423.505(i)(3) with respect to contracts or written arrangements between Part D sponsors and pharmacies or other providers, first tier, downstream and related entities, to ensure that Part D sponsors' contracts with these entities include provisions for regularly updating any prescription drug pricing standard used by sponsors to reimburse their network pharmacies, as provided in § 423.505(b)(21). Specifically, § 423.505(i)(3)(viii)(A) requires that sponsors' pharmacy contracts include a provision establishing regular updates of any prescription drug pricing standard used by the Part D sponsor, consistent with § 423.505(b)(21), and § 423.505(i)(3)(viii)(B) requires that a Part D sponsor's pharmacy contract indicate the source used by the Part D sponsor for making any such pricing updates. We finalized these regulations in a final rule entitled, ''Medicare Program; Medicare Advantage Program and Prescription Drug Benefit Programs'' at 76 FR 54600 (September 1, 2011) (''September 2011 final rule'').

When we finalized these regulations, we did not provide a specific definition for ''prescription drug pricing standard,'' because we believed that it was unnecessary at that time. Instead, we provided the following examples of prescription drug pricing standards: ones that are based on ''wholesale average cost, average manufacturer price, and average sales price.'' At the time, we believed these examples sufficiently illustrated what is meant by a prescription drug pricing standard, which we described as ''an accepted methodology based on published drug pricing.'' We also stated that defining the standard beyond this may be overly prescriptive and might not be flexible enough to evolve with industry changes.

Since publication of the September 2011 final rule, we have concluded that our description of ''prescription drug pricing standard'' in the preamble to the final rule was unintentionally too restrictive. Pharmacy representatives have noted that many contracts between Part D sponsors/PBMs and their network pharmacies set reimbursement through the application of MAC prices. It is our understanding that MAC prices generally refer to lists of drugs that include the maximum amount that a plan will pay for multi-source drugs, whether generics or multi-source brands. Based on numerous conversations with pharmacy representatives, we further understand that there is no standardization in the pharmacy benefits industry as to the criteria used to determine inclusion of drugs on MAC lists or as to the methodology used to determine the MAC prices, but that the latter is based in part on the costs of the drugs and fluctuate, sometimes frequently. We also understand that MAC prices seem to be set in some relation to a lowest cost generic product alternative available on the market at a given time. Additionally, we understand that MAC prices are not typically based exclusively on published drug pricing, but are based at least in part on internal Part D sponsor/PBM methodologies. Finally, we understand that many Part D sponsors and PBMs have asserted that because MAC prices are not based solely on published drug pricing, MAC prices are not a ''prescription drug pricing standard,'' and thus, not subject to the updating requirements.

Pharmacy representatives further report to us that pharmacies are forced to sign contracts that reimburse based on MAC prices that change without notice. These representatives state that pharmacies consequently do not know exactly what price they will be paid for which drugs, and thus the pharmacies cannot confirm that their reimbursements are correct nor engage in proper business planning.

As noted previously, we stated in the preamble to the final regulation that a ''prescription drug pricing standard'' is an accepted methodology based on published drug pricing. This is because we were unaware at the time that there is at least one standard based on costs of the drugs that is not based strictly on published drug pricing. Now that we have become aware of these types of pricing standards, we wish to clarify our regulatory requirement. We believe that the updating requirement should apply to pricing standards based on the cost of a drug, even when the standard is not based on published drug pricing, an approach consistent with the intent of the statute. The text of MIPPA section 173 itself indicates the provision's purpose—Part D sponsors must update their prescription drug pricing standards regularly ''to accurately reflect the market price of the drug.'' We believe that this statement of purpose indicates that the Congress intended to provide pharmacies with a means of ensuring that they have current data on the amount of reimbursement that they can expect.

When the source of a prescription drug pricing standard is published publicly, such as with AWP or WAC, pharmacies can determine their reimbursement for all drugs at any given time and can monitor these sources to ensure they are being reimbursed correctly. However, when a prescription drug pricing standard is not published publicly, network pharmacies are unable to promptly determine whether their reimbursement is consistent with their contractual arrangements. This, in turn, presents risks to the Medicare Part D program in a number of ways. For example, disclosure of the source used to determine drug prices is necessary for pharmacies to ensure accurate payment of their claims, which is necessary for accuracy in the costs submitted to CMS by Part D sponsors on PDEs without unnecessary later adjustments that are disruptive to the operation of the Part D program.

In addition, when network pharmacies are unable to determine whether their reimbursement is

consistent with their contractual arrangements, the accuracy of the prices displayed in the Medicare Prescription Drug Plan Finder (''MPDPF'') is questionable. While these prices only provide an estimate of Part D drugs costs at particular pharmacies, beneficiaries do use the MPDPF to make drug purchasing choices. If a pharmacy does not know what it will be paid for drugs on any given day, it cannot test the MPDPF and validate the prices. Thus, there is no assurance that the posted prices are accurate, and pharmacies are deprived of the opportunity to compete based on more accurate prices, and beneficiaries may make choices based on erroneous estimated drug costs. This is contrary to the public policy goal of facilitating competition in the health care system and supporting consumers to be informed purchasers of health care. Also, when CMS compares posted prices to prices submitted on PDEs to evaluate the estimates provided in the MPDPF, there can be no assurance that those values correspond to the payments pharmacies actually receive.

For these reasons, we now believe it is necessary to define ''prescription drug pricing standard'' in regulation. Therefore, we propose to add a definition to § 423.501 that would state that a ''prescription drug pricing standard'' means ''any methodology or formula for varying the pricing of a drug or drugs during the term of a pharmacy reimbursement contract that is based on the cost of a drug, which includes, but is not limited to, drug pricing references and amounts that are based upon average wholesale price, wholesale average cost, average manufacturer price, average sales price, maximum allowable cost (MAC), or other cost, whether publicly available or not.'' We propose to include the phrase, ''includes, but is not limited to,'' to signify that the examples specified in the regulation text are not exhaustive.

We expect some commenters may ask what pharmacy reimbursement method would not be considered a ''prescription drug pricing standard,'' since the regulations apply only ''if'' a Part D sponsor uses a standard for reimbursement that is based on the cost of the drug. In our view, a fixed fee drug price schedule that is not expected by the parties to vary during the term of the contract between the Part D sponsor/PBM would be not be a ''prescription drug pricing standard,'' as there would be no reason to update the list at least every 7 days.

In addition, in order to make the regulations regarding prescription drug pricing standards easier to reference, we are proposing the following technical changes for consolidation purposes: (1) To combine the current requirements contained in § 423.505(b)(21) (i) and (ii) into (i) and eliminate the reference to the effective contract year 2009 as no longer necessary. These requirements generally state that Part D sponsors agree to update any prescription drug pricing standard (as would be defined in § 423.501) on January 1 of each contract year and not less frequently than once every 7 days thereafter. We also propose to move the current requirement to indicate the source used for making any such updates to (b)(21)(ii) from § 423.505(i)(3)(viii)(B). We propose this latter move of regulation text, so that it is clearer by its placement in the regulation that this requirement is on Part D sponsors.

For new paragraph § 423.505(b)(21)(iii), to be clear, we are proposing a new requirement and not a technical change. We are proposing that Part D sponsors agree in their contracts with CMS to disclose all individual drug prices to be updated to the applicable pharmacies in advance of their use for reimbursement of claims, if the source for any prescription drug pricing standard is not publicly available. This means, in conjunction with the proposed definition of a ''prescription drug pricing standard'' discussed previously, that Part D sponsors would have to convey to network pharmacies in advance the actual MAC prices to be changed. We are requiring that the actual MAC prices be disclosed in advance because, if the pharmacies are not able to use the updates as a reference against which they can check their reimbursements, there would be no point to the statutory requirement.

As a final technical change, we are proposing to eliminate language in § 423.505(i)(3)(viii)(A) about establishing regular updates of any prescription drug pricing standard used by the Part D sponsor which is and would be duplicative to language in 423.505(b)(21). As a result of the changes described previously, there would be no paragraphs (A) and (B) to § 423.505(i)(3)(viii), and this provision would simply require that, if applicable, each and every contract governing Part D sponsors and first tier, downstream, and related entities, must contain provisions addressing the prescription drug pricing standard requirements of § 423.505(b)(21). We believe these proposed technical changes will make the regulation text easier to reference and understand.

29. Any Willing Pharmacy Standard Terms & Conditions (§ 423.120(a)(8))

Section 1860D–4(b)(1)(A) of the Act requires Part D plans to permit any pharmacy meeting the standard Terms and Conditions (T&C) to participate in the plan's network. We used this authority to establish requirements under § 423.120(a)(8) and § 423.505(b)(18) that plan sponsors have reasonable and relevant T&C for network participation in their standard contract, and allow any pharmacy meeting the T&C to participate as a network pharmacy for that plan. Section 1860D–4(b)(1)(B) of the Act permits sponsors to reduce cost sharing ''below the level otherwise required,'' notwithstanding paragraph (A). Thus, the statute permits a ''preferred'' cost sharing level (using the definition specified in section III.A.27 of this proposed rule) to be offered at some network pharmacies. Since the beginning of the program, we have required sponsors to offer standard T&Cs to any willing pharmacy in order to achieve broad network access, but have permitted sponsors to offer different T&Cs in return for preferred cost sharing to a smaller subset of its network. We have previously stated that we believed our interpretation of these two seemingly conflicting statutory provisions struck an appropriate balance between the need for broad pharmacy access and the need for Part D plans to have appropriate contracting tools to lower costs. In this section we are proposing that in place of sponsors having one contract with standard terms for any willing pharmacy and a second preferred cost sharing contract for a limited subset of pharmacies, that sponsors instead have standard T&C for network participation that list all combinations of cost sharing and negotiated prices possible for retail settings under the plan, allowing any willing pharmacy the opportunity to offer preferred cost sharing if the pharmacy can offer the requisite level of negotiated prices.

When discussing cost sharing, distinctions are made in this section between plans offering a preferred cost sharing level and plans that do not. For the purposes of this section, the cost sharing levels offered at retail pharmacies not contracted to offer preferred cost sharing (previously referred to as ''non-preferred pharmacies'') are referred to as standard cost sharing levels. Cost sharing levels offered at retail pharmacies at the preferred T&C (previously referred to as ''preferred pharmacies''), are referred to as preferred cost sharing levels.

Because under our proposal for preferred cost sharing, pricing terms for pharmacies offering preferred cost sharing could not exceed the pricing terms for pharmacies offering standard cost sharing (see discussion in section III.A.27 of this proposed rule), we will use the terms ''ceiling price'' and ''floor price'' to refer to the upper and lower limits put on pricing terms. As proposed, the negotiated prices charged by pharmacies offering preferred cost sharing must be at or below the agreed upon ceiling price (determined by using the defined preferred cost sharing T&C pricing), which must be less than the floor price, or lowest negotiated price, charged at network pharmacies offering standard cost sharing.

We heard from many pharmacies, many of them small independent community pharmacies, that plans do not offer any willing pharmacy the opportunity to offer preferred cost sharing. Instead, some pharmacies are being offered only the plan's standard T&C, at the highest level of beneficiary cost sharing. We received more than 200 comments in response to our discussion of this topic in the Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and PDP Payment Policies and Final Call Letter (2014 Call Letter) pp. 175–176 at *http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2014.pdf*. Most of these comments were from pharmacies concerned about barriers to entry for participation in preferred networks, and many of these argued that such limited networks violate the statutory intent of the network access provisions at section 1860D–4(b)(1) of the Act. In particular, these commenters disagreed that such barriers were consistent with the any willing pharmacy requirement as stated in 1860D–4(b)(1)(A) of the Act.

Consequently, we have reviewed our original regulatory interpretation of these provisions, not only in light of these complaints, but also in light of our experience in the Part D program. We believe that an alternative reading of sections 1860D–4(b)(1)(A) of the Act and (B) of the Act to reduce barriers is not only permissible, it would have the following key policy benefits, which we describe as follows:

- Increased access for beneficiaries to preferred level cost sharing with any willing pharmacy able to agree to the T&C that include preferred cost sharing.
- Improved opportunity for competition among pharmacies contracting with the sponsor to charge no more than the ceiling price stated in the contract for preferred cost sharing, reducing costs charged to the program.
- Improved clarity for beneficiaries surrounding cost sharing levels available at retail and mail order pharmacies.

Elsewhere in this proposed regulation we discuss clarifications to the requirements for offering preferred cost sharing within a sponsor's network (see section III.A.27 of this proposed rule). In III.A.27 we discuss our analysis of 2011 benefit designs incorporating preferred cost sharing. We found that some retail pharmacies are actually offering to sell Part D drugs (particularly generic versions) at prices below those offered by the network pharmacies eligible for preferred cost sharing. In such cases, the lower negotiated prices offering the program superior savings are offered to enrollees at the higher standard cost sharing levels, while the same drugs being offered to enrollees at lower preferred cost sharing levels may be costing the program as much or more. The lower cost sharing ''price'' signal is not aligned with either the true price of the drug or better overall value to the program, and therefore the defective signal incentivizes inefficient purchasing decisions from the perspective of the Part D program. If some retail pharmacies are willing to provide deeper discounts than those that sponsors are currently negotiating with pharmacies in return for offering preferred cost sharing, we can conclude that, all other things being equal, competition will be increased and aggregate negotiated prices will be reduced if these more competitive retail pharmacies have the opportunity to qualify for preferred cost sharing. Therefore, we now believe that this opportunity for pharmacies to gain entry into previously limited networks should be a component of the any willing pharmacy requirements for retail pharmacies, allowing more pharmacies the option to offer preferred level cost sharing if they are willing to charge no more than the ceiling price stated in the contract.

We have heard the assertion that limited networks achieve greater savings than broader networks, and that moreover, allowing more participants into a limited network than those hand-picked by the sponsor will necessarily lead to increased prices. However, we have been running a natural experiment of sorts relative to this assertion in the Part D program. If limited networks *per se* led to significantly lower costs, we would see consistently significant savings in those network segments relative to the rest of the sponsors' networks. However, an April 2013 analysis by CMS, ''Negotiated Pricing Between Preferred and Non-Preferred Pharmacy Networks'', reviewed actual program experience and indicated that this is not the case across the board (see *http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/PharmacyNetwork.pdf*). As the 2012 claims show, there is wide variation in discounting across sponsors. Consistent savings are not seen uniformly. In some cases, pharmacies extending high discounts are ones that have been excluded from limited networks offering preferred cost sharing, while some pharmacies within the limited networks offer effectively no discounts compared to the rest of the network. Therefore, we believe that opening up these limited networks to any pharmacy willing to charge no more than the contract's ceiling price to qualify for offering the lower preferred cost sharing is necessary to restore price competition in these networks. Consequently, for any sponsor that offers both standard and preferred cost sharing under any of its benefit packages, we propose that the sponsor's contracts for network retail pharmacies include not only the T&C for standard cost sharing, but also the T&C for offering preferred cost sharing, stating negotiated pricing levels that must be agreed upon to qualify for offering preferred cost sharing. As discussed previously, the ceiling price that a pharmacy can charge for a drug filled at a preferred cost sharing level, must be less than the floor price, or minimum price, charged by network pharmacies under that plan offering standard cost sharing levels. Retail pharmacies would elect to participate according to one set of terms or the other, but not both.

We have also heard the argument that the pharmacies in currently limited networks are offering deeper discounts solely in return for increased market share and that they will withdraw such offers if the limited network is opened up to other pharmacies that can meet those T&C. We are skeptical that such participants in the highly competitive retail market will abandon their market share by returning to the broader network T&C. As some network pharmacies offering standard cost sharing have been able to extend discounts in pricing even deeper than what is seen in some pharmacies offering preferred cost sharing, it is not obvious that negotiated prices would necessarily increase in the aggregate in the event that a limited number of pharmacies consider changing from preferred to standard cost sharing. We

have also been informally told by one sponsor with preferred cost sharing in a limited network that its preferred cost sharing T&C already are offered to any willing pharmacy. For these reasons, we do not believe that our proposal would result in increased prices. We note that our proposed alternative statutory interpretation still would permit sponsors to limit preferred cost sharing to those pharmacies accepting T&C with stated ceiling prices. Aggressive price concessions to fall below the stated ceiling price (solely in the form of lower negotiated price, in accordance with our proposed change to that definition at § 423.100 discussed at section III.A.25 of this proposed rule) would have to be met by all pharmacies offering preferred cost sharing, including pharmacies that are related parties of the Part D sponsor or its PBM. Sponsors could not offer preferred cost sharing for higher negotiated prices than the ceiling price listed in the T&C, but would be free to negotiate even deeper discounts from individual pharmacies in the limited network. Publicly posted pricing standards would effectively set a pricing floor for all pharmacies accepting a plan's standard T&C and set a pricing ceiling for pharmacies accepting the preferred cost sharing T&C. These benchmarks better align price with value, while maintaining sponsor flexibility to negotiate with all pharmacies in its network. Therefore, we are confident that requiring that a Part D plan sponsor offer T&C for every level of cost sharing approved in its benefit packages to any willing pharmacy would not limit competitive negotiations, nor would it in and of itself lead to increased negotiated prices.

We also believe that there is a limit to the number of cost sharing levels offered under a benefit plan that can be well understood by beneficiaries. When establishing its network, a Part D sponsor does not offer identical T&C for network participation to every pharmacy. Certain terms will necessarily differ among contracts with the different types of pharmacies needed to provide all Part D drugs, if for no other reason than to address the different access and service standards established by CMS. These various types include at a minimum: Retail, mail-order, long-term care institutional, limited-distribution-drug specialty, and home infusion therapy pharmacies. Terms will also differ with respect to negotiated prices and the level of cost sharing that a pharmacy's claims will be subject to. For instance, long-term care institutional, specialty, and infusion pharmacies are generally offered at the standard level of cost sharing (for the applicable formulary tier) for a month's supply of a covered drug. Retail and mail-order pharmacies, in contrast, currently may contract with plans to be offered at more than one cost sharing level.

Cost sharing at retail and mail-order pharmacies currently vary on three dimensions: Whether the cost sharing is standard or preferred, on the quantity dispensed (or ''days' supply''), and on dispensing location.

a. Preferred Cost Sharing

Under § 423.120(a)(9), sponsors can offer lower preferred cost sharing levels to some retail and mail order pharmacies in their network who agree to offer superior price concessions. While beneficiaries may actively seek out preferred cost sharing among retail and mail order pharmacies, this is less common among long term care, specialty, and infusion pharmacy settings. Any preferred cost sharing structure would be required to meet certain conditions as previously proposed and would be required to be submitted to CMS for approval as part of a sponsor's plan benefit package. Plans are not currently required to offer a preferred cost sharing level, nor would they be required to if this proposal is implemented. However, for pharmacies that do contract to offer preferred cost sharing, our proposal means that preferred cost sharing must be available to all enrollees covered by that plan's contract and electing to use that pharmacy. This would include consistently charging preferred cost sharing and consistently billing no more than the ceiling price for all prescriptions, whether a one month or extended days' supply is dispensed.

b. Extended Days' Supply

Additionally, different cost sharing levels may be offered for extended days' (generally greater than 34 and no more than 102) supplies, at both retail and mail order pharmacies. To avoid unnecessarily complicated benefit designs, plans should create no more than two cost sharing distinctions based on days' supply: One month supply (not to exceed 34 days) or extended days' supply (greater than 34-days' supply). In manual guidance (see section 50.10 of Chapter 5 of the Medicare Prescription Drug Benefit Manual) we have further interpreted the ''level playing field'' provision to mean that sponsors electing to offer extended days' supplies of covered Part D drugs need to make available to retail pharmacies, upon request, an ''Extended Supply Addendum'' to their standard contracting terms and conditions for retail pharmacies. This Addendum provides one of two extended-days'-supply contracting options: (1) To be offered at the same cost sharing rate as mail order if a retailer can match the mail-order T&C, or (2) to be offered at another higher cost-sharing level, but in no case higher than three times the amount enrollee would have paid at the same retail pharmacy had the enrollee had his or her prescription filled in multiple 1-month supply increments at the applicable retail pharmacy cost sharing (standard or preferred) cost sharing rate. The nature of long term care, specialty, and infusion pharmacy dispensing makes a price differential based on days' supplies largely unnecessary.

c. Mail Order Cost Sharing

Section 1860D–4(b)(1)(D) of the Act (and § 423.120(a)(10)) require sponsors to provide for extended days' supplies at retail when extended days' supplies are available at mail, but explicitly permits differential cost sharing between the two settings. For plans offering both preferred cost sharing and mail order options, the mail order cost sharing for an extended days' supply can be less than the preferred cost sharing for an extended days' supply filled at retail. However, for 1-month supplies, we propose that the cost sharing at mail order (for prescriptions for 34 days or less) cannot be less than the standard cost sharing at retail (for prescriptions for 34 days or less), regardless of whether a preferred cost sharing level is available. In general, we believe that filling initial prescriptions or routine 30-day supplies at mail-order is not good practice. Given the need to order or re-order mail order prescriptions well in advance of when the medication runs out (to allow time for shipping), the opportunity for gaps in therapy caused by delayed orders rises. When using mail order for one month supplies, a beneficiary would have to order the next month's supply shortly after receiving a new order, and complaints received by CMS indicate that billing errors and delayed shipments occur. It is our understanding that mail order is most efficient when processing extended days supplies, when all billing and processing can be addressed well in advance of needing to ship the next supply. However, we recognize that for some populations, monthly mail order supplies are an acceptable option, so we are not seeking to disincentivize this option. Rather, we are proposing that 1-month supplies filled by mail order pharmacies cannot

have cost sharing lower than a comparable one month supply filled at retail, so as not to provide an incentive to fill short supplies of chronic medications through mail order.

We believe that a more simplified benefit design, incorporating these three variables and accommodating a more clearly defined set of cost sharing levels, would promote better understanding of Part D plan benefits, both in terms of beneficiary cost sharing and prices charged to the program, as well as streamlined contracting options. We also find it important to expressly state the total number of possible cost-sharing levels, to clarify expectations and to preempt the introduction of additional or unauthorized cost-sharing levels in the future.

For prescriptions not subject to Long Term Care, specialty pharmacy, or home infusion pricing, the interaction of the following four provisions of section 1860D–4(b)(1) of the Act point to three authorized levels of cost sharing: Standard, preferred, and extended days' supplies for retail and mail order pharmacies.

- Section 1860D–4(b)(1)(A) of the Act details the participation of Any Willing Pharmacy in a plan's network, provided that they meet T&C offered by the plan, authorizing a standard cost sharing level. This proposal offers retail and mail order pharmacies a chance to not just participate in the plan's network, but to select among a plan's various T&C for participation. By listing the T&C required for offering preferred cost sharing on the contract offered to any willing pharmacy, instead of only offering these T&C to select pharmacies, a greater percentage of network pharmacies can offer beneficiaries the lower cost sharing, while also offering reduced negotiated prices and savings to the Part D program.
- Section 1860D–4(b)(1)(B) of the Act permits discounting for some network pharmacies, authorizing a preferred cost sharing level. This proposal continues to permit both a standard and preferred cost sharing level within a plan's network.
- Section 1860D–4(b)(1)(C) of the Act defines the authority to establish rules defining convenient access, permitting a mail order cost sharing level. Expanding requirements for any willing pharmacy contracts, with any pharmacy (and presumably a greater number of pharmacies) now offered the opportunity to compete for preferred cost sharing if the pharmacy can offer the requisite level of negotiated prices, would expand beneficiary access to lower cost sharing options within the network.
- Section 1860D–4(b)(1)(D) of the Act creates a level playing field by ensuring that if extended days' supply benefits are available at mail order, beneficiaries can get the same benefit at retail pharmacies. Extended days' supply cost sharing at mail order does not have to equal extended days' supply cost sharing at retail, however, we propose to require that it cannot be less than the standard cost sharing offered at retail pharmacies for extended days' supply. As previously discussed, it is our understanding that mail order is most efficient when processing extended days supplies, when all billing and processing can be addressed well in advance of needing to ship the next supply. While we are not proposing to disincentivize mail order for supplies of less than 90 days, nor do we believe it is appropriate to incentivize through lower cost sharing the use of mail order in situations where gaps in therapy may be more likely to occur.

When assessed together, we believe these four sections direct Part D plans to create a network offering convenient access not only to various types of pharmacies but also to various types of cost sharing. Permitting three retail cost sharing levels, as the statute implies, reflects the levels of cost sharing also observed in the commercial market. However, unique to Part D, the available cost sharing levels must also meet the Medicare requirements assuring pharmacy access for Medicare beneficiaries.

We would like to minimize the number of variations on these three levels to the following options and to ensure that standard T&C for network participation offer every level available for each respective pharmacy type. First, we propose to limit long term care, specialty, and infusion pharmacy cost sharing to the standard monthly rate, as is industry practice today. Second, we propose to limit retail pharmacies to the three authorized levels; either the standard or preferred monthly rate (for supplies up to 34 days), and one extended days' supply cost sharing rate not exceeding three times the monthly retail rate (either three times the standard monthly retail rate or three times the preferred monthly retail rate, depending upon the T&C of the pharmacy's contract). Third, we propose to limit the levels of cost sharing at mail-order pharmacies to one monthly rate and one extended day mail order cost sharing rate (for any supplies greater than 34 days) for reasons discussed previously. We additionally solicit comments on the frequency of mail order being used to fill prescriptions lasting one month or less. We note that these proposals would not alter our requirements around the dispensing of any days' supplies less than 30 days, which is still subject to the ''daily cost sharing'' provision at § 423.153(b)(4) (which we propose to further clarify in section III.E.9 of this proposed rule).

In summary, we propose to use the authority in section 1860D–4(b)(1)(C)(i) of the Act to establish rules defining convenient access within a Part D pharmacy network, combined with the authority in section 1860D–4(b)(1)(A) of the Act to revise the any willing pharmacy requirements, to ensure that any pharmacy that can meet the applicable T&C for offering standard or preferred cost sharing can join the network on those terms. We believe the network access provisions in section 1860D–4(b)(1) of the Act support expanding § 423.120(a)(8) to all levels of cost sharing offered under a sponsor's benefit plans. We believe that doing so supports the Congressional intent to have plans compete on negotiated prices by making this price competition more open and accessible to pharmacies. Specifically, we propose to revise § 423.120(a)(8) to require that, in establishing its contracted pharmacy network, a Part D sponsor offering qualified prescription drug coverage must comply with all of the following requirements:

- Must offer and publicly post standard terms and conditions for network participation for each type of pharmacy in the network subject to the following:

++ May not require a pharmacy to accept insurance risk as a condition of participation in the PDP sponsor's contracted pharmacy network.

++ Must offer payment terms for every level of cost sharing offered under the sponsor's plans consistent with CMS limitations on the number and type of cost sharing levels, and for every type of similarly situated pharmacy.

- Must contract with any willing pharmacy able to meet one set of the terms and conditions offered by that plan for that type of pharmacy.

We also propose to make conforming changes to the contracting provisions at § 423.505(b)(18) to require Part D sponsors to agree to have standard T&C for network participation that meet the requirements described in § 423.120(a)(8), with reasonable and relevant T&C of participation for each type of pharmacy in its network. We believe these proposed requirements would better ensure that each Part D plan: (1) Provides convenient access to Part D drugs in all Part D settings and to the extent practical, at all cost sharing

levels; and (2) offers cost sharing levels that encourage beneficiaries to make choices that minimize costs not only for themselves, but also to the Medicare Part D program as a whole.

We solicit comments on these proposals to expand the any willing pharmacy T&C and to streamline the levels of cost sharing offered under those standard T&C. Based on the current level of negotiated prices in the Part D program, we conclude that if a greater number of pharmacies were given the option to compete for each cost-sharing level offered under the plan, that beneficiaries would have more pharmacy options offering the lowest cost-sharing level for reduced prices. We cannot compel sponsors to negotiate lower negotiated prices, nor can we compel pharmacies to accept plan sponsors' T&C for participation, but we can create benefit specifications and network access standards that promote streamlined benefit comparisons and that maximize opportunities for price competition. We believe these proposals will increase beneficiary understanding of and access to cost sharing that is better aligned with the lowest negotiated prices, improve market competition, and increase downward pressure on total program costs.

30. Enrollment Requirements for the Prescribers of Part D Covered Drugs (§ 423.120(c)(5) and (6))

To improve our ability to oversee the Medicare Part D program, we are proposing to implement section 6405(c) of the Affordable Care Act effective January 1, 2015. This section provides the Secretary with authority to require that prescriptions for covered Part D drugs must be prescribed by a physician enrolled under section 1866(j) of the Act (42 U.S.C. 1395cc(j)) or an eligible professional as defined at section 1848(k)(3)(B) of the Act (42 U.S.C. 1395w–4(k)(3)(B)). We are proposing in revised 42 CFR 423.120(c)(5) and new (6) that a prescriber of Part D drugs must have: (1) An approved enrollment record in the Medicare FFS program (that is, original Medicare); or (2) a valid opt-out affidavit on file with a Part A/Part B Medicare Administrative Contractor (A/B MAC) for a prescription to be eligible for coverage under the Part D program.

Our long-standing Part D policy has been that drugs cannot be eligible for Part D coverage unless they are dispensed upon prescriptions that are valid under applicable state law. We incorporated this policy (§ 423.100 and § 423.104) in the April 12, 2012 final rule (77 FR 22072) entitled, ''Medicare Program: Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes.''

Inherent in this policy is the notion that valid prescriptions of covered Part D drugs are written by qualified prescribers, meaning prescribers who have an active professional health care license that conveys prescribing privileges to them under applicable state law. A prescription is not valid under any state law if it is not written by a qualified prescriber. Indeed, we note that not all of the eligible professional types under section 1848(k)(3)(B) of the Act can necessarily prescribe drugs under state law.

To help ensure that Part D drugs are prescribed only by qualified prescribers, we are proposing that physicians and eligible professionals enroll in the Medicare program in order to prescribe covered Part D drugs. We are proposing an enrollment deadline of January 1, 2015, which would provide physicians and eligible professionals with at least 6 months after the publication of a final rule to initiate and complete the Medicare enrollment process for the purposes of prescribing covered Part D drugs. We are soliciting comments regarding the effective date of this provision and the reason(s) why we should consider an earlier or later implementation date for this provision.

Our proposal to implement section 6405(c) of the Affordable Care Act with respect to Part D prescribers complements our recent steps to help ensure that prescriptions covered by the Part D program are written by qualified health care practitioners. In 2012, we provided sponsors with guidance in an October 1, 2012 HPMS memorandum titled, ''Revised Reporting Requirements for Prescriber Identifiers and Other Prescription Drug Event Fields.'' We also required every PDE record submitted by a Part D sponsor to CMS to contain an active and valid individual prescriber national provider identifier (NPI) beginning January 1, 2013. PDE records are summary records of every prescription filled under the Part D program and contain prescription drug cost and payment data that enables CMS to make payments to plans and otherwise administer the Part D benefit. Thus, the PDE NPI requirement ensures that we have a record of the prescriber's active and valid individual NPI for every prescription covered under the program.

In the final rule implementing the NPI PDE requirement, we explained that the consistent use of a single validated identifier would enable us to provide better oversight over possible fraudulent activities in the Part D program. When promulgating § 423.120(c)(5) (77 FR 22143, April 12, 2012), we stated that CMS, the National Benefit Integrity Medicare Drug Integrity Contractor, and oversight agencies would be able to more efficiently, and therefore more effectively, identify patterns of unusual prescribing that may be associated with improper and/or fraudulent activities.

While requiring NPIs on every PDE record was an important first step in identifying and monitoring prescribers in the Part D program, the system that assigns and maintains NPI data—the National Plan and Provider Enumeration System (NPPES)—is not a practitioner credentialing system. The information stored in NPPES is self-reported by the applicant and is not required to be independently verified by HHS or CMS. This has left open some program vulnerabilities as described in recent OIG reports on this issue. For instance, in a June 2013 report, the OIG found that the Part D program inappropriately paid for drugs ordered by individuals who clearly did not appear to have the authority to prescribe. (See ''Medicare Inappropriately Paid for Drugs Ordered by Individuals Without Prescribing Authority'' (OEI–02–09–00608). This raises concerns about patient safety and the appropriateness of Part D payments. In addition, there have been reports that the prescriptions of physicians with suspended licenses have been covered by the Part D program. This should not happen, and we believe we can better address this type of vulnerability by verifying the credentials of prescribers as physicians or eligible professionals through either their enrollment in the Medicare FFS program with an approved enrollment record or their submission of a valid opt-out affidavit on file with a NPI at an A/B MAC.

The Medicare FFS enrollment process requires that an A/B MAC screen and validate each enrollment application submitted by a physician or eligible professional prior to the decision to approve or deny enrollment in the Medicare program. Thus, when a physician, including an intern or resident, or eligible professional submits an enrollment application (for example, the CMS–855I or CMS–855O or the Internet-based Provider Enrollment, Chain and Ownership System (PECOS) version of these enrollment forms) to an A/B MAC, the A/B MAC approves or denies the application to enroll into the Medicare FFS program based on whether the practitioner meets the program requirements for his/her for medical specialty. The Medicare FFS enrollment application collects and

verifies identifying information about the applicant, and his or her credentials, such as the license number. For example, an A/B MAC verifies each applicant's social security number and NPI at the time of enrollment, when changes or updates are submitted, and during the 5-year revalidation process. The A/B MAC also verifies state licensing board information prior to enrolling an individual practitioner, and monthly thereafter, to determine if the state suspended or revoked a physician or eligible professional's medical license. In addition, A/B MACs verify that physician and eligible professionals are not excluded from receiving payments under any federal health program by checking the System for Award Management (SAM), a process similar to that which Part D sponsors currently use to ensure that physicians and eligible professionals are not excluded by the OIG). Thus, by leveraging the state licensing and OIG exclusion information maintained within PECOS, CMS' national fee-for-service enrollment database, we believe that we can help ensure that physicians and eligible professionals are State licensed to prescribe covered Part D drugs.

As an alternative to submitting an enrollment application for Medicare billing privileges, physicians and certain eligible professionals may enroll in Medicare for the sole purpose of ordering and certifying services in the Medicare program by completing the Medicare enrollment application—Registration for Eligible Ordering and Referring Physicians and Non-Physician Practitioners (CMS–855–O). Once an A/B MAC determines that a physician or eligible professional meets all program requirements to solely order services, they are enrolled in the Medicare program and are placed into an approved status in PECOS. A physician or eligible professional may submit a CMS–855O application as a means of complying with our proposed requirement, if he or she is enrolling solely to order or certify Medicare items or services.

Section 1861(r) of the Act, defines a physician as a doctor of medicine, doctor of osteopathy, doctor of dental surgery or dental medicine, doctor of podiatric medicine, doctor of optometry, or a chiropractor who is acting within the scope of his license when he/she prescribes a drug within Part D of Medicare. We note that physicians and eligible professionals may enroll in the Medicare program, but whether these individuals can prescribe is a matter of state law where the physician specialty or eligible professionals practices. For instance, a doctor of optometry may enroll in Medicare, but only be able to prescribe certain drugs within a state, and a clinical psychologist may enroll in Medicare, but may or may not be able to prescribe medications under state law. Our proposal to require physicians and eligible professionals to enroll in the Medicare program to prescribe covered Part D drugs does not solicit comment on the types of health care physicians and eligible professionals who can write a valid prescription under state law. We will continue to defer to state law regarding the physicians and eligible professionals that can prescribe covered Part D drugs. As such, a Part D sponsor would remain responsible for ensuring that a prescriber has the authority to prescribe under state law.

Depending on state law, interns and residents may enroll in the Medicare FFS program to receive Medicare billing privileges or to solely order/certify services in Part A and Part B of the Medicare program. Under our proposal, interns and residents with an approved enrollment record in PECOS would also be allowed to prescribe covered Part D drugs in the Medicare program as long as the state permits this practice. We believe that this approach is consistent with the policy that we previously established in the April 27, 2012 final rule (77 FR 25284) entitled, ''Medicare and Medicaid Programs: Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements.

A small number of physicians and eligible professionals elect to opt out of enrolling in the Medicare program for a 2-year period by submitting an affidavit to the A/B MAC and only bill the Medicare program for covered emergency or urgent care furnished to a Medicare beneficiary. Under section 1802(b) of the Act and the implementing regulations at 42 CFR 405.400 et seq., certain physicians and eligible professionals can opt out of the Medicare program and enter into private contracts with Medicare beneficiaries. By entering into these types of contracts, these individuals do not bill the Medicare program for non-emergency services that they furnish to Medicare beneficiaries. In addition, § 422.220 states, ''An MA organization may not pay, directly or indirectly, on any basis, for services (other than emergency or urgently needed services as defined in § 422.2) furnished to a Medicare enrollee by a physician (as defined in section 1861(r)(1) of the Act) or other practitioner (as defined in section 1842(b)(18)(C) of the Act) who has filed with the Medicare carrier an affidavit promising to furnish Medicare-covered services to Medicare beneficiaries only through private contracts under section 1802(b) of the Act with the beneficiaries. An MA organization must pay for emergency or urgently needed services furnished by a physician or practitioner who has not signed a private contract with the beneficiary.''

Generally, a physician or eligible professional makes the decision to opt out of the Medicare program because they have decided to furnish services on a private contracting basis. Therefore, we are proposing a similar opt-out policy as the Medicare FFS program uses for ordering services within Part B of the Medicare program and certifying services within Part A of the Medicare program. We believe that allowing opt-out physicians and eligible professionals to continue to prescribe covered Part D drugs to a Medicare enrollee would ensure consistency with the Part B program in this regard. In addition, an A/B MAC verifies medical licensure for opt-out physicians and eligible professionals on a monthly basis. Accordingly, we are soliciting comments on whether a prescription of opted-out physicians and eligible professionals should be considered covered under the Part D program as long as the opt-out physician or eligible professional furnishes their NPI to an A/B MAC.

Under our proposal, the prescriptions of physicians or eligible professionals who are not enrolled in the Medicare FFS program or who are not enrolled in Medicare in an approved status would not be coverable under the Part D program. Specifically, in revised § 423.120(c)(5), we are proposing that beginning January 1, 2015, a Part D sponsor must deny or must require its PBM to deny a claim for a Part D drug from a pharmacy, including at the point of sale, if the claim does not contain an active and valid physician or eligible professional NPI. Also, the Part D sponsor must deny or must require its PBM to deny a pharmacy claim for a Part D drug if: (1) The physician or eligible professional is not enrolled in Medicare in an approved status and (2) the physician or eligible professional does not have a valid opt-out affidavit on file with an A/B MAC. We believe that the implementation of this policy will promote quality health care and prevent fraud by ensuring that prescribers of Part D drugs are physicians and eligible professionals who have a valid state license. We note that a prescriber NPI is essential on the pharmacy claim for Part D sponsors and PBMs to determine whether the

prescriber is enrolled in Medicare in an approved status or has a valid opt-out affidavit on file with the Medicare FFS program.

We also note this provision, if adopted, would preclude almost all prescribers located outside of the United States, Puerto Rico, Guam, the Virgin Islands, and the Northern Mariana Islands from prescribing covered Part D drugs to a Medicare beneficiaries, since these physicians and eligible professionals may not be eligible to enroll in the Medicare program. In the April 12, 2012 final rule entitled, ''Medicare Program; Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes'' (77 FR 22144), we stated that it was our understanding that seven states (Arizona, Florida, Maine, North Dakota, Texas, Vermont and Washington) currently permit pharmacies to fill prescriptions from foreign prescribers, to varying degrees. Under our current requirements (see Publication 100–18, Chapter 5 (Medicare Prescription Drug Benefit Manual), section 90.2.1 (Foreign Prescribers) of the Internet-Only Manual), Part D sponsors must pay a claim with an active and valid NPI of a foreign prescriber. If there is not one at point of sale, sponsors do not have to cover the claim and research the NPI, as they do with domestic prescribers under current 423.120(c). Our proposed policy would change this, as no prescription would be covered if the prescriber is not enrolled in Medicare and does not have a valid opt-out affidavit on file with an A/B MAC.

We are also proposing that beginning January 1, 2015, a beneficiary's request for reimbursement from a Part D sponsor must be for a Part D drug that was dispensed in accordance with a prescription written by a physician or eligible professional who—

- Is identified by his or her legal name in the request; and
- Is enrolled in Medicare in an approved status; or
- Has a valid opt-out affidavit on file with an A/B MAC.

Finally, we are also proposing to add provisions to 42 CFR 423.120(c)(6) that a Part D sponsor would not be able to submit a PDE to CMS, unless it pertains to a claim for a Part D drug that was dispensed pursuant to a prescription written by a physician or, when permitted by applicable law, an eligible professional who: (1) Is enrolled in Medicare in an approved status; or (2) has a valid opt-out affidavit on file with the A/B MAC. Proposed § 423.120(c)(6) would also provide that a Part D sponsor must submit to CMS only a PDE that contains an active and valid prescriber NPI.

Under our proposal, CMS would furnish or make available to Part D sponsors a list of physicians and eligible professionals that have an approved enrollment record within the Medicare FFS program or who have a valid opt-out affidavit on file with the A/B MAC. Part D sponsors would no longer be required to check the NPPES database to determine whether a prescriber has an active and valid individual prescriber NPI. For these reasons, the language of 423.120(c)(5) would be revised, as Part D sponsors would have to determine from the list whether the prescriber is enrolled in the Medicare FFS program in an approved status or has a valid opt-out affidavit on file with an A/B MAC before allowing coverage of a prescribed Part D drug. We believe that verifying whether a prescriber is enrolled in Medicare with an approved enrollment record (or valid opt-out affidavit) would involve an effort similar to the one sponsors use now to determine if a prescriber has an active and valid individual NPI. If the prescriber were not listed as enrolled in Medicare in an approved status or on file with the A/B MAC with a valid opt-out affidavit, the drug would not be covered under the Part D program and a claim, including a non-standard claim from a Medicare enrollee, would be denied by a pharmacy or the sponsor. Our proposal to require a prescriber to be enrolled in the Medicare FFS program or have an opt-out affidavit on file with an A/B MAC, would allow a sponsor to confirm that a prescriber's license had been previously verified to ensure that the prescriber is a physician or eligible professional and has an active health care license under applicable state law.

With more than 1 million physicians and eligible professionals enrolled in the Medicare FFS program and more than 9,000 valid opt-out affidavits on file with an A/B MAC, we do not believe that there are a large number of physicians or eligible professionals who prescribe covered drugs for Part D enrollees who are not enrolled in an approved status in Medicare. Our proposed revisions to § 423.120 reflect the existing usage of the CMS–855I, Medicare Enrollment Application—Physicians and Non-Physician Practitioners (OMB Approval Number 0938–0685) and the CMS–855O (OMB Approval number 0938–1135), and, as such, we do not believe that it is necessary to change our existing paperwork burden estimates associated with completing the CMS–855I or the CMS–855O.

We are also soliciting comments on whether we should consider requiring all pharmacies (for example, network, non-preferred, home infusion, non-retail or mail order, and out-of-network) to enroll or maintain enrollment in the Medicare FFS program in order to dispense covered Part D drugs. In a May 2013 OIG report titled, ''Retail Pharmacies with Questionable Part D Billing, (OEI–02–09–00600),'' the OIG found that 2,637 or approximately 4.4 percent of pharmacies, had questionable billing in 2009. The report also highlighted several cities (Miami, Florida, Los Angeles, California, and Detroit, Michigan) with significantly high levels of questionable billing than the national average.

We believe that requiring Medicare FFS enrollment for network pharmacies would leverage the credentialing, identity verification and other safeguards that are part of the FFS enrollment process, allowing Part D sponsors to leverage an important program integrity tool for their networks. Alternatively, we seek comment on whether requiring FFS enrollment for network pharmacies is a ''best practice'' in pharmacy contracting by plan sponsors, and should be an integral part of sponsors' required fraud, waste and abuse programs.

Finally, we are soliciting public comments from doctors of dental surgery or dental medicine, including family dentists, regarding our proposal that doctors of dental surgery or dental medicine enroll in the Medicare program in order to prescribe covered Part D drugs. While many dentists have enrolled in Medicare program within the last 2 years to order bill the Medicare program or order services within the Medicare program, we will continue to conduct outreach to professional organizations/associations to increase the likelihood that all dentists have sufficient notice and therefore time to enroll in the Medicare program in order to prescribe covered Part D drugs.

31. Improper Prescribing Practices (§ 424.535)

a. Background and Program Integrity Concerns

Notwithstanding our proposal discussed in the previous section, we believe that additional program safeguard enhancements are necessary to protect the Medicare Trust Funds from fraud, waste and abuse while ensuring that Part D enrollees and Part B Medicare beneficiaries maintain access to quality health care.

As alluded to earlier, the OIG has conducted several studies addressing program integrity issues related to the Medicare Part D program. Two such reports are of particular relevance to the provisions we are proposing in this section.

The first, which we have already referenced, is titled, ''Medicare Inappropriately Paid for Drugs Ordered by Individuals Without Prescribing Authority'' (OEI–02–09–00608), issued on June 21, 2013. The report found that Medicare paid $26.2 million for drugs prescribed by individuals with National Plan & Provider Enumeration System (NPPES) taxonomy codes indicating that they did not have the authority to prescribe these drugs. Such persons included counselors, chiropractors, social workers, physical therapists, registered nurses, occupational therapists, and speech-language pathologists. Some of these individuals—specifically, chiropractors, physical therapists, occupational therapists, and speech language pathologists—are eligible to enroll in the Medicare program to furnish Part B services.

The second study is titled, ''Prescribers with Questionable Patterns in Medicare Part D'' (OEI–02–09–00603), also issued in June 2013. This report highlighted a number of instances in which physicians and eligible professionals prescribed inordinate amounts of drugs to Part D beneficiaries in 2009. For example—

- Medicare paid a total of $9.7 million—151 times more than the average—for one California physician's prescriptions; most of this physician's prescriptions were filled by two independent pharmacies, both of which the OIG had identified as having questionable billing;
- One hundred and eight general-care physicians each ordered an average of 71 or more prescriptions per beneficiary, more than 5 times general-care physicians' national average of 13; and
- An Ohio physician ordered more than 400 drugs each for 13 of his 665 beneficiaries.
- A Texas physician ordered more than 400 prescriptions each for 16 beneficiaries and prescribed 700 or more drugs for 3 of these beneficiaries.

The OIG also noted examples of physicians prescribing a high percentage of Schedule II and III drugs in 2009. In one case, 78 percent of the prescriptions a Florida physician ordered were for Schedule II drugs even though the OIG found that 4 percent of the prescriptions ordered by prescribers nationwide were for Schedule II drugs. For one beneficiary, the physician prescribed a 605-day supply of morphine sulfate, a 524-day supply of oxycodone HCl, a 460-day supply of fentanyl, and a 347-day supply of hydromophone HCl.

In both reports, as well as in other Part D studies, the OIG recommended that CMS exercise greater oversight of the Part D program, not only to curb the specific practices outlined previously but also to stem the overall risk of fraud and abuse that the program presents. The OIG has expressed particular concern over the potential for beneficiaries to become addicted to or otherwise be seriously harmed by certain drugs if they were inappropriately prescribed in dangerously excessive amounts. We share this concern.

Although we have recently taken steps to tighten and strengthen our supervision of the Part D program, problems remain. We continue to receive reports of questionable prescribing practices. Some of these prescribers have been referred to our Medicare Drug Integrity Contractor (MEDIC) for investigation. Yet even if we find improper practices, such as a particular physician's unreasonably high volume or unsafe amounts of Schedule III controlled substance prescriptions, CMS does not possess the legal authority to take administrative action against the prescriber. This means, in many cases, that the prescriber can continue prescribing drugs that will be covered under Part D and, if he or she is enrolled in Medicare FFS, remain so enrolled to furnish medical services. We believe this is inconsistent with the OIG's recommendations in its various Part D reports, and with our goal of protecting and promoting the health and safety of Medicare beneficiaries and safeguarding the Medicare Trust Funds.

b. Drug Enforcement Administration (DEA) Certification of Registration

The DEA implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, and the Controlled Substances Import and Export Act, as amended, and collectively referred to as the Controlled Substances Act (CSA) (21 U.S.C. 801–971); the implementing regulations for these statutes are in 21 CFR Parts 1300 through 1321. The CSA makes possession of authority under state law to dispense controlled substances a requirement for both obtaining and maintaining a DEA Certificate of Registration. Consistent with 21 U.S.C. 822(e), 21 CFR 1301.12(a) states: ''A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person.'' The term ''dispense'' under 21 U.S C. 802(10) means ''to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance . . .''

We view a DEA Certificate of Registration to prescribe controlled substances as similar to a state's requirement that a physician or eligible professional be licensed or certified by the state to furnish health care services. We have required that physicians and eligible professionals meet state licensure or certification requirements in order to enroll in the Medicare FFS program to furnish health care services. In fact, certain suppliers, such as air ambulance suppliers, must also meet national certification standards by a federal agency (the Federal Aviation Administration (FAA)) to enroll or remain enrolled in the Medicare program. Failure to obtain or maintain appropriate licensure or certification can result in the denial or revocation of the provider or supplier's Medicare under § 424.530 and § 424.535, respectively.

We believe there is a similarity between the need to obtain and maintain DEA registration to dispense controlled substances, and the need for an air ambulance supplier to meet FAA certification requirements, and for a physician or eligible professional to meet state licensure or certification requirements in order to enroll in and maintain enrollment in Medicare FFS. The Medicare FFS licensure and certification requirements are designed to ensure that physicians, eligible professionals, and other suppliers are qualified to furnish health care services within the Medicare program. In a similar way, the DEA Certificate of Registration is designed to ensure that physicians and eligible professionals meet the statutory criteria established by the CSA to dispense controlled substances.

Physicians, eligible professionals, and pharmacies with a valid DEA Certificate of Registration are allowed to dispense controlled substances. A DEA Certificate of Registration is not required to dispense non-controlled substances, including covered Part D drugs that are not considered to be controlled substances. Thus, under our current regulations, a physician or eligible professional may prescribe covered Part

D non-controlled drugs to a Part D enrollee even though his or her DEA Certificate of Registration has been suspended or revoked. As the agency that administers the Part D drug program, we believe it is both appropriate and necessary to expand our Medicare FFS provider enrollment requirements to ensure that only physicians and eligible professionals who are in good standing with state licensing boards and, as applicable the DEA, are writing prescriptions for covered Part D drugs in the Medicare program.

c. Proposed Provisions

In light of the foregoing discussion, we are proposing several changes to 42 CFR Part 424, subpart P, in order to enhance our Medicare Part D and Part B program integrity efforts.

(1) DEA Certificate and State Authority

We propose to add a new § 424.530(a)(11) granting CMS the authority to deny a physician or eligible professional's Medicare enrollment application if: (1) His or her DEA Certificate is currently suspended or revoked; or (2) the applicable licensing or administrative body for any state in which the physician or eligible professional practices has suspended or revoked the physician or eligible professional's ability to prescribe drugs; and (3) such suspension or revocation is in effect on the date he or she submits his or her enrollment application to the Medicare contractor. We believe this approach is consistent with our policy under § 424.530(a)(1) of denying enrollment to providers and suppliers that do not meet applicable licensure and certification requirements.

Similarly, we propose to add a new § 424.535(a)(13) granting CMS the authority to revoke a physician or eligible professional 's Medicare enrollment if (1) his or her DEA Certificate is suspended or revoked, or (2) the applicable licensing or administrative body for any state in which the physician or eligible professional practices suspends or revokes the physician or eligible professional's ability to prescribe drugs. Again, this approach is consistent with our requirement that providers and suppliers maintain compliance with all applicable licensure and certification requirements.

We believe that the loss of the ability to prescribe drugs via a suspension or revocation of a DEA Certificate or by state action is a clear indicator that a physician or eligible professional may be misusing or abusing his or her authority to prescribe such substances. This raises concerns that the physician or eligible professional's improper practices may be duplicated in the Medicare program. We must therefore take steps to ensure that Medicare beneficiaries are protected and the Medicare Trust Funds.

(2) Patterns or Practices of Prescribing

(a) Grounds for Revocation

We also propose to add a new § 424.535(a)(14) that would permit CMS to revoke a physician or eligible professional's Medicare enrollment if CMS determines that he or she has a pattern or practice of prescribing Part D drugs that—

- Is abusive and represents a threat to the health and safety of Medicare beneficiaries, or
- Fails to meet Medicare requirements.

We believe we have several bases for the legal authority for this proposal. First, sections 1102 and 1871 of the Act give the Secretary the authority to establish requirements for the efficient administration of the Medicare program. Second, section 1866(j) of the Act states that the Secretary shall establish by regulation a process for the enrollment of providers of services and suppliers.

We also note that on April 29, 2013, we published in the **Federal Register** a proposed rule entitled, ''Medicare Program: Requirements for the Medicare Incentive Reward Program and Provider Enrollment'' (78 FR 25013). We proposed therein to add a new § 424.535(a)(8)(ii) that would give CMS the discretion to revoke a provider or supplier's Medicare enrollment if the provider or supplier has a pattern or practice of submitting claims for services that fail to meet Medicare requirements. Our purpose was to place providers and suppliers on notice that they were under a legal obligation to always submit correct and accurate claims and that failure to do so may result in the revocation of Medicare enrollment if such failures establish a pattern of incorrect or inaccurate claims. We believe that this concept should also extend to revoking Medicare enrollment for Part D prescribers who engage in abusive prescribing practices. In our view, if a physician or eligible professional repeatedly and consistently fails to exercise reasonable judgment in his or her prescribing practices, we should have the ability to remove such individuals from the Medicare program to protect beneficiaries' safety and health as well as Medicare Trust Funds.

(b) Criteria To Be Considered

Many patterns and practices of prescribing, though perhaps questionable on their face, do not upon investigation involve abusive or fraudulent behavior nor involve substandard medical care. Therefore, we are proposing to base any revocation under proposed § 424.535(a)(14) on situations that fall outside the norm of appropriate prescribing, and only after carefully considering the factors outlined later in this section. A thorough, detailed investigation by CMS of the physician or eligible professional's prescribing practices would be a prerequisite for the use of § 424.535(a)(14). Honest physicians and eligible professionals who engage in reasonable prescribing activities would not be impacted by our proposal. We note further that CMS, rather than the Part D plans, would make all determinations under our proposed provisions, though information contained in referrals from Part D Plan sponsors may be used as part of CMS' analysis to make revocation decisions.

We choose not to define ''abusive'' and ''threat to the health and safety of Medicare beneficiaries'' in this proposed rule, primarily because the myriad of questionable situations that warrant the possible application of § 424.535(a)(14) requires that CMS have the flexibility to address each case on its own merits. We believe that the sounder approach would be to propose a list of criteria that CMS would use in determining whether a prescriber is engaging in prescribing practices sufficient to warrant a revocation.

In determining instances of a pattern or practice of prescribing that is abusive and a threat to the health and safety of Medicare beneficiaries, CMS proposes to consider several factors, including—

- Whether there are diagnoses to support the indications for which the drugs were prescribed;
- Whether there are instances where the necessary evaluation of the patient for whom the drug was prescribed could not have occurred (for example, the patient was deceased or out of state at the time of the alleged office visit);
- Whether the physician or eligible professional has prescribed controlled substances in excessive dosages that are linked to patient overdoses;
- The number and type(s) of disciplinary actions taken against the physician or eligible professional by the licensing body or medical board for the state or states in which he or she practices, and the reason(s) for the action(s);
- Whether the physician or eligible professional has any history of ''final adverse actions'' (as that term is defined under § 424.502);

• The number and type(s) of malpractice suits that have been filed against the physician or eligible professional related to prescribing that have resulted in a final judgment against the physician or eligible professional or in which the physician or eligible professional has paid a settlement to the plaintiff(s) (to the extent this can be determined);

• Whether any State Medicaid program or any other public or private health insurance program has restricted, suspended, revoked, or terminated the physician or eligible professional's ability to prescribe medications, and the reason(s) for any such restriction, suspension, revocation, or termination; and

• Any other relevant information provided to CMS.

In determining whether a physician or eligible professional has a pattern or practice of prescribing that fails to meet Medicare requirements, CMS would consider the following factors, including whether the physician or eligible professional—

• Has a pattern or practice of prescribing without valid prescribing authority;

• Has a pattern or practice of prescribing for controlled substances outside the scope of the prescriber's DEA Certificate of Registration;

• Has a pattern or practice of prescribing drugs for indications that were not medically accepted—that is, for indications neither approved by the Food and Drug Administration (FDA) nor medically accepted under 1860D–2(e)(4) of the Act—and whether there is evidence that the physician or eligible professional acted in reckless disregard for the health and safety of the patient.

To be covered under Part D, Medicare requires that a drug be dispensed upon a prescription that is valid under state law, that the drug meets the definition of a Part D drug, and that it be prescribed by a valid prescriber for a medically accepted indication. Therefore, a physician or eligible professional evidencing a pattern or practice of prescribing without valid prescribing authority, or for controlled substances outside the scope of the prescriber's DEA Certificate of Registration, would face potential revocation of Medicare enrollment. In addition, a physician or eligible professional with a consistent pattern or practice of prescribing drugs for indications that were not medically accepted—that is, for indications neither approved by the FDA nor medically accepted under 1860D–2(e)(4) of the Act—could potentially face revocation. In the latter example, we would anticipate revoking enrollment only in cases where there is evidence of reckless disregard for the health and safety of the patient, not when the prescribing is based on peer reviewed literature or community standards of medical practice.

We reiterate our earlier statement that all criteria would be carefully examined before determining whether a revocation under § 424.535(a)(14) is warranted. In the vast majority of cases, no single factor would or could be dispositive. Nonetheless, there are certain criteria that, if met, would weigh very heavily and perhaps decisively towards a finding that a revocation is justified. A primary example would be that the physician or eligible professional is prescribing drugs without legal authorization. Even if a review of the other criteria did not indicate a pattern of improper activity, unauthorized prescribing is so serious a matter that the practitioner's continued retention of his or her Medicare enrollment would be unacceptable.

We stated in section III.A.30, of this proposed rule that prescriptions ordered by physicians and eligible professionals who are not enrolled in Medicare in an approved status would not be coverable under the Part D program.

We welcome and indeed encourage comments on our proposed additions of § 424.530(a)(11) and of § 424.535(a)(13) and (14). We are especially interested in receiving comments on the following issues:

• Whether certain proposed criteria should not be used.

• Whether criteria that we did not propose should be used.

• Whether certain criteria should be given more or less weight than others.

• Whether our proposed additions of § 424.530(a)(11) and of § 424.535(a)(13) and (14) should be expanded to include pharmacy activities.

32. Transfer of TrOOP Between PDP Sponsors Due to Enrollment Changes During the Coverage Year (§ 423.464)

Sections 1860D–23 and 1860D–24 of the Act specify that requirements for Part D sponsor coordination of benefits with State Pharmaceutical Assistance Programs and other plans providing prescription drug coverage, including treatment of expenses incurred by these payers toward a beneficiary's out-of-pocket (TrOOP) threshold. Part D coordination of benefit requirements are codified at § 423.464 which define ''other prescription drug coverage'' for COB purposes to include, among other entities, other Part D plans and specify Part D plan requirements for determining when an enrollee has satisfied the out-of-pocket threshold.

Related regulations at § 423.104(d), codifying the requirements in section 1860D–2(b) of the Act, require sponsors to track beneficiary TrOOP and gross covered drug costs and correctly apply these costs to the benefit limits to correctly position the beneficiary in the benefit and provide the catastrophic level of coverage at the appropriate time. When a beneficiary transfers enrollment between Part D plans during the coverage year, the enrollee's gross covered drug costs and TrOOP must be transferred between plans and applied by the subsequent plan in its administration of the Part D benefit. The procedures for a prior plan to report these TrOOP-related data and for the plan of record to receive, upload, and use the data position the beneficiary in the correct phase of the benefit was expressed in guidance outlining sponsor responsibilities related to the 2006 Enrollment Reconciliation process. CMS April 2006 guidance detailing instructions for the Enrollment Reconciliation-related data transfer noted the process would be applicable on an on-going basis when a beneficiary's enrollment in a plan terminated due to enrollment in another plan.

This initial manual data transfer process was replaced in 2009 by an automated process for TrOOP-related data transfer developed by CMS and the industry in collaboration with National Council for Prescription Drug Programs (NCPDP). Our guidance released in 2008 describing sponsor implementation of the automated TrOOP balance transfer process reiterated sponsor requirements for data reporting by the prior plan and use of the data for proper positioning of the beneficiary in the benefit by the current plan. We have continued to specify these requirements in subsequent updated versions of the guidance.

Automated TrOOP balance transfer is supported by the NCPDP Financial Information Reporting (FIR) transaction standard, which is used to electronically transfer TrOOP-related data between plans. When a beneficiary transfers enrollment to another plan during the coverage year, transactions are sent sequentially by the CMS Part D Transaction Facilitator to all Part D plans in which the beneficiary was enrolled during the coverage year or that paid claims on the beneficiary's behalf. Sponsors must receive and respond to each transaction, accept the data reported by the enrollee's prior plan, and use these data in the administration of the Part D benefit.

To ensure Part D benefits are correctly administered when a beneficiary transfers enrollment during the coverage year, we propose to codify these requirements in federal regulations. Specifically, we propose to amend § 423.464(f)(2) by adding a new paragraph (C) requiring Part D sponsors to—

- Report benefit accumulator data in real-time in accordance with the procedures established by CMS;
- Accept in real-time data reported in accordance with CMS-established procedures by any prior plans in which the beneficiary was enrolled, or that paid claims on the beneficiary's behalf, during the coverage year; and
- Apply these costs promptly.

In our guidance on automated TrOOP balance transfer, we express our expectation that sponsors successfully transfer accumulator data for beneficiaries making enrollment changes during the coverage year in a timely manner 100 percent of the time. Although sponsors may be reporting and accepting these data in accordance with our expectations, we have been informed that some sponsors may not be promptly loading the data received into their systems so it is available for claims processing. As a result, the beneficiary's previously incurred costs and gross covered drug costs are not considered in the processing of claims received by the new plan sponsor soon after the enrollment change. With this change we seek to clarify that, since the automated TrOOP transfer process enables the accumulators to available to the new plan within a day or 2 of the new enrollment effective date or, if later, the date CMS processes the enrollment change, we expect the new plan sponsor to apply the data promptly after receipt and use it in benefit administration.

33. Broadening the Release of Part D Data (§ 423.505)

We are proposing to revise our regulations governing the release of Part D data to expand the release of unencrypted prescriber, pharmacy, and plan identifiers contained in prescription drug event (PDE) records, as well as to make other changes to our policies regarding release of Part D PDE data. In the May 28, 2008 **Federal Register** (76 FR 30664) we published a final rule entitled ''Medicare Program; Medicare Part D Claims Data,'' (hereinafter referred to as the Part D data final rule) to implement regulations that govern the collection of PDE data under the authority of section 1860D–12(b)(3)(D) of the Act and the disclosure of this data in accordance with section 1106 of the Act. The provisions governing the collection and disclosure of PDE data are codified at § 423.505(b)(8), (f)(3) and (l).

PDE data are summary records of individual claim transactions at the pharmacy containing CMS-defined standard fields submitted by Part D sponsors that document the final adjudication of a Part D dispensing event. The Part D data final rule governed the collection and disclosure of the original 37 elements of PDE data, but was updated to apply to any additional elements that were added to the PDE record. This update was in a final rule issued in April 2010 (75 FR 19678) entitled, ''Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (hereinafter referred to as the April 2010 final rule).

In the preamble to the Part D data final rule (73 FR 30671), we stated, ''we [ ] believe that it is in the interest of public health to share the information collected under [the authority of 1860D–12(b)(3)(D)] with entities outside of CMS.'' We explained that the release of PDE data assists CMS in evaluating the Medicare Part D program and assessing related policies. We further stated such release was in the interest of public health and would improve the clinical care of beneficiaries.

In addition to setting forth the significant public policy reasons for disclosure of PDE data, we made clear in the preambles of both the Part D data final rule and the April 2010 rule that our primary concerns in releasing PDE data are protecting the confidentiality of beneficiary identifiable information and commercially sensitive data of Part D sponsors. Part D sponsors are private organizations that contract with the federal government to administer the Part D benefit by offering prescription drug plans to Medicare beneficiaries who may voluntarily enroll in one. Therefore, as described in the Part D data final rule and the April 2010 rule, the release of PDE data is subject to certain protections, described here generally, such as encryption of beneficiary information and aggregation of commercially sensitive data of Part D sponsors. In addition, whenever PDE data is released, we only release the minimum data necessary for a given purpose, as determined in the sole discretion of CMS after review of the requestor's detailed request for data. If releasing data to an external entity, in the Part D data final rule, CMS indicated that the requestor must be a legitimate researcher, meaning the requestor has the requisite experience and is working for, or on behalf of, a reputable institution. (In the preamble to the Part D data final rule (73 FR 30674 citing 45 CFR 164.501), we used the definition of ''research'' contained in the HIPAA Privacy Rule, which defines the term as ''a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.'' In the Part D data final rule (73 FR 30674), we also indicated that, consistent with our current policies for Part A and B data, identifiable Part D data would not be disclosed for commercial purposes.

The following describes the current policy for the release of Part D data more specifically by PDE element: Beneficiary, prescriber, pharmacy, and plan identifiers are generally encrypted when released. We only release unencrypted beneficiary, prescriber, pharmacy, or plan identifiers to other government agencies or states, if these identifiers are necessary for the project, and we only release unencrypted beneficiary, prescriber, and pharmacy identifiers to external entities if needed to link to another dataset. We do not release unencrypted plan identifiers to external entities, except to HHS grantees, as permitted under the criteria described in the April 2010 rule and codified in the regulations at 42 CFR 423.505(m)(1)(iii)(C).

Under the Part D data final rule, drug cost data in PDE records are generally aggregated when released. Drug cost data are available in disaggregated format only to other HHS entities and congressional oversight agencies. Drug costs data in PDE records consist of the drug ingredient cost, applicable dispensing fee and any required state sales tax. However, upon request we would exclude sales tax from the aggregation at the individual claim level if necessary for a project.

As this is a time of unprecedented change for CMS and the health care system in general, we believe the current regulations governing the release of PDE data need to be re-considered. The agency has an important role to play in supporting opportunities to accelerate the transition to a data-driven and information-based health care delivery system in this country. CMS itself is transforming from a passive payer of claims towards a value-based purchaser of health care, while at the same time, other health care payer and provider incentives have shifted toward broader coverage and coordinated care. These trends are all a positive and expected outgrowth of the passage and implementation of the Affordable Care Act.

Concurrent with the changes to CMS' role and the health care system in general is the fact that we now have several years of experience with release of PDE data from the Medicare Part D program. We believe the current limitations on the release of certain data elements hinder the use of PDE data in this new health care environment, and inhibit accompanying insights into prescription drug benefit plans that could result from broader release of the data. Our experience has led us to conclude that broader release of PDE data to external entities can increase the positive contributions researchers make to the evaluation and function of the Part D program, and improve the efficiency of the program and the clinical care of its beneficiaries, which is in the interest of public health. Expanded access to PDE data by external entities will allow the researchers to study additional aspects of the Medicare program and health care, and their findings will be released publicly. Such contributions are in the interest of the Medicare Part D program and public health now more than ever as the Affordable Care Act transforms CMS's role and the nation's health care system.

For these reasons, we believe increased access to prescriber, pharmacy, and plan identifiers by all categories of requestors is of utmost importance. This new policy would facilitate research by entities outside CMS that involves identifiable plans, prescribers, and pharmacies. Furthermore, we believe we can relax the current policies on the release of this PDE data, while still protecting beneficiary confidentiality and commercially sensitive data of Part D sponsors.

Accordingly, we are proposing to permit the release of unencrypted prescriber, pharmacy, and plan identifiers contained in PDE records to all current categories of requestors (including, other HHS entities and the Congressional oversight agencies, non-HHS executive branch agencies and states, and external entities). We note that because the minimum necessary policy will still apply to all such releases, this proposed policy change with respect to HHS entities/Congressional oversight agencies and non-HHS executive branch agencies/states is more a formality, since this data is available in unencrypted format to these same entities under the current Part D data regulations ''if needed.'' For this reason, we focus on the release of unencrypted prescriber, pharmacy, and plan identifiers to external entities as discussed later in this section.

We emphasize that we are not proposing any changes to our release policies with respect to beneficiary identifiable data and the drug cost data of Part D sponsors. In addition, other data that is still viewed by some at this time to be commercially-sensitive data of Part D sponsors, for example, data on bids, rebates and other price concessions, are outside the scope of the changes to current PDE data release policies that we are proposing here. We note that bid data is not collected through PDE records, and while rebates and other price concessions may be reflected in PDE records, we are not proposing to make any changes to the policies governing release of such data.

We understand that there may be concerns about releasing unencrypted prescriber, plan, and pharmacy identifiers to external entities, as they have been raised in the past, and we would like to address them upfront. In the preamble to the Part D data final rule (73 FR 30675), we addressed specific concerns about expanding access to prescriber information by external entities, particularly for pharmaceutical companies and others who may want to influence physicians' prescribing patterns and interfere with a physicians' professional judgment. We stated that an encrypted version of the prescriber identifier, which allows for the linkage of all of a prescriber's claims without divulging the prescriber's identity, would meet the needs of most researchers.

However, in our view today, the vast majority of physicians have prescribed and do prescribe what they believe are the appropriate medications for their patients, and they should have no concerns with transparency in their prescribing patterns. Moreover, there are other measures in place to prevent inappropriate influence by external entities on prescribers. For example, section 6002 of Affordable Care Act requires applicable manufacturers of drugs covered under the Part D program to report annually to the Secretary certain payments or other transfers of value to physicians. This requirement was implemented through a final rule that appeared in the February 8, 2013 **Federal Register** (78 FR 9458) entitled, ''Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership of Investment Interests''. In addition, the federal Anti-Kickback Law (section 1128B(b) of the Act) provides that anyone who knowingly and willfully solicits, receives, offers, or pays anything of value to influence the referral of federal health care program business, including Medicare and Medicaid, can be held accountable for a felony. Finally, we would point out that when data are completely transparent, it is easier for the attempts of some to use the data for purposes of inappropriate manipulation to be countered by others who have access to the same data. We note that it appears that prescriber data are already available commercially from pharmacy data aggregators. For these reasons, we believe that our earlier concerns about the release of unencrypted prescriber identifiers in PDE data to external entities are no longer warranted.

Our proposal to release unencrypted prescriber identifiers means that legitimate external researchers will be able to conduct research that involves identifiable prescribers using PDE data. In the Part D data final rule (73 FR 30676), a commenter argued that providing access to linked physician identifiable claims in order to pool them with employer data would allow analysis to reduce cost of care delivery and improve the quality of care. In response, we did not disagree with the commenter, but referenced a variety of pay for performance and value-based health care initiatives being undertaken by CMS in an effort to encourage health care providers to furnish high quality health care and to provide cost and quality information to consumers. We noted that we intended to use PDE data in those activities. We declined, however, to adopt a policy that would include making unencrypted prescriber identifiers available for release to external entities (except when needed to link to another data set).

However, in light of the goals of the Affordable Care Act to improve the quality of health care, including through better access to information, we now acknowledge our agreement with the commenter regarding the importance of providing access to prescriber-identifiable claims. As we noted previously in this section, now more than ever, it is vital that researchers have more data to investigate ways to reduce the cost of care and improve its quality. Studying the prescribing trends of identifiable prescribers can assist all stakeholders in the health care system, from both public and private health care payers, to patients, and even to physicians themselves, by identifying prescribing benchmarks and determining the reasons for variations.

With respect to the release of plan identifiers, we recognized that it might be asserted that in the Part D data final rule and April 2010 rule we included this data when discussing commercially sensitive data of Part D sponsors that would generally be encrypted when

released to external entities. However, we point out that we focused on the separate costs paid by Part D sponsors for ingredient costs or dispensing fees as being the confidential data on the claim (73 FR 30668), and we are not proposing any changes to our policies with respect to the release of ingredient costs or dispensing fees. However, we are proposing to release unencrypted plan identifiers to all categories of requestors.

In comments in response to the Part D data proposed rule, commenters requested clarification that the plan-specific information we were proposing to disclose related only to Part D claims data and would not include competitively sensitive financial data regarding rebates, discounts, or other negotiated price concessions. The commenters expressed concerns that release of competitively sensitive data could undermine the competitive bid process, asserting that plans would be able to adjust their bids on the basis of knowledge of each other's data, resulting in higher drug costs for all. In response to these concerns, we replied in the preamble to the Part D data final rule that we shared the commenters' concerns about the need to protect sensitive data under the Part D program. We stated that because the Medicare drug benefit is based on a competitive business model, we believe releasing commercially or financially sensitive data to the public could negatively impact Part D sponsors' ability to negotiate for better prices, and ultimately could affect the ability of sponsors to hold down prices for beneficiaries and taxpayers. Therefore, we explained (73 FR 30668) that we were adopting a number of protections to mitigate these concerns, which include our minimum necessary, legitimate researcher, and aggregation policies described previously.

These policies would also not change under our current proposal, except that plan identifiers (including internal plan/pharmacy identification numbers on the claim that represent reference numbers assigned by the plan at the time a drug is dispensed), would be available for release to all categories of requestors without encryption. In other words, our current policy on release of ingredient cost and dispensing fee data would not change under our proposal, meaning the minimum necessary data regarding ingredient costs and dispensing fees would continue to be available for release in disaggregated form only to other HHS entities and congressional oversight agencies. Non-HHS executive branch agencies and external entities could still only obtain the minimum necessary ingredient cost and dispensing fee data, only in aggregated form, and only if it is released to a legitimate researcher.

We are proposing this change to our regulations governing the release of plan identifiers, because we no longer believe plan identifiers in PDE data are commercially sensitive data of Part D sponsors that should not be available for release (unless encrypted). Indeed in the April 2010 rule (75 FR 19675 through 19676), in which we expanded access to unencrypted plan identifiers to include HHS grantees under certain conditions on the basis that it would allow for the study of beneficiary plan choices, which would assist CMS in better understanding and improving the Medicare program, we responded to opposing comments that we believed allowing broader access by grantees of non-HHS entities and external researchers could also further assist CMS, even though we declined to adopt such broader access at the time, because we believed that additional time was needed to evaluate the issue.

Moreover, an analysis of Part D plans, their network pharmacies, and average drug costs, can already be accomplished through data posted on CMS' Web site and/or purchased in public use files. Additionally, the MPDPF allows users to view and compare all available prescription drug plan choices, including plan and pharmacy specific estimates of the costs of individual drugs. These data can be manipulated by researchers to reveal information about specific plans and pharmacies that contributes to the evaluation and functioning of the Part D program and can be used to improve the public health. Therefore, in light of the public policy rationale for increasing access to PDE data by all categories of requestors, we believe that plan identifiers should be available in unencrypted format.

We did not respond to any comments specifically addressing pharmacy identifiers in our Part D data final rule and April 2010 rule. However, for the same reasons that we are proposing to make prescriber and plan identifiers available for release in an unencrypted format, we no longer see a reason that pharmacy identifiers should not be available for release in unencrypted format. Accordingly, we also propose to release unencrypted pharmacy identifiers to all categories of requestors, which would also be a change in the current regulations governing the release of PDE data.

We would like to address one final aspect of our policies governing the release of Part D data. As discussed previously, in the preamble to the Part D data final rule, we explained that consistent with CMS's existing policies with respect to Parts A and B data, CMS would not release PDE data for commercial purposes (but external researchers may be funded by commercial firms if the researchers are free to publish their results regardless of the findings). However, given reasons that we have highlighted previously which provide the impetus for the changes that we are proposing to make to our rules governing the release of PDE data, we are also soliciting comment on the current restriction on the release of PDE data for commercial purposes. We are not making a specific proposal in this regard, but rather wish to receive comments for consideration in light of the proposed changes to the requirements governing the release of Part D data that are included in this proposed rule.

In addition to the proposed changes with respect to prescriber, pharmacy, and plan identifiers described previously, and our request for comment on the restriction on the release of Part D PDE data for commercial purposes, we are proposing a few other changes to our regulations governing the release of PDE data and also wish to clarify our existing policies with respect to several issues related to the PDE data. First, we are proposing to add supporting program integrity purposes, including coordination with states, as an additional purpose deemed necessary and appropriate by the Secretary for which a Part D sponsor must agree to submit all data elements included in all its drug claims under section 1860D–12(b)(3)(D) of the Act. The regulation at § 423.505(f)(3) currently contains a non-exclusive list of purposes deemed necessary and appropriate. We believe that the use of these data for supporting program integrity purposes has always been included, even though not explicitly listed. However, given the importance of our ability to release PDE data for program integrity purposes, including for coordination with states on program integrity, we are proposing to add this purpose explicitly to the non-exclusive list in § 423.505(f)(3).

Second, we are clarifying that non-final action data (for example, information on claims subject to subsequent adjustment) are available to entities outside of CMS. Non-final action data are captured through the data element, ''Original versus Adjusted PDE (Adjustment/Deletion code).'' This is a PDE field which distinguishes original from adjusted or deleted PDE records, so CMS can adjust claims and make accurate payment for revised PDE records, and is thus not point-of-sale

data. With the increasing focus on coordination of care, requests for access to non-final action PDE data have also increased. Such data are also routinely requested for evaluation and research projects. The Part D data final rule (73 FR 30683) included an appendix that explained in more specific detail the restrictions relative to the available PDE elements for the different categories of requestors. This appendix stated (73 FR 30685) that the data element ''Original versus Adjusted PDE (Adjustment/Deletion code)'' was available to other (that is, non-CMS) HHS entities and the congressional oversight agencies, while for non-HHS executive branch agencies, states, and external entities, it stated that ''Final Action claims would be provided, so this element should not be needed.'' Thus, this appendix did not explicitly address the question of whether non-final action data would be available for release to these entities, because such data were not expected to be needed. However, since it is clear that these entities do need access to non-final data, we are clarifying that non-final action data are also available for release to non-HHS executive branch agencies, states, and external entities under the Part D data final rule.

Finally, we believe these proposed changes to the Part D regulations governing PDE data release do not raise any new issues under the Privacy Act and that the changes are consistent with the System of Records that currently applies to the relevant data. Thus, we are not proposing any changes to the System of Records, ''Medicare Drug Data Processing System (DDPS),'' System No. 09–70–0553, as we are not proposing any changes to the data we are collecting, to how the data may be used, to the entities that may receive the data, or to the manner of transmission of the data. Rather we are proposing a change in the format in which the data may be provided when released to certain categories of requesters.

In light of the proposed changes to our policies governing the release of PDE data described previously, we are proposing changes to the current applicable regulatory text as described later in this section. We are also proposing to eliminate the appendix that accompanied the Part D data final rule (73 FR 30683) that explained in more specific detail which PDE elements would be available to different categories of requestors, and any restrictions that applied. We believe this appendix is no longer necessary, as our proposals would eliminate most of the distinctions with respect to the PDE data available for release to the different categories of requesters, with the exception of Total Drug Costs, which will continue to be available in disaggregated form only to other (that is, non-CMS) HHS entities and the congressional oversight agencies, and we propose to revise the regulation at § 423.505(m)(1)(iii)(B) to account for this distinction. We also clarify that we will exclude sales tax from the aggregation, if necessary for the project. We also propose changes to the regulatory text to incorporate notes from the current Appendix that are not addressed by the existing reference to CMS data sharing procedures in § 423.505(m)(1)(ii).

Therefore, consistent with the foregoing, we propose the following revisions to the applicable regulatory text:

- Section 423.505(f)(3) would be revised to add supporting program integrity purposes, including coordination with states, as an additional purpose.
- Section 423.505(m)(1)(iii) would be revised to remove references to encrypting certain identifiers since prescriber, plan, and pharmacy identifiers would no longer be subject to encryption when released.
- Section 423.505(m)(1)(iii)(A) would be revised to clarify that, subject to the restrictions contained in paragraph (m)(1), all elements on the claim are available not only to HHS, but also to other executive branch agencies and states, since there is no longer any distinction between the two categories.
- Section 423.505(m)(1)(iii)(B) would be revised to incorporate a note from the appendix, which states: ''Upon request, CMS excludes sales tax from the aggregation at the individual level, if necessary for the project'' at the end of the provision.
- Section 423.505(m)(1)(iii)(C) would be deleted as no longer necessary since unencrypted plan identifiers, including the internal plan/pharmacy identification numbers, would be available for release.
- Section 423.505(m)(1)(iii)(D) would be re-lettered as (C) and references to encryption of pharmacy and prescriber identifiers would be deleted, since these identifiers would be available for release in unencrypted format. Additional language regarding beneficiary identifiers would be added to the existing provision to reflect the current policy on release of this identifier as reflected in the appendix that would be eliminated.
- Section 423.505(m)(3) would be revised to incorporate a note from the appendix that would be eliminated about the status of the Congressional Research Service as an external entity when it is not acting on behalf of a Congressional committee in accordance with 2 U.S.C. 166(d)(1).

34. Establish Authority To Directly Request Information From First Tier, Downstream, and Related Entities (§ 422.504(i)(2)(i), and § 423.505(i)(2)(i))

Pursuant to section 1857(d)(2) and 1860D–12(b)(3)(c) of the Act, existing regulations at 42 CFR 422.504(i) and 42 CFR 423.505(i) establish various conditions that entities contracting as a first tier, downstream, or related entity (FDR) to an MA organization or Part D sponsor must agree to in order to participate in the MA or Part D program. One such condition at § 422.504(i)(2)(i) and § 423.505(i)(2)(i) is that HHS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, contracts, computer or other electronic systems, including medical records and documentation of the first tier, downstream, and related (FDR) entities related to CMS' contract with the Part C and D sponsor.

CMS (or its designee(s)) conduct routine audits of Part D sponsors and MA organizations, as well as conduct audits to investigate allegations of noncompliance with Part C and/or Part D rules and requirements. While § 422.504(d) and § 423.505(d) address Part D and MA organizations' own maintenance of records and the rights of CMS to inspect those records, § 422.504(i)(2)(i) and § 423.505(i)(2)(i) also require plan sponsors require that their FDRs agree to this CMS right to inspection. Plan sponsors regularly contract with FDRs to perform critical Part C and D operating functions. For example, many (if not most) Part D sponsors delegate critical Part D functions to their PBMs. As a result, many of the records that we or our designees would need to review and evaluate when we audit a Part D sponsor or MA organization reside with its FDRs.

Our existing regulation at § 423.505 (i)(3)(iv) states that the contracts between the Part D sponsor and its FDRs must indicate whether records held by the FDR pertaining to the Part D contract will be provided to the sponsor to provide to CMS (upon request), or will be provided directly to CMS or its designees by the FDR (the Part C regulation is silent on this matter). As such, we have not previously required Part C or Part D FDRs to provide information directly to CMS.

Two separate reports by the OIG (OEI–03–08–00420, dated October 2009 and OEI 03–11–00310, dated January 2013), have highlighted barriers experienced by the Medicare Drug

Integrity Contractor (MEDIC), the entity contracted by CMS to be responsible for detecting and preventing fraud, waste, and abuse in the Medicare Parts C and D programs nationwide, in obtaining requested information in an expeditious manner. The 2009 OIG report discussed that CMS' and its designees' (in this case, the MEDIC) lack of authority to directly obtain information from pharmacies, PBMs, and physicians has hindered the MEDIC's ability to investigate potential fraud and abuse and the OIG recommended that CMS change its regulations to establish its authority to obtain necessary information directly from FDRs. The OIG's 2013 report reiterated the recommendation that CMS have a more direct route to obtain records held by FDRs so that CMS would be able to obtain necessary records in a timely fashion. While the 2013 report pointed out that sponsors and their FDRs generally cooperate in providing the information requested by the MEDIC, it often takes months for it to reach the MEDIC because the MA organization or Part D sponsor acts as a gatekeeper.

In the past, we chose not to be prescriptive regarding whether a first tier, downstream, or related entity must make its books and records available to us directly or through the Part C or D sponsor. As a consequence of what we have learned through the OIG investigations and the seriousness with which we approach our fraud, waste, and abuse oversight obligations, we are now proposing to specify at § 422.504(i)(2)(ii) and § 423.505(i)(2)(ii) that HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any records by obtaining them directly from any first tier, downstream, or related entity. This proposed regulatory change would not grant CMS any investigative or audit authority that we do not already possess. It would merely guarantee us a direct and expeditious route to the information we need to obtain for purposes of program oversight. This regulatory change would also reduce the burden on the plan sponsor. The plan sponsor would no longer need to act as the gatekeeper between CMS and its first tier, downstream, or related entity. Upon making contact with the first tier, downstream, or related entity, we would simultaneously notify the plan sponsor concerning the nature of the request. This will ensure that the plan sponsor will have notice that we are contacting one of its subcontractors.

We are proposing to revise the regulation at § 422.504(i)(2)(i) and § 423.505(i)(2)(i) to make clear that CMS and its designees may ''collect'' records, in addition to our existing authority to ''audit, evaluate, and inspect'' information. The addition of ''collect'' removes any doubt that, in addition to our other options for obtaining records, we have the authority to request information to be reviewed in some location other than onsite at a sponsor's or FDR's facility. Furthermore, the proposed provision is intended to clarify only that CMS may contact FDRs directly and request that they provide Part C or D-related information directly to CMS. The question as to whether CMS has the authority to enter the premises of FDRs, is to be determined by interpreting other applicable statutory and regulatory authority.

We also propose to delete the existing provision at § 423.505(i)(3)(iv) which gives Part D sponsors the choice as to how information sought from their FDRs will be provided to CMS. Section 423.505 would be renumbered so that paragraphs (v)–(viii) would become paragraphs (iv)–(vii).

35. Eligibility of Enrollment for Incarcerated Individuals (§ 417.1, § 417.460, § 422.74, and § 423.44)

Entitlement and enrollment in the Medicare program (Part A and Part B) is contingent on entitlement to Social Security retirement and disability benefits as outlined in sections 226 and 226A of the Act, and enrollment in the Medicare program for individuals not receiving retirement or disability benefits is outlined in sections 1818 and 1818A of the Act. These sections do not preclude entitlement to or enrollment in the Medicare program for individuals who are incarcerated in prisons or other penal facilities. However, section 1862(a)(3) of the Act excludes Medicare payment for services which are paid directly or indirectly by another government entity, including federal, state and local prisons, and penal facilities. Given that Medicare entitlement flows from entitlement to Social Security retirement and disability benefits, we established regulations at § 411.4(b) and implemented section 1862(a)(3) of the Act through a payment exclusion process in the FFS program, outlined in section 50 of Chapter 16 of the Medicare Benefit Policy Manual and section 10.4 of the Medicare Claims Payment Manual.

The Medicare payment exclusion process includes the receipt of incarceration status for individuals via regular data exchanges from the SSA to CMS. Once we receive the data, the incarceration status is noted on the individual's record and is retained in the FFS claims processing systems. Upon receipt of submitted FFS claims, CMS denies payment of both Part A and Part B claims for individuals with records on which incarceration is denoted. The denial of claims continues until the individual is no longer considered incarcerated and that information is reported by SSA to CMS. Individuals who are entitled to premium-free Part A will maintain their entitlement and will remain enrolled in Part B as long as premiums are paid. Similarly, individuals who are enrolled in premium Part A and/or Part B maintain their enrollment as long as premiums are paid. Sections 1851(a)(3)(B), 1860D–1(a)(3)(A), and 1876(a)(1)(A) of the Act outline the eligibility requirements to enroll in MA, Part D, and Medicare Health Maintenance Organization/Competitive Medical Plans (cost plans). In all options, individuals must have active Medicare coverage. Specifically, to enroll in MA, an individual must be entitled to Part A and enrolled in Part B; to enroll in a PDP, an individual must be eligible for Part D by either being entitled to Part A and/or enrolled in Part B; to enroll in a Medicare cost plan, an individual must be enrolled in Part B but Part A is not required.

In addition, sections 1851(b)(1)(A), 1860D–1(b)(1)(B)(i), and 1876(d) of the Act provide that Medicare beneficiaries are eligible to enroll in an MA plan, PDP, or cost plan only if they reside in the geographic area served by the plan, known as the plan's ''service area.'' As noted earlier, an individual who is incarcerated still meets the eligibility requirements for Part A and Part B and is eligible generally to enroll in an MA plan, PDP, or cost plan. However, residence in a plan's service area is also a condition for eligibility to enroll in an MA plan, PDP or cost plan. See § 422.50(a)(3)(i) for MA plans, § 423.30(a)(1)(ii) for PDPs, and § 417.422(b) for cost plans. If a member no longer resides in the service area, plans must disenroll that individual per rules at § 422.74(a)(2)(i) and § 422.74 (d)(4) for MA plans, § 423.44(b)(2)(i) for PDPs, and § 417.460(b)(2)(i) for cost plans.

a. Changes in Definition of Service Area for Cost Plans (§ 417.1)

In order to implement the exclusion from Medicare coverage for incarcerated individuals under section 1862(a)(3) of the Act in the case of MA plans and PDPs, we explicitly excluded facilities in which individuals are incarcerated from an MA plan's service area by including this exclusion in the definition of ''service area'' (54 FR 41734 and 72 FR 47410). Specifically, ''service area'' is defined in § 422.2 for

MA plans and § 423.4 for PDPs and both definitions indicate that facilities in which individuals are incarcerated are considered outside of the service area.

We did not include a similar service area exclusion in the case of cost plans. To the extent that cost plans do not incur costs for incarcerated enrollees because their health care costs are covered by the facility, there would be no costs claimed on the cost report, and no Medicare payment. Nonetheless, to ensure that no cost payments are made, we propose to revise the definition of service area in § 417.1 to specifically note that facilities in which individuals are incarcerated are not a part of the service area. This adjustment will ensure parity among the various Medicare plan coverage options and be the basis for ensuring that services are not paid for by the Medicare Trust Funds for those who are not eligible for them.

b. Involuntary Disenrollment for Incarcerated Individuals Enrolled in MA, PDP and Cost Plans (§ 417.460, § 422.74, and § 423.44)

Sections 1860D–1(b)(1)(B)(i), 1851(b)(1)(A), and 1876(a)(1)(A) of the Act provide that individuals whose permanent residence is outside the plan's service area are ineligible to enroll in or to remain enrolled in the MA, Part D, or cost plan. Based on the definition of service area established in § 422.2 and § 423.4, this applied to individuals who were incarcerated as well. As such, individuals who became incarcerated while enrolled were ineligible to remain enrolled because they did not meet the eligibility criterion of residing in the MA plan or PDP's service area. As noted previously, the regulations for cost plans currently do not exclude incarcerated individuals from enrolling or remaining enrolled in these plans.

At the time of the implementation of Part D, the data regarding incarceration were not as robust as they are at the present time. To compensate, we provided instructions in sub-regulatory guidance that required MA plans and PDPs to investigate a notification from CMS of an individual's incarcerated status. If a plan could not confirm the status, the plan would then apply the policy for investigation of a possible out-of-area status which would allow an incarcerated individual to remain enrolled in the plan for up to 6 or 12 months for MA plans or PDPs, respectively. Cost plans, on the other hand, are not currently subject to similar instructions and therefore individuals are not disenrolled solely because they are determined to be incarcerated.

Today we believe that the data that CMS receives from SSA regarding the incarceration status of Medicare beneficiaries are reliable enough for the purpose of involuntary disenrollment from MA, Part D, and cost plans. Thus, we propose to amend § 417.460(b)(2)(i), § 417.460(f)(1)(i), § 422.74(d)(4)(i), § 422.74(d)(4)(v) and add § 423.44(d)(5)(iii) and § 423.44(d)(5)(iv) to establish that MA organizations, PDPs, and cost plan organizations must disenroll individuals incarcerated for 30 days or more upon notification of such status from CMS. As a part of this change, CMS will review the incarceration data provided by SSA. Where possible, CMS will involuntarily disenroll individuals who are incarcerated based on the data provided by SSA, and will notify the plan in which the individual is enrolled of this action. For all such disenrollments, the effective date of disenrollment will be the first of the month after the start of incarceration date as reported by SSA. We believe these proposed changes will prevent months of improper payments to MA, Part D, and cost plans and significantly lessen the burden for MA plans and PDPs by not requiring investigation to verify residence as outlined in section 50.2.1 in Chapter 2 of the Medicare Managed care Manual and Chapter 3 of the Medicare Prescription Drug Benefit Manual.

In connection with this change, we would also propose to deny enrollment requests for individuals if CMS data indicates an active incarceration status of at least 30 days. Based on the data received from SSA, if incarceration is denoted, we will deny that enrollment based on the data provided by SSA and will notify the plan of the denial. This would replace the current process requiring plans to accept the enrollment and immediately begin the process to verify that the individual was out of the plan's service area. We will provide operational instructions in subregulatory guidance.

In addition, we will clarify that in instances where a plan receives information about an individual's possible incarceration from a source other than CMS or learns of some other permanent residence change, the existing requirements to research a possible change in address would still apply. Finally, we note that the exceptions to involuntary disenrollment for not residing in the plan's service area (§ 417.460(f)(2) and § 422.74(d)(4)(iii)) would not apply to members who are determined to be incarcerated. However, individuals involuntarily disenrolled will be able to enroll in a plan following their release from incarceration using an existing special enrollment period outlined in section 30.4.1 in Chapter 2 of the Medicare Managed Care Manual and section 30.3.1 in Chapter 3 of the Medicare Prescription Drug Benefit Manual (Special Enrollment Periods (SEP) for Changes in Residence). Individuals wanting to enroll in an open cost plan may do so as long as the cost plan is accepting applications for enrollment, following section 30.1 of Chapter 17–D of the Medicare Managed Care Manual.

36. Rewards and Incentives Program Regulations for Part C Enrollees (§ 422.134)

CMS has provided subregulatory guidance regarding the types of rewards and incentives that may be offered to current Medicare Advantage (MA) plan enrollees. (See Section 70.2, Chapter 3 of the Medicare Managed Care Manual). Generally, such activities are limited to a set monetary cap, and cannot be offered in the form of cash or other monetary rebates or considered a health benefit. This guidance generally flows from our authority to regulate marketing by MA organizations and our recognition that certain marketing efforts may be targeted to current enrollees to encourage continued enrollment and reenrollment in a particular plan.

Every year, CMS receives inquiries from MA organizations that wish to expand the scope of the rewards and incentives that currently may be offered to beneficiaries enrolled in their MA plans. In some cases, MA organizations wish to extend rewards and incentives already offered to their commercial members to their Medicare enrollees and there is some evidence to suggest that health-driven reward and incentive programs for currently enrolled members of health plans may lead to meaningful and sustained improvement to their health behaviors and health outcomes.

CMS would like to enable MA organizations to offer health-driven rewards and incentives programs that may be applied to more health-related services and activities than are allowed under current guidance. We are concerned about the possibility that such programs would be targeted only to healthier enrollees, and discourage sicker enrollees from participating in such incentives and in remaining enrolled in the plan. Furthermore, we would like to strengthen our existing subregulatory guidance and offer the opportunity for public review and

comment on our requirements for rewards and incentives programs. We propose to amend our regulations to establish parameters for rewards and incentives programs offered to enrollees of MA plans. We also propose to include specific requirements regarding rewards and incentives so as to ensure that such programs do not discriminate against beneficiaries, including those who are sick or disabled.

Section 1856(b)(1) of the Act provides authority for the establishment of MA standards by regulation, and section 1857(e)(1) of the Act provides authority to impose contract requirements that CMS finds ''necessary and appropriate.'' Section 1852(b)(1)(a) of the Act states that MA organizations may not discriminate against beneficiaries on the basis of health status and that CMS may not approve an MA plan if that offering is susceptible to discrimination based on an individual's health status. Further, section 1857(g)(1)(D) of the Act provides authority for taking intermediate sanction action against an MA organization which ''engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment by eligible individuals'' as a result of their health status or history. We propose to rely upon the aforementioned rulemaking and substantive authority to establish requirements for rewards and incentives programs offered by MA organizations to Medicare beneficiaries enrolled in their MA plans.

Specifically, we propose adding a new provision at § 422.134 that would allow MA organizations to offer reward and incentive programs to their current Medicare enrollees to encourage their participation in activities that focus on promoting improved health, preventing injuries and illness, and promoting efficient use of health care resources. We would require that reward-eligible activities be designed so that all enrollees are able to earn rewards without discrimination based on race, gender, chronic disease, institutionalization, frailty, health status, and other impairments. Any rewards and incentives program implemented by an MA organization under our proposal must accommodate enrolled beneficiaries who are institutionalized or who need a modified approach to enable effective participation.

To meet the proposed CMS requirements, a reward or incentive would have to be earned by completing the entire health-related service or activity and may not be offered for completion of less than all required components of the eligible service or activity. Under this proposal, rewards and incentives would be subject to a monetary cap in an amount CMS determines could reasonably be expected to affect enrollee behavior while not exceeding the value of the health-related service or activity itself. We intend to provide guidance on this qualitative standard on a regular basis.

In addition, our proposal would require MA organizations that offer rewards and incentives programs to provide information about the effectiveness of such programs to CMS upon request. If we determine that the rewards and incentives programs are not compliant with our regulatory standard, we may require that the MA organization modify the basic parameters of the program.

37. Expand Quality Improvement Program Regulations (§ 422.152)

Section 1852(e) of the Act requires MA organizations to have an ongoing quality improvement program for the purpose of improving the quality of care provided to enrollees. Our current regulations at § 422.152 require an MA organization to have a quality improvement program that measures, records, and reports on the quality of care it is providing to enrollees and to develop criteria for a chronic care improvement program. We have recently expanded our quality improvement program to include more specific and structured chronic care improvement program requirements that are outcomes based and health driven as well as require each MA organization to have a written quality improvement program plan (approved form CMS–10209). Currently, chronic care improvement programs must be measurable, reported on annually, and has a clinical focus (as determined by CMS).

We propose revising paragraph (a) of § 422.152 in order to codify our recent expansion of the quality improvement program policies and revising paragraph (c) of § 422.152 to codify our recently expanded chronic care improvement program policies. These revised paragraphs will more accurately reflect current quality care improvement program policies and requirements.

Additionally, paragraph (g) of § 422.152 lists quality improvement program requirements that are specific to special needs plans (SNPs). We propose revising paragraph (g) to clarify that the requirements listed there are in addition to program requirements listed in paragraphs (a) and (f) of § 422.152 and are not instead of the regular quality improvement program requirements.

Finally, we propose to delete paragraph (h)(2) of § 422.152 as it pertains to plan year 2010 and is no longer relevant.

38. Authorization of Expansion of Automatic or Passive Enrollment Non-Renewing Dual Eligible SNPs (D–SNPs) to Another D–SNP To Support Alignment Procedures (§ 422.60)

At this time, SNPs are only authorized through 2014. This proposed provision, which would take effect in 2015, is contingent upon, and would only apply, if SNPs continue to be authorized after 2014.

Since D–SNPs were implemented in 2006, expectations for them to serve as a vehicle for aligning Medicare and Medicaid benefits for dually eligible individuals have been articulated. In 2007, the Congress passed the Medicare Improvements for Patients and Providers Act (MIPPA), which set 2013 as the deadline for all D–SNPs to have contracts with states to coordinate their enrollees' Medicaid coverage. In 2010, the Congress passed the Affordable Care Act, section 2602 of which established a new CMS office charged with implementing goals to improve the coordination between the federal government and states for individuals eligible for benefits under both Medicare and Medicaid programs in order to ensure that such individuals get full access to the items and services to which they are entitled. Specifically listed in sections 2602(c)(2) and (6) of the Affordable Care Act, we are tasked with simplifying the processes for Medicare-Medicaid enrollee to access the items and services they are entitled to under the Medicare and Medicaid programs, and improving care continuity and ensuring safe and effective care transitions for Medicare-Medicaid enrollees.

Our current authority does not allow us to limit involvement in the D–SNP program to fully integrated D–SNPs; thus, the majority of Medicare-Medicaid enrollees enrolled in D–SNPs continue to receive their Medicare and Medicaid benefits and services from two different organizations. At the same time, some states are approaching this problem from a slightly different angle, and are attempting to align care for Medicare-Medicaid enrollees under the same organization by requiring that the same organization that provides Medicaid benefits also provide Medicare benefits. However, states' efforts stall when the Medicare-Medicaid enrollee is enrolled with one organization for his/her Medicaid coverage, but in a D–SNP offered by another MA organization. The statute generally requires that

Medicare beneficiaries make an active choice of their health plan, so neither plans nor states can choose where the beneficiary enrolls.

The resulting fragmentation of care can generally be addressed through existing mechanisms. For example, State Medicaid Agencies may pursue waiver authority from CMS to require Medicare-Medicaid enrollees to enroll in Medicaid Managed Care Organizations (MCO) that also offer a D–SNP. Likewise, anMA organization offering a D–SNP could novate its contract with CMS to the organization offering the Medicaid MCO, so that the entire contract, including the D–SNP, and its enrollees, is now held by the same organization that offers the enrollees' Medicaid managed care plan. However, while we can approve novations, we cannot mandate that the parties enter into such arrangements. Moreover, when an MA organization elects to non-renew its Medicare contract, rather than novate the contract, we do not have the authority to move enrollees under that contract to another MA organization offering a D–SNP.

Another possible solution to the problem of fragmented care lies in section 1851(c)(1) of the Act, which we have interpreted to provide flexibility in developing mechanisms by which beneficiaries may complete voluntary MA enrollment elections (per section 1851(a)(1) of the Act). These flexibilities include a process described as ''passive enrollment,'' whereby beneficiaries are notified of the enrollment opportunity and provided sufficient advance information to determine if they will accept this option. A beneficiary who is offered a passive enrollment completes the request to enroll by not declining the offer. However, we have limited passive enrollment to situations in which enrollees in MA plans that are terminating immediately have little or no time to choose another MA plan option or stand-alone PDP, and are at risk for losing their prescription drug coverage (see 42 CFR 422.60(g)).

Generally, we have declined to afford ourselves such discretion to provide passive enrollment in more situations, in part, because of concerns raised by beneficiary advocates about the challenges beneficiaries face in navigating a new provider network and understanding information about new benefits. In addition, we have also been concerned that, were we to widen the scope of our authority to allow passive enrollment in other situations not involving an immediate termination, we would be faced with the seemingly impossible task of sorting through requests by MA organizations to passively enroll members to other plans within their organization, or across organizations, and granting or denying such requests without appearing to act in an arbitrary and capricious manner, or unintentionally interfering with the voluntary nature of the MA program. Thus, we have limited our use of our passive enrollment authority by regulation to those situations in which beneficiaries faced an immediate plan termination or potential harm, and where we could, through passive enrollment, ensure that beneficiaries maintained access to affordable coverage, including prescription drug coverage.

To date, we have not considered D–SNP non-renewals to fall under either category, because, by definition, non-renewals occur with appropriate, 90 days' notice to affected enrollees, just prior to the start of the annual enrollment period, when enrollees have access to the Medicare & You handbook and other materials, as well as ample time to consider their health care choices.

However, it is worth noting that returning to Original Medicare, whether due to an immediate contract termination or non-renewal, poses potential disadvantages for the beneficiary as well, that is, the loss of supplemental benefits such as dental or vision benefits, and beneficiary confusion as he or she attempts to navigate the health care system (and two sets of benefits) without case management or other support that may have been provided by the MA plan. We have the authority to widen the scope of the regulation slightly to allow for passive enrollment when a Medicare-Medicaid enrollee is enrolled in a D–SNP that is non-renewing its contract with Medicare, and is enrolled in a Medicaid MCO (Managed Care Organization) that also offers a D–SNP, and the networks and benefits of the non-renewing D–SNP and the future D–SNP are substantially similar. By exercising passive enrollment in this additional limited circumstance, we could better ensure better continuity of care, particularly prescription drug coverage, but also possibly supplemental benefits, and ensure beneficiaries enjoy use of the same providers, with little or no change in the benefits offered. Our use of passive enrollment in this case would also further promote alignment of Medicare and Medicaid benefits offered by the same organization. Through sub-regulatory guidance, we would interpret the ''substantially similar'' standard as it relates to the networks, benefit packages, formularies, and out of pocket costs of the non-renewing and gaining D–SNP. As already required by § 422.60(g)(2), we would ensure beneficiaries are notified of the costs and benefits of the plan, and of their ability to decline enrollment or choose another plan. As part of our proposal to add this additional basis for passive enrollment, we propose to restructure paragraph (g).

B. Improving Payment Accuracy

1. Implementing Overpayment Provisions of Section 1128J(d) of the Social Security Act (§ 422.326 and § 423.360)

This section of the proposed rule would implement section 6402 of the Affordable Care Act, which established new section 1128J(d) of the Act entitled Reporting and Returning of Overpayments. Section 1128J(d)(4)(B) of the Act defines the term overpayment as any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title. The definition of person at section 1128J(d)(4)(C) of the Act includes a Medicare Advantage organization (as defined in section 1859(a)(1) of the Act) and a Part D sponsor (as defined in section 1860D–41(a)(13) of the Act). The definition does not include a beneficiary.

Section 1128J(d)(1) of the Act requires a person who has received an overpayment to report and return the overpayment to the Secretary, the state, an intermediary, a carrier, or a contractor, as appropriate, at the correct address, and to notify the Secretary, state, intermediary, carrier or contractor to whom the overpayment was returned in writing of the reason for the overpayment. Section 1128J(d)(2) of the Act requires that an overpayment be reported and returned by the later of: (1) The date which is 60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable. Section 1128J(d)(3) of the Act specifies that any overpayment retained by a person after the deadline for reporting and returning an overpayment is an obligation (as defined in 31 U.S.C. 3729(b)(3)) for purposes of 31 U.S.C. 3729.

Finally, section 1128J(d)(4)(A) of the Act defines ''knowing'' and ''knowingly'' as those terms are defined in 31 U.S.C. 3729(b). Specifically, the terms ''knowing'' and ''knowingly'' mean that ''a person with respect to information: (1) Has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the

information; or (3) acts in reckless disregard of the truth or falsity of the information.'' There need not be ''proof of specific intent to defraud.''

To implement section 1128J(d) of the Act for the Part C Medicare Advantage program and the Part D Prescription Drug program, we are proposing two new sections, § 422.326 and § 423.360, respectively, both titled, ''Reporting and Returning of Overpayments.'' These sections propose rules for MA organizations and Part D sponsors to report and return an identified overpayment to the Medicare program. We are using the term Part D sponsor, as defined at § 423.4, to refer to the entities that offer prescription drug plans (PDPs) under part 423 and thus are subject to section 1128J(d) of the Act.

We propose conforming amendments to § 422.1, § 422.300, and § 423.1 that add a reference to section 1128J(d) of the Act to the existing list of statutory authorities for the regulations governing the MA organizations and Part D sponsors. We also propose to amend § 422.504(l) and § 423.505(k) to incorporate a reference to the proposed § 422.326 and § 423.360, respectively, in order to extend the existing data certification requirement to data that MA organizations and Part D sponsors submit to CMS as part of fulfilling their obligation to return an overpayment under section 1128J(d) of the Act. Section 422.504(l) refers to certification of data ''as a condition for receiving a monthly payment'' and § 423.505(k) refers to certification of data for enrollees ''for whom the organization is requesting payment.'' Our proposal to implement section 1128J of the Act contains requirements that apply after CMS has completed prospective monthly payments for a year, and organizations are no longer ''requesting payment'' because applicable reconciliation has occurred. Applicable reconciliation is the point when organizations submit their final data for the previous payment year. Accordingly, if an MA organization or Part D sponsor has identified an overpayment, there clearly is a different state of ''best knowledge, information, and belief'' than the state of knowledge, information, and belief that existed prior to applicable reconciliation. Thus, we propose to require that the CEO, CFO, or COO must certify (based on best knowledge, information, and belief) that information the MA organization or Part D sponsor submits to CMS for purposes of reporting and returning of overpayments under § 422.326 and § 423.360 is accurate, complete, and truthful.

We remind all stakeholders that even in the absence of a final regulation on these statutory provisions, MA organizations and Part D sponsors are subject to the statutory requirements found in section 1128J (d) of the Act and could face potential False Claims Act liability, Civil Monetary Penalties (CMP) Law liability, and exclusion from Federal health care programs for failure to report and return an overpayment. Additionally, MA organizations and Part D sponsors continue to be obliged to comply with our current procedures for handling inaccurate payments.

a. Terminology (§ 422.326(a) and § 423.360(a))

We propose to adopt the statutory definition of overpayment, where an overpayment exists when—after ''applicable reconciliation''—an MA organization or Part D sponsor is not entitled to funds it has received and/or retained. In order to clarify the statutory definition of overpayment, we propose definitions of two key terms at § 422.326(a) and § 423.360(a): ''funds'' and ''applicable reconciliation.''

We propose to define ''funds'' as payments an MA organization or Part D sponsor has received that are based on data that these organizations submitted to CMS for payment purposes and for which they have responsibility for the accuracy, completeness, and truthfulness of such data under existing § 422.504(l) and § 423.505(k). For Part C, the data submitted by the MA organization to CMS includes § 422.308(f) (enrollment data) and § 422.310 (risk adjustment data). For Part D, data submitted by the Part D sponsor to CMS includes data submitted under § 423.329(b)(3), § 423.336(c)(1), § 423.343, and data provided for purposes of supporting allowable costs as defined in § 423.308 of this part which includes data submitted to CMS regarding direct or indirect remuneration (DIR).

There are additional payment-related data CMS uses to calculate Part C and Part D payments that are submitted directly to CMS by other entities, such as the Social Security Administration (SSA), which is the authoritative source for data they submit to CMS. We believe that MA organizations and Part D sponsors cannot be held accountable for the accuracy of data controlled and submitted to us by other entities.

For example, the SSA is the authoritative source for date of death. An MA organization or Part D sponsor generally do not submit a date of death directly to CMS' systems; it comes from the SSA data feed. When the SSA submits to CMS corrected data regarding a beneficiary's date of death, CMS' systems recalculate the payments made to the plan for that beneficiary and recoup the incorrect payment in a routine retroactive payment adjustment process.

When CMS recoups an incorrect payment from an MA organization or Part D sponsor based on data corrections submitted by authoritative sources such as the SSA, CMS would not consider this recoupment to be the return of an overpayment by an MA organization or Part D sponsor under proposed § 422.326 and § 423.360. Therefore, the proposed meaning of ''funds'' refers to a payment amount that an MA organization or Part D sponsor received from CMS that is based on data that the MA organization or Part D sponsor controls and submits to CMS.

The term ''applicable reconciliation'' refers to an event or events after which an overpayment can exist under section 1128J(d) of the Act. We propose definitions of the term applicable reconciliation that are specific to the Part C and Part D.

For Part C, we propose that applicable reconciliation occurs on the date that CMS announces as the final deadline for risk adjustment data submission. (See section II.B.6 of this proposed rule for a discussion of the final deadline for risk adjustment data submission established at § 422.310(g).) For each payment year, we apply three sets of risk scores to adjust payments: Initial and midyear risk scores during the payment year (both sets are based on incomplete diagnosis data from the data collection year); and final risk scores after the payment year using data MA organizations submit on or before the final deadline for risk adjustment data (which reflects complete data for the data collection year). Currently, the final deadline for risk adjustment data submission is a month after the end of the payment year. In future years, we expect to announce a date that will be about 6 to 8 weeks after the end of the payment year to accommodate the current subregulatory requirement that MA organizations review the monthly enrollment and payment reports they receive from CMS within 45 days of the availability of the reports. Moving this deadline means that the risk adjustment data submission deadline would also function as the Part C applicable reconciliation date. We would announce a final risk adjustment data submission deadline that falls on or just after the conclusion of this 45-day period for the January payment.

For Part D sponsors, we propose that applicable reconciliation is the later of either: The annual deadline for

submitting prescription drug event (PDE) data for the annual Part D payment reconciliations referred to in § 423.343 (c) and (d) or the annual deadline for submitting DIR data. The annual deadline for submitting PDE data is the last federal business day prior to June 30th of the year following the benefit year being reconciled. The annual deadline for submitting DIR data is announced annually through subregulatory guidance and generally occurs around the last business day in June the year following the benefit year being reconciled. We select these events to define the Part D applicable reconciliation because these data are used for the purposes of determining final Part D payment reconciliation. Note that MA organizations would still have to submit all final risk adjustment diagnoses for Part D on the final deadline for risk adjustment data submission.

The proposed approach to defining applicable reconciliation establishes dates that differ for Part C and Part D. One effect of this approach is that risk adjustment and enrollment data for Part D are subject to the § 423.360 overpayment requirements at a later date than risk adjustment and enrollment data for Part C. The final risk adjustment data submission deadline for Parts C and D data would continue to be earlier than the deadline for final submission of PDE and DIR data. For this reason, we considered an alternative approach to defining applicable reconciliation, where there is one date for applicable reconciliation for both Parts C and D risk adjustment data and enrollment data (which would be about 6 to 8 weeks after the end of the payment year, going forward), and then the Part D program would be subject to a second applicable reconciliation date the date for final submission of PDE data or DIR data, whichever is later. We are proposing a single date for each program, and we seek comment on these two approaches.

Note that payment errors identified as a result of any corrections to risk adjustment data submitted by MA organizations (and other organizations required to submit risk adjustment data to CMS) on or before the annual final risk adjustment data submission deadline are handled as part of the current annual process of risk adjustment payment reconciliation. Because these payment errors are prior to the date defined in this proposed rule as ''applicable reconciliation,'' we do not consider these errors to be overpayments for the purpose of § 422.326 and § 423.360. That is, any deletions of risk adjustment data in the file submitted on or before the final risk adjustment data submission deadline for a payment year, would result in payment errors that are addressed with processes that have been in place prior to our codification of section 1128J(d) of the Act in proposed § 422.326 and § 423.360.

Likewise, for Part D, any payment errors identified as a result of any corrections to PDE or DIR data submitted on or before the later of the annual deadline for submitted PDE and DIR data are handled as part of the current Part D reconciliation process.

It is our expectation that MA organizations and Part D sponsors must be continuously diligent regarding the accuracy and completeness of payment-related data they submit to CMS for a payment year, whether during or after that payment year, and whether before or after applicable reconciliation dates. This expectation is based on existing requirements at § 422.310, § 422.504(l), § 423.329(b)(3)(ii), and § 423.505(k), and our proposed amendments that clarify and strengthen these requirements.

b. General Rules for Overpayments (§ 422.326(a) Through (c); § 423.360(a) Through (c))

We propose at § 422.326(b) and § 423.360(b) that if an MA organization or Part D sponsor has identified that it has received an overpayment, the MA organization or Part D sponsor must report and return that overpayment in the form and manner set forth in the section. In paragraphs § 422.326(c) and § 423.360(c), we propose that the MA organization or Part D sponsor has identified an overpayment if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the existence of the overpayment. The terms ''reckless disregard'' and ''deliberate ignorance'' are part of the definitions of the ''knowing'' and ''knowingly'' in section 1128J of the Act, which provides that the terms ''knowing'' and ''knowingly'' have the meaning given those terms in the False Claims Act (31 U.S.C. 3729(b)(3)). Without such a proposal to include ''reckless disregard'' and ''deliberate ignorance'', some MA organizations and Part D sponsors might avoid performing activities to determine whether an overpayment exists. We also provide that if an MA organization or Part D sponsor has received information that an overpayment may exist, the organization must exercise reasonable diligence to determine the accuracy of this information, that is, to determine if there is an identified overpayment.

Finally, in paragraphs § 422.326(d) and § 423.360(d), we propose the requirements for reporting and returning an identified overpayment. An MA organization or Part D sponsor must report and return any overpayment it received no later than 60 days after the date on which it identified it received an overpayment. The statute provides an alternative deadline: the date any corresponding cost report is due, if applicable. We propose that this alternative deadline is not applicable to the Parts C or D programs because, in general, MA organizations and Part D sponsors are paid based on their bids, and not based on their actual incurred costs.

The MA organization or Part D sponsor must notify CMS, using a notification process determined by CMS, of the amount and reason for the overpayment. Also within this 60-day time period, the organization must return identified overpayments to CMS in a manner specified by CMS, including the amount and reason for the overpayment. We codify at paragraph (3) the statutory requirement that any overpayment retained by an MA organization or Part D sponsor after the 60-day deadline for reporting and returning is an obligation under 31 U.S.C. 3729(b)(3).

It also is important to note that the MA organization and Part D sponsor are deemed to have returned the overpayment when they have taken the actions that we will specify, in forthcoming operational guidance, to submit the corrected data that is the source of the overpayment. We will recover the returned overpayment through routine processing according to the systems schedule established in the annual operations budget. That is, payments are recovered through the established payment adjustment process, not on the 60-day schedule that applies to each MA organization or Part D sponsor that has identified an overpayment. Rerunning reconciliation each time an entity identifies an overpayment that triggers its 60-day clock is simply not feasible for CMS.

Further, there will be circumstances when we may ask the MA organization or Part D sponsor to provide an auditable estimate of the overpayment amount, reason for overpayment, and make a payment to CMS. This may occur, for example, when the Part D reopening occurs prior to the end of the look-back period or if an MA organization or Part D sponsor had a thoroughly-documented catastrophic loss of stored data. Information about the nature of such a request would be detailed in forthcoming operational guidance.

c. Look-Back Period for Reporting and Returning Overpayments

We propose at § 422.326(e) and § 423.360(e) to codify a look-back period for MA organizations and Part D sponsors. MA organizations and Part D sponsors would be required to report and return any overpayment that they identify within the 6 most recent completed payment years. The statute of limitations related to the False Claims Act is 6 years from the date of the violation or 3 years from the date the relevant government official learns of the situation, but in no case more than 10 years from the date of the violation. CMS proposes 6 years as the look-back period because we believe this best balances government's interest in having overpayments returned with entities' interest in finality. Six years also is consistent with the CMP provisions, and maintenance of records requirements under the contracts. Note that overpayments resulting from fraud would not be subject to this limitation of a look-back period.

2. Determination of Payments (§ 423.329)

Section 423.329 (d) describes the low-income cost-sharing subsidy payment amount. Currently, that amount is defined as the amount described in § 423.782. However, § 423.782 refers to the cost-sharing paid by the beneficiary, not the cost-sharing subsidy paid on behalf of the low-income subsidy eligible individual. As such, we propose a technical change to § 423.329(d) to correctly describe the low-income cost-sharing subsidy payment amount as it is intended by statute and has been implemented and described in interpretive guidance by CMS.

The low-income cost-sharing subsidy amount is correctly described in Chapter 13 of our Medicare Prescription Drug Benefit Manual, Premium and Cost-Sharing Subsidies for Low-Income Individuals (Rev. 13, July 29, 2011). Under the basic benefit defined at § 423.100, the low-income cost-sharing subsidy payment amount is the difference between the cost sharing for a non-LIS beneficiary under the Part D plan and the statutory cost-sharing for the LIS eligible beneficiary. Under an enhanced alternative plan described at § 423.104(f), the cost-sharing subsidy applies to the beneficiary liability after the plan's supplemental benefit is applied. We propose to amend § 423.329(d) consistent with this guidance.

Pursuant to § 423.2305, any coverage or financial assistance other than basic prescription drug coverage, as defined in § 423.100, offered by an employer group health or waiver plans is considered ''other health or prescription drug coverage.'' This definition applied to all of Medicare Part D. (See 77 FR 22071 and 22082; April 12, 2012). Therefore, the subsidy amount received by an employer group health or waiver plan is the subsidy amount received by a Part D plan offering defined standard coverage, as defined in § 423.100.

Based on the preceding, we propose to amend § 423.329(d) by deleting the reference to § 423.782 and amending § 423.329(d) to define the low-income cost-sharing subsidy payment amount on behalf of a low-income subsidy eligible individual enrolled in a Part D plan for a coverage year as the difference between the Part D cost-sharing for a non-low-income subsidy eligible beneficiary under the Part D plan and the statutory cost-sharing for a low-income subsidy eligible beneficiary.

3. Reopening (§ 423.346)

a. Part D Plan Payments Reopening

As stated in our final rule entitled, ''Medicare Program; Medicare Prescription Drug Benefit'' published on January 28, 2005 (70 FR 4194, 4316), the Secretary's right to inspect and audit any books and records of a Part D sponsor or MA organization regarding costs provided to the Secretary would not be meaningful, if upon finding mistakes pursuant to such audits, the Secretary were not able to reopen final determinations made on payment. Therefore, we established reopening provisions that would allow us to ensure that the discovery of any overpayment or underpayment could be rectified. In the rule, we established that a reopening was at our discretion and could occur for any reason within 1 year of the final determination of payment, within 4 years for good cause, or at any time when there is fraud or similar fault. We now propose to amend the reopening provisions such that we may perform one reopening within 5 years after the date of the notice of the initial determination to the Part D sponsors. We also propose to amend the provision to accommodate reopening the Coverage Gap Discount Reconciliation described at § 423.2320(b).

At the time the proposed regulations for reopening were published in our proposed rule entitled, ''Medicare Program; Medicare Prescription Drug Benefit'' in the **Federal Register** on August 3, 2004 (69 FR 46694), we had no experience in Medicare Part D to be able to gauge the need for a reopening of an initial payment determination. We patterned the provisions after the Medicare claims reopening regulations found in part 405. The proposed reopening provisions were subsequently adopted in our final rule published on January 28, 2005 (70 FR 4316) entitled, ''Medicare Program; Medicare Prescription Drug Benefit.

Under the current regulation at § 423.346 (a), CMS may reopen for any reason within 1 year of the final determination of payment, within 4 years for good cause, or any time for fraud or similar fault. ''Good cause'' is defined in the regulation at § 423.346 (b) as: new and material evidence that was not readily available at the time the final determination was made; a clerical error in the computation of payments; or when evidence that was considered in making the determination clearly shows on its face that an error was made. We now better understand the need for reopening a payment determination and modify our regulation at § 423.346 to align with our experience.

We have generally performed global reopenings as a result of plan sponsor requests, and substantial revisions of PDE and DIR data due to plan corrections, CMS corrections of systems error, post reconciliation claims activity, and audit and other post reconciliation oversight activity. To date, contract years 2006, 2007, and 2008 have been reopened, and we have already released guidance stating that we intended to eventually perform a global reopening of 2011 once there is stability in the data for that year. This experience indicates to us that we will likely have to perform a reopening of the initial payment determination for every contract year. Therefore, we propose to remove the current timeframes for a reopening described in § 423.346 (a)(1) through (a)(3), remove paragraphs (b) describing good cause referred to in paragraph (a)(2), modify paragraph (c) to eliminate the reference to ''good cause,'' and amend paragraph (a) such that CMS may reopen one time within 5 years of notice of the initial payment determination.

Based upon our experience, we believe that 5 years is adequate time to allow for data stability. By 5 years after the initial payment determination, additional PDEs or PDE adjustments associated with coordination of benefits will be submitted by Part D sponsors consistent with the timeframe described at § 423.466(b). We know that audits and other post reconciliation oversight activity often take place more than 5 years from notice of the initial payment determination. However, in light of the overpayment provision at section 6402(a) of the Affordable Care Act, which established section 1128J(d) of the Act and that we propose to codify

at § 423.360, we do not believe that it is necessary to reopen a payment reconciliation after that 5-year period, nor do we believe it is necessary to reopen a reconsidered payment determination. Therefore, we propose to amend § 423.346 (a) such that CMS will only reopen the initial payment determination and will not reopen a reconsidered payment determination.

As stated in our final rule entitled, ''Medicare Program; Medicare Prescription Drug Benefit'' published in the **Federal Register** on January 28, 2005 (70 FR 4194), CMS can initiate a reopening on its own or an organization could request a reopening, but such reopenings are at CMS' discretion. In determining whether to reopen, we will consider a number of issues, including, but not limited to, whether the contract has terminated and received a final settlement. We will not approve a request to reopen for a contract that has terminated and received a final settlement. In addition, when we perform a reopening on its own initiative, contracts that have been terminated and settled will not be included in the reopening.

b. Coverage Gap Discount Reconciliation Reopening

Under § 423.2320(b), CMS performs a Coverage Gap Discount Reconciliation in which CMS reconciles interim payments with invoiced manufacturer discount amounts made available to each Part D plan's enrollee under the Discount Program. Since the interim coverage gap payments are estimates (76 FR 63017, 63027 (October 11, 2011)), a cost-based reconciliation is performed to ensure that Part D sponsors are paid dollar for dollar for all manufacturer discount amounts as reported on invoiced PDE data submitted for Part D payment reconciliation. Manufacturer discount amounts reported on PDE records submitted after the PDE submission deadline for reconciliation continue to be invoiced to manufacturers within a maximum of 3 years of the date of dispensing, and manufacturers remit payments for invoiced coverage gap discount amounts to Part D sponsors.

We propose to establish a reopening provision for the Coverage Gap Discount Reconciliation for the same reasons and under the same authority that we established a reopening provision for the Part D payment reconciliation process described in our final rule, ''Medicare Program; Medicare Prescription Drug Benefit'' published on January 28, 2005 (70 FR 4194, 4316). In a Health Plan Management System (HPMS) memorandum dated April 30, 2010, we stated that the final reconciled discount program payments are subject to the reopening provision in § 423.346. We anticipate rarely needing to reopen the Coverage Gap Discount Reconciliation as a result of the invoicing process that continues to occur after the reconciliation process. However, we want to leave open the option to reopen if unforeseen events result in underpayments or overpayments to Part D sponsors. Therefore, we propose to amend § 423.346 to accommodate reopening a Coverage Gap Discount Reconciliation.

Based on the preceding, we propose to revise § 423.346 by removing the phrase ''or reconsidered'' from paragraph (a), amending paragraph (a) to account for the proposed timing of the Part D reopening, removing paragraphs (a)(1) through (3) and (b)(1) through (3); adding a new paragraph (b) to accommodate a Coverage Gap Discount Reconciliation reopening; and revising paragraph (c) to eliminate the reference to ''good cause.''

4. Payment Appeals (§ 423.350)

Pursuant to § 423.2320 (b), we perform a Coverage Gap Discount Reconciliation in which we reconcile interim payments with invoiced manufacturer discount amounts made available to each Part D plan's enrollee under the Discount Program. Current regulations do not describe the appeals process for a Coverage Gap Discount Reconciliation. We propose to establish an appeals provision for the Coverage Gap Discount Reconciliation for the same reasons and under the same authority that was used to establish the Part D payment reconciliation appeals process described in our final rule, ''Medicare Program; Medicare Prescription Drug Benefit'' published on January 28, 2005 (70 FR 4194, 4317). In an HPMS memorandum dated April 30, 2010, CMS stated that the final reconciled discount program payments are subject the appeals provisions in § 423.350, and we now propose to revise § 423.350 to accommodate a Coverage Gap Discount Reconciliation appeals process.

Consistent with the Part D payment appeals process currently described at § 423.350, the proposed changes establish an appeals process whereby the final reconciliation of the interim Coverage Gap Discount Program payments may be subject to appeal. As stated in our final rule describing the Part D payment appeals process (70 FR 4317 (January 28, 2005)), the Part D payment appeals process only applies to perceived errors in the application of the payment methodology and the payment information submitted by the Part D sponsor cannot be appealed through this process. In the January 28, 2005 final rule (70 FR 4317), Part D plans are expected to submit payment information correctly and within the established timelines. We codified at § 423.350(a)(2) that payment information submitted to CMS under § 423.322 and reconciled under § 423.343 is final and may not be appealed nor may the appeals process be used to submit new information after the submission of information necessary to determine retroactive adjustments and reconciliations. We propose to amend § 423.350(a)(2) to include information that is submitted and reconciled under § 423.2320(b) is final and may not be appealed nor may the appeals process be used to submit new information after the submission of information necessary to determine retroactive adjustments and reconciliations.

Also consistent with the Part D payment appeals process, we propose that the request for a reconsideration of the Coverage Gap Discount Reconciliation must be filed within 15 days from the date of the final payment, which is the date of the final reconciled payment made under § 423.2320 (b). Therefore, we propose to amend § 423.350(b)(1) by adding a new paragraph (iv) to define the timeframe for filing a reconsideration of the Coverage Gap Discount Reconciliation.

Based on the preceding, we propose to revise § 423.350 by adding a new paragraph (a)(1)(v) to allow for an appeal of a reconciled coverage gap payment under § 423.2320 (b), by revising paragraph (a)(2) to indicate that the payment information submitted to CMS and reconciled under § 423.2320(b) is final and may not be appealed, and by adding a new paragraph (b)(1)(iv) to define the timeframe for appealing the final reconciled payment under § 423.2320(b).

5. Payment Processes for Part D Sponsors (§ 423.2320)

In our final rule entitled, ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes'' (77 FR 22071, 22086; April 12, 2012), CMS described the payment process for Part D sponsors under the Coverage Gap Discount Program. Under § 423.2320(a), CMS provides monthly interim Coverage Gap Discount Program payments as necessary for Part D sponsors to advance coverage gap discounts to beneficiaries. Part D

sponsors report the gap discount amounts to CMS, and through a contractor, CMS invoices the manufacturers on a quarterly basis for the applicable discount amounts. The manufacturers repay each Part D sponsor directly for the invoiced amounts under the Medicare Coverage Gap Discount Program Agreement (Agreement) described at § 423.2315. Under § 423.2320(b), CMS reconciles the interim payments with amounts invoiced to manufacturers.

In the event that a manufacturer fails to the provide the applicable discounts in accordance with the Agreement, we must impose civil money penalties (CMPs) equal to the sum of the applicable discount the manufacturer would have paid under the Agreement and 25 percent of that amount. The CMP that is equal to the sum of the applicable discount the manufacturer would have paid under the agreement is used to pay the applicable discount that the manufacturer had failed to provide.

In our final rule describing the payment process for Part D sponsors under the Coverage Gap Discount Program, we did not contemplate a payment process in the event that a manufacturer becomes bankrupt and does not pay the Part D sponsors for quarterly invoiced amounts under the Agreement. Even though we will impose a CMP on a bankrupt manufacturer in an effort to collect the unpaid invoiced amounts, the bankruptcy settlements will likely result in the CMP being modified or reduced. In order to ensure that the Part D sponsors have the funds available to advance the gap discounts at the point-of-sale, as required under section 1860D–14A(c)(1)(A)(ii) of the Act, we now propose to amend § 423.2320 such that we will assume financial liability for the applicable discount by covering the costs of the quarterly invoices that go unpaid by a bankrupt manufacturer at the time of the Coverage Gap Discount Reconciliation described at § 423.2320(b). We would then file a proof of claim with the bankruptcy court to recover those costs from the bankrupt manufacturer.

The proposed policy that CMS assume financial liability for the applicable discounts in the event of a manufacturer bankruptcy is consistent with CMS' payment processes for Part D sponsors under the Medicare Coverage Gap Discount Program. Under § 423.2320 (a), CMS provides interim payments to ensure that Part D sponsors have the funds available to advance the coverage gap discount to beneficiaries at point of sale. Under § 423.2320 (b), CMS reconciles the interim payments with the invoiced manufacturer discount amounts in order make the PDP sponsor whole for the gap discount amount provided to the beneficiaries at point of sale. (For more information on these provisions, see October 11, 2011 final rule (76 FR 63017, 63027).) In order to remain consistent with the intent of the Coverage Gap Discount Reconciliation to make the Part D sponsor whole for the gap discounts amounts advanced at point of sale, CMS must provide payments to the Part D sponsor to cover the cost of the applicable discount in the event that the manufacturer cannot pay the quarterly invoices due to a bankruptcy. We propose to cover the costs of unpaid quarterly invoices only in the event that a manufacturer becomes bankrupt. We would not cover the cost of unpaid quarterly invoices for any other reasons because, in the event that a manufacturer fails to pay the quarterly invoices, we will impose CMPs that will cover the cost of the unpaid invoices. In the event that a manufacturer becomes bankrupt, we are concerned that the court will either modify or reduce the amount of the CMP, making the CMP process ineffective for covering the cost of the invoices and leaving the Part D sponsor in the position of having to cover the costs of the gap discount.

We propose to implement this policy by adjusting the Coverage Gap Discount Reconciliation to account for quarterly invoices that go unpaid as a result of a manufacturer becoming bankrupt. This adjustment will only occur for manufacturer discount amounts as they are reported on PDEs submitted by the submission deadline for the Part D reconciliation.

Based on the preceding, we propose to add a new paragraph (c) to § 423.2320 to describe a process for accounting for quarterly invoiced amounts that go unpaid by a bankrupt manufacturer.

6. Risk Adjustment Data Requirements (§ 422.310)

We propose to strengthen existing regulations related to the accuracy of risk adjustment data by amending § 422.310 on risk adjustment data validation. First, we propose to renumber existing paragraph § 422.310(e) as paragraph (e)(2) and add new paragraph (e)(1), which would require that any medical record reviews conducted by an MA organization must be designed to determine the accuracy of diagnoses submitted under § 422.308(c)(1) and § 422.310(g)(2). (Paragraph § 422.308(c)(1) addresses adjustments to payments for health status, and paragraph § 422.310(g)(2) addresses deadlines for risk adjustment data submission, including the final risk adjustment data submission deadline prior to CMS' calculation of the final risk factors for a payment year.) Under our proposal, medical record reviews conducted by an MA organization cannot be designed only to identify diagnoses that would trigger additional payments by CMS to the MA organization; and medical record review methodologies must be designed to identify errors in diagnoses submitted to CMS as risk adjustment data, regardless of whether the data errors would result in positive or negative payment adjustments. This proposed amendment furthers our goals of improving payment accuracy and reducing payment errors.

We also propose to amend § 422.310(g) regarding deadlines for submission of risk adjustment data. Our current procedures generally permit submission of risk adjustment data after the final risk adjustment submission deadline only to correct overpayments. We propose to revise the regulation to explicitly permit late submissions only to correct overpayments but not to submit diagnoses for additional payment.

Finally, we propose to align this regulation with proposed § 422.326 by making two additional changes in paragraph (g). First, we propose the deletion of the January 31 deadline in subparagraph (2) and replacing it with the statement that CMS will announce the deadline by which final risk adjustment data must be submitted to CMS or its contractor. This means that the risk adjustment data submission deadline would also function as the Part C applicable reconciliation date for purposes of proposed § 422.326 on overpayment rules, as discussed in section II.B.1.b. of this proposed rule. Second, we propose to add subparagraph (3) to § 422.310(g). Proposed paragraph (3) cites § 422.326 as the source of rules for submission of corrected risk adjustment data after the final risk adjustment data submission deadline, that is, after applicable reconciliation as defined at § 422.326(a).

7. RADV Appeals

a. Background

We published Risk Adjustment Data Validation (RADV) appeals regulations in the April 15, 2010 **Federal Register**. These rules were proposed and finalized under CMS's authority to establish Medicare Advantage (MA) program standards by regulation at section 1856(b)(1) of the Act and are found at § 422.311 et seq.

As explained in the preamble of that final rule, Subpart G of the MA regulations at part 422 describes how

payment is made to MA organizations. These payment principles are based on sections 1853, 1854, and 1858 of the Act. Subpart G also sets forth the requirements for making payments to MA organizations offering local and regional MA plans, including calculation of MA capitation rates. Section 1853(a)(3) of the Act requires that we risk adjust our payments to MA organizations. Risk adjustment strengthens the Medicare program by ensuring that accurate payments are made to MA organizations based on the health status plus demographic characteristics of their enrolled beneficiaries and ensures that MA organizations are paid appropriately for their plan enrollees (that is, less for healthier enrollees expected to incur lower health care costs and more for less healthy enrollees expected to incur higher health care costs). Accurate payments to MA organizations also help ensure that providers are paid appropriately for the services they provide to MA beneficiaries. In general, the current risk adjustment methodology relies on enrollee diagnoses, as specified by the International Classification of Disease, currently the Ninth Revision Clinical Modification guidelines (ICD–9–CM) to prospectively adjust capitation payments for a given enrollee based on the health status of the enrollee. Diagnosis codes determine the risk scores, which in turn determine the risk adjusted reimbursement. As a result, physicians and providers must focus attention on complete and accurate diagnosis reporting according to the official ICD–9–CM coding guidelines (that is, coding diagnoses accurately and to the highest level of specificity).

MA enrollee Hierarchical Condition Categories (HCCs) are assigned based on risk adjustment diagnoses from FFS claims and from risk adjustment data submitted to us by MA organizations via the Risk Adjustment Payment System (RAPS). The CMS–HCCs contribute to an enrollee's risk score, which is used to adjust a base payment rate. Essentially, the higher the risk score for an enrollee, the higher the expected health care cost for the enrollee. The HCC data that MA organizations submit to CMS via the RAPS system is self-reported by the MA organization and does not go through a validation review before being incorporated into a given beneficiary's risk-profile. Since there is an incentive for MA organizations to potentially over-report diagnoses so that they can increase their payment, the Agency audits plan-submitted diagnosis data a few years later to ensure they are supported by medical record documentation.

Verifiable medical record documentation is the key to accurate payment and successful data validation. We annually select contracts for RADV audits. RADV audits are intended to confirm the presence of risk adjustment conditions (that is, diagnoses that map to HCCs) as reported by MA organizations for their enrollees and confirmed via medical record documentation. RADV audits occur after the final risk adjustment data submission deadline for the MA contract year. We validate the HCC data submitted by MA organizations by reviewing hospital inpatient, hospital outpatient, and physician/practitioner provider medical records. The focus of this medical record review activity is on diagnoses related to the enrollee's HCC profile. Risk adjustment discrepancies are identified when the enrollee's HCCs used for payment (based upon MA organization-submitted data) differ from the HCCs assigned based on the medical record, under the RADV audit process. Risk adjustment discrepancies can be aggregated to determine an overall level payment error. In turn, payment error for a sample of contract enrollees can be extrapolated to calculate a contract-level payment error estimate.

Since finalizing these rules in 2010, we have conducted additional RADV audits and believe that some of the appeals provisions finalized in the 2010 RADV Appeals final rule should now be modified to prevent confusion, and to strengthen the RADV appeals process. We therefore, propose revisions to the RADV appeals regulations finalized in the April 15, 2010 **Federal Register**. These proposed revisions clarify program requirements and simplify the RADV appeals process. These proposed RADV provisions will apply to any RADV determinations issued on or after the effective date of this regulation.

b. RADV Definitions

We propose to amend the RADV definitions at § 422.2 as follows:

- Removing the following definitions:
  - ++ ''Initial Validation Contractor (IVC)'' means the first level of medical record review under the RADV audit process.
  - ++ ''RADV payment error calculation appeal process'' means an administrative process that enables MA organizations that have undergone RADV audit to appeal the CMS calculation of an MA organization's RADV payment error.
  - ++ ''The one best medical record for the purposes of Medicare Advantage Risk Adjustment Validation (RADV)'' means the clinical documentation for a single encounter for care (that is, a physician office visit, an inpatient hospital stay, or an outpatient hospital visit) that occurred for one patient during the data collection period. The single encounter for care must be based on a face-to-face encounter with a provider deemed acceptable for risk adjustment and documentation of this encounter must be reflected in the medical record.
- Adding the following definition:
  - ++ ''RADV appeal process'' means an administrative process that enables MA organizations that have undergone RADV audit to appeal the Secretary's medical record review determinations and the Secretary's calculation of an MA organization's RADV payment error.
- Revising the following definitions:
  - ++ Risk adjustment data validation (RADV) audit means a payment audit of a Medicare Advantage (MA) organization administered by CMS or the Secretary that ensures the integrity and accuracy of risk adjustment payment data.
  - ++ ''Attestation process'' means a CMS-developed RADV process that enables MA organizations undergoing RADV audit to submit CMS-generated attestations for eligible medical records with missing or illegible signatures or credentials. The purpose of the CMS-generated attestations is to cure signature and credential issues for eligible medical records. CMS-generated attestations do not provide an opportunity for a provider or supplier to replace a medical record or for a provider or supplier to attest that a beneficiary has the medical condition.

c. Publication of RADV Methodology

In the October 22, 2009 Notice of Proposed Rule Making (NPRM), and as reinforced in the April 15, 2010 Final Regulation, CMS indicated that we would, ''publish its RADV methodology in some type of public document—most likely, a Medicare Manual, so that the public can review and provide comment as it deems necessary''. We also indicated that we would provide an annual notice of RADV audit methodology. Our last RADV-related notice of methodology was published in February, 2012. We will continue to publish a notice of the methodology employed, but will do so only if there is a change in the RADV methodology that would require publication. We note that these notices of RADV audit

methodology updated information provided on RADV audit methodology provided in the October 22, 2009 proposed rule and April 15, 2010 final rule.

In addition, we provided in the October 22, 2009 proposed rule preamble that we would provide an expanded explanation of methodology and payment error calculation factors as a part of each audit report of findings that we send to MA organizations that undergo RADV audit. Such explanation and factors have been and will continue to be part of the RADV audit report(s) that CMS provides health plans that have undergone RADV audits.

d. Proposal To Update RADV Appeals Terminology (§ 422.311)

Current RADV regulations utilize the following terms for the CMS-issued RADV audit report: Audit report post medical record review; RADV audit report; IVC-level RADV audit report; and RADV audit report of finding. This use of multiple terms to refer to what is the same audit report (the RADV audit report that CMS issues following conclusion of the medical record review portion of the audit) is potentially confusing. Therefore, we propose amending the RADV regulations throughout to adopt one common term to refer to RADV audit reports: ''RADV Audit Report''. By standardizing terminology throughout the RADV regulations, the proposed amendment provides clarity which may lead to increased efficiency. We welcome comment on this proposal.

As mentioned earlier in the description of RADV-related definitions that have changed, we have revised certain RADV-related definitions to accommodate changes to both the RADV audit process and the RADV appeals process. One definition that we have removed from the RADV regulations is Initial Validation Contractor, or IVC. The RADV medical record review process no longer utilizes ''initial'' and ''secondary'' validation contractors to conduct medical record review under RADV. Instead we now utilize medical record reviewers to code medical records undergoing RADV review. These reviewers may be employed by the same or different medical record review contractors. Therefore, the term ''IVC'' is no longer relevant to the RADV audit process. We therefore propose to remove this term from the RADV regulations at the following citations: § 422.311(c)(2)(i)(B) through (D); § 422.311(c)(2)(ii)(B), § 422.311(c)(2)(iii)(A), § 422.111(c)(2)(v), (vi), § 422.311(c)(3)(ii)(A), and § 422.311(c)(3)(iii)(A) and (B). We invite comment on this proposal.

e. Proposal To Simplify the RADV Appeals Process

Currently, there are two types of RADV-related appeals processes described in Federal regulations at § 422.311 et seq.: Medical record review-determination appeals and RADV payment error calculation appeals. RADV medical record review-determination appeal requirements and procedures are discussed at § 422.311(b)(3) and § 422.311(c)(2). Medical record review determination appeal is a two-stage administrative appeal process: The first step is a hearing by a hearing officer, followed by a CMS Administrator-level review. This appeal procedure provides MA organizations with an opportunity to appeal RADV medical record review determinations that are made by coders reviewing the medical record documentation submitted by MA organizations undergoing RADV audit. The second type of RADV appeal, payment error calculation appeal, is discussed at § 422.311(c)(3). Payment error calculation appeal is a three-pronged appeal process: Reconsideration, followed by a hearing officer review, followed by CMS Administrator-level review. This appeal process was specifically designed to afford MA organizations the opportunity to appeal CMS's contract-level RADV payment error calculation.

We propose that the administrative appeals language described at § 422.311(b)(3) and § 422.311(c)(2) for RADV medical record review determination appeals and § 422.311(c)(3) for RADV payment error calculation appeals be replaced with new regulatory language proposed § 422.311(c)(1) et seq., that combines the two existing RADV appeal policies and procedures into one set of requirements and one process. We propose to combine the two RADV appeals processes into one combined RADV appeals process that is comprised of three administrative steps: Reconsideration, hearing officer review, and CMS Administrator-level review. A three-step administrative appeals process comprising reconsideration, hearing officer review, and Administrator-levels of review is a common administrative appeals model used elsewhere within the Medicare managed care program, such as in appealing contract award determinations and intermediate sanctions. The combined RADV appeal process that we are proposing at new § 422.311(c)(1) et seq., also has the benefit of simplifying what is today a complex two-track appeal process into one process. While both CMS and the MA industry will benefit from simplifying this process, MA organizations also obtain an additional level of review under the combined approach since MA organizations will be afforded a reconsideration appeal step for medical record review determinations that is today—not part of the existing RADV appeal process. Shortening the existing two-track appeal process should also reduce the resources and level of effort needed from both MA organizations and CMS in participating in a RADV appeal proceeding. Under this proposal, MA organizations can simply request to appeal their RADV audit findings one time and specify whether they want to appeal either their medical record review determination(s), payment error calculation, or both. The specific details regarding this proposed process follow. We propose these changes based upon our experience with RADV appeals and because we hope to reduce the burden associated with undertaking RADV appeals on both MA organizations and CMS. The details of this proposed policy and procedure follows.

(1) Issues Eligible for RADV Appeal

Current regulations at § 422.311(c)(2) et seq., and § 422.311(c)(3) et seq., specify RADV-related medical record review and payment error calculation documents and issues eligible for the medical record review determination and payment error calculation appeal processes. We propose to amend the policies and procedures around issues eligible for RADV appeals at § 422.311(c)(2) and § 422.311(c)(3) by combining proposed policies and procedures for the existing two-pronged appeal approach into one set of policies and procedures for RADV appeals at the new § part 422.311(c)(2)(iv). At § 422.311(c)(2)(i), we propose that as a general rule, MA organizations may appeal RADV medical record review determinations and RADV payment error calculation, though in order to be eligible to pursue these appeals, we specify at proposed § 422.311(c)(2)(i)(A) and (B) that MA organizations must adhere to established RADV audit procedures and requirements and adhere to RADV appeals procedures and requirements. At § 422.311(c)(2)(ii) we propose that failure to follow RADV audit procedures and requirements and RADV appeals procedures and requirements will render the MA organization's request for RADV appeal invalid. Furthermore, at proposed § 422.311(c)(2)(iii) we stipulate that the

MA organization's written request for medical record review determination appeal must specify the audited HCC(s) that have been identified pursuant to RADV audit as being in error, and further specify that MA organizations must provide a justification in support of the audited HCC(s) that the MA organization elects to appeal. At § 422.311(c)(2)(i) (iv) we propose that for each audited HCC, MA organizations may appeal one medical record that has undergone RADV medical record review and that if an attestation was submitted to cure a signature or credential issue, that attestation may likewise be included in the HCC appeal. For example, if an MA organization submitted a medical record that did not contain a signature and/or credential—and the MA organization submitted an attestation to cure the error that CMS subsequently failed to accept—the MA organization could choose to appeal CMS's determination to not accept the submitted attestation. We reiterate that the purpose of CMS-generated attestations is to cure signature and credential errors associated with an eligible submitted medical record and not to provide an opportunity for a provider or supplier to attest that a beneficiary has a certain medical condition. Evidence for the existence of the medical condition is found in a medical record.

We are proposing to modify our language at § 422.311(c)(2)(i)(v) to clarify existing RADV appeals provisions which stipulate that MA organizations must adhere to the ''one best medical record'' policy. Under changes to the RADV audit methodology announced by CMS in February 2012, we now allow MA organizations to submit more than one medical record (that is, more than the ''one best medical record'') during the RADV audit process to validate an audited CMS–HCC. However, for purposes of appealing a CMS medical record review determination, we will not permit organizations to appeal multiple medical records but will instead—require that MA organizations identify a record from amongst those records submitted, and to submit that record for appeal. For each audited HCC, MA organizations may appeal only one medical record that has undergone RADV review. This policy was published in the February 2012 White Paper and is not included in this proposed rule.

At § 422.311(c)(2)(vi) we propose that a written request for RADV payment error calculation appeal must clearly specify the MA organization's own RADV payment error calculation and must also specify where the payment error calculation was erroneous.

(2) Issues Not Eligible for RADV Appeals

At § 422.311(c)(3) we propose documents and issues that are ineligible for RADV appeals. Consistent with the overall approach of combining into one RADV appeals process what was heretofore two separate RADV appeals processes—by way of this new proposed section, we propose to amend existing regulations at § 422.311(c)(3). At new § 422.311(c)(3), we propose that MA organizations' request for appeal may not include HCCs, medical records or other documents beyond the audited HCC, selected medical record and any accompanying attestation that the MA organization chooses to appeal. We specify at § 422.311(c)(3)(ii) that the MA organizations may not appeal CMS's medical record review determination methodology or CMS's payment error calculation methodology. This is a clarification to existing RADV regulations at § 422.311(c)(3)(D) which specifies that MA organizations may not appeal CMS's payment error calculation methodology. At § 422.311(c)(3)(iii) we specify that MA organizations may not appeal RADV medical record review-related errors when appealing RADV error-calculation issues since medical record review determination issues must be resolved before we can calculate RADV payment errors. And at § 422.311(c)(3)(iv) we specify that RADV errors that result from an MA organization's failure to submit a medical record are not eligible for appeal.

(3) Manner and Timing of a Request for RADV Appeal

We propose to replace existing RADV regulations at § 422.311(c)(2)(iii) et seq., and § 422.311(c)(3)(iii) et seq., regarding the manner and timing of a request for RADV appeals. Again, at § 422.311(c)(5), we propose to combine the formerly two separate sets of requirements and procedures into one RADV appeals process addressing the request for RADV appeal. At § 422.311(c)(5)(i) we propose that at the time the Secretary issues her RADV audit report, the Secretary notifies audited MA organizations that they may appeal RADV HCC errors that are eligible for medical record review determination appeal and may appeal the Secretary's RADV payment error calculation. At § 422.311(c)(5)(ii) we specify that MA organizations have 30 days from the date of CMS's issuance of the RADV audit report to file a written request with CMS for RADV appeal. This request for RADV appeal must specify whether the MA organization requests medical record review determination appeal, whether the MA organization requests RADV payment error calculation appeal, or whether the MA organization requests both medical record review determination appeal and RADV payment error calculation appeal— and in each instance— the issues with which the MA organization disagrees, and the reasons for the disagreements. See proposed regulations at § 422.311(c)(6) et seq.

At new § 422.311(c)(5)(ii) we specify that while MA organizations may now elect to appeal either medical record review determination, payment error calculation, or both—they must notify CMS which issues they will appeal at the same time. This new provision replaces existing RADV appeals requirements regarding notification at § 422.311(c)(2)(iii) and § 422.311(c)(3)(iii)(C).

For MA organizations that elect both medical record review determination appeal and RADV payment error calculation appeal, we specify at § 422.311(c)(5)(iii)(A) and (B) that the Secretary will adjudicate the request for RADV payment error calculation following conclusion of reconsideration of the MA organization's request for medical record review determination appeal. This is necessary because RADV payment error calculations are based upon the outcomes of medical record review determinations. For example, for an MA organization that appeals both medical record review determinations and payment error calculations, the reconsideration official would first adjudicate and rule on the medical record review determinations and then proceed to recalculate the RADV payment error.

(4) Reconsideration Stage

Under current RADV appeals procedures, only the RADV payment error calculation appeal process contains a reconsideration step. We propose to amend existing regulations at § 422.311(c)(3)(iii)(C) and § 422.311(c)(3)(v), (vi), and (vii) by proposing a new reconsideration stage for RADV appeals at § 422.311(c)(6) et seq. Reconsideration is the first stage of the new RADV appeals process and will apply to both medical record review determinations and error calculation issues being appealed. Therefore, MA organizations that elect to appeal RADV audit findings de facto begin the appeal process with the reconsideration step. At proposed § 422.311(c)(6)(i) we specify that a MA organization's written request for medical record review

determination reconsideration must specify the audited HCC identified as being in error that the MA organization wishes to appeal; and to provide a justification in support of the audited HCC chosen for appeal. At proposed § 422.311(c)(6)(ii) we specify that the MA organizations' written request for payment error calculation reconsideration must include the MA organization's own RADV payment error calculation that clearly indicates where the RADV payment error calculation was erroneous. The request for payment error calculation reconsideration may also include additional documentary evidence pertaining to the calculation of the error that the MA organization wishes the reconsideration official to consider.

At proposed § 422.311(c)(6)(iii) we describe the conduct of the reconsideration process that is being proposed. We specify that for medical record review determination reconsideration, a medical record review professional who was not involved in the initial medical record review determination of the disputed HCC reviews the medical record and accompanying dispute justification; and reconsiders the initial audited HCC medical record review determination. For payment error calculation reconsideration, CMS ensures that a third party not involved in the initial RADV payment error calculation reviews the RADV payment error calculation, reviews the MA organization's own RADV payment error calculation, and recalculates the payment error in accordance with CMS's RADV payment error calculation procedures.

At proposed § 422.311(c)(6)(iv), we specify that the reconsideration official issues a written reconsideration decision to the MA organization, and that the reconsideration official's decision is final unless the MA organization disagrees with the reconsideration official's decision. If the MA organization disagrees with the reconsideration official's decision, it may request a hearing.

(5) Hearing Stage

Existing regulations at § 422.311(c)(2)(iv) through (ix) and § 422.311(C)(4) et seq., specify the procedures under which CMS conducts hearings under the RADV appeals process for medical record review and payment error calculation. We propose to replace these provisions with new hearing requirements and procedures at § 422.311(c)(7)(iv).

At § 422.311(c)(7)(i), we propose that at the time the RADV appeals reconsideration official issues his/her reconsideration determination to the MA organization, the reconsideration official notifies the MA organization of any RADV audited HCC errors and or payment error calculations that are eligible for RADV hearing. At § 422.311(c)(7)(ii), we specify that a MA organization that requests a hearing officer review must do so in writing in accordance with procedures established by CMS. At § 422.311(c)(7)(iii), we specify that a written request for a hearing must be filed with the Hearing Officer within 30 days of the date the MA organization receives the reconsideration officer's written reconsideration decision. If the MA organization appeals the medical record review reconsideration determination, the written request for RADV hearing must include a copy of the written decision of the reconsideration official; must specify the audited HCCs that the reconsideration official confirmed as being in error; and must specify a justification as to why the MA organization disputes the reconsideration official's determination. If the MA organization appeals the RADV payment error calculation, the written request for RADV hearing must include a copy of the written decision of the reconsideration official and must include the MA organization's own RADV payment error calculation that clearly specifies where the CMS's payment error calculation was erroneous.

At § 422.311(c)(7)(iv), we propose that a CMS hearing officer conduct the RADV hearing. At § 422.311(c)(7)(v), we specify terms and conditions under which a hearing officer may be disqualified. A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision. A party to the hearing who objects to the assigned hearing officer must notify that officer in writing at the earliest opportunity. The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw. If the hearing officer withdraws, another hearing officer will conduct the hearing. If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to CMS.

At § 422.311(c)(7)(vi) we propose that the hearing officer reviews the medical record and any accompanying attestation that the MA organization selected for review, the reconsideration official's payment error calculation (if appealed), the reconsideration official's written determination, and the written justification submitted by the MA organization and CMS in response to the reconsideration official's determination.

At § 422.311(c)(7)(vii) we propose RADV appeal hearing procedures. We propose that the hearing officer has full power to make rules and establish procedures, consistent with the law, regulations, and rulings. These powers include the authority to dismiss the appeal with prejudice and take any other action which the hearing officer considers appropriate, including for failure to comply with RADV audit and appeals rules and procedures. We propose that the hearing be altogether on the record unless the hearing officer, at his or her full discretion, approves a parties request for a live or telephonic hearing regarding some or all of the medical records in dispute, or if the hearing office schedules a live or telephonic hearing on its own motion. The hearing officer's review will be solely limited to the record. The record is comprised of the RADV reviewed medical record and any accompanying attestation that the MA organization selected for review, the reconsideration official's payment error calculation (if appealed), the reconsideration official's written determination, the written justification submitted by the MA organization in response to the reconsideration official's determination, and written briefs from the MA organization explaining why they believe the reconsideration official's determination was incorrect. In addition, the record will be comprised of a brief from CMS that responds to the MA organization's brief.

In terms of specifying the conduct of the hearing, we propose at § 422.311(c)(7)(vii)(B) that the hearing officer neither receives testimony nor accepts any new evidence that is not part of the record. At § 422.311(c)(7)(vii) we propose that the hearing officer be given the authority to decide whether to uphold or overturn the reconsideration official's decision, and pursuant to this decision—to send a written determination to CMS and the MA organization, explaining the basis for the decision.

At § 422.311(c)(7)(ix), we propose that in accordance with the hearing officer's decision, a third party not involved in the initial RADV payment error calculation recalculate the MA organization's RADV payment error and issue a new RADV audit report to the appellant MA organization and CMS. For MA organizations appealing the

RADV payment error calculation only, we propose that a third party not involved in the initial RADV payment error calculation recalculate the MA organization's RADV payment error and issue a new RADV audit report to the appellant MA organization and CMS. At § 422.311(c)(7)(x) we propose that the hearing officer's decision be final unless the decision is reversed or modified by the CMS Administrator.

(6) CMS Administrator Review Stage

Existing regulations at § 422.311(c)(2)(x) et seq., and § 422.311(C)(4)(vi) et seq., specify the CMS Administrator-level review procedures that CMS adheres to under the current RADV appeals process for medical record review determinations and payment error calculation. We propose to replace these regulations with new RADV appeal-related CMS Administrator review requirements and procedures at § 422.311(c)(8).

At § 422.311(c)(8)(i) and (ii), we propose that a request for CMS Administrator review must be made in writing within 30 days of receipt of the hearing officer's decision; and must be filed with the CMS Administrator by CMS or an MA organization. At § 422.311(c)(8)(iii), we propose that after receiving a request for review, the CMS Administrator has the discretion to elect to review the hearing officer's decision or to decline to review the hearing officer's decision. At § 422.311(c)(8)(iv) we propose that if the CMS Administrator elects to review the hearing decision—the Administrator acknowledges the decision to review the hearing decision in writing and notifies CMS and the MA organization of their right to submit comments within 15 days of the date of the notification. At § 422.311(c)(8)(iv)(B), we propose that the CMS Administrator be limited to the review of the record and that the record be comprised of the hearing record, and written arguments from the MA organization and/or CMS explaining why either or both parties believe the hearing officer's determination was correct or incorrect.

Regarding Administrator-level review procedures at § 422.311(c)(8)(vi), we propose that the Administrator reviews the record and determines whether the hearing officer's determination should be upheld, reversed, or modified. At § 422.311(c)(8)(v), we propose that the Administrator render his or her final decision in writing to the parties within 60 days of acknowledging his or her decision to review the hearing officer's decision. At § 422.311(c)(8)(vi), we propose that the decision of the hearing officer become final if the Administrator declines to review the hearing officer's decision or does not make a decision within 60 days.

Combining these existing RADV medical record review determination and payment error calculation appeals policies and processes improves the overall appeals process by strengthening the depth and integrity of these procedures. We also believe that doing so improves overall RADV appeals procedures by providing clarity that leads to greater efficiencies in adjudicating RADV appeals. We welcome comments on these proposals.

f. Proposal To Expand Scope of RADV Audits

Federal regulations at § 422.311(a) specify that RADV audits are conducted by CMS. We propose to amend this regulation at § 422.311(a) by specifying that the Secretary of the Department of Health and Human Services, along with CMS, may conduct RADV audits beginning with the effective date of this regulation. We also propose to amend RADV definitions at § 422.2 to specify that The Secretary of the Department of Health and Human Services, along with CMS, may conduct RADV audits. We welcome comment on this proposal.

g. Proposal To Clarify the RADV Medical Record Review Determination Appeal Burden of Proof Standard

Our regulations at § 422.311(c)(3)(iv) specify that for RADV payment error calculation appeals, MA organizations bear the burden to prove that CMS failed to follow its stated RADV payment error calculation methodology. However, RADV regulations do not specify a burden of proof standard for the RADV medical record review determination appeal process. The absence of a clearly-defined burden of proof standard for RADV medical record review determination appeals creates an appeal environment where MA organizations, CMS and RADV appellate officials are free to interpret and apply different burden of proof standards when arguing or reviewing appeals cases. We propose to amend the rule with new § 422.311(c)(4) which specifies that the burden of proof for all RADV determinations—be they payment error calculation or RADV medical record review determinations—is on MA organizations to prove, based on a preponderance of the evidence, that CMS's determination was erroneous.

This approach would stand in contrast to a burden of proof standard in which the MA organization were to prove that a valid diagnoses exists on the record, and that therefore, the audited HCC has been validated. This proposed amendment to the rule provides the medical record review determination process a clear burden of proof standard which more aligns with the existing RADV payment error calculation appeals burden of proof standard. Doing so also improves the overall RADV appeals procedures by providing clarity that leads to greater efficiencies in adjudicating RADV appeals. We invite comment on this proposal.

h. Proposal To Change RADV Audit Compliance Date

Currently, the compliance date for RADV audits is the due date when MA organizations selected for RADV audit must submit medical records to CMS or its contractors. We are proposing to change the compliance date for meeting RADV audit requirements for the validation of risk adjustment data to the due date when MA organizations selected for RADV audit must submit medical records to the Secretary—and not only CMS. See proposed regulation language at § 422.311(b)(2).

B. Improving Payment Accuracy

8. Recovery Audit Contractor (RAC) Determination Appeals (Proposed Part 422 Subpart Z and Part 423 Subpart Z)

a. Background

Section 306 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) required the Secretary to conduct a demonstration to determine whether recovery auditors could be used effectively to identify improper payments paid under Medicare Part A and Part B claims. We conducted the demonstration from March 2005 to March 2008 in six states. The Recovery Audit demonstration established recovery auditors as a successful tool in the identification and prevention of improper Medicare payments.

In December 2006, the Tax Relief and Health Care Act of 2006 (TRHCA) (Pub. L. 109–432) was enacted. Section 302(a) of the TRHCA created a permanent Medicare Recovery Audit Contractor (RAC) program and added a new paragraph (h) to section 1893 of the Social Security Act (the Act) that required us to establish a national recovery audit program for Medicare Part A and Part B. The national Medicare Fee-For-Service (FFS) Recovery Audit program was established on January 1, 2010.

Section 6411(b) of the Affordable Care Act amended section 1893(h)(1) of the Act by requiring the establishment of recovery audit programs for Medicare

Parts C and D, in addition to the RAC program already in place for Medicare A and B.

On December 27, 2010, we published a notice in the **Federal Register** (75 FR 81278) requesting comments on how to best implement the RAC program for Parts C and D. Analysis of the comments received assisted us with implementation of the Part C and D RACs.

In January 2011, we entered into a recovery audit contract for Part D. The Part D RAC began recouping identified overpayments in 2012. On December 7, 2012, we published a Request for Quotation (RFQ) via the General Services Administration's (GSA) eBuy seeking quotations on the implementation of a Medicare Part C RAC. We anticipate the award of a Part C RAC contract in FY 2014.

Given that we began recouping overpayments determined by the Part D RAC in 2012, and we anticipate recouping overpayments in Part C after awarding a Part C RAC contract in FY 2014, it is appropriate to provide a codified administrative appeals process to allow for plans to challenge the overpayment findings generated by the RACs just as we provide for challenges to overpayment determinations elsewhere in the Medicare program. In crafting our proposed appeals process for Parts C and D RAC determinations, we reviewed existing appeals processes in other areas, including Parts A and B RAC determinations, Part C RADV Audits, Part D payments, etc.

b. Proposed RAC Appeals Process

After reviewing the agency's existing appeal processes, we determined that the general mechanisms set forth in § 422.311 and § 423.350 offered the most appropriate models for the Part C and D RAC appeals process.

The Part D RAC currently reviews PDE data to identify overpayments and underpayments that are paid back to the plans. When overpayments are identified, Part D plans are notified and funds are recovered. If plans disagree with the calculated overpayment amounts or whether the overpayments are proper, they may appeal the Part D RAC's determination directly to the CMS Center for Program Integrity.

A multilevel independent appeals process is an important component of the Part C and Part D RAC program as it allows plans to appeal determinations they contend are made in error. The administrative appeals mechanisms in this proposed rule would apply to all Part C and Part D RAC determinations. As CMS implements the Part C RAC, we would determine if additional changes to the proposed appeals process are necessary.

Based on the foregoing, we propose to add a new subpart Z in Parts 422 and 423, respectively that would include the proposed provisions discussed in this section. In accordance with CMS direction and criteria, the Part C or Part D RAC would conduct an issue specific audit of CMS' payment(s) to plans. An independent validation of all Part C and Part D RAC-identified improper payments would be conducted. If both the Part C or Part D RAC and the independent validation determine that an improper payment was made, the Part C or Part D RAC would send a notice of improper payment to the plan. If the Part C or Part D RAC determines an overpayment was made to the plan, it would send a demand letter requesting repayment. The demand letter would: (1) Explain the reason for the overpayment determination; (2) explain our recoupment process; and (3) contain instructions on how the plan may appeal the Part C or Part D RAC's finding. There would be no minimum monetary threshold for an appeal at any level.

The following three level process sets forth our proposed administrative appeals process for overpayment determinations by the Part C and Part D RACs. Please note that the appeals process set forth applies to both § 422.2600 and § 423.2600. Because the sections largely mirror one another, discussions in this preamble would apply to both programs, unless otherwise noted.

(1) Reconsiderations (§ 422.2605 and § 423.2605)

At § 422.2605 and § 423.2605, we propose that if the plan believes the part C or Part D RAC did not apply CMS' stated payment methodology correctly, a plan may appeal the determination to an independent reviewer. CMS' payment methodology itself, however, is not subject to appeal. That is, while miscalculations and factual or data errors may be appealed, the plan may not appeal the substantive basis for the overpayment determination. This is consistent with the approach to Part D reconciliation appeals at § 423.350(a)(1), which states that the Part D plan may appeal ''if CMS did not apply its stated payment methodology correctly.'' The Part D reconciliation appeals process does not permit the underlying payment methodology to be appealed.

Examples of appealable issues would include, but are not be limited to: (1) A Part C or Part D RAC determination that a plan provider/pharmacy was excluded from Medicare when the service was furnished; (2) a Part C or Part D RAC determination that a payment was a duplicate payment; or (3) whether the Part C or Part D RAC miscalculated an overpayment.

In paragraph (a), we propose that the plan's request for reconsideration must be filed with the independent reviewer within 60 calendar days from the date of the demand letter. In paragraph (b)(1), we propose that the request for reconsideration must be in writing and must provide evidence or reasons or both to substantiate the request. In paragraph (b)(2), we propose that the plan must include with its request all supporting documentation, evidence, and substantiation it wants the independent reviewer to consider. This material must be submitted in the format requested by CMS. Documentation, evidence, or substantiation submitted after the filing of the reconsideration request would not be considered.

In paragraph (c), we propose that CMS may file a rebuttal to the plan's reconsideration request. The rebuttal must be submitted to the independent reviewer within 30 calendar days of the independent reviewer's notification to CMS that it has received the plan's reconsideration request. CMS would notify and send its rebuttal to the plan at the same time it is submitted to the independent reviewer. In paragraph (d), we propose that the independent reviewer would conduct the reconsideration. Specifically, the independent reviewer would review the notification of improper payment, the evidence, and findings upon which it was based, and any evidence that the plan or CMS submitted in accordance with regulations. In paragraph (e), we propose that the independent reviewer would inform CMS and the plan of its decision in writing. In paragraph (f), we propose that a reconsideration decision would be final and binding unless the plan requests a hearing in accordance with § 422.2605 and § 423.2605. Finally, in paragraph (g), we propose that a plan that is dissatisfied with the independent reviewer's reconsideration decision would be entitled to a review by a hearing official as provided in § 422.2610 and § 423.2610.

(2) Hearing Official Determinations (§ 422.2610 and § 423.2610)

In proposed § 422.2610 and § 423.2610, we outline the process for requesting review of the record by a CMS hearing official. In paragraph (a), we propose that a request for review must be filed with CMS within 15 days from the date of the independent reviewer's issuance of a determination.

The request must be in writing and must provide a basis for the request. In paragraph (b), we propose that the plan must submit with its request all supporting documentation, evidence, and substantiation that it wants to be considered. Documentation, evidence, or substantiation submitted after the filing of the request would not be considered.

In paragraph (c), we propose that a CMS-designated hearing official would conduct the review. A hearing would not be conducted, either live or via telephone, unless the hearing official, in his or her sole discretion, chooses such a mechanism. In all cases, the hearing official's review would be limited to information that: (1) The Part C or Part D RAC used in making its determinations; (2) the independent reviewer used in making its determinations; (3) the plan submits with its hearing request; and (4) CMS submits per paragraph (d). Neither the plan nor CMS would be allowed to submit new evidence.

In paragraph (d), we propose that CMS may file a rebuttal to the plan's hearing request. The rebuttal must be submitted within 30 calendar days of the plan's submission of its hearing request. CMS would send its rebuttal to the plan at the same time it is submitted to the hearing official. In paragraph (e), we propose that the CMS hearing official would decide the case within 60 days and send a written decision to the plan and CMS, explaining the basis for the decision. In paragraph (f), we propose that the hearing official's decision would be final and binding, unless the decision was reversed or modified by the CMS Administrator in accordance with § 422.2615 and § 423.2615.

(3) Administrator Review (§ 422.2615 and § 423.2615)

In proposed § 422.2615 and § 423.2615, we discuss the Administrator review process. In paragraph (a), we propose that if a plan is dissatisfied with the hearing official's decision, the plan may request that the CMS Administrator review the decision. The request must be filed with the CMS Administrator within 15 calendar days of the date of the hearing official's decision. The request must provide evidence or reasons or both to substantiate the request. In paragraph (b), we propose that the plan must submit with its request all supporting documentation, evidence, and substantiation that it wants to be considered. Neither the plan nor CMS would be allowed to submit new evidence. Documentation, evidence or substantiation submitted after the filing of the request would not be considered.

In paragraph (c), we propose that after receiving a request for review, the Administrator would have the discretion to review the hearing official's decision in accordance with paragraph (e) or to decline to review said decision.

In paragraph (d), we propose that the Administrator would notify the plan of whether he or she intends to review the hearing official's decision. If the Administrator declines to review the hearing official's decision, the hearing official's decision is final and binding. If the Administrator agrees to review the hearing official's decision, CMS may file a rebuttal statement within 30 days of the Administrator's notice to the plan that the request for review has been accepted. CMS would send its rebuttal statement to the plan at the same time it is submitted to the Administrator. In paragraph (e), we propose that if the Administrator agrees to review the hearing official's decision, the Administrator would determine, based upon this decision, the hearing official record, and any arguments submitted by the plan or CMS in accordance with this section, whether the determination should be upheld, reversed, or modified. The Administrator would furnish a written decision to the plan and to CMS. The Administrator's decision would be final and binding.

C. Strengthening Beneficiary Protections

1. Providing Good Quality Health Care (§ 422.504(a)(3) and § 423.505(b)(27))

Section 1857(e)(1) of the Act, together with section 1860D–12(b)(3) of the Act, which incorporates its terms for Part D, authorizes CMS to include terms and conditions in our contracts with MA organizations and PDP sponsors that are consistent with Part C and Part D requirements, respectively, and that the Secretary finds are ''necessary and appropriate.'' Furthermore, the requirements set forth in section 1860D–4(b), (c), and (d) of the Act include specifications for a Part D sponsor to administer a benefit that not only accurately and efficiently process claims but also meets beneficiary healthcare needs, and to take affirmative action to improve outcomes and achieve patient satisfaction. Under this authority, we propose to add a requirement to CMS contracts with MA organizations and Part D sponsors that explicitly requires that Part C and Part D plans demonstrate that they are providing good quality health care by achieving good or improving scores on CMS performance standards for outcomes, intermediate outcomes, process, patient experience, and patient access to care. We believe that adding this requirement would help ensure our beneficiaries receive the right care at the right time.

While we believe that we have conveyed this expectation in other ways, such as through our performance and quality measurement and rating methodologies, we have never explicitly articulated this requirement in regulation. In short, we are proposing here that it is not enough to simply administer a benefit plan, but that Part C and Part D sponsors should constantly seek out ways to actively promote and advance the health of its enrollees.

In order to create a requirement that helps ensure that Medicare beneficiaries are receiving consistently good quality care, and to have the ability to enforce such a requirement, we sought existing guidance to shape the meaning of ''good quality health care.'' The Affordable Care Act required HHS to develop the National Strategy for Quality Improvement in Health Care (the National Quality Strategy), which, like our Three-Part Aim, combines the three broad objectives of better health for the population, better care for individuals, and affordable care. In addition, our Star Ratings program was developed to include quality and performance measures to increase the level of accountability for MA organizations and PDP sponsors to administer a good quality benefit to Medicare beneficiaries. By linking a concept as subjective in nature as good quality health care to objective metrics and measures in the Star Ratings program, we believe plans and sponsors can reasonably employ tangible strategies that improve the quality of services and benefits provided to Medicare beneficiaries.

To give concrete and verifiable meaning to this requirement, we propose to specify that good quality health care refers to MA organizations and Part D sponsor performance in the five categories identified in CMS's Star Ratings program—patient outcomes, intermediate outcomes, patient experience, patient access to care, and process. Achievement of this type of performance is based on organizational capability and implementation by the MA organizations and Part D sponsor. Articulating and codifying this requirement underscores for the public and our plans and sponsors the critical importance we place on aligning the administration of Part C and Part D benefits with the achievement of good quality health care as illustrated by, but not limited to, these specific performance standards. Leveraging what

plans have already put into practice with regard to these five categories means that plans should not encounter any additional burden in complying with this proposed regulation. Instead, the proposed change gives plans an opportunity to demonstrate the value they offer their enrollees, while providing a means for us to enforce or take corrective action when a Part C or Part D plan fails to provide good quality health care.

There are several reasons we propose including in regulation a contract requirement that plans administer a benefit promoting good quality health care. We reward MA organizations with quality bonus payments when they achieve high scores within the Star Ratings. At the same time, we believe that it is appropriate that we react correspondingly if an MA organization does not provide good quality care. In addition, our existing requirements that MA organizations have a quality improvement (QI) program (§ 422.152) and Part D sponsors have a Medication Therapy Management Program (§ 423.153(d)) further reinforce our belief that MA organizations and Part D sponsors are already striving to administer a good quality benefit. Moreover, we examined our authority at § 422.502(b) and § 423.503(b), which allows us to ensure that plan performance is routinely evaluated. Based on the methodology we use to calculate plan performance for both MA organizations and Part D sponsors, we are able to determine which plans are outliers—that is, those organizations whose performance is consistently poor. With regard to the particular proposed contractual requirement to administer a good quality benefit, we can evaluate a plan's scores in Performance Metrics category within the plan performance review. Plans are held accountable for achieving good scores on the review, and this evaluation allows us to appropriately deny an organization's application to operate if it is determined that they are an outlier.

Therefore, we propose adding paragraph (b)(27) to § 423.505, Requirements for contracts, to state, ''A PDP sponsor is required to administer a PDP benefit that provides good quality health care demonstrated by scores of 3 or higher on CMS performance standards for patient outcomes, intermediate outcomes, process, patient experience, and patient access to care.''

Similarly, we propose adding paragraph (a)(3)(iv) to § 422.504, Contract Provisions, to state that MA organizations agree to provide benefits, ''in a manner that provides good quality health care demonstrated by scores of 3 or higher on CMS performance standards for patient outcomes, intermediate outcomes, process, patient experience, and patient access to care.''

2. MA–PD Coordination Requirements for Drugs Covered Under Parts A, B, and D (§ 422.112)

Under § 422.112(b) of the MA program regulations, coordinated care plans must ensure continuity of care and integration of services through arrangements with contracted providers. We believe that an important aspect of this coordination is ensuring that all needed services, including drug therapies, are provided in a timely manner. We have become aware of situations in which enrollees' access to needed Medicare-covered drugs has been delayed or denied due to the MA organization's failure to effectively coordinate Part B and Part D benefits for certain drugs, both at the point-of-sale (POS) and during the coverage determination process.

As defined in § 423.100, ''Part D'' drugs do not include drugs for which payment as so prescribed and dispensed or administered to an enrollee is available for that enrollee under Part A or Part B. In other circumstances, these drugs are covered under the Part D benefit, but coverage generally cannot be determined based solely on the drug itself. These drugs include certain infusion agents, oral anti-cancer therapies, oral anti-emetics, immunosuppressants, and injectables.

We do not believe MA–PD plans are adopting or administering uniform policies that allow them to expeditiously determine whether a drug is covered under Part A/Part B or Part D at the POS. The resulting POS rejection of coverage under the Part D benefit does not uniformly include messaging that a Part B prior authorization determination is required, nor consistently result in a corresponding authorization under Part B. This can result in lengthy drug treatment delays while the enrollee or his or her provider attempts to determine why the drug was not covered and then pursues a coverage determination from the MA–PD plan. For example, an MA–PD enrollee may present a prescription for a covered chemotherapy drug at his or her pharmacy only to be told that the claim has been rejected under the Medicare Part D benefit, resulting in the enrollee leaving the pharmacy counter without his/her drug. The enrollee may not know that the drug is covered under Part B. In some cases, the enrollee must take steps on his or her own to find out why coverage for a prescription was rejected at the POS and then contact the plan to obtain the Part B-covered medication. Unless the MA–PD plan has a robust process in place to make a timely and appropriate payment determination at the POS, there may be unnecessary delays, during which the enrollee is denied access to the needed medication.

We have issued guidance in section 20.2.2. Chapter 6 of the Medicare Prescription Drug Benefit Manual related to how Part D plan sponsors should make determinations whether a drugs is covered under Part B or Part D. We have also outlined in Appendix C of Chapter 6 considerations for Part D plan sponsors—and by extension, MA organizations that offer MA–PD plans—to take into account when making determinations as to whether a drug is covered under Part B or Part D. We expect plans to work with network pharmacies and providers to determine coverage and payment for these drugs with the goal of limiting disruptions to beneficiaries and pharmacies and ensuring access to medically necessary prescription drugs. For example, we have stated in subregulatory guidance that, when adjudicating claims for these drugs, Part D plan sponsors are permitted to rely on information submitted on the prescription (for example, to determine whether the prescription is related to a Medicare covered organ transplant) and may require their network pharmacies to obtain documentation to determine whether payment should be made under Part B or Part D.

During recent MA–PD plan audits, we also have seen that some plans are not adequately coordinating the respective Part D and Part B drug benefits when an enrollee or his or her provider requests a drug coverage determination from the plan. For example, in response to a POS claim rejection for an immunosuppressant drug that cannot be resolved at the POS, an enrollee's provider may submit a coverage determination request to the MA organization offering an MA–PD, which is generally processed under the Part D benefit. In some cases, MA–PD plans deny coverage and issue a denial notice under the Part D benefit on the basis that the drug is, or may be, covered by Part B, but the plan either fails to make a determination regarding Part B coverage or does not authorize payment under the Part B benefit.

Occurrences like these cause inappropriate and avoidable delays, or, even worse, result in situations in which the enrollee fails to receive needed medication altogether. In the case of chemotherapy or

immunosuppressive drugs, such delays could have rapid and serious medical consequences for the beneficiary.

Part D drug benefits and drug benefits under Parts A and B should be coordinated by MA organizations offering MA–PDs so that enrollees receive needed medications on a timely basis. We are proposing to add a new paragraph (b)(7) to § 422.112 to require MA–PDs to establish adequate messaging and processing requirements with network pharmacies (that is, Part D contracted providers) to ensure that appropriate payment is assigned at the POS, and to ensure that, when coverage is denied under Part D due to available coverage under Part A or Part B, such Part A or Part B coverage is authorized or provided to the enrollee as expeditiously as the enrollee's health condition requires. Our proposed regulation would require that MA PDs have systems in place to accurately and timely adjudicate claims at the POS.

In addition, we would like to ensure that MA–PD plans are coordinating their drug benefits appropriately during the coverage determination process. If an MA organization offering Part D denies Part D coverage due to the availability of Part A or Part B coverage, we expect the MA organization to ensure the decision results in authorization or provision of the drug under Part A or Part B pursuant to the requirements in parts 422 and 423, subpart M under our proposed regulation. We do not expect MA–PD enrollees to have to request an initial coverage determination more than once.

To avoid unnecessary delays and inappropriate denials of critical medications, we have considered requiring MA–PD plans to authorize coverage of all Part A, Part B and D medications at the POS so that the enrollee can receive covered medication without delay. The determination as to whether the drug is covered under Part A, Part B or Part D and the amount of the appropriate cost sharing would occur later if necessary. However, we recognize that such a requirement may interfere with medically appropriate pre-authorization requirements, and may trigger retrospective enrollee liability depending on the difference in enrollee cost sharing for coverage under Part A, Part B and Part D and retrospective TROOP adjustments and Part D reconciliation.

We solicit comments on our proposal, as well as other possible approaches to minimizing delays in beneficiary access to needed medications caused by inadequate coordination of the Part A, Part B and Part D drug benefits at the POS and during the coverage determination process. In particular, we would appreciate organizations sharing their expertise regarding best practices for this benefit coordination at the POS and plan processes that enhance those coverage determinations. We also are soliciting comments on challenges MA organizations offering Part D currently encounter in their efforts to integrate these benefits.

3. Good Cause Processes (§ 417.460, § 422.74 and § 423.44)

Section 1851(g)(3)(B)(i) of the Act provides that MA organizations 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 rules related to enrollment, disenrollment, and termination for Part D plan sponsors that are similar to those established for MA organizations under section 1851 of the Act. In addition, section 1860D–13(a)(7) of the Act mandates that the premiums paid by individuals with higher incomes be increased by the applicable Part D Income Related Monthly Adjustment Amount (Part D IRMAA), for the months in which they are enrolled in Part D coverage.

Consistent with these sections of the Act, subpart B in both the Part C and Part D regulations sets forth our requirements with respect to involuntary disenrollment procedures at § 422.74 and § 423.44, respectively. An MA or Part D plan that chooses to disenroll beneficiaries for failure to pay premiums must be able to demonstrate to us that it made a reasonable effort to collect the unpaid amounts by notifying the beneficiary of the delinquency, providing the beneficiary a period of no less than 2 months in which to resolve the delinquency, and advising the beneficiary of the termination of coverage if the amounts owed are not paid by the end of the grace period.

In addition, current regulations at § 417.460(c) specify that a Health Maintenance Organization (HMO) or competitive medical plan (cost plan) may disenroll a member who fails to pay premiums or other charges imposed by the plan for deductible and coinsurance amounts. While there is not a grace period parallel to MA and Part D, the other procedural requirements for cost plans to disenroll a member on this basis are similar to those for MA and Part D plans. The cost plan must demonstrate that it made reasonable efforts to collect the unpaid amount and send the enrollee written notice of the pending disenrollment at least 20 days before the disenrollment effective date.

In the April 2011 final rule (76 FR 21432) we amended both the Parts C and D regulations at § 422.74(d)(1)(v), § 423.44(d)(1), and § 423.44(e)(3) regarding involuntary disenrollment for non-payment of premiums or Part D–IRMAA to allow for reinstatement of the beneficiary's enrollment into the plan for good cause. In the April 2012 final rule (77 FR 22071), we extended the policy of reinstatement for good cause to include beneficiaries enrolled in cost plans in § 417.460(c)(3); thus aligning the cost plan reinstatement provision with the MA and PDP plan provisions.

These good cause provisions authorize CMS to reinstate a disenrolled individual's enrollment without an interruption in coverage in certain circumstances where the non-payment was due to circumstances that the individual could not reasonably foresee and could not control, such as unexpected hospitalization. Since the inception of these provisions, we have received feedback from plans on ways to improve the good cause process and make it more efficient for both the plans and us. Over the past year, we have already used this feedback to improve the operational aspects of the policy by updating Chapter 2 of the Medicare Managed Care Manual and Chapter 3 of the Medicare Prescription Drug Benefit Manual to clarify notice language and the process and timing of receiving payments during the extended grace period, as outlined in § 417.460(c)(3), § 422.74(d)(1)(v), and § 423.44(d)(1)(vi). In addition, we updated the Complaints Tracking Module (CTM) Standard Operating Procedures (SOP) to permit plans to transfer requests for reinstatement for good cause to CMS. We are now proposing to make additional revisions to § 417.460, § 422.74, and § 423.44 to make changes to the good cause review process.

The ability for individuals to be reinstated during the extended grace period for good cause is outlined in § 417.460, § 422.74 and § 423.44. Since its inception, the process of accepting, reviewing, and processing beneficiary requests for reinstatement for good cause has been carried out exclusively by CMS. In multiple cases, individual MA organizations and Part D plans have indicated that they wanted to be the point of contact for their current and past members. In addition, several plans have raised concerns regarding complaints by their members who are seeking reinstatement and who have to contact CMS instead of the plan to make this request.

In light of this feedback, the experience we have gained since the initial implementation of the good cause

process, and in the interest of making the process more efficient, we solicited public input on improving the process in the draft 2014 Call Letter issued on February 15, 2013. In the Call Letter, we indicated that we were considering making changes to the good cause process. Specifically, we stated that we were exploring expanding the plans' role in the process to include accepting the initial requests for reinstatement by former plan members and gathering information prior to submitting the requests to us. We requested comments from MA organizations and Part D plan sponsors on our proposal to expand the plans' role and any other ways we might improve the process to receive and review good cause requests for reinstatement.

The vast majority of the comments we received from stakeholders in response to the Call Letter were in favor of expanding the plans' role, given the fact that plans can readily access a former enrollee's premium billing and payment history and, as such, are in a position to identify and efficiently resolve other disenrollment disputes that are erroneously being received as good cause requests. A number of plans indicated a preference to independently implement the good cause process through enhanced subregulatory guidance. A few commenters indicated that CMS should retain responsibility over all aspects of the good cause process to ensure objectivity.

In response to this feedback we are proposing to amend § 417.460(c)(3), § 422.74(d)(1)(v), and § 423.44(d)(1)(vi) to permit an entity acting on behalf of CMS to effectuate reinstatements when good cause criteria are met. This regulatory change would allow us to designate another entity, including the plans or an independent contractor, to complete portions or all of the good cause process. It is our intent to expand the role of plans to include accepting incoming requests for reinstatement directly from former enrollees and making the good cause determinations using the existing regulatory standard. This proposed change would enable plans to be more responsive to their current and former members, and lessen the burden the plans have in coordinating with us regarding the good cause and reinstatement process. It further aims to lessen the number of complaints generated due to miscategorization of the reinstatement requests as an allegation of plan error, which the plans must then resolve and refer back to us for a good cause determination.

Ensuring objectivity in the review of these cases and equity among beneficiaries regarding the determination of good cause for cases is critically important. Thus, we would establish operational policy and processes in subregulatory guidance to set parameters for the application of the good cause standard, including the submission to CMS of certain cases for review to ensure that plans remain impartial and equitable in their assessment and treatment of former members who have been disenrolled for nonpayment of premiums. These changes would be accompanied by the development of an oversight protocol for any activities currently carried out by us for which we name the plans or an independent contractor our designee to carry out.

In addition to our proposal here to permit a CMS designee to determine reinstatements for good cause, we are taking this opportunity to propose a technical change to the language in § 417.460 to clarify that good cause protections for enrollees in cost plans apply to instances where there was a failure to pay either plan premiums or cost sharing. In extending the good cause provision to cost plans in the April 2012 final rule, we correctly referenced failure to pay premiums as a basis for disenrollment from a cost plan, but in two instances we neglected to include a reference to ''other charges'' as a basis for disenrollment. We propose to make a technical change to § 417.460(c)(3) and (c)(4) to clarify that the good cause provisions are applicable to individuals who have been disenrolled for non-payment of other charges (for example, deductible or coinsurance amounts), in addition to non-payment of premiums.

4. Definition of Organization Determination (§ 422.566)

Based on our updated guidance, program experience, and information collected during audits of MA organizations, we are proposing to revise the current regulatory definition of ''organization determination'' set forth at § 422.566(b) to create a single, uniform definition. As described later in this proposed rule, the definition of organization determination referenced in our manual guidance (Chapter 13 of the Medicare Managed Care Manual, section 30), required plan marketing documents (such as the EOC), and Part C data requirements (*Medicare Part C Plan Reporting Requirements, Technical Specifications Document*—Measure 6) is more inclusive than the definition currently reflected in this regulation.

Section 1852(g) of the Act requires MA organizations to have a procedure for making determinations regarding whether an enrollee is entitled to receive a health service and the amount (if any) that the individual is required to pay for such service. Our regulations at 42 CFR part 422, subpart M codify the procedures MA organizations must follow when processing organization determinations. Section 422.566(b) defines which actions are considered organization determinations, but does not currently include all types of coverage decisions made by a provider under contract with an MA organization.

Our current manual guidance, required model EOC documents, and Part C plan reporting requirements clarify that organization determinations include fully favorable, partially favorable, and unfavorable decisions made by an MA organization concerning payment or provision of an item or a service. Additionally, requirements elsewhere in Part 422 provide certain beneficiary protections in the MA program, including a requirement that MA organizations provide or make payment for all services covered by Medicare Parts A and B (see § 422.101(a)), and contract requirements that limit beneficiary financial liability for fees that the MA organization is legally obligated to pay for services provided by contract and non-contract providers (see § 422.504(g)). Our proposed changes would clarify what actions are included and therefore ensure that enrollees receive required Medicare notices (for example, notice of termination in certain healthcare settings) and due process rights.

We are proposing to make minor modifications to regulatory language at § 422.566(b)(1) through (b)(3) to improve the uniformity of our guidance on what actions are considered organization determinations. We are restating these provisions for consistency within this section and to further underscore an ''organization determination'' includes any coverage decision—fully favorable, partially favorable, and unfavorable—made by an MA organization concerning payment or provision of an item or a service. At § 422.566(b)(1) and (b)(2), we refer to an organization determination as ''any determination'' by an MA organization (that is, fully favorable, partially favorable, and unfavorable). At 422.566(b)(3), we are proposing to replace the reference to the MA organization's ''refusal to provide or pay'' with reference to ''any determination not to provide or pay for'' items or services made by the MA organization to improve consistency of the regulatory language.

Chapter 13, section 30 of the Medicare Managed Care Manual states that

approval for an item or service by the plan or its delegated entity (that is, provision of an item or service by a contract provider, such as inpatient admission to a contract hospital) is an organization determination. We are also proposing to add new language to the regulation text at § 422.566(b)(6) that clarifies that a provider under contract with an MA organization that furnishes an item or service to an enrollee has made a favorable organization determination on behalf of the MA organization. We believe this clarification to the regulatory definition is necessary to clearly distinguish when a contract provider is making an organization determination on behalf of the MA organization from instances where a contract provider is not making an organization determination on behalf of the MA organization. We have repeatedly stated that a contract provider's refusal to furnish an item or service is a treatment decision, not an adverse organization determination made on behalf of the MA organization. In a case where a contract provider refuses to furnish an item or service, the enrollee has the right to request an organization determination from the MA organization. In addition, the provider may request the organization determination on the enrollee's behalf.

The proposed revision to the regulation text at § 422.566(b)(6) would also clarify that a service or item provided by a noncontract provider due to a referral from a contract provider constitutes a favorable organization determination, and therefore ensures that enrollees would be protected by limitations on their financial liability. (For more information, see § 422.504(g) of the regulations and Chapter 4, section 170 of the Medicare Managed Care Manual). We stated in the January 28, 2005 final rule (70 FR 4618) that if a network physician performs a service or directs an MA beneficiary to another provider to receive a plan covered service (regardless of whether the provider is following the plan's internal procedures, such as obtaining the appropriate plan pre-authorization), the enrollee cannot be held liable for more than applicable plan cost sharing for those services. When a contract provider refers an enrollee out of the network, the enrollee has a reasonable expectation that the items or services provided by the non-contract provider will be covered by the plan. Enrollees cannot be held to a higher standard than plan contracting providers to adhere to plan rules.

Proposed new paragraph § 422.566(b)(6) would also clarify that a favorable organization determination has been made if: (1) The MA organization decides to provide or pay for an item or service, including a decision to continue providing or paying for an item or service; or (2) a contract provider or facility, acting on behalf of the MA organization, furnishes (or continues to furnish) an item or service.

Together, our proposed revisions to § 422.566(b) are intended to codify our current guidance, creating a single, uniform definition of organization determination.

5. MA Organization Extension of Adjudication Timeframes for Organization Determinations and Reconsiderations (§ 422.568, § 422.572, § 422.590, § 422.618, and § 422.619)

Section 1852(g)(2) of the Act requires MA organizations to provide for reconsideration, or review, of organization determinations within a timeframe specified by the Secretary, but generally no later than 60 days from the date of receipt of the request for reconsideration. Section 1852(g)(3)(B) of the Act requires MA organizations to maintain procedures for expediting organization determinations and reconsiderations when a physician's request indicates that applying the standard timeframe could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function or when, in the case of an enrollee's request, the MA organization makes such a determination on its own. In expedited cases, the MA organization generally must issue its decision no later than within 72 hours of receipt of the request. Section 1852(g)(3)(B)(iii) of the Act permits the Secretary to extend this 72-hour decision making timeframe in certain cases.

Our regulations at 42 CFR part 422, subpart M codify the procedures MA organizations must follow in issuing standard and expedited organization determinations and reconsiderations. Specifically, the current regulations at § 422.568(b), § 422.572(b), and § 422.590(a)(1) and (d)(1) set forth the standard and expedited timeframes within which plans are required to process such decisions and describe the circumstances under which plans are permitted to extend decision making timeframes by up to 14 calendar days.

Based on information ascertained during recent MA program audits, we have found that some MA organizations are routinely and inappropriately invoking extensions of the adjudication timeframes for organization determinations and reconsiderations. We have identified circumstances in which MA organizations are routinely invoking the 14 day extension: (1) In cases where the plan lacks adequate internal controls to ensure coverage requests are reviewed and adjudicated within the required regulatory timeframe; and (2) in cases where the plan is awaiting receipt of supporting clinical documentation from one of its contract providers. We believe the current language that permits extension of the adjudication timeframes set forth in § 422.568(b), § 422.572(b), § 422.590(a)(1) and § 422.590(d)(2) is being interpreted more broadly than our intent in adopting these rules. Therefore, we propose to revise these regulatory provisions to more clearly define our intended standard for when it is appropriate for an MA organization to extend an adjudication timeframe.

Routinely invoking an extension of the applicable adjudication timeframe is counter to the intent of the statutory and regulatory requirements for timely determinations that emphasize the health needs of the beneficiary in determining the appropriate adjudication timeframe. Extensions should be permitted only in limited circumstances, and only if the extension is in the enrollee's interest. MA organizations are required by regulation to render all coverage decisions as expeditiously as the enrollee's health condition requires. When plans choose to subject an item or service to a prior authorization requirement, we expect them to have the resources to process those requests in a timely manner.

We believe MA organizations have interpreted existing regulations to mean that there is a broader set of circumstances in which it would be appropriate to invoke an extension than we intended, such as the need for medical evidence from a contract provider. We are proposing to amend the regulation text to clarify our original intent that an extension should not be routinely invoked for any category of coverage request, but in particular not for purposes of obtaining additional medical evidence from contract providers. Thus, we propose to revise the extension language in § 422.568(b), § 422.572(b), and § 422.590(a)(1), and to add new § 422.590(e), which would incorporate and clarify existing text at § 422.590(a)(1) and (d)(2) in order to more clearly identify when it is appropriate for an MA organization to invoke an extension of the adjudication timeframe. We also propose revisions to § 422.590(d) and redesignation of existing subparagraphs § 422.590(e) through (g) as part these changes.

First, we propose to retain the current provisions in these various regulations

that permit an extension at the request of the enrollee. Additionally, we propose to modify the current regulatory provisions that permit an extension ''if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an MA organization's decision to deny).'' Our proposed revised language would result in two more specific provisions permitting an extension, which we believe clarifies the intent of our existing requirements.

Additionally, we propose language to clarify at § 422.568(b)(1)(ii), § 422.572(b)(1)(ii), and § 422.590(e)(1)(ii) that an extension may be justified and in the enrollee's interest due to the need to obtain additional medical information that may result in changing the MA organization's denial of coverage of an item or service only from a non-contract provider. We believe the arrangement between an MA organization and its contract providers is such that clinical documentation should generally be readily available and that there are mechanisms for an MA organizations to ensure that contract providers produce necessary documentation in a timely manner (for example, via their contract). We believe that any delay in decision-making caused by an extension to obtain additional medical evidence from a contract provider would be in the plan's interest but not generally in the interest of the enrollee. Therefore, we are proposing to specify at § 422.568(b)(1)(ii), § 422.572(b)(1)(ii), and § 422.590(e)(1)(ii) that one circumstance in which it may be appropriate for an MA organization to invoke an extension is when the extension is in the enrollee's interest due to the need for additional medical evidence from a non-contract provider only.

When the MA organization needs additional information that may change a decision to deny coverage, it is our expectation that the MA organization promptly solicit necessary clinical documentation in all cases and that extension of the timeframe not be routinely invoked. It is also our expectation that the full 14 days not be routinely taken, even if an extension is warranted, and that all coverage requests be reviewed, and decisions issued, as expeditiously as the enrollee's health condition requires within that period, as required by regulation.

In addition, we propose to include a provision (new language to be codified at § 422.568(b)(1)(iii), § 422.572(b)(1)(iii), and § 422.590(e)(1)(iii)) to clarify that an extension of the adjudication timeframe may be permitted when the extension is justified due to extraordinary, exigent or other non-routine circumstances, and it is in the enrollee's interest. We recognize that there may be limited, non-routine circumstances in which the adjudication timeframe may need to be extended even if the enrollee does not request the extension and no additional documentation must be obtained from a non-contract provider. We emphasize that the extension must be both: (1) Due to extraordinary, exigent or other non-routine circumstances; and (2) in the enrollee's interest. For example, a natural or man-made disaster may impede a contract provider's ability to provide the MA organization with timely clinical information, and invoking an extension may be in the enrollee's interest if that information is necessary to approve coverage. It is our expectation that these exceptions would be rare. MA organizations that overuse or misuse the authority to invoke an extension may be subject to corrective action.

In all cases where an extension is invoked, the MA organization is responsible for documenting the justification for the extension in the case file, complying with the requirement to notify the enrollee in writing of the reasons for the delay, and informing the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension.

In an effort to improve clarity in our guidance related to extensions and to remove duplicative language, we have made corresponding, technical edits to subpart M. Specifically, we are proposing in § 422.590 to remove paragraph (d)(2) and add a new paragraph (e). To correspond with this proposed change, we propose to update related cross-references and language accordingly. Specifically, at § 422.618(a)(1), we propose to replace the reference to § 422.590(a)(1) with a reference to § 422.590(e). In § 422.619(a), we propose to replace the reference to § 422.590(d)(2) with a reference to § 422.590(e). Also, we propose to make corresponding changes within § 422.568(b), § 422.572(b), and § 422.590(d) to ensure consistency in the structure and language of these provisions.

D. Strengthening Our Ability To Distinguish Stronger Applicants for Part C and D Program Participation and To Remove Consistently Poor Performers

1. Two-Year Prohibition When Organizations Terminate Their Contracts (§ 422.502, § 422.503, § 422.506, § 422.508, and § 422.512)

Section 1857(c)(4)(A) of the Act prohibits organizations from re-entering the MA program in the event that a previous contract with the organization was terminated at the request of the organization within the preceding 2-year period, except in circumstances that warrant special consideration. Furthermore, section 1857(e) of the Act permits us to add contract provisions that are not inconsistent with Part C of the Act and that we find necessary and appropriate for the administration of Medicare Part C. We propose to amend the text and application of regulations implementing these provisions of the Act. In the April 15, 2010 final rule (75 FR 19678), we characterized our current policy on the 2-year ban applicable to voluntary non-renewals and mutual terminations as applying the ban based on plan type and service area. We provided the following example to illustrate application of the rule: an MA organization's non-renewal of a Private Fee-for-Service MA plan would not prohibit the MA organization from immediately applying for an MA HMO contract for the same service area. Similarly, our current policy, absent this proposal, would not apply the 2-year ban on an MA organization that non-renewed a contract in one region from applying immediately for the same type of MA product in a different region.

This current policy unnecessarily narrows the scope of the 2-year prohibition and precludes us from preventing poor performing MA organizations from reentering the MA program. We have reconsidered the wisdom of this policy and believe that the MA program would be better served if we applied the 2-year ban flowing from non-renewals and mutual terminations to new contracts or service area expansions regardless of the product type or service area of the non-renewed or terminated contract. We note that we are retaining our ability to exercise discretion in applying the 2-year ban when there are special circumstances that warrant special consideration, as provided in the current regulations text at § 422.503(b)(6)(ii), § 422.506(a)(4), and § 422.512(e).

First, we propose to address how a non-renewal or mutual termination of an MA contract would be treated.

Specifically, we propose to amend the regulation text at § 422.506(a)(4) and § 422.512(e) to explicitly apply the 2-year prohibition to applications for service area expansions in addition to applications for new contracts. These changes to § 422.506 and § 422.512 would make the text of these regulations consistent with the text at § 422.503(b)(7) and § 422.508(c) with regard to the 2-year prohibition imposed as a condition of a mutual termination of an MA contract. We read the current text at § 422.503(b)(7) to permit us to deny a contract to a MA organization that has participated in a mutual contract termination, regardless of contract type, product type, or service area, within the past 2 years. We also note that the current text of § 422.503(b)(6) is not explicit on this point but may be read to permit contract denials for new contracts and service area expansions, consistent with our proposal; we intend to apply this interpretation to the existing text at § 422.503(b)(6). We also propose to add the following sentence to paragraphs (c) and (d) of § 422.508 to make it clear that a mutual termination of a MA contract would result in a ban of all contract types and service area expansions: ''This prohibition may apply regardless of the product type, contract type or service area of the previous contract.'' These proposed amendments are in harmony with our policy, as articulated in the preamble to the April 15, 2010 final rule (75 FR 19703) to apply the 2-year ban consistently in the context of voluntary non-renewals and mutual terminations.

2. Withdrawal of Stand-Alone Prescription Drug Plan Bid Prior to Contract Execution (§ 423.503)

Occasionally, organizations new to Part D that have qualified for a Medicare PDP sponsor contract withdraw their bids after we have announced the low-income subsidy (LIS) benchmark but prior to executing the contract for the coming plan year. These withdrawals interfere with our administration of the Part D program, in particular the auto assignment of LIS beneficiaries. To address this problem, we are proposing to adopt regulatory provisions that would impose a 2-year application ban on organizations not yet under contract with us as PDP sponsors that withdraw their applications and bids after we have issued our approvals. We are making this proposal under our authority at section 1860D–12(b)(3)(D) of the Act to adopt additional contract terms, including the conditions under which we would enter into contracts, not inconsistent with the Part D statute.

In February of each year, we solicit applications from organizations seeking to qualify to enter into a contract to offer stand-alone PDPs in the upcoming plan year. These organizations, along with current PDP sponsors who wish to continue participating in the Part D program, submit bids in June for our review and approval. We review these applications and bids with the expectation that, upon approval, the organizations would enter into PDP sponsor contracts with us in September to provide the Part D benefit for the plan year starting the following January.

As part of the annual bid review, we calculate the LIS benchmark for each PDP Region based on the bids for basic PDPs submitted annually by current PDP sponsors that will operate in that region in the coming year. Sponsors whose monthly premiums fall at or below the benchmark in a region receive auto-enrollments from us of LIS-eligible beneficiaries in those regions. We normally announce the LIS benchmark in late July or early August.

In recent years, some organizations have withdrawn their applications and bids following the announcement of the LIS benchmark. Because these organizations withdrew prior to executing a contract, and we cannot compel them to sign the contract, they are not subject to our compliance or oversight authority, and nothing in our current regulations prevents these applicants from withdrawing their applications late enough in the process to cause significant disruption. In contrast, when an existing PDP sponsor withdraws its bid, we treat such an action as an election by the PDP sponsor to non-renew its contract in that PDP Region, which renders the sponsor ineligible to submit another application for 2 years, under our regulations at § 423.507(a)(3). We propose to make a regulatory change to ensure equal treatment between new applicants and existing PDP plan sponsors, which would allow us to maintain an accurate depiction of the contracting landscape. Specifically, we propose to amend § 423.503 by adding paragraph (d) which would impose a 2-year Part D application ban on organizations approved by CMS as qualified to enter into stand-alone PDP sponsor contracts but which elect, after our announcement of the LIS benchmark, not to enter into such contract and withdraw their PDP bids. This proposed regulatory change, in effect, would subject a withdrawing applicant to the same penalty we may apply to an organization already under contract that elects to terminate or non-renew its PDP contract.

It is critical that we have an accurate portrayal of the number and type of plan benefit packages that would be available to beneficiaries in every PDP Region, especially during the end of the summer when much of the bid review, both the formulary and actuarial components, has been completed. During this period, we need to confirm that there are the required minimum number of plans available in each PDP region. We also need accurate plan information at the end of the summer so that we can meet the production deadlines associated with the annual election period, including publication of the Medicare & You handbook as well as updating the Medicare Plan Finder Web site and our payment and enrollment systems. An applicant that withdraws its application late in the process alters the contracting landscape, potentially disrupting preparations we have already made, including those related to the auto assignment of LIS beneficiaries, for the upcoming plan year.

We acknowledge that PDP plan applicants may need to withdraw their pending contracts for a variety of legitimate business reasons. For this reason, we afford applicants several months to withdraw their applications, without penalty, following the application due date in February and the bid submission deadline of the first Monday in June. However, in adopting the proposed regulatory authority, we would place a reasonable limit on prospective PDP sponsors' option to withdraw bids and applications without penalty. By imposing consequences on applicants that withdraw their bids following the announcement of the LIS benchmark, we also would discourage any ''gaming'' of the bid review and auto assignment processes (for example, by participating in the bid review process until it learns that it will not qualify for auto assignments) that can occur when applicants opt out of participation in the PDP at the last minute.

3. Essential Operations Test Requirement for Part D (§ 423.503(a) and (c), § 423.504(b)(10), § 423.505(b)(28), and § 423.509)

We propose to create, through regulation, a new step in the application and contracting process with newly contracted entities operating as stand-alone PDP sponsors or MA organizations offering Part D plans (MA–PDs). This step will be an ''essential operations'' test which we would administer to ''newly contracted entities.'' We use the term ''newly contracted entity'' in this preamble to describe an organization that has

entered or applied to enter into a Part D contract with us for the first time for the upcoming plan year, and neither it, nor another subsidiary of the organization's parent organization, is offering Part D benefits during the current benefit year. This would include organizations that are offering EGWPs for the first time.

Currently, with the exception of the LIS readiness audits, we have no test for assessing the effectiveness of the arrangements organizations represent to us in their applications and bids prior to the actual start of delivery of benefits on January 1. An essential operations test would allow us to test whether an organization's arrangements appear likely to allow the organization to effectively administer its contract. We are proposing to require organizations to pass an essential operations test either—(1) as a qualification to contract, with failure to pass the test nullifying our approval of the application; or (2) after contract execution as a contract requirement but prior to the start of the benefit year, with a failure to pass the test triggering an immediate contract termination under § 423.509.

Pursuant to section 1860D–12(b)(3)(D) of the Act, which incorporates by reference section 1857(e)(1) of the Act, we have the authority to add contract provisions that are necessary and appropriate to carry out the Part D program; section 1860D–11(b) provides authority for the collection of additional information as part of the bid as we may require to carry out the Part D program. Based on this authority we propose adding § 423.504(b)(10) and § 423.505(b)(28) to include passing the essential operations test as a condition to enter into and a term of the Part D contract. Additionally, pursuant to our authority at section 1860D–12(b)(3)(B) and (b)(3)(F) of the Act (which incorporate by reference section 1857(c)(2) and (h) of the Act, respectively, to apply to the Part D program), the current regulations at § 423.509(a) and (b)(2)(i), authorize immediate termination of contracts with Medicare Part D plan sponsors in certain circumstances. We believe that immediate termination would be authorized under the standard of section 1857(h)(2) of the Act because the inability of a plan sponsor to ensure future members' access their drug benefit, as evidenced by failure to pass the essential operations test, would constitute an imminent and serious risk to beneficiary health and safety. We propose adding § 423.509(a)(4)(xii) and (b)(2)(i)(D) to subpart K to reflect this new cause for immediate termination. (Of note, we are reorganizing § 423.509(a) to group the statutory basis for termination together followed by examples of violations that would meet the statutory basis. This new regulation is an example of a violation.) Additionally, we propose to explicitly include the essential operations test as a means to evaluate Part D applicants in § 423.503(a)(1) and to add § 423.503(c)(4) to subpart K to establish failure of an essential operations test as grounds for nullifying a CMS approval of application notice.

The heart of the Part D benefit is the sponsor's ability to process claims for prescription drugs in real-time because, unlike health benefits, where claims payment normally follows the delivery of services, pharmacies require confirmation of claims payment at the point-of-sale either from an insurer or the covered individual. Success in Part D claims processing depends largely on the sponsor's ability to perform enrollment, benefit administration, and claims adjudication operations seamlessly at the point-of-sale. That is, the sponsor must be able to do all of the following essential operations in real time and at the point-of-sale to a satisfactory level: Identify a beneficiary as a member of one of its Part D plans; determine whether the drug requested is, in fact, appropriately covered under Part D (for example, that the drug is not covered: (a) Under Part B, (b) as part of end-stage renal disease (ESRD) treatment, or (c) as a hospice benefit); determine the phase of the benefit the beneficiary is currently in; and provide the pharmacy with instructions so that the beneficiary can be charged appropriate copays/coinsurance and deductibles.

We are proposing the essential operations test and associated regulatory changes because of our experience with certain newly contracted entities in the Part D program that experienced significant operational difficulties at the start of the benefit year as a result of their inexperience administering Part D benefits. To prevent the recurrence of this problem and ensure that new sponsors are prepared to and actually can deliver Part D benefits at an acceptable level, starting with the 2015 contract year application cycle, we propose that we may require newly contracted entities to pass an essential operations test conducted by us beginning in the fall of 2014.

Often these newly contracted entities have little or no prior experience in administering health and drug benefit plans. Unfortunately, by the time deficiencies in the sponsor's operations and ability to provide the Part D benefit become apparent (typically when we receive complaints about significant numbers of inappropriately rejected claims at the pharmacy), the sponsor has already executed an agreement with us, which has prevented us from moving quickly to remove the sponsor from the program and prevent further beneficiary harm. In these instances, we have found it necessary to provide inordinate amounts of resource-intensive technical assistance to sponsors that were not prepared to effectively administer Part D benefits when they signed their contract. The essential operations test would help to prevent the recurrence of problems of this nature.

The essential operations test for newly contracted entities would entail testing of sponsors' command of Part D benefit administration rules and systems related to these areas. Initially, the testing would consist of scenario testing with sponsors' key staff to show us that they have a firm grasp of the Part D policies and essential operations. The test would be able to verify whether an applicant's administrative and management arrangements, as attested to in its application, are sufficient for the applicant to carry out functions listed in § 423.504(b)(4)(ii) such as furnishing prescription drug services and implementing utilization management programs.

Provided we have the resources, in the future, the test would likely become significantly more sophisticated and involve live testing of sponsors' systems with test data. The more involved test would also likely include testing the processes related to enrollment such as MARx communication and processing; LIS processing and determinations; coverage determinations, appeals, and grievances (CDAG) processing; and real-time coordination of benefits data exchange and processing. For instance, the sponsor would need to demonstrate the ability to pay test claims correctly in real-time consistent with its CMS-approved benefit packages (including formulary) and the Part D transition fill policy.

The timing of the essential operations test must fit within the timeline of the annual Part D contracting process, which is driven largely by the bid deadline and plan election period dictated by statute. In preparation for an upcoming benefit year beginning on January 1, we must solicit and review applications from organizations seeking a MA–PD or PDP sponsor contract in February of the preceding year. We issue application determinations (that is, approval or denial) in May. All existing Part D sponsors and new applicants must submit their plan

benefit package (PBP) bids (including formularies) in June. Then, we complete the bid review approval and negotiation processes at the end of August. Once we have approved the submitted bids, sponsors can then execute their contracts with us. Historically, we have executed all contracts by mid-September so we can finalize preparations for the marketing season, which begins on October 1, and the annual election period (AEP), which begins on October 15. These preparations include publishing the Medicare & You handbook in September, which lists approved plans; releasing the Medicare Plan Finder Web site using plan-specific data; reviewing and approving sponsors' marketing materials; and granting sponsors access to our enrollment systems.

In contrast to an audit, the application process currently only requires that sponsors demonstrate to us that they have the necessary legal arrangements in place (for example, a risk-bearing license, executed contracts with first-tier and downstream entities, pharmacy network descriptions, etc.). Likewise, bid and formulary approvals indicate that the plans to be offered by the new sponsor are acceptable to us, not that the sponsor will necessarily be successful in implementing those plans.

Under our current schedule, the essential operations test we propose to require as part of the application and contracting process would occur after contracts are signed in September but before the start of the benefit year on January 1. We would most likely complete the tests by November 15. In the future, we aim to conduct the essential operations tests prior to signing contracts with applicants which is why we are also proposing to add passing the test as a qualification to contract. Ultimately, in the event of an organization failing the test, we would apply the appropriate proposed regulatory provision based on the timing of the test administration.

a. Failing Essential Operations Test as Cause for Immediate Termination

Once a sponsor signs its contract, it is obligated to perform all of the required functions to support the benefits described in the contract even though the sponsor does not start offering benefits until January 1. Given the volume of preparations and tight resource constraints between our approving bids in late August and the start of the AEP in October, the first opportunity we currently have to devote resources to the essential operations test is most likely in late September to November. We are currently not likely to be in the position to conduct essential operations tests prior to contracting because it would be challenging to conduct the test prior to approving the benefit structure against which we would test a sponsor's ability to process claims accurately. If we find that a sponsor does not have the requisite systems and processes in place to offer Part D benefits in real-time, we would consider this cause for immediate termination of the sponsor's Part D contract in order to protect beneficiaries from harm at the start of the contract year.

Pursuant to section 1857(h)(2) of the Act (incorporated by reference into PDP by section 1860D–12(b)(3)(F) of the Act), we have the authority to immediately terminate a contract with a sponsor (without notice and opportunity for a hearing) when a delay in termination would pose an imminent and serious risk to the health of beneficiaries enrolled in the sponsor's plans. Also, under § 423.509(b)(2)(i) and § 423.652(b)(2), unlike standard CMS terminations, the effective date of an immediate termination is not stayed when the sponsor requests a hearing under § 423.650(a)(2). Because enrollment and accurate benefit administration through real-time claims processing are so fundamental to the delivery of the Part D benefit, if a sponsor fails to demonstrate to us that it can perform these essential operations, we would view this as a substantial failure to meet the Part D contract requirements on the following grounds: (1) Evidence that the sponsor was carrying out the contract in a manner that was inconsistent with the effective and efficient administration of the plan; and (2) evidence that the sponsor did not substantially meet the applicable conditions set out in the Part D regulations which would ultimately justify, depending upon timing of the test, our termination of a contract consistent with § 423.509(a)(1) through (3) based on the sponsor's failure to meet our proposed contract terms at § 423.504(b)(10) and § 423.505(b)(28). We believe that a newly contracted entity's failure to demonstrate certain critical capabilities and failing the essential operations test represents a substantial failure to carry out its Part D contract and is evidence that the sponsor is not prepared to carry out the contract in a manner that is consistent with the efficient and effective administration of the Part D program. Such a failure poses an unacceptable risk to the new sponsor's future members' access to Part D drugs, which would constitute an imminent and serious risk to beneficiary health and safety, justifying our immediate termination of the sponsor's contract. For MA organizations that must offer Part D benefits pursuant to § 423.104(f)(3)(i), failing the test would support the termination of the organization's Part D addendum as well as its MA contract under § 422.510(a)(3) because the inability to offer Part D benefits means that the organization no longer meets the applicable conditions associated with offering Part C benefits.

Given our experience with sponsors' abilities to resolve systemic systems problems in a timely manner, we believe that sponsors that fail the test would most likely not have sufficient time before the start of the benefit year to remedy the breadth and magnitude of the failures we would have identified during the test. Even if the sponsor attested that it had corrected problems we identified, we would not have time to conduct a second test to validate the sponsor's corrections prior to the start of the new benefit year. Simply put, we believe the risk of harm to enrollees' health and safety is too great to move forward with a sponsor that has such significant and critical problems so close to the start of the plan year. Thus, an immediate termination of the contract before the start of the year would be the only way to protect beneficiaries and ensure successful operation of the Part D program by absolving the sponsor and us of the responsibilities in the contract.

b. Failing Essential Operations Test as Failure of a Qualification to Contract and Grounds for Nullification of Approval

If an organization fails an essential operations test we conducted prior to contract signature, no termination would be necessary as we would simply nullify our previous conditional approval of the organization's Part D contract qualification application. Section 423.503(a) describes the mechanisms we use to evaluate an applicant and determine whether the applicant is qualified to contract. These mechanisms currently include application review and on-site visits. The general term ''on-site visit'' is used to describe interactions with applicants that include our visiting the applicant's facility and vice versa, either in person or virtually. We are proposing to explicitly include the essential operations test as a qualification to contract at § 423.503(a)(1) to authorize our use of the test and any information learned in the course of the essential operations test in making the contract determination. Our experience over the

past few years with newly contracted entities that have passed the paper-based application, but failed to have fully-functional administrative and management arrangements in place to effectively offer benefits in January, has demonstrated to us that implementing an essential operations test is key to the successful administration of the Part D program for all beneficiaries.

We would view failure of the essential operations test as a determination that the applicant would not be qualified to contract with us. As a result, we would nullify our approval on that basis. Successful applicants receive a conditional approval at the end of May of their Part D application pursuant to § 423.503(c)(1). The letter informs applicants that the conditional approval is based on the information contained in their application, and if we subsequently determined that any of the information was inaccurate or that qualification requirements are not met, we would withdraw the approval of the application. Through that notice, we preserve the right to nullify our approval. If that occurs, we would not provide appeal rights described in subpart N to applicants that have their approval nullified based on failing the essential operations test.

We are proposing to not afford applicants appeal rights because CMS would not be able to conduct the appeals process provided for in Part 423, Subpart N, within the timeframe imposed by § 423.650(c), which requires CMS to have all contract application appeals decided by September 1 for contracts to be effective on January 1 of the following year. We could not conduct a test in late August, find that the applicant failed the test, and move through a fair appeal process for both parties in less than 2 weeks. Therefore, we would not afford appeal rights to applicants that fail the test prior to contracting under our proposal.

4. Termination of the Contracts of Medicare Advantage Organizations Offering PDP for Failure for 3 Consecutive Years To Achieve 3 Stars on Both Part C and Part D Summary Star Ratings in the Same Contract Year (§ 422.510)

In the final rule adopted April 12, 2012 (77 FR 22168), we set forth at § 422.510(a)(14) and § 423.509(a)(13) that a Medicare contracting organization's consistent failure to achieve at least a 3-star summary star rating for 3 consecutive years provides a sufficient basis for us to make a decision to terminate our contract with a MA organization or stand-alone PDP sponsor. This termination standard was based on the criteria we used then to mark low-rated contracting organizations with a ''low performing icon (LPI)'' on the Medicare Plan Finder Web site. Recently, we revised our LPI assignment criteria for MA organizations that offer PDP benefits (MA–PDs) to more accurately reflect their contract performance. We propose here to revise the contract termination regulation related to consistent low star ratings to reflect the new LPI assignment methodology announced in the contract year 2014 Call Letter. Specifically, we are proposing to modify our existing authority at § 422.510(a) [3] by clarifying that MA–PD organizations that do not achieve at least 3 stars in both their Part C and D ratings in the same year for 3 consecutive years may be subject to termination.

In the April 12, 2012 final rule (77 FR 22072), we finalized the contractual requirement at § 422.504(a)(18) and § 423.505(b)(25) that MA organizations and PDP plan sponsors attain each year summary ratings of at least 3 stars (the ''average'' performance rating). We explained that, because the star rating calculations are based on an organization's performance across a wide array of operational measures, the summary star ratings are an accurate indicator of the extent to which the organization has in place effective administrative and management arrangements necessary to administer Part C and Part D benefit plans, as required under § 422.504(a)(17) and § 423.505(b)(24).

We further established, as part of the same rulemaking, our authority at § 422.510(a)(14) and § 423.509(a)(13) to terminate the contracts of organizations offering MA and stand-alone PDPs when those organizations fail to achieve at least 3 stars on either their Part C or Part D summary rating for at least 3 consecutive years. At the time, we stated that since the measures that make up the star ratings provide evidence of the sufficiency of a contracting organization's administrative and management capability, it was reasonable for us to conclude that an organization receiving a summary rating below 3 stars for 3 consecutive years had substantially failed to meet that requirement, providing us justification for terminating the contract of that organization. We also explained that 3 consecutive years was sufficient time for sponsors to analyze the underlying causes of their low ratings and take corrective action that would result in at least a 3-star summary rating. The rulemaking also called for an MA–PD organization's Part C summary rating to be tracked separately from its Part D summary rating. That is, we could terminate an MA–PD organization contract if it failed for 3 straight years to achieve at least a 3-star Part C summary rating, regardless of its Part D summary ratings. Similarly, we could terminate the same organization if it failed to achieve at least a 3-star Part D summary rating for 3 straight years, regardless of its Part C performance. Since in most instances an MA organization must also offer Part D benefits, consistently low Part D summary ratings justify a termination of the entire MA–PD contract since the organization could no longer meet its obligation to offer Part D benefits. We stated that we would allow a 3-year transition period before we would begin using the star rating-based termination authority to issue termination notices to any sponsors whose performance met the criteria in late 2014 with an effective date of January 1, 2015.

At the time we adopted this regulation, we identified certain organizations on the Medicare Plan Finder (MPF) Web site as consistently low performing organizations with the display of the LPI next to the organization's other plan information. In the contract year 2014 Call Letter released in April 2013, we announced a change in the methodology for assigning the LPI mark to plan sponsors. On page 105 of the notice, we noted that some stakeholders had raised concerns that MA–PD contractors could switch back and forth from poor performance on Part C to poor performance on Part D from year to year without ever being identified as a poor performer and marked with the LPI. We noted that such a situation was potentially misleading to beneficiaries, and we decided to address the matter by revising, effective in 2014, the criteria for the assignment of the LPI indicator to those organizations that fail for 3 consecutive years to achieve both Part C and Part D summary ratings of at least 3 stars in the same year for 3 consecutive years. We concluded this announcement by observing that MA–PD organizations are responsible for providing adequate care and services across both Part C and Part D and that the LPI methodology change encourages consistent improvement in the quality of care by MA–PD organizations across all of the Part C and Part D measures.

We believe that the justification for the change in the LPI methodology also requires a change in the way we would

[3] Elsewhere in this proposed rule, we proposed to reorganize and renumber § 422.510(a). The discussed provision is current codified at § 422.510(a)(14) but we are proposing to redesignate it as § 422.510(a)(4)(xi).

apply the standard for MA–PD contract termination based on star rating performance. The performance of an MA–PD organization must be assessed across the totality of its obligations under its Medicare contract. Organizations should not be permitted to target their compliance efforts from year to year on alternating sets of contract requirements, just barely meeting our minimum requirements in order to stay one step ahead of our enforcement authorities. Beneficiaries rightly expect quality in the delivery of all of their Medicare benefits, covering both health care and prescription drugs. MA–PD organizations that alternate their low star ratings from year-to-year between Part C and Part D are in fact subjecting their members to substandard performance every year. This is an unacceptable outcome that does not promote the best interests of Medicare beneficiaries.

If an MA–PD organization is not able to achieve at least an ''average'' star rating across all of its Part C and Part D operations in at least 1 year out of 3, it would become clear that the organization had both substantially failed to meet the administrative and management requirements of a Medicare contractor and could not take effective corrective action over the same 3-year period.

The artificiality of the division between Part C and Part D star rating performance becomes apparent when one notes the extent to which the measures for each part assess the MA–PD organization's performance of similar functions or responsibilities. According to the most recent methodology we used to calculate star ratings, ''The Medicare Health & Drug Plan Quality and Performance Ratings—2013 Part C & Part D Technical Notes,'' (*http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html*) the Part C measures are divided into 5 domains and the Part D measures into 4. Three of the Part C domains are virtually identical to those of Part D, with variations where necessary to reflect differences in terminology and features between health and drug plans. For example, Domain 1 for Part D, ''Drug Plan Customer Service,'' consists of measures that largely correspond to those of Part C's Domain 5, ''Health Plan Customer Service.'' Both contain measures that reflect call center performance (including foreign language availability) and processing of appeals. The Part D Domain 2, ''Member Complaints, Problems Getting Services, and Improvement in the Drug Plan's Performance,'' measures an organization's performance in largely the same categories as Part C's Domain 4, ''Member Complaints, Problems Getting Services, and Improvement in the Health Plan's Performance.'' Both domains consist of measures that reflect beneficiaries' complaints about the plan, their access to benefits, their decision to leave the plan, and the plan's quality improvement. Domain 3 of both the Part C and Part D measures are entitled ''Member Experience with the Health/Drug Plan'' and reflect plan members' experience with their plans such as assessment of their ability to access covered services (needed prescription drugs in the case of Part D, physician appointments, and coordination of care in the case of Part C). Domain 4 for Part D, ''Patient Safety and Accuracy of Drug Pricing,'' corresponds to Part C's Domain 1, ''Staying Healthy: Screenings, Tests and Vaccines,'' and Domain 2, ''Managing Chronic (Long Term) Conditions,'' in that they all capture an MA–PD organization's attention to the clinical impact of the Medicare services they provide to their members. The Part D measures in Domain 4 reflect the extent to which plan members maintain adherence to their medication regimens and receive prescriptions for high risk medications. The Part C Domains 1 and 2 address clinical performance as it is carried out by a health plan, including the extent to which it has conducted screenings of its members for breast cancer, colorectal cancer, and high cholesterol and manages long term conditions such as diabetes, high blood pressure, and rheumatoid arthritis.

The similarity in the Part C and Part D measures means that the operations associated with these 2 programs are not so different as to justify separate Part C and Part D analyses of MA–PD organization's delivery of Medicare benefits to the same set of beneficiaries in the same service area. MA–PD organizations do not contract with us to provide separate Part C and Part D benefits. Rather, it is more correct to say that their contract obligates them to provide effective customer service, access to care, and promote clinical outcomes across the entire range of Medicare benefits. Therefore, the better way to assess an MA–PD organization's administrative and management compliance is not to see whether it can meet Part C or Part D requirements, but whether it can meet the customer service, access to care, and clinical performance requirements in the delivery of all types of Medicare benefits. The only way to accurately measure the performance of such functions is to examine the organization's ratings in the Part C and Part D measures in the related domains. For example, an MA–PD organization cannot be said to be providing satisfactory customer service to its members if it achieves a 3-star rating in only its Part C operations.

Therefore, we propose to revise § 422.510(a) [4] to clarify that MA-only contracts are subject to CMS termination when they fail for 3 consecutive years to achieve a Part C star rating of at least 3 stars. Additionally, we propose to add a subparagraph to § 422.510(a) to establish as a basis for termination of MA–PD contracts the failure for 3 consecutive years of the contract to achieve at least 3 stars in both its Part C and D ratings in the same year. When we first adopted the star rating-based contract termination authority in April 2012, we stated that we would afford organizations a 3-year transition period before we would use that authority to make contract termination decisions. This period was necessary to allow organizations to make adjustments to their operations to reflect the dramatic increase in the consequences associated with low star rating performance created by our new termination authority. Accordingly, the regulation states that we may use only those star ratings issued after September 1, 2012, to make a decision to terminate a contract based on consistently low star ratings. Thus, organizations that fail to achieve at least a 3-star rating upon the release in September 2014 of the 2015 ratings would be the first group of Medicare contractors eligible for termination under our new authority. We are not proposing to extend this grace period as part of this proposed adjustment to the current policy, because there is no reason why failures under the current regulations (which contain the ''loophole'' we are closing here) should not count towards the 3-year mark along with failures under the revised standard once in place.

[4] Elsewhere in this proposed rule, we would reorganize and renumber § 422.510(a) and § 423.509(a) to better reflect the bases for contract termination in connection with our statutory authority to terminate. Using the current numbering, this proposal would be codified as § 422.510(a)(14) but under our proposal here, it would be codified as § 422.510(a)(4)(xi).

III. Provisions of the Proposed Regulation

E. Implementing Other Technical Changes

1. Requirements for Urgently Needed Services (§ 422.113)

Our regulations at § 422.113(b) require MA organizations to cover urgently needed services furnished outside a plan's service area or contracted network of providers when the enrollee is in need of such services but is outside of the service area or is in the service area but the plan network is temporarily unavailable due to extraordinary and unusual circumstances. Further requirements built in to the definition of ''urgently needed services'' specify additional criteria for out-of-network coverage of these services: (1) The need for services was a result of unforeseen illness, injury or condition; and (2) it is not reasonable, given the circumstances, for the enrollees to obtain the services through the organization offering the MA plan.

In the preamble to our June 29, 2000 final rule implementing the current requirements (65 FR 40199), we clarified the intended meaning of ''extraordinary and unusual circumstances'' as ''an earthquake or strike.'' However, it is our experience in administering the MA program that there are other much less severe circumstances in which the plan network may be unavailable or inaccessible to an enrollee who is in the authorized service area and needs immediate care due to an unforeseen illness, injury or condition. Examples of such circumstances include the need for urgent care outside of the network's business hours, (for example, during the weekend or at night).

Many MA plans have responded to the need for urgently needed services by contracting with clinics that have hours of operation well beyond those of traditional physicians' offices to furnish services to their enrollees when the plan network is not available.

To better align the regulations with current practices regarding access to urgently needed care services, we are proposing to revise the regulation by removing the phrase ''under extraordinary and unusual circumstances'' at § 422.113(b)(1)(iii). The proposed regulatory language would read as follows:

(iii) Urgently needed services means covered services that are not emergency services as defined in this section, provided when an enrollee is temporarily absent from the MA plan's service (or, if applicable, continuation) area (or provided when the enrollee is in the service or continuation area but the organization's provider network is temporarily unavailable or inaccessible) when the services are medically necessary and immediately required—

2. Skilled Nursing Facility Stays (§ 422.101 and § 422.102)

Under section 1814(a)(2)(B) of the Act, Medicare Part A generally only covers skilled nursing facility services (SNF) following a qualifying 3-day hospital stay. However, under section 1812(f) of the Act, we may authorize Part A coverage of SNF care without a prior hospital stay if two conditions are met. First, the coverage of these services must not result in any increase in Medicare program payments, and second, the coverage must not alter the acute care nature of the benefit. For reasons discussed later in this proposed rule, in an August 22, 2003 final rule (68 FR 50847), we exercised this authority under section 1812(f) of the Act with respect to SNF services covered under MA plans.

The reason that we took this step is that, in the absence of this exercise of this authority, MA organizations could only cover SNF services without a 3-day prior hospital stay as a supplemental benefit. In such a case, if an MA enrollee is in a SNF pursuant to such coverage in the middle of a 100-day covered stay, and disenrolls from the MA plan, or the MA plan is terminated or non-renewed during such a stay, the beneficiary would lose SNF coverage, as it would not be covered under Medicare Part A because it would not have met the condition for coverage of a 3-day prior hospital stay. By exercising the authority under section 1812(f) of the Act to make the stay a Part A covered benefit, the stay would remain covered even if the individual is no longer enrolled in the MA plan.

Our determination that SNF services provided by MA organizations without a 3-day prior hospital stay met the two tests in section 1812(f) of the Act was based on the fact that MA organizations are paid a monthly per-Medicare enrollee payment to provide all contracted services. Thus, Medicare costs would not be affected by permitting SNF services to be covered by Medicare without the prior 3-day hospital stay for so long as the beneficiary was enrolled in the MA plan because the plan is paid a fixed amount without regard to services received. We determined that this would provide incentives for the MA organizations to provide care more cost effectively. Some evidence at the time indicated that MA organizations, particularly coordinated care plans, could shorten hospital stays and shift patients to post-acute or subacute settings, such as SNFs, more quickly than under the original Medicare program. If SNF care is the appropriate level of care, MA organizations are then able to use SNF care rather than more expensive hospital care for similar patients requiring posthospital care. For some patients and diagnoses, the MA organization is able to bypass the hospital stay and admit the beneficiary directly to a SNF.

Because the previously discussed rulemaking exercised authority under section 1812(f) of the Act to authorize Part A coverage in the absence of an otherwise-required 3-day prior hospital stay, the regulations addressing ''basic benefits'' (which include benefits under Part A) at § 422.101 were revised to include provision for this Part A coverage at § 422.101(c).

Notwithstanding the fact that, when the option under § 422.101(c) is elected by an MA organization, the services are covered under Part A, at least some MA organizations did not include the costs of such stays in the Part A portion of their adjusted community rate (ACR) submissions, and in later years, in their bids. Rather, they continued to treat these Part A-covered services as ''supplemental benefits.'' We understand why MA organizations did this, as the services (other than in the case described previously when an MA enrollee receiving such services is no longer enrolled in an MA plan covering them) would not be covered under Part A if the enrollee were not enrolled in the MA plan. However, because of the section 1812(f) of the Act waiver, these services technically were services ''covered under Part A,'' included under § 422.101(a), not supplemental benefits under § 422.102.

We had determined in promulgating the August 2003 final rule that the services in this situation had to be treated as covered under Part A in order to protect coverage for a beneficiary who changes from MA coverage to original Medicare coverage mid-stay. However, in light of the fact that MA organizations have, over a period of years, been treating these benefits as supplemental benefits, we have determined that we can protect a beneficiary in the situation described without requiring an MA organization to include a SNF stay without a 3-day prior hospitalization as a Part A benefit under its MA plan by modifying our exercise of section 1812(f) of the Act authority to waive the 3-day prior hospitalization requirement *only* in cases in which an MA enrollee receiving SNF services without a 3-day

prior hospital stay changes from coverage under the MA plan to Medicare coverage under Original Medicare (or another MA plan that does not cover such stays as a supplemental benefit). This addresses the concern we were addressing in our August 2003 final rule without requiring MA organizations to change their treatment of this MA plan benefit.

In order to effectuate this proposed change in the scope of our section 1812(f) waiver, we are proposing to move the provision describing an MA organizations' authority to furnish covered SNF stays without the qualifying inpatient hospital stay required under original Medicare to a new § 422.102(f) in the section of the regulations governing supplemental benefits.

We also propose to make a conforming revision in the cross-reference to this provision that currently appears at § 409.30(b)(2)(ii), to—(1) reflect this provision's relocation from § 422.101 to § 422.102; and (2) reflect the fact that the Part A coverage provided for thereunder is not for the entire ''duration of the SNF stay'', but only for the period after the individual is no longer enrolled in the MA plan offering the coverage of the SNF stay as a supplemental benefit.

3. Agent and Broker Training and Testing Requirements (§ 422.2274 and § 423.2274)

Pursuant to our authority under sections 1851(h)(2), 1860D–1(b)(1)(B)(vi), 1851(j)(2)(E), and 1860D–4(l)(2) of the Act, we previously codified agent and broker training and testing requirements at § 422.2274(b) and (c) and § 423.2274(b) and (c) to require all agents and brokers selling Medicare products be trained and tested annually through a CMS endorsed or approved training program, or as specified by us, on Medicare rules and regulations specific to the plan products they intend to sell.

Since the training and testing requirements were implemented, we have embarked on various activities to improve and ensure the efficacy of training and testing. Specifically, we launched an online training and testing pilot in 2009 to increase understanding of the standardized Medicare program requirements. Although the pilot was successful, our ability to accommodate all agents and brokers nationally is limited and maintaining the training and testing module requirements creates a significant financial burden. Additionally, endorsing other entities limits our oversight of training and testing information, and assurance of consistency among program requirements. Moreover, through our monitoring efforts, we have found that MA organizations and Part D sponsors are complying with the annual guidance released by us. Specifically, we found that plans provided adequate detail on the level of information that must be covered in agent and broker training and testing materials. As a result, we propose to revise § 422.2274(b) and (c) and § 423.2274(b) and (c) to accomplish several things (i) remove CMS endorsed or approved training and testing as an option; (ii) require that agents and brokers be trained annually on Medicare rules and regulations; and details specific to the plan products they intend to sell: And (iii) require agents and brokers to be tested annually to ensure appropriate knowledge and understanding of the training topics. We believe this proposed change continues to ensure that all agents and brokers selling Medicare products have a comprehensive understanding of Medicare program rules. We previously proposed (see the provisions for ''Reducing the Burden of the Compliance Program Training Requirements (§ 422.503(b)(4)(vi)(C) and § 423.504(b)(4)(vi)(C)'') to require a standardized compliance training program. Under those provisions, MA organizations and Part D sponsors will not be permitted to develop and implement plan specific training materials or supplemental materials. The proposed change in this section is exclusive to the requirements for conducting marketing activities under the MA and Part D program.

4. Deemed Approval of Marketing Materials (§ 422.2266 and § 423.2266)

Sections 1851(h) and 1860D–1(b)(1)(B)(vi) of the Act establish the requirements regarding the review and approval of marketing materials created by MA organizations and Part D sponsors. Sections § 422.2266 and § 423.2266 provide the regulatory requirements for materials that are deemed approved. If we have not disapproved the distribution of marketing materials and forms submitted by an MA organization or Part D sponsor with respect to the plan in the area, we are deemed not to have disapproved in all other areas covered by the MA organization or Part D sponsor except with regard to any portion of the material or form that is specific to the particular area. Sections § 422.2262 and § 423.2262 also provide the requirements for the review and distribution of marketing materials. The provisions stated in § 422.2266 and § 423.2266 are also part of the review and distribution process of marketing materials, and therefore should be moved to align with the requirements in § 422.2262 and § 423.2262. Therefore, we propose moving the substance of the current requirements in § 422.2266 and § 423.2266 to § 422.2262 (a)(2) and § 423.2262(a)(2), respectively. We propose reserving § 422.2266 and § 423.2266.

In addition, we also believe that the current regulatory requirements in § 422.2266 and § 423.2266 do not clearly state when and to what extent marketing materials are considered deemed approved. Therefore, we propose to simplify the language presently contained in § 422.2266 and § 423.2266 by stating, ''if CMS does not approve or disapprove marketing materials within the specified review timeframe, the materials will be deemed approved. Deemed approved means that an MA organization or Part D sponsor may use the material.'' We believe this change clarifies the present regulatory requirement for deemed marketing materials.

5. Cross-Reference Change in the Part C Disclosure Requirements (§ 422.111)

Prior to the publication of subpart V, Medicare Marketing Requirements, marketing-related rules were found in subpart B, Eligibility, Election, and Enrollment. These rules (codified in § 422.80) included review of marketing materials and election forms. With the publication of our September 18, 2008 final rule (73 FR 54208), the marketing-related requirements were moved into the new subpart V and § 422.80 was removed. Since that time, we have discovered an incorrect cross-reference to § 422.80 at § 422.111(d)(1) for procedures MA organizations must follow when submitting its rules changes to us for review. The correct reference should be subpart V, Medicare Advantage Marketing Requirements. We are proposing in these regulations to correct the reference contained in § 422.111(d)(1).

6. Managing Disclosure and Recusal in P&T Conflicts of Interest: Formulary Development and Revision by a Pharmacy and Therapeutics Committee Under Part D (423.120(b)(1))

Section 1860D–4(b)(3)(A)(ii) of the Act requires Part D sponsors who use formularies to include on their P&T committees at least one practicing physician and at least one practicing pharmacist, each of whom is independent and free of conflict with respect to the sponsor and the plan and who has expertise in the care of elderly or disabled persons. In our August 3,

2004 proposed rule (69 FR 46659), we proposed to interpret ''independent and free of conflict'' to mean that such P&T committee members could have no stake, financial or otherwise, in formulary determinations. In our January 28, 2005 final rule (70 FR 4256), we adopted this interpretation, and clarified that we would consider a P&T committee member not to be free of conflict of interest if he or she had any direct or indirect financial interest in any entity—including Part D plans and pharmaceutical manufacturers—that would benefit from decisions regarding plan formularies.

In a recent report (''Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions,'' OEI–05–10–00450), the HHS OIG recommended improvements in our requirements for Part D plan P&T committees. Specifically, the OIG report recommended that we establish minimum standards to ensure that these committees have clearly articulated and objective processes to determine whether disclosed financial interests are conflicts and to manage recusals due to conflicts of interests. The OIG report also suggested that we tell sponsors that they need to designate an objective party, such as a compliance officer, to flag and enforce the necessary recusals. In other words, the identification and evaluation of whether a disclosed financial interest represents a conflict of interest should be made by a knowledgeable and accountable representative of the sponsor's organization, such as the compliance officer, and not solely by the P&T committee members themselves. We concurred that P&T committees should have clearly articulated and objective processes to determine whether disclosed financial interests are conflicts, and to manage recusals arising from any such conflicts. Therefore, to address these recommendations, we propose to revise our formulary requirements pertaining to development and revision by a P&T committee at § 423.120(b)(1) to make it clear that the sponsor must establish such processes. Moreover, we propose that these processes must be clearly articulated and documented, and enforced by an objective party.

In our response to the OIG report, we noted that statutory and regulatory provisions (section 1860D–4(b)(3) of the Act and 42 CFR § 423.120(b)) indicate that it is the plan sponsor's responsibility to meet the formulary requirements, which include development of these processes. We also noted that we believe the agency's current Part D formulary review provides appropriate protections to beneficiaries from any adverse effects resulting from potential conflicts of interest. The agency thoroughly reviews Part D formularies to prevent discrimination against Medicare beneficiaries based on age, disease, or setting in which they receive care. The review process ensures inclusion of a broad distribution of therapeutic categories and classes by using reasonable benchmarks to ensure drug lists are robust. Further, we ensure that cost-sharing levels and utilization management strategies are appropriate and non-discriminatory. We identify potential outliers at each review step for further investigation and require reasonable clinical justification when outliers appear to create beneficiary access problems. We devote extensive resources to plan formulary oversight—and reserve the right to reject any formulary—to ensure compliance with industry best practices for formulary development and to ensure beneficiaries' access to clinically appropriate therapies.

Therefore, if a P&T committee, while operating under a potential conflict of interest were to create a formulary representative of such conflicts, the formulary would likely be discriminatory. Because a discriminatory formulary would not be approved, the only potential impact we can envision would be that the bid could be more expensive and, therefore, less competitive. However, in this case, beneficiaries could easily evaluate these higher premiums in the marketplace and choose a more efficient plan to meet their needs. As a result, we would expect that, given our level of formulary review, a conflict of interest in the P&T committee would disadvantage the sponsor rather than the beneficiary or the Medicare program.

We have also been asked to consider whether the practicing physician and the practicing pharmacist on the P&T committee who must be free of conflict of interest from Part D plans and pharmaceutical manufacturers should also be free of conflict of interest from Pharmacy Benefit Managers (PBMs). As discussed previously, we believe that our current formulary review process confers appropriate protections to beneficiaries from any potential adverse effects of conflicts of interest. Additionally, we have devoted extensive resources to the oversight of plan formularies and audit of P&T committee proceedings to ensure that they comply with industry best practices for development and management, and ensure beneficiaries' access to clinically appropriate therapies.

P&T committees must first base their clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate, consistent with the program goal of maintaining a competitive market. Therefore, given that sponsors must balance both quality and costs in developing formularies, and that PBMs are the entities that negotiate for price concessions on behalf of sponsors, we believe that it is appropriate that PBMs have an interest in formulary decisions. However, we solicit comment on the pros and cons of defining PBMs as entities that could benefit from formulary decisions from which one practicing and one practicing pharmacy on the P&T committee must be free of conflict of interest.

As discussed previously, we believe the potential effects of conflicts of interest would theoretically result in either discriminatory or inefficiently priced plans. However, our formulary review process prevents discrimination, and higher priced plans will be subject to competition on premiums in the marketplace. Nonetheless there may be risks to formularies that we have not anticipated. In addition, we believe that sponsors should be accountable for objectively managing potential conflicts of interest as directed by the statute. Therefore, we propose revising our regulations at § 423.120(b)(1) to renumber the existing provisions and add a new paragraph (b)(1)(iv) to require that the sponsor's P&T committee clearly articulates and documents processes to determine that the requirements under paragraphs (b)(1)(i), through (iii) have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts.

7. Definition of a Part D Drug (§ 423.100)

Section 1860D–2(e) of the Act defines a covered Part D drug as a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1927(k)(2) of the Act; or a biological product described in clauses (i) through (iii) of subparagraph (B) of such section, or insulin described in subparagraph (C) of such section and medical supplies associated with the injection of insulin (as defined in regulations of the Secretary), and such term includes a

vaccine licensed under section 351 of the Public Health Service Act (and, for vaccinations administered on or after January 1, 2008), its administration, and any use of a covered Part D drug for a medically accepted indication (as defined in paragraph (4)). We codified this definition in § 423.100.

a. Combination Products

The FDA approves and regulates many products that include drug-drug and drug-device combinations. However, for the purposes of the Part D program, only combination products approved and regulated by the FDA as drugs, vaccines, or biologics (or any approved combinations of these) are potentially eligible for Part D coverage, in line with the Part D drug definition. We have previously addressed the status of combination products through guidance, including initially a published Q&A response and later in Section 10.3 of Chapter 6 of the Medicare Prescription Drug Benefit Manual (Part D Manual). This guidance has specified that combination products that contain at least one Part D drug component are Part D drugs when used for a medically accepted indication, unless such product, as a whole, belongs in one of the categories of drugs excluded from coverage under the Part D program. We now propose to address this issue in regulation to codify and clarify our policy.

We propose to add paragraph (vii) under the definition of a Part D drug to further clarify that only those combination products approved and regulated in its combination form by the FDA as a drug, vaccine, insulin, or biologic, as described in paragraph (i), (ii), (iii), or (v) of the Part D drug definition, may be eligible for Part D coverage. Our proposal would make it clear that the definition of a Part D drug excludes products where a combination of items are bundled or packaged together for convenience (such as one box packaging together multiple products, each in separate bottles), where the bundle has not been evaluated and approved by the FDA. This proposal would not affect products where multiple active ingredients (including at least one Part D eligible prescription-only ingredient) are incorporated into a single pill or single injection, as such products would have had to go through FDA approval in this combined form, meeting the Part D requirement. Combination products that are FDA approved would then be treated like other Part D drugs, eligible for coverage only when being used for a medically accepted indication and not otherwise excluded from Part D coverage (for example, because it is covered as prescribed and dispensed or administered under Medicare Part B).

This proposed policy is intended to clarify that a combination product containing at least one constituent ingredient that would, if dispensed separately, meet the definition of a Part D drug is eligible for Part D coverage only if it has received FDA approval in its combined form. Combination products not FDA approved as drugs under the Federal Food, Drug, and Cosmetics Act would not satisfy section 1927(k)(2)(A)(i) of the Act, defining covered outpatient drugs as those approved for safety and effectiveness as a prescription drug. Combination vaccines not licensed as a vaccine under section 351 of the Public Health Service Act similarly would not satisfy the definition of a Part D drug as defined in section 1927(k)(6).

Our proposal would not require that all constituent ingredients of a combination product be FDA-approved prescription drugs. An example would be an FDA-approved prescription drug that combines a Part D drug with a non-Part D covered vitamin. Conversely, a product combining a Part D drug with a medical food, dietary supplement, or another Part D drug, where the combined product has not received FDA approval as a prescription drug, vaccine, or biologic would not be eligible for Part D coverage.

b. Barbiturates and Benzodiazepines

We also propose to amend the definition of a Part D drug to address certain exclusions by revising paragraph (2)(ii). When the Part D benefit started in 2006, all uses of barbiturates and benzodiazepines were excluded from coverage by statute. In 2008, section 175 of the MIPPA amended section 1860D–2(e)(2)(A) of the Act to include coverage for barbiturates when used in the treatment of epilepsy, cancer, or a chronic mental health disorder and for benzodiazepines when used for any medically accepted indication, effective January 1, 2013. In 2010, section 2502 of the Affordable Care Act amended section 1927(d) of the Act, to remove barbiturates and benzodiazepines from the list of drugs subject to exclusion from coverage, effective for services provided on or after January 1, 2014. Thus, this subsequent statutory change effectively includes barbiturates as a Part D drug for all medically accepted indications. The proposed revision to § 423.100 would conform our definition of Part D drug to the new statutory requirement.

c. Medical Foods

We propose to add paragraph (2)(iii) to the list of exclusions from the definition of Part D drug to specify that medical foods, as defined in 21 U.S.C. 360ee, are not Part D drugs. Medical foods are not described in subparagraphs A(i), A(ii) or A(iii) of section 1927(k)(2) of the Act, and therefore do not meet the statutory definition of a covered Part D drug, nor do they fall under other categories eligible for Part D coverage listed in the Part D drug definition, such as biologics, vaccines, and insulin.

Moreover, as described previously in the section on combination products, a product with relevant components including some or all ingredients meeting the definition of a Part D drug would not be eligible for Part D coverage unless the combined product has also been approved by the FDA as a drug, vaccine, or biologic.

The proposed clarifications involving coverage for approved combination products and non-coverage of medical foods would not affect current policies surrounding Part D coverage of parenteral nutrition. (See the Part D manual guidance, Chapter 30.7 regarding the payment for parenteral and enteral nutrition items and services.) Extemporaneously compounded prescription drug products (addressed separately in Chapter 6 of the Part D manual and in § 423.120) also would not be affected by the proposed changes. Part D coverage for extemporaneously compounded prescriptions is available for the ingredients that independently meet the definition of a Part D drug when the product needed is one requested by the provider to meet a specific medical need, where there is no commercially available alternative. The convenience packaging of unapproved combination products for broad distribution does not meet the criteria set out specifically for extemporaneously compounded prescriptions.

8. Thirty-Six Month Coordination of Benefits (COB) Limit (§ 423.466(b))

In our April 15, 2010 final rule (75 FR 19819), we exercised our authority under sections 1860D–23 and 1860D–24 of the Act to impose a timeframe on the coordination of benefits between PDP sponsors and other payers including State Pharmaceutical Assistance Programs (SPAPs), other providers of prescription drug coverage, or other payers. In the preamble of the final rule, we explained our approach to determining the 3-year timeframe,

including the benefits derived from its establishment.

We stated, ''PDP sponsors must coordinate benefits with SPAPs, other entities providing prescription drug coverage, beneficiaries, and others paying on the beneficiaries' behalf for a period not to exceed 3 years from the date on which the prescription for a covered PDP drug was filled.'' The phrase ''a period not to exceed 3 years'' has caused confusion among some sponsors, who interpreted this to mean that the coordination of benefits period could be shorter than 3 years, and have consequently imposed tighter timeframes for coordination of benefits.

To clarify the requirement and avoid further confusion, we are proposing to remove from the regulation the phrase ''not to exceed,'' and adding the word ''of.'' This would clarify that sponsors must employ a coordination of benefits period of 3 years, and would remove any uncertainty about whether they may impose a shorter coordination of benefits period.

We also propose to revise the heading of § 423.466 to reference claims adjustments, which are addressed in § 423.466(a).

9. Application and Calculation of Daily Cost-Sharing Rates (§ 423.153)

We are proposing technical changes to the daily cost-sharing rate rule to clarify the application and calculation of daily cost-sharing rates and cost-sharing under the rule. We reminded Part D sponsors in the contract year 2014 Final Call Letter that, beginning January 1, 2014, in accordance with § 423.153(b)(4)(i), they must establish and apply a daily cost-sharing rate whenever a prescription is dispensed by a network pharmacy for less than a 30 days' supply, unless the drug is excepted in the regulation. These provisions were finalized in a rule entitled ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes'' (77 FR 22072) (''April 12, 2012 final rule''). We provided information in the contract year 2014 Final Call Letter about changes to the PBP to accommodate a mandatory Daily Copayment field for any tier where the plan enters a Copayment Field to assist sponsors that have been confused about how to calculate daily cost-sharing rates. We also noted in the contract year 2014 Final Call Letter that the daily cost-sharing rate rule does not address how pharmacy dispensing fees are to be negotiated, calculated, or paid. We did so because we had heard that some sponsors are prorating dispensing fees as part of implementing the LTC short-cycle dispensing requirement of § 423.154 effective beginning January 1, 2013 and may be incorrectly referencing the upcoming daily cost-sharing rate rule as the reason. We made clear that there is no necessary connection between daily cost-sharing rates charged to beneficiaries and how dispensing fees are paid to pharmacies. Nothing in the daily cost-sharing rate rule at § 423.153(b)(4) requires the proration of dispensing fees, and we proposed a prohibition on the proration of dispensing fees in the LTC setting in another section of this proposed rule, because we believe it encourages inefficient dispensing in LTC facilities. In light of continuing confusion among some Part D sponsors about the daily cost-sharing rate rule, we believe technical changes to the rule are warranted.

Currently, under § 423.100, in cases when a copayment is applicable, ''daily cost-sharing rate'' is defined as the ''monthly copayment under the enrollee's Part D plan, divided by 30 or 31 and rounded to the nearest lower dollar amount, if any, or to another amount, but in no event to an amount that would require the enrollee to pay more for a month's supply of the prescription than would otherwise be the case.'' When we drafted this definition, we used the numbers ''30'' and ''31,'' as these are the numbers of days that are typically in a month's supply in Medicare Part D prescription drug benefit plans. However, we clarified in the Call Letter that the maximum amount that can be entered for the Daily Copayment field in the PBP will be based on the 1-month copayment amount divided by the actual number of days entered for the 1-month supply for that specific tier. Therefore, we are proposing to replace these numbers with the phrase ''the number of days in the approved month's supply for the drug dispensed'' to address how Part D sponsors that have other days' supplies as their month's supplies are to calculate daily cost-sharing rates.

Also, under our existing definition of ''daily cost sharing rate'' in § 423.100, as noted above, and with respect to copayments, the daily copayment cannot be an amount that would require the enrollee to pay more for a month's supply of the prescription than would otherwise be the case. For example: If a plan uses a 31-day supply as its 1-month supply and establishes a one-month copayment of $70 for Tier 3, then the Daily Copayment field entry for that tier could not be higher than $2.25 ($70/31 = $2.258). Thus, if a plan must round the daily cost-sharing rate to a dollar and cents figure, the highest amount the plan could round to would be the nearest lower dollar and cents amount, as shown in the example. If a plan rounded the daily cost-sharing rate up, then if an enrollee eventually received a month's supply of a medication, the enrollee would pay more than ''would otherwise be the case,'' meaning more than the 1-month cost sharing specified in the approved benefit package. In the example, if a plan were to round the daily cost-sharing rate up to $2.26, an enrollee who eventually receives a month's supply of the medication would pay $70.06, which is higher than the approved $70 copay for that tier. In other words, rounding up is not permitted under the current definition of ''daily cost-sharing rate'' and this has been another cause of confusion for some Part D sponsors.

While our original intention was to prohibit significant increases in cost sharing, such as charging the full 30-day copay for both the trial supply and any subsequent refill of a medication, the current limitation on any increase in cost sharing over the 30-day supply amount has reportedly led to unnecessarily complicated programming, as well as proration of other amounts on the claim, such as the dispensing fees, as discussed previously. Therefore, we are proposing to replace the language ''lower dollar amount, if any, or to another amount,'' with ''the nearest cent.'' We believe this language would be the simplest way to convey the concept of rounding, while realizing this language would allow Part D sponsors to round daily cost-sharing rates up or down to the nearest 2 decimal places. For instance, in the example provided previously, the daily cost-sharing rate would actually be rounded to $2.26, as this amount would be the nearest cent. For the reasons we describe in the following paragraph, we believe this slight change in policy is not significant and that the proposed revised regulation text would address current confusion about the daily cost-sharing rate rule. The revised definition of ''daily cost-sharing rate'', if adopted, would read with respect to copayments: ''as applicable, the established monthly copayment under the enrollee's Part D plan, divided by the number of days in the approved month's supply for the drug dispensed and rounded to the nearest cent.''

As noted previously, the daily cost-sharing rate rule applies whenever a prescription is dispensed by a network pharmacy for less than a 30 days' supply, unless the drug is excepted in the regulation. However, as detailed in

the preamble to the April 12, 2012 final rule (77 FR 22072), it is primarily expected to incentivize Part D enrollees to talk with their prescribers about trial supplies, when they are prescribed an expensive chronic medication for the first time. By obtaining a less-than-30-days' supply, beneficiaries reduce their cost sharing when the medication is discontinued in the first month due to poor tolerance or side effects, which also benefits the Part D program by reducing costs of unused medications. In addition, as noted in the April 12, 2012 final rule (77 FR 22072), we believe some enrollees will be encouraged to request that their pharmacists assist them with synchronizing the refill dates of multiple medications, because they could do so without having to pay a full month's cost sharing for the shortened days' supplies necessary to synchronize refill dates. Although permitted under the rule, we do not foresee enrollees choosing to continue to receive chronic medications incrementally on a sequential basis. We anticipate that enrollees who tolerate a chronic medication would obtain months' supplies after the first incremental fill, and enrollees who are synchronizing medications are expected to do so through one incremental fill of all medications except one. Therefore, even though the proposed revised definition of ''daily cost-sharing rate'' could result in an enrollee who receives the remainder of month's supply after receiving an incremental fill paying slightly more than he or she otherwise would have for a month's supply, we believe such cases would be rare, if any, and the amounts involved are nominal anyway. We are more concerned that the regulation text with respect to rounding is clearer, and in this regard, we solicit comments on whether sponsors need any additional rounding guidance.

We are also proposing other technical changes to the daily cost-sharing rate rule at § 423.153(b)(4)(i) to improve the regulation's clarity. First, we are proposing to consolidate the language of § 423.153(b)(4)(i)(A) into § 423.153(b)(4)(i) and to consolidate § 423.153(b)(4)(i)(B)(1) and (2) into a new paragraph § 423.153(b)(4)(ii). Second, we are proposing that the language in § 423.153(b)(4)(i) that addresses the application of the daily cost-sharing rate in the case of a monthly copayment be revised for clarity, and moved to a new paragraph (b)(4)(iii)(A). This paragraph would state that in the case of a drug that would incur a copayment, the Part D sponsor must apply cost-sharing as calculated by multiplying the applicable daily cost-sharing rate by the days' supply actually dispensed when the beneficiary receives less than a 30 days' supply. Again, this is not a change in policy but is merely a technical change to the regulation text for better clarity. Third, we are proposing that § 423.153(b)(4)(iii)(B) would state that, in the case of a drug that would incur a coinsurance percentage, the Part D sponsor shall apply the coinsurance percentage for the drug to the days' supply actually dispensed. We note that this means, with respect to dispensing fees, that the enrollee's portion of additional dispensing fees for the incremental supply would be calculated by application of this percentage. We believe all the foregoing technical clarifications will assist sponsors in correctly setting, calculating, and applying daily cost-sharing rates in the retail and LTC settings beginning January 1, 2014 whenever a prescription is dispensed by a network pharmacy for less than a 30 days' supply, unless the drug is excepted in the regulation.

10. Technical Change To Align Regulatory Requirements for Delivery of the Standardized Pharmacy Notice (§ 423.562)

The current regulations at § 423.562(a)(3) require Part D plan sponsors to make arrangements with their network pharmacies to distribute notices instructing enrollees how to contact their plans to obtain a coverage determination or request an exception. This is accomplished through delivery of a standardized notice, CMS–10147—''Medicare Prescription Drug Coverage and Your Rights'' (''pharmacy notice''). Section 423.562(a)(3) cross-references § 423.128(b)(7)(iii), added in our April 2011 final rule (76 FR 21432), which requires plans to have a system in place that transmits codes to network pharmacies so the pharmacy is notified to deliver the pharmacy notice at the point of sale (POS) in designated circumstances where the prescription cannot be filled as written.

Pursuant to the 2011 regulatory change, we issued subsequent guidance (HPMS memoranda dated October 14, 2011 (''Revised Standardized Pharmacy Notice'') and December 27, 2012 (''Revised Guidance for Distribution of Standardized Pharmacy Notice'') which clarifies that distribution of the pharmacy notice is required upon receipt of certain transaction responses indicating that the claim is not covered by Part D, as well as revised manual guidance in Chapter 18, section 40.3.1 of the *Medicare Prescription Drug Benefit Manual* related to operationalization of this requirement specific to a variety of specialty pharmacy settings.

In practice, we have never based distribution of or referral to the pharmacy notice on whether or not the enrollee disagrees with information provided by the pharmacist, but rather on whether the drug in question can be provided under Part D and whether the enrollee is able to obtain the covered drug at the pharmacy counter. Because the existing regulation text at § 423.562(a)(3) ties delivery of the pharmacy notice to the enrollee's disagreement with information provided by the pharmacist, we are proposing to remove this reference.

This proposed technical change would not alter the circumstances under which the pharmacy notice must be delivered to an enrollee and will align the regulation and the operational requirements for distribution of the pharmacy notice. In addition, this proposed change would be consistent with both the current OMB-approved instructions regarding the pharmacy notice and current CMS manual guidance.

We do not prohibit distribution of the pharmacy notice in any circumstance, so pharmacies may choose to also provide a copy of the notice in circumstances where the enrollee disagrees with the information provided (for example, if the enrollee believes they are being charged an incorrect cost-sharing amount), but the notice is not required under the standards established in § 423.128(b)(7)(iii). Provision of the pharmacy notice is not a prerequisite for an enrollee to request a coverage determination or access the appeals process. Similarly, a plan sponsor's failure to comply with the requirements of § 423.128(b)(7)(iii) or § 423.562(a)(3) does not in any way limit an enrollee's right to request a coverage determination or appeal.

11. Special Part D Access Rules During Disasters or Emergencies (§ 423.126)

Section 1860D–4(b) of the Act requires us to ensure beneficiaries have access to covered Part D drugs. When a disaster strikes or is imminent, beneficiaries may find they have trouble accessing drugs through normal channels or must move to safer locations far away from their regular pharmacies. In order to ensure that beneficiaries do not run out of their medications during or as a result of a disaster or emergency, we issued guidance on December 18, 2009 identifying when, in the course of a disaster, Part D sponsors would be

expected to relax ''refill-too-soon'' (RTS) edits. We now propose to codify a revised version of that policy. Proposed § 423.126(a)(1)(i) would require Part D sponsors to relax RTS edits in the event of any imminent or occurring disaster or emergency that would hinder an enrollee's access to covered Part D drugs. By this we mean that there is an anticipated or actual disaster or emergency, as evidenced by a declaration of a disaster or emergency issued by an appropriate federal, state, or local official, and it is reasonable to conclude that such disaster or emergency or preparation therefore would make it difficult for beneficiaries to obtain refills of their medications because the disaster or emergency or anticipation thereof has affected, or will affect, their ability to have timely access to their usual pharmacies. For example, if federal, state or local authorities issue mandatory evacuation orders to populations or segments of the population in a geographic area, it would be reasonable to conclude that the evacuation would hinder an LTC resident's ability to get a refill after he or she is evacuated from the facility. In such an instance, then, Part D sponsors with enrollees in the affected area would be required to relax RTS edits so that the LTC pharmacies could provide beneficiaries with refills to take with them to the location to which they are being evacuated. Our proposed requirement would apply to one refill for each drug the beneficiary is taking for refills sought within 30 days of the date the plan sponsor began relaxing RTS edits. We believe this timeframe would be sufficient to ensure that beneficiaries who are unable to obtain refills during the emergency or disaster will be able to do so as soon as they can safely access a network pharmacy. We solicit comment as to whether 30 days after the date of the triggering declaration provides an appropriate amount of time to ensure that beneficiaries do not run out of their medications. In particular, we would be interested in learning about any situations in which a beneficiary affected by an actual or impending disaster or emergency would be likely to go to a pharmacy more than 30 days after the triggering declaration such that the resumption of RTS edits after 30 days would be problematic. We also solicit comment as to how it would be feasible for Part D sponsors to identify pharmacies or beneficiaries located in affected areas for which they would be required to relax edits and, how long it might then take to program the necessary changes.

Although we believe our proposal provides a general framework for when RTS edits must be relaxed, we solicit comment on whether we should impose more particular requirements in cases where a disaster or emergency could result in a voluntary or mandatory evacuation of an LTC facility. We are also concerned that if a disaster strikes the area in which an LTC facility is located but not the area in which its servicing LTC pharmacy is located, the appropriate edits may not be relaxed. Accordingly, we solicit comment as to whether it would be more feasible to establish beneficiary specific edits limited to residents of LTC facilities in affected areas given that evacuation decision-making is rarely a straightforward, linear process (for example, not just based on the declaration of a disaster or emergency), but rather, often involves a myriad of facility-specific factors. In particular, we solicit comment on the practicality of requiring Part D sponsors to relax RTS edits for residents of a particular LTC facility after that facility decides on its own initiative to evacuate through use of National Council on Prescription Drug Programs (NCPDP) Submission Clarification Code (SCC) code 13, which conveys that there is an emergency. We solicit comment as to whether use of this code number, 13, is specific enough to signal that sponsors need to loosen RTS edits and whether it would be practical for LTC facilities to request that their LTC pharmacies enter the SCC code 13. Lastly, we would be interested in any other ideas on how to structure workable edits or institute manual procedures to best target only enrollees who live in LTC facilities located in areas affected by a disaster.

We would also be interested in hearing from any commenters who would recommend any other triggering events that would require Part D sponsors to relax RTS edits. In particular, we solicit comment as to whether it would be feasible to require sponsors to relax edits after the issuance by the National Weather Service (NWS) of a Hurricane or Tropical Storm watch or warning. The NWS typically issues watches 36 hours in advance of adverse weather conditions possibly hitting an area, while the NWS issues watches 48 hours (2 days) in advance of those conditions possibly hitting an area. All watches/warnings are posted on the NWS Web site immediately after their issuance. We solicit comment as to whether watch/warnings would require RTS overrides in the whole state, or just areas under the watch or warning. We are also interested in comments regarding the time generally needed to move residents of LTC facilities with their medication supplies to safety.

Lastly, we believe that sponsors are in the best position to determine how to relax the specific RTS edits when required under our proposal. However, we also wish to ensure that all sponsors relax RTS edits in a consistent manner in order that enrollees have the same critical access to drugs when disasters and emergencies are imminent or have occurred—regardless of the specific plan in which they are enrolled. Accordingly, we solicit comments on the types of situations that might arise and the extent to which sponsors should be allowed to exercise some discretion in complying with this proposed requirement.

And, as has been the case under our current guidance, Part D sponsors may consider extending the implementation of the RTS edits but are not required to do so. However, if sponsors choose to reinstate the RTS edits, they need to work closely with enrollees who indicate that they are still displaced or otherwise impacted by the disaster or emergency.

12. MA Organization Responsibilities in Disasters and Emergencies (§ 422.100)

Section 1852(d) of the Act requires MA organizations to provide proper and continued access to services, including making medically necessary benefits available and accessible 24 hours a day and 7 days a week. When a disaster occurs or is imminent, beneficiaries may find they have trouble accessing services through normal channels or must move to safer locations that are outside of their service areas. To date, we have relied on issuing subregulatory guidance for MA organizations through the HPMS system and have included that guidance in Chapter 4 of the Medicare Managed Care Manual. During a disaster, we expect MA organizations to continue to follow applicable standing regulations, including ensuring continuing access to care in addition to complying with our subregulatory guidance.

We are proposing to add paragraph (m) to § 422.100 to codify and further clarify an MA organization's responsibilities when health plan services are affected by public health emergencies or disasters. This provision is intended to ensure that beneficiaries continue to have access to care in situations where normal business operations are disrupted due to public health emergencies, disasters and warnings of imminent disasters. The proposed new paragraph (m) requires MA organizations to ensure access to

covered services that are furnished at non-contracted facilities and to charge no more cost sharing for services obtained by enrolled beneficiaries out-of-network than they would pay in-network. These requirements provide protections for enrolled beneficiaries, including those who move to safer locations that are outside of their service areas, who have trouble accessing services through normal channels due to the unusual circumstances created by the disaster or emergency. Additionally, the proposed new paragraph (m) provides MA organizations with guidance on the bases for determining the beginning and end of a disaster or emergency and requires that the organization post on its Web site and convey to enrollees and contracted providers at least annually, the disaster and emergency policies in order to facilitate enrollee access to needed services while normal care delivery is unavailable. In addition, this enables out-of-network providers to be informed of the terms of payment for furnishing services to affected enrollees.

13. Termination of a Contract Under Parts C and D (§ 422.510 and § 423.509)

a. Cross-Reference Change (§ 423.509(d))

Section 1857(h)(1)(B) and 1860D–12(b)(3)(F) of the Act describes the procedures for termination for both Part C and Part D plan sponsors respectively. These statutory provisions give an organization an opportunity for a hearing before its contract is terminated.

We codified organizations' appeal rights under subpart N of parts 422 and 423. Under the Part C § 422.510(d), a reference to the appeal rights ''in accordance with subpart N'' is made. However, in the corresponding section for Part D Plan sponsors at § 423.509(d), the reference to the appeal rights reads ''in accordance with § 423.642.'' The Part C and Part D references should be the same. We are proposing to align the Part C and Part D appeal rights language under § 422.510(d) and § 423.509(d) by replacing the inconsistent language at § 423.509(d) to now read ''in accordance with subpart N of this part.'' This change is proposed only to ensure consistent wording is used in both regulatory sections and in no way changes the meaning or policy encompassed in this provision.

b. Terminology Changes (§ 422.510 and § 423.509)

Sections 1857(c) and 1860D–12(b)(3)(B) of the Act authorize contract terminations for Part C MA organizations and Part D plan sponsors respectively. In the current termination regulations at § 422.510 and § 423.509, there is inconsistent use of the terms ''days'' and ''calendar days''. Calendar days are the appropriate term that should be used consistently throughout these sections. Therefore, we are proposing to replace the word ''days'' with ''calendar days'' in both § 422.510 and § 423.509. This change is proposed only to ensure consistent wording is used in § 422.510 and § 423.509 and in no way changes the meaning or policy encompassed in these provisions.

c. Technical Change To Align Paragraph Headings (§ 422.510(b)(2))

Sections 1857(c)(2) and 1860D–12(b)(3)(B) of the Act provide us with the authority to terminate contracts, for Part C and Part D sponsors respectively. The Part C paragraph heading at § 422.510(b)(2) incorrectly reads ''Expedited termination of contract by CMS.'' The Part D corresponding paragraph heading at § 423.509(b)(2) correctly reads ''Immediate termination of contract by CMS''. The Part C and Part D paragraph headings should be the same. Therefore, we are proposing to revise the paragraph of § 422.510(b)(2) to read ''Immediate termination of contract by CMS''. This change is proposed only to ensure consistent wording is used in both regulatory sections and in no way changes the meaning or policy encompassed in this provision.

d. Terminology Change (§ 423.509(b)(2)(C)(ii))

Sections 1857(c)(2) and 1860D–12(d)(3)(B) of the Act provide us with the authority to terminate contracts, for Part C and Part D sponsors respectively. In § 423.509(b)(2)(C)(ii) the regulation incorrectly references ''MA organization.'' This section concerns Part D, so the correct reference is ''Part D Plan Sponsor''. Therefore, we are proposing to change § 423.509(b)(2)(C)(ii) to appropriately reference Part D plan sponsor; not MA organization (Part C), as it currently states. This change is proposed only to ensure accurate wording is used in both regulatory sections and in no way changes the meaning or policy encompassed in this provision.

14. Technical Changes To Align Part C and Part D Contract Determination Appeal Provisions (§ 422.641 and § 422.644)

Sections 1857(h) and 1860D–12(b)(3)(F) of the Act describe the procedures for termination for both Part C MA organizations and Part D Plan sponsors, respectively. These statutory provisions provide an organization with an opportunity for a hearing before its contract is terminated. Appeal procedures were established under sections 1856(b)(2) and 1860D–12(b)(3) of the Act for both Part C and Part D sponsors, respectively. Sections 422.641 and 423.641, list the types of Part C and Part D contract determinations that may be appealed.

(a) Technical Change (§ 422.641)

Currently in § 422.641, the contract termination is discussed in paragraph (b) and contract non-renewal is discussed in (c). Conversely, in § 423.641 the contract terminations are discussed in (c) and contract non-renewal is discussed in (b). Therefore, we are proposing to align the Part C list order for (b) and (c) in the contract determinations section at § 422.641 with its Part D corresponding section at § 423.641. This change is proposed only to ensure consistency between the two parts and in no way changes the meaning or policy encompassed in this provision.

(b) Technical Changes (§ 422.644(a) and (b))

Sections 1857(h)(1)(B) and 1860D–12(b)(3)(F) of the Act describe the procedures for termination for both Part C and Part D sponsors, respectively. These statutory provisions provide an organization with an opportunity for a hearing before its contract is terminated. Appeal procedures were established under § 1856(b)(2) of the Act for both Part C and Part D sponsors. In § 423.642 we specify that the notice is based upon a contract determination made ''under § 423.641.'' Therefore, since Part C and Part D language should be consistent the same reference should be made in the Part C corresponding § 422.644. To remedy this error, we are proposing to insert ''under § 422.641'' into § 422.644(a) for Part C contract determinations. This change is proposed only to ensure consistent wording is used in both regulatory sections and in no way changes the meaning or policy encompassed in this provision.

In addition, the Part D Plan sponsor language in § 423.642(b) states that ''(b) The notice specifies the—(1) Reasons for the determination; and''. The Part C language in § 422.644(b) states that ''(b) The notice specifies—(1) The reasons for the determination; and''. Part C and Part D language should be consistent, therefore, the same reference should be made in the Part C corresponding section § 422.644. To remedy this error, we are proposing to align the Part C language at § 422.644(b) with that of the Part D language at § 423.642(b) for consistency between both the Part C and

Part D termination regulations. Specifically, we propose to change § 422.644(b) by deleting the word ''the'' and revising it to read ''(b) The notice specifies the—(1) Reasons for the determination; and''. This change is proposed only to ensure consistent wording is used in both regulatory sections and in no way changes the meaning or policy encompassed in this provision.

15. Technical Changes To Align Parts C and D Appeal Provisions (§ 422.660 and § 423.650)

Sections 1857(h)(1)(B) and 1860D–12(b)(3)(F) of the Act describe the procedures for termination for both Part C and Part D, respectively. These statutory provisions provide organizations with an opportunity for a hearing before its contract is terminated. Appeal procedures were established under § 1856(b)(2) of the Act for both Part C and Part D sponsors. We propose to make technical changes in our regulations at § 422.660(a)(2), § 422.660(a)(3), and § 423.650(a)(2) to ensure consistency. Specifically, we are proposing to replace the term ''under'' with the phrase ''in accordance with'' in § 422.660(a)(2), § 422.660(a)(3), and § 423.650(a)(2). This change is proposed only to ensure consistent wording is used in § 422.660 and § 423.650 and in no way changes the meaning or policy encompassed in these provisions.

In addition, we are proposing to make a technical change in our regulations at § 423.650(a)(4) to ensure consistency with the authorizing language contained in sections 1856(b)(2), 1857(h), and 1860D–12(d)(3)(F) of the Act which gives us the authority to terminate contracts for both Part C and Part D sponsors. Under the Part C § 422.660(a)(4), a reference to imposing intermediate sanctions and civil money penalties ''in accordance with § 422.752(a) through (b) of this part'' is made. The corresponding section for Part D is at § 423.650(a)(4). However, the reference to imposing intermediate sanctions and civil money penalties reads ''in accordance with § 423.752(a) and (b)''. The Part C and Part D references should be the same and both state ''(a) through (b)''. Specifically, we are proposing to replace the word ''and'' with ''through'' in § 423.650(a)(4). This change is proposed only to ensure consistent wording is used in both regulatory sections and in no way changes the meaning or policy encompassed in this provision.

Sections 422.660(b)(4) and 423.650(b)(4) give a general reference to § 422.752 and § 423.752, but do not refer the reader to the applicable paragraphs contained in those sections. Therefore, we are proposing to modify § 422.660(b)(4) and § 423.650(b)(4) to add the language ''§ 422.752(a) through (b)'' and ''§ 423.752(a) through (b)'', respectively, to refer the reader to the applicable regulations for intermediate sanctions. This change is proposed only to accurately reflect applicable regulatory requirements and in no way changes the meaning or policy encompassed in this provision.

16. Technical Changes Regarding Intermediate Sanctions and Civil Money Penalties

Sections 1857(g) and 1860D–12(b)(3)(E) of the Act provides us with the authority to impose intermediate sanctions (sanctions) and CMPs on Part C and Part D sponsors, respectively.

a. Technical Changes to Intermediate Sanctions Notice Receipt Provisions (§ 422.756(a)(2) and § 423.756(a)(2))

Under § 422.756(a)(2) and § 423.756(a)(2) the current language states that written requests for rebuttal by the MA organization or Part D plan sponsor must be received within ''10 calendar days from the receipt of notice''. This language is inconsistent with other the language that appears in other sections within subpart O, the appeals section in subpart N and the termination sections in subpart K. In those sections we state that written requests must be received within ''10 calendar days after receipt of the notice''. The language in all sections should be consistent. Therefore, we are proposing to modify the language at § 422.756(a)(2) and § 423.756(a)(2) to state ''10 calendar days after receipt of the notice''. This change is proposed only to ensure consistent wording is used in all sections and in no way changes the meaning or policy encompassed in this provision.

In addition, we are proposing to correct the grammatical error that exists in current § 422.756(a)(2) and § 423.756(a)(2). The Part C and Part D language currently reads, ''CMS considers receipt of notice as the day after notice is sent by fax, email, or submitted for overnight mail''. To fix the grammatical errors we are proposing to revise the language in both § 422.756(a)(2) and § 423.756(a)(2) to read ''CMS considers receipt of the notice as the day after the notice is sent by fax, email, or submitted for overnight mail.'' This change is proposed only to make a grammatical correction and in no way changes the meaning or policy encompassed in this provision.

b. Cross-Reference Changes (§ 422.756(b)(4) and § 423.756(b)(4))

Under § 422.756(b)(4) and § 423.756(b)(4), we furnish our procedures for imposing intermediate sanctions and civil money penalties on MA organizations and Part D sponsors, respectively. The current language at § 422.756(b)(4) states that MA organizations, if sanctioned, must follow the right to a hearing procedure as specified at § 422.660 and § 422.684. The current language at § 423.756(b)(4) states that Part D sponsors, if sanctioned, must follow the right to a hearing procedure as specified at § 423.650 and § 423.662. However, MA organizations and Part D sponsors must adhere to procedures promulgated within subpart N of the regulations, not just § 422.660 and § 422.684; and § 423.650 and § 423.662, respectively. Therefore, we are proposing to modify the language at § 422.756(b)(4) and § 423.756(b)(4) to state that MA organizations and Part D sponsors ''must follow the right to a hearing procedures as specified in subpart N''. This change is proposed only to accurately reflect applicable regulatory requirements and in no way changes the meaning or policy encompassed in this provision.

c. Technical Changes (§ 422.756(d) and § 423.756(d))

In § 422.756(d) and § 423.756(d) we provide alternatives to sanctions, including non-renewal or termination of the organizations contract. However, the paragraph heading of both § 422.756(d) and § 423.756(d) only refers to terminations by CMS. Therefore, we are proposing to revise the paragraph heading to ''Non-renewal or termination by CMS'' in both sections to reflect the content specified within the provision. This change is proposed only to accurately reflect applicable regulatory requirements and in no way changes the meaning or policy encompassed in this provision.

Within § 422.756(d) and § 423.756(d) we state that we may decline to authorize the renewal of an organization's contract in accordance with § 422.506(b)(2) and (b)(3) for MA organizations and in accordance with § 423.507(b)(2) and (b)(3) for Part D sponsors. However, in both § 422.756(d) and § 423.756(d), all of paragraph (b) applies to the provisions. Therefore, we are proposing to change both provisions § 422.756(d) and § 423.756(d) to read ''§ 422.506(b)'' and ''§ 423.507(b)'', respectively. This change would accurately reflect that all of paragraph (b) applies in both provisions. This

change is proposed only to accurately reflect applicable regulatory requirements and in no way changes the meaning or policy encompassed in this provision.

Within § 422.756(d) and § 423.756(d), we refer to the sanctions described in paragraph (c) of each section but in each section, paragraph (c) refers to the effective date and duration of sanctions, rather than sanctions which are described in § 422.750 and § 423.750, respectively. Therefore, we are proposing to change the current language at § 422.756(d) to read ''In addition to or as an alternative to the sanctions described in § 422.750 . . .'' and change the language at § 423.756(d) to read ''In addition to or as an alternative to the sanctions described in § 423.750.'' This change would accurately reflect the applicable provision referenced in both § 422.756(d) and § 423.756(d). This change is proposed only to accurately reflect applicable regulatory requirements and in no way changes the meaning or policy encompassed in this provision.

d. Technical Changes To Align the Civil Money Penalty Provision With the Authorizing Statute (§ 422.760(a)(3) and § 423.760(a)(3))

The provisions at § 422.760(a)(3) and § 423.760(a)(3) state, ''the harm which resulted or could have resulted from conduct of an MA organization'' and ''the harm which resulted or could have resulted from conduct of a Part D plan sponsor'', respectively. However, this language is not consistent with the authorizing statutory provisions, nor is it consistent with other provisions in the corresponding sections. Therefore, we are proposing to align the language with paragraph (b) in both § 422.760(a)(3) and § 423.760(a)(3). The language would be revised to state ''The adverse effect to enrollees which resulted or could have resulted . . .'' in both § 422.760(a)(3) and § 423.760(a)(3). This change is proposed only to accurately reflect applicable statutory requirements and in no way changes the meaning or policy encompassed in this provision.

e. Technical Changes To Align the Civil Money Penalty Hearing Notice Receipt Provisions (§ 422.1020(a)(2), § 423.1020(a)(2), § 422.1016(b)(1), and § 423.1016(b)(1))

Sections 1857(g)(4) and 1860D–12(b)(3)(E) of the Act provides us with the authority to impose civil money penalties on Part C and Part D sponsors, respectively. Under § 422.1020(a)(2) and § 423.1020(a)(2), we discuss our procedures for appealing CMPs. The current language in both sections state written requests for appeal by the MA organization or legal representative or authorized official must be filed within 60 calendar days from the receipt of notice of initial determination, to request a hearing before the Administrative Law Judge to appeal any CMS decision. However, this language does not align with the appeal language in subpart N. Therefore, we are proposing to change the language at § 422.1020(a)(2) and § 423.1020(a)(2) to align it with the language within subpart N for appeals. Specifically, we are changing both § 422.1020(a)(2) and § 423.1020(a)(2) to state ''within 60 calendar days after receipt of the notice of initial determination''. This change is only to ensure consistent wording is used in all sections and in no way changes the meaning or policy encompassed in this provision.

In addition, under § 422.1016 and § 423.1016, we furnish our procedures for filing briefs with the Administrative Law Judge or Departmental Appeals Board, and opportunity for rebuttal. The provisions at § 422.1016(b)(1) and § 423.1016(b)(1) state, ''the other party will have 20 days from the date of mailing or personal service to submit any rebuttal statement or additional evidence''. However, this language is not consistent with provisions in other corresponding sections. Therefore, we are proposing to revise the language at § 422.1016(b)(1) and § 423.1016(b)(1) to state ''The other party will have 20 days from the date of mailing or in person filing''. This change is proposed only to ensure consistent wording is used in all sections and in no way changes the meaning or policy encompassed in this provision.

17. Technical Change to the Restrictions on Use of Information Under Part D (§ 423.322)

We are proposing a technical change to § 423.322 due to section 6402(b)(1) of the Affordable Care Act which amended section 1860D–15(f)(2) of the Act. For background, most of the payment provisions for the Part D program are found in section 1860D–15 of the Act. Subsections (d) and (f) of section 1860D–15 of the Act authorize the Secretary to collect any information needed to carry out this section. However those subsections, as originally enacted, also stated that ''information disclosed or obtained under [section 1860D–15 of the Act] may be used by officers, employees, and contractors of [HHS] only for the purpose of, and to the extent necessary, in carrying out [section 1860D–15 of the Act].'' Thus, section 1860D–15 of the Act contains provisions that limit the use of information disclosed or obtained under its authority.

Section 6402(b)(1) of the Affordable Care Act amended section 1860D–15(f)(2) of the Act to relax the limitation on the use of information that is disclosed or obtained under section 1860D–15 of the Act. Specifically, the Affordable Care Act removed the word ''only'' from subsection (f)(2)(A) and added a new subsection (ii) which states that information disclosed or obtained under section 1860D–15 of the Act may be used by officers, employees, and contractors of HHS for the purposes of, and to the extent necessary, in ''conducting oversight, evaluation, and enforcement under this title.'' Section 6402(b)(1) also added a new subsection (B) which states that information disclosed or obtained pursuant to section 1860D–15 of the Act may be used ''by the Attorney General and the Comptroller General of the United States for the purposes of, and to the extent necessary in, carrying out health oversight activities.'' Thus, the Affordable Care Act considerably broadened the purposes for which HHS, its contractors, and the Attorney General and Comptroller General may use the information disclosed or obtained pursuant to section 1860D–15 of the Act by removing the word ''only'' in subsection (A) and adding a new clause (ii) and a new subsection (B). However, we note, that the Affordable Care Act did not change the existing restriction on the use of information under subsection (d).

In light of the Affordable Care Act amendment to section 1860D–15(f) of the Act, we are proposing to make conforming changes to § 423.322.

IV. 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.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

A. ICRs Related to Eligibility of Enrollment for Individuals Not Lawfully Present in the United States (§ 417.2, § 417.420, § 417.422, § 417.460, § 422.1, § 422.50, § 422.74, § 423.1, § 423.30, and § 423.44)

We are proposing to amend § 417.2, § 417.420, § 417.422, § 417.460, § 422.1, § 422.50, § 422.74, § 423.1, § 423.30, and § 423.44 to include the eligibility requirement of citizenship or lawful presence to enroll in MA, Part D, or cost plans. To implement these regulations, we would relay data regarding an individual's lawful presence status to plans through the MARx system so that the plans will be aware of an individual's eligibility when requesting enrollment and notify plans when current members lose lawful presence status. This data is already available to us; thus no new data will be collected, and there is no new information collection or burden on organizations.

B. ICRs Related to Improper Prescribing Practices and Patterns (§ 424.535(a)(13) and (14))

Our proposed additions of § 424.535(a)(13) and (14) would result in an increase in revocations and associated appeals. However, we are unable to estimate the number of revocations and appeals. We do not have data available that can be used to make such a projection, as each situation would have to be carefully reviewed and addressed on a case by case basis. Since we would invoke § 424.535(a)(8)(iii) only in the most egregious of circumstances, we believe that the number of revocations under this provision would be small. The concomitant increase in the ICR burden would therefore be minimal.

C. ICRs Related to Applicants or Their Contracted First Tier, Downstream, or Related Entities To Have Experience in the Part D Program Providing Key Part D Functions (§ 423.504(b)(8)(i) Through (iii))

Proposed § 423.504(b)(8)(i) through (iii) would require that Part D organizations seeking a new Medicare contract must have arrangements in place such that either the applicant or a contracted entity that will be performing certain key Part D functions has at least 1 full benefit year of experience providing the function or providing the function for another Part D plan sponsor. The burden associated with this requirement is the time and effort put forth by Part D applicants to answer questions about such experience as part of the Part D application process. For entities that hold an existing Part D contract, or whose parent or another subsidiary of that parent has already held a Part D sponsor contract for at least a year, it is estimated that it will take each Part D applicant for a new contract 2 minutes to provide 1 or 2 new sentences in the organizational history section of the application, and 1 minute to respond to yes-no questions about experience with the 3 functions for which experience is required, for a total of 3 minutes per applicant. For entities new to Part D, it is estimated that it will take each Part D applicant for a new contract 2 minutes to provide 1 or 2 new sentences in the organizational history section of the application, 1 minute to respond to yes-no questions about experience with the 3 functions for which experience is required, and 1 additional minute to provide at least 1 contract number of an existing or recent Part D sponsor under which the entity to provide the key function obtained its experience, for a total of 4 minutes. Based on the number of Part D applications we receive each year, we would anticipate no more than 60 Part D applications for a new contract, of which no more than 15 would be entities new to Part D. Thus, the burden for the 45 existing entities at 3 minutes each, plus the burden for the 15 new entities at 4 minutes each, brings the total burden hours to approximately 3.25 hours. If approved, the new application questions would be addressed under currently approved OMB control number (OCN) 0938–0936.

D. ICRs Related to Eligibility of Enrollment for Incarcerated Individuals (§ 417.460, § 422.734, and § 423.44)

We are proposing to amend § 417.460(b)(2)(i), § 417.460(f)(1)(i), § 422.74(d)(4)(i)(A), § 422.74(d)(4)(v), and § 423.44(d)(5) to clarify the eligibility requirement for residing in the plan's service area related to incarceration for the purposes of enrolling into and remaining enrolled in MA, Part D, and Medicare cost plans. To implement these regulations, we would relay data to plans regarding an individual's incarceration through the MARx system so that the plans would be aware of the individual's eligibility when requesting enrollment and notify the plans of loss of eligibility for current members. This data is already available to us. Thus no new data would be collected, and there is no new information collection or burden on organizations.

E. ICRs Related to Rewards and Incentives Program Regulations for Part C Enrollees (§ 422.134)

This requirement does not impose any new information collection requirements. This is an existing recordkeeping requirement in which MA organizations must retain information pertaining to any rewards and incentives programs in accordance with our regulations at 42 CFR 422.118. We believe the burden associated with this requirement is exempt from the PRA under 5 CFR 1320.3(b)(2) as we believe this is a usual and customary business practice. Furthermore, any requests to furnish the information in a form and manner we designate are unique, that is, non-standardized and specific to each individual MA organization.

F. ICRs Related to Expanding Quality Improvement Program Regulations (§ 422.152)

This requirement does not impose any new information collection requirements. PRA approval is current under OCN 0938–1023.

G. ICRs Related to Revisions to Good Cause Processes (§ 417.460, § 422.74, and § 423.44)

We are proposing to amend § 417.460, § 422.74, and § 423.44 to establish the ability for us to designate an entity other than CMS to implement the good cause process. To implement these regulations, the plan will already have the enrollment data necessary to make the good cause determinations within the process. Thus no new data would be collected. However, there would be additional burden to the plan in terms of completing the operational process, such as responding to requests for reinstatement from former members, gathering the attestation from the individual regarding his or her reason for not paying the plan premiums within the grace period, making the determination as to whether the individual meets the good cause criteria and maintaining the case notes and documentation to support its determination should it need to be reviewed. As plans already provide customer service to their current and past members, we estimate that this burden would be approximately 30 minutes for each reinstatement request. According to the most recent wage data provided by the Bureau of Labor Statistics (BLS) for May 2012, the mean

hourly wage for the category of ''Customer Service Representatives''—which we believe, considering the common point of entry for all issues at the plan, is the most appropriate category—is $15.92. With fringe benefits and overhead, the per hour rate is $24.03. It is calculated that the cost for 30 minutes would be $12.01. Not all plans disenroll for non-payment of premiums. However, for those who do implement this voluntary policy, it results in an average of 20,000 disenrollments each month. In response, we receive an average of 698 requests for reinstatement per month. The plan representative cost of $12.01 for each case is multiplied by 698 cases. Therefore, based on the proposed change, handling of these requests would result in a total monthly cost of $8,383 for all plans in the MA, Part D, and cost plan programs.

H. ICRs Related to the Definition of Organization Determination (§ 422.566)

The burden associated with this proposal is the time necessary for MA organizations to process organization determination requests, issue a decision and, where appropriate, effectuate any approved coverage decision. When an MA organization issues an adverse organization determination, it must give the enrollee written notice pursuant to the requirements in § 422.568(d) and (e) and § 422.572(e). This requirement is subject to the PRA, and the burden associated with it is currently approved under OCN 0938–0829. The information collection requirements are not expected to change because the proposed revisions to the definition of organization determination would not alter the frequency with which the current OMB-approved notice is required, nor the time required to issue the notice. The proposed change to § 422.566(b)(3) would codify certain adverse decisions which MA organizations already treat operationally as adverse organization determinations subject to the standardized denial notice. The proposed addition of § 422.566(b)(6) applies only to favorable organization determinations which do not require written notice.

I. ICRs Related to Skilled Nursing Facility Stays (§ 422.101 and § 422.102)

We propose to relocate the MA regulation language currently located at § 422.101(c), ''Requirements Related to Basic Benefits'' to § 422.102(a)(5), ''Supplemental Benefits.'' We are proposing to move the provision because it describes MA organizations' authority to furnish covered SNF stays without the qualifying inpatient hospital stay required under original Medicare. For the past 10 years, MA organizations have offered the waiver of the 3-day inpatient hospital stay as a supplemental benefit. Thus, placing the provision in the section related to supplemental benefits is appropriate.

We also propose to make a conforming revision in the cross-reference to this provision that currently appears at § 409.30(b)(2)(ii), in order to reflect this provision's relocation from § 422.101 to § 422.102. This is a simple relocation of current regulation. There are no new PRA requirements.

J. ICRs Related to Changes to Audit and Inspection Authority (§ 422.503(d)(2) and § 423.504(d)(2))

We are proposing a change to § 422.503(d)(2) and § 423.504(d)(2) to include authority that will permit CMS to require MA organizations and Part D sponsors to hire an independent auditor to conduct full or partial program audits and/or perform validation exercises to confirm correction of deficiencies found during an audit. We currently conduct these audits and validation exercises, and collect data associated with these activities under OCN 0938–1000. We do not believe that requiring MA organizations and Part D sponsors to hire an independent auditor to conduct these audits or validation exercises will impose any additional burden on MA organizations and Part D sponsors.

K. ICR Related to Recovery Audit Contractor Determinations (Part 422, Subpart Z and Part 423, Subpart Z)

The information collection burden associated with our proposed requirements consists of the submission of requests for: (1) Reconsiderations; (2) CMS hearing official determinations; and (3) CMS Administrator reviews. Based on existing Part D appeals data, we estimate that plans will file the following numbers of requests on an annual basis:

TABLE 7— ESTIMATED NUMBER OF PART C & D RAC APPEAL REQUESTS

Type of request	Number of requests per year
Reconsideration	104
CMS Hearing Official	10
Administrator Review	2
Total	116

The reasons for the decrease in requests at higher appeal levels are that: (1) The plan may succeed in its appeal and thus have no need to appeal to the next level; and (2) the plan may simply wish to forgo further appeals. We stress that the figures in Table 7 are mere projections, though, again, they are based on the number of Part D appeals that have been submitted to date.

We estimate that it would take a plan 5 hours to prepare and file an appeal request. In terms of cost, it has been our experience that most appeals have been prepared by high-level officials of the plan. According to the most recent wage data provided by the Bureau of Labor Statistics (BLS) for May 2012, the mean hourly wage for the category of ''General and Operations Managers''—which we believe, considering the variety of officials who have submitted appeals, is the most appropriate category—is $55.22. With fringe benefits and overhead, the per hour rate is $83.35. Multiplying this figure by 580 hours (or 116 submissions × 5 hours) results in a projected annual cost burden of $48,343, as outlined in Table 8.

TABLE 8—ESTIMATED ANNUAL REPORTING/RECORDKEEPING BURDEN

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/ maintenance costs ($)	Total cost ($)
§ 422.2605	N/A	52	52	5	260	83.35	83.35	0	21,671.00
§ 422.2610	N/A	5	5	5	25	83.35	83.35	0	2083.75
§ 422.2615	N/A	1	1	5	5	83.35	83.35	0	416.75
§ 423.2605	N/A	52	52	5	260	83.35	83.35	0	21,671.00
§ 423.2610	N/A	5	5	5	25	83.35	83.35	0	2083.75

TABLE 8—ESTIMATED ANNUAL REPORTING/RECORDKEEPING BURDEN—Continued

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/ maintenance costs ($)	Total cost ($)
§ 423.2615	N/A	1	1	5	5	83.35	83.35	0	416.75
Total	N/A	116	116	N/A	580	.....	.....	0	48,343

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, CMS–4159–P

Fax: (202) 395–6974; or

Email: *OIRA_submission@omb.eop.gov*

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

The purpose of this proposed rule is to make revisions to the MA program (Part C) and Prescription Drug Benefit Program (Part D), implement provisions specified in the Affordable Care Act, and make other changes to the regulations based on our continued experience in the administration of the Part C and Part D programs. These latter revisions are necessary to: (1) Clarify various program participation requirements; (2) make changes to strengthen beneficiary protections; (3) strengthen our ability to identify strong applicants for Part C and Part D program participation and remove consistently poor performers; and (4) make other clarifications and technical changes.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This proposed rule has been designated an ''economically significant'' rule under section 3(f)(1) of Executive Order 12866. Accordingly, we have prepared a regulatory impact analysis that details the anticipated effects (costs, savings, and expected benefits), and alternatives considered by proposed requirement. Finally, in accordance with the provision of the Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

Two provisions result in a total of 4,768 annual burden hours and a total annualized monetized impact of $148,939. See sections IV.G. and IV.K. of this proposed rule for details regarding the burden associated with the requirements of this proposed rule. 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. This proposed rule primarily affects the Federal government, Medicare Advantage plans, and Part D Sponsors.

Part D sponsors and MA plans, entities that will be affected by the provisions of this rule, are not generally considered small business entities. MA plans and Part D sponsors must meet 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. We determined that there were very few MA plans and Part D sponsors that fell below the size thresholds for ''small'' businesses established by the Small Business Administration (SBA). Currently, the SBA size threshold is $7 million in total annual receipts for health insurers (North American Industry Classification System, or NAICS, Code 524114) and we have confirmed that most Part D sponsors have Part D receipts above the $7 million threshold.

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. Consequently, we do not believe that this threshold would be reached by the proposed requirements in this proposed rule because this proposed rule would 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

would 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 proposed rule would 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 2013, that threshold is approximately $141 million. This proposed rule is not 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.

Table 14 details the proposed rule's impacts by entity, including the federal government and MA organizations and Part D sponsors. We note that the estimated savings do not represent net social benefits because they consist of transfers of value from drug manufacturers, pharmacies, incarcerated individuals and individuals not lawfully present in the United States to the federal government, MA organizations, Part D sponsors and beneficiaries who continue in the programs.

C. Anticipated Effects

1. Effects of Closing Cost Contract Plans to New Enrollment

In our proposal to ensure that organizations do not move enrollees from one of their cost or MA plan types to another based on financial or some other interest, we propose to revise § 422.503(b)(5) so that an entity seeking to contract as an MA organization must ''not accept new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan if the MA organization and reasonable cost contract are offered by the same parent organization.'' We believe this provision will have minimal or no financial impact as only a handful of parent organizations currently offer MA and cost plans in the same service area. In addition, as the regulation requires that affected cost plans close to new enrollment, not that they terminate operations, we believe that there will be little or no impact to beneficiaries.

2. Effects of Two-year Limitation on Submitting a New Bid in an Area Where an MA Has Been Required To Terminate a Low-Enrollment MA Plan

Under § 422.506(b)(1)(iv), we must non-renew a MA plan that does not have a sufficient number of enrollees to establish that it is a viable independent plan option. We have established the threshold for termination due to insufficient number of enrollees at fewer than 500 enrollees for non SNPs and fewer than 100 enrollees for SNPs over a specified time period of 3 years. If we did not implement this, an MA organization required to terminate or consolidate one of its MA plans due to sustained low enrollment could avoid the consequences of such a requirement by submitting a bid for a new plan in the same service area.

We are proposing to amend the MA regulations at § 422. 504(a)(19) to impose a contractual requirements that when CMS non renews, or asks the MA organization to terminate an MA plan due to sustained low enrollment pursuant to § 422.506(b)(1)(iv), the MA organization may not introduce any new MA plan in that service area for 2 contract years. We believe this requirement will enhance our ongoing efforts to ensure that MA organization offerings in a service area present beneficiaries with viable plans that are responsive to their needs. We see no financial impact on MA organizations as this requirement has very limited application and imposes no independent financial burden.

3. Effects of Authority To Impose Intermediate Sanctions and Civil Money Penalties

We are proposing to make two changes to existing authority for the imposition of intermediate sanctions and civil money penalties (CMPs). First, under the Affordable Care Act, new authority was provided to the Secretary, which now permits CMS to impose intermediate sanctions for additional contract violations in the areas of marketing and enrollment. This new authority further permits CMS to impose intermediate sanctions on contracting organizations' that employ or contract with organizations, agents, and suppliers who commit any of the contract violations contained in § 422.752 and § 423.752.

Second, we are clarifying our authority to impose CMPs for the aforementioned contract violations. Current regulations designate the OIG as the sole government agency with the authority to impose CMPs for the contract violations contained in § 422.752 and/or § 423.752. We are modifying the language of these provisions to clarify that CMS or the OIG may impose CMPs for these contract violations except the provision that relates to the misrepresentation of falsification of information furnished to CMS, an individual or entity.

We believe these provisions would not result in additional burden to sponsors nor would they have a financial impact on sponsors.

4. Effects of Contract Termination Notification Requirements and Contract Termination Basis

In current regulations, we are required to provide 90-day notice to organizations whose contracts are being terminated by CMS. The authorizing statute at section 1857(h)(1)(B) and 1860D–12(b)(3)(F) of the Act states that the Secretary must provide reasonable notice and opportunity for hearing (including the right to appeal the initial determination) before terminating a contract (except under certain circumstances). We are proposing to modify the notice timeframe from 90 days to 45 days. We believe these provisions would not result in additional burden to sponsors nor would it have a financial impact on sponsors.

5. Effects of Reducing the Burden of the Compliance Program Training Requirements

We are proposing to lessen the burden placed on contracting organizations and their first tier, downstream and related entities (FDRs). Current regulations specify that contracting organizations are required to provide general compliance program training for their FDRs upon initial contracting and annually thereafter. To lessen this burden, we would require all contracting organizations to accept a

certificate of completion of the CMS Standardized General Compliance Program Training and Education Module as evidence of satisfaction of this program requirement. Under this program change, contracting organizations would not be permitted (or required) to develop or implement organization specific training for FDRs. We anticipate that this would greatly reduce the burden on various sectors of the industry including, but not limited to, insurance providers, hospitals, suppliers, pharmacists and physicians. We anticipate that this change would actually provide savings for sponsors and the FDRs since FDRs would only have to take one training as opposed to the possible numerous trainings they may take under current requirements. Additionally, sponsors would save because they would not be required to provide training materials to each FDR with which they contract.

We believe these provisions would not result in additional burden to sponsors nor would they have a financial impact on sponsors.

6. Effects of Audit and Inspection Authority

We are proposing two changes to § 422.503(d)(2) and § 423.504(d)(2) that would allow CMS to require sponsors (MA organizations and Part D sponsors) to hire an independent auditor to conduct full or partial program audits of the sponsors' operational areas and/or correction validation exercises. We currently conduct program audits of approximately 30 sponsors per year. Under this proposal, each MA organization and/or Part D sponsor would be required to hire an independent auditor to perform a full or partial program audit at least every 3 years. There are currently 298 sponsors in the Parts C & D programs. Under this new authority, approximately 99, or one-third of these organizations would be required to hire an independent auditor to perform a program audit, beginning in contract year 2015. Once the sponsor's audit is concluded in the year in which it was chosen, the sponsor would not be subject to another audit until its third year occurs (that is, plans selected for audit in contract year 2015, would not be selected for audit again until contract year 2018); unless the sponsor demonstrates behavior that we believe poses a risk to Medicare beneficiaries, the Trust Fund or both. Sponsors demonstrating this type of noncompliance may be subjected to a CMS program audit at any time in order to identify and mitigate any risk of potential harm to our beneficiaries. This proposal ensures that all sponsors will be audited on at least a 3-year cycle while continuing to maintain the integrity of the program by allowing CMS to continue to conduct audits when it believes beneficiaries are at risk.

Each independent auditor would work within CMS' specifications and guidelines. We would make available to the sponsors all of the methods of evaluations, methodologies and protocols to be used by the independent auditor when conducting the audit. We would also provide technical assistance to auditors as necessary.

We currently conduct program audits that examine the following operational areas:

- Formulary and Benefits Administration (Part D)
- Coverage Determinations, Appeals & Grievances (Part D)
- Organization Determinations, Appeals & Grievances (Parts C)
- Compliance Program effectiveness (Parts C & D)
- Outbound Enrollment Verification (OEV) (Parts C & D)
- Special Needs Plan Model of Care (SNP MOC) implementation (Parts C & D)

We estimate that the independent auditor hired will need to have a team consisting of the following professionals:

- Formulary and Benefits Administration—pharmacist, a senior claims analyst, and a senior auditor.
- Coverage Determinations, Part D Appeals, Part D Grievances—pharmacist, senior auditor.
- Organization Determinations, Part C Appeals, Part C Grievances—nurse practitioner, senior auditor, auditor.
- Compliance Program effectiveness—two auditors (at least one senior).
- Outbound Enrollment Verification (OEV)—two auditors (at least one senior).
- Special Needs Plan Model of Care (SNP MOC) implementation—two auditors (at least one senior).

We used the most recent (2010) wage statistics supplied by the Department of Labor, Bureau of Labor Statistics to develop estimates of direct wages. We also added fringe benefits, overhead costs, and general and administrative expenses using percentages that are consistent with CMS contracts. Based on our experience and in consultation with program experts, we developed an estimate of the hourly burden. The estimated mean cost per hour for each sponsor is $35.80 (wages, fringe benefits, and overhead). The team of 14 professionals (listed previously) is necessary for the performance of each program audit. The estimated mean number of hours the team will need to perform the audit per sponsor is 160. The mean cost per sponsor to procure and support the auditor is therefore: $14 \times 160 \times \$35.80 = \$80,192$. The auditing costs will be allowable costs in the plan's bid. Since, sponsors will only be subjected to these audits every 3 years; it is our expectation that sponsors will include one-third of this cost in its bid each year. Therefore, each plan year, the total cost included in a sponsors bid is: $\$80,192 \div 3 = \$26,731$.

The total annual estimated burden hours related to the time and effort for all sponsors being audited is estimated to be 298 sponsors $\times$ $26, 731 per sponsor, per year = $7,965,838. Therefore, the estimated annual cost for this requirement is $7,965,838.

We are also proposing to revise our regulations to permit CMS to require MA organizations or Part D sponsors with audit results that reveal non-compliance with CMS requirements to hire an independent auditor to validate that correction has occurred. As mentioned previously, under our existing authority we currently conduct approximately 30 audits per year. Based on our experience, the number of deficiencies identified and requiring corrective action can vary widely from sponsor to sponsor, which therefore affects the time and effort required for subsequent correction validation. Therefore, we have decided to provide an estimate that assumes that each sponsor audited has failed 50 percent of all elements audited; thereby requiring correction validation. We recognize that some sponsors may have far fewer elements that require validation and some sponsors may have more elements that require validation, but we believe that this is the most accurate estimate we can provide of the number of sponsors that will undergo validation and the associated effort required with that validation.

Under these circumstances we estimate that the independent auditor hired will need to have a team consisting of the following professionals:

- Formulary and Benefits Administration—pharmacist, a senior claims analyst, and a senior auditor.
- Coverage Determinations, Part D Appeals, Part D Grievances—pharmacist, senior auditor.
- Organization Determinations, Part C Appeals, Part C Grievances—nurse practitioner, senior auditor.
- Compliance Program effectiveness—one senior auditor.
- Outbound Enrollment Verification (OEV)—one senior auditor.

• Special Needs Plan Model of Care (SNP MOC) implementation—one senior auditor.

We used the same wage statistics provided previously to develop an estimate of the hourly burden (which includes fringe benefits, overhead costs, and general and administrative expenses that use percentages that are consistent with CMS contracts). The estimated mean cost per hour for these sponsors is $35.80. A team of 10 professionals (listed previously) is necessary for the performance of each correction validation. The average hourly cost for a validation with a team of 10 professionals is the same as the average hourly cost of an initial audit with a team of 14 professionals because in both scenarios, the mix of auditors to specialists (or non-auditors) is roughly 70 percent auditors and 30 percent specialists. Since the need for specialists can vary widely (that is, in some validations they may not be needed at all, and in other cases, all of the specialists from the original audit may be needed), we determined that the average breakdown of the team is the same for initial audit and validation. Therefore, the average hourly cost has not changed, despite the change in the number of team members. The estimated mean number of hours the team will need to perform the correction validation per sponsor is 80. The mean cost per sponsor to procure and support the independent auditor is therefore: 10 × 80 × $35.80 = $28,640. The validation costs will be allowable costs in the plan's bid. Under existing regulations the total annual estimated burden hours related to the time and effort for sponsors to perform the correction validation is estimated to be 30 sponsors × $28,640 per sponsor, per year = $859,200. Therefore, the estimated annual cost for this requirement under existing regulations is $859,200.

If the provision proposing that we acquire the authority to require sponsors to hire an independent auditor to conduct program audits is finalized, the number of sponsors being audited per year will increase from 30 (current) to 99 (proposed). Using the same weighted data assuming that each sponsor audited has failed at least 50 percent of audited elements, the estimated mean cost per sponsor to procure and support the independent auditor is: 10 × 80 × $35.80 = $28,640. The correction validation costs will be allowable costs in the plan's bid. Since, sponsors will only be subjected to these audits/validations every 3 years; it is our expectation that sponsors will include one-third of this cost in its bid each year. Therefore, each plan year, the total cost included in a sponsors bid is: $28,640 ÷ 3 = $9,547. The total annual estimated burden hours related to the time and effort for all sponsors being audited to perform the correction validation is estimated to be 99 sponsors × $9,547 per sponsor, per year = $945,120. Therefore, the potential estimated annual cost for this requirement is $945,120.

7. Effects of Procedures for Imposing Intermediate Sanctions and Civil Money Penalties Under Parts C and D

We are proposing to make changes to our authority for imposing intermediate sanctions and for determining when such sanctions will be lifted. Sections 1857(g) and 1860D–12(b)(3)(E) of the Act provide the Secretary the ability to impose intermediate sanctions on MA organizations and PDP sponsors. Intermediate sanctions consist of suspension of enrollment, suspension of marketing and suspension of payment. Current regulations governing intermediate sanctions are contained in subparts O of part 422 and part 423. Sections 422.756 and § 423.756 provide specific procedures for imposing intermediate sanctions, and include provisions which address the duration of the sanction and the standard that we apply when determining if a sanction should be lifted. As specified in the Act and regulations, when intermediate sanctions are imposed on contracting organizations, the sanctions remain in place until the Secretary/CMS is satisfied that the basis for the sanction determination has been corrected and is not likely to recur.

In the October 2009 proposed rule (74 FR 54634), we proposed a change that included a rule that allows us to require a plan under a marketing and/or enrollment sanction to market or accept enrollments or both for a limited period of time. As we explained in that proposed rule, the purpose of the test period is to assist us in making a determination as to whether the deficiencies that are the bases for the intermediate sanctions have been corrected and are not likely to recur. The test period provides us with the opportunity to observe a sanctioned plans ability to enroll or market to Medicare beneficiaries prior to lifting the sanction.

We are proposing to extend the applicability of such a test period to include all intermediate sanctions and to clarify that while we may require a sponsor to receive enrollments during this test period, the sponsor would not receive any LIS annual or auto facilitated reassignments.

We believe these provisions would not result in additional burden to sponsors nor would they have a financial impact on sponsors.

8. Effects on Timely Access to Mail Order Services

We believe it is necessary and appropriate to establish mail order fulfillment requirements defining maximum turnaround times from when the pharmacy receives the prescription order to when it is shipped. This would underscore the importance of consistent and reliable access to medications, protecting beneficiaries from inconsistent or unreliable practices that may otherwise jeopardize timely access to prescriptions. The proposed standards are in alignment with requirements already in place in the market, and as such we do not expect significant financial impacts to implement.

9. Effects of Collections of Premiums and Cost Sharing

In the proposed provision, ''Waivers and Incorrect Collections of Premiums and Cost Sharing,'' we propose to codify our existing guidance pertaining to the waiver of premiums and cost sharing by Part D sponsors and to specifically require sponsors to refund incorrect collections of premiums and cost sharing or retroactively collect underpayments of cost sharing. Since our policy on waivers of premiums and cost sharing has been specified in informal guidance since the beginning of the Part D program and the timeframe for sponsor refunds and recoveries is codified in regulations at § 423.466(a) indicating that such refunds and collections are required, we do not believe the proposed changes would result in any additional costs.

10. Effects of Enrollment Eligibility for Individuals Not Lawfully Present in the United States

In section III.A.10. of this proposed rule, we discuss our proposals to add 'citizenship or lawful presence' as an eligibility requirement to enroll and remain enrolled in MA, Part D, and section 1876 cost contracts to align with section 401 of the PRWORA mandating that aliens not lawfully present in the United States are not eligible to receive any federal benefit. In CY 2012, there were close to 50 million Medicare beneficiaries. Approximately 34.4 million beneficiaries were enrolled in MA plans, PDPs or cost plans, which accounted for 68.8 percent of the total Medicare population. In the same year, an average of 4,285 Medicare beneficiaries enrolled in MA or Part D plans were identified by SSA as being unlawfully present. By directing MA

plans, PDPs, and cost plans to disenroll individuals who, at the time of notification from CMS, are not lawfully present, we intend to prevent improper payment for these individuals to MA plans, PDPs, and cost plans for periods when these individuals were ineligible to receive such services. Based on data for capitation payments for MA and PDPs, as well as the prepayments provided to cost plans, we estimate that the disenrollment of individuals who are unlawfully present would result in a decrease in payments made by CMS and would result in a cost savings of $10 million in 2015. We estimate, based on the numbers previously mentioned, that this change could save the MA program approximately $5 million in 2015, increasing to $8 million in 2019, and could save the Part D program (includes the Part D portion of MA–PD plans) approximately $5 million in 2015, increasing to $9 million in 2019. As cost plans are paid based on the reasonable costs delivering Medicare-covered services to their enrollees, instead of the fixed capitation amounts paid to MA plans and PDPs, we believe the impact to cost plans associated with this provision to be negligible.

TABLE 9—PROJECTED NUMBER OF INDIVIDUALS DISENROLLED DUE TO LOSS OF LAWFUL PRESENCE AND ESTIMATED SAVINGS TO THE MEDICARE ADVANTAGE PROGRAM BY PROVISION FOR CALENDAR YEARS 2015 THROUGH 2019

	2015	2016	2017	2018	2019	Totals (CYs 2105–2019)
Projected number of unlawfully present beneficiaries enrolled in MA plans	1,118	1,247	1,375	1,503	1,632	6,875
Projected federal impact due to unlawfully-present individuals disenrolled 6 months sooner	[1] −$5	[1] −$6	[1] −$6	[1] −$7	[1] −$8	−$32

Note: Estimates reflect scoring by the CMS, Office of the Actuary, and 2012 lawful presence data provided by the SSA.
[1] Million.

TABLE 10—PROJECTED NUMBER OF INDIVIDUALS DISENROLLED DUE TO LOSS OF LAWFUL PRESENCE AND ESTIMATED SAVINGS TO THE MEDICARE PART D PROGRAM BY PROVISION FOR CALENDAR YEARS 2015 THROUGH 2019

	2015	2016	2017	2018	2019	Totals (CYs 2015–2019)
Projected number of unlawfully present beneficiaries enrolled in Part D plans (including MA–PDs)	5,780	6,276	6,771	7,267	7,762	33,856
Projected federal impact due to unlawfully-present individuals disenrolled 6 months sooner	[1] −$5	[1] −$6	[1] −$7	[1] −$8	[1] −$9	[1] −$35

Note: Estimates reflect scoring by the CMS, Office of the Actuary, and 2012 lawful presence data provided by the SSA.
[1] Million.

11. Effects of Part D Notice of Changes

This section would codify current guidance for Part D sponsors to inform beneficiaries about changes to plan benefits from year to year and also correct an oversight whereby such a regulation currently exists for Part C but not for Part D. We anticipate that this proposal would result in no additional costs because Part D sponsors already typically provide this information.

12. Effects of Separating the Annual Notice of Change (ANOC) From the Evidence of Coverage (EOC)

Currently, members must receive the plan's combined ANOC/EOC prior to the Annual Election Period (AEP). We propose to separate the distribution and dissemination requirements, such that, the ANOC is received by beneficiaries before the AEP and the EOC is received closer to the enrollment effective date. This way, beneficiaries who choose to leave their current plans and enroll in other plans will only receive an EOC from the plan in which they have enrolled. We believe that this will reduce confusion among beneficiaries about which EOC is for the plan in which they have enrolled. It eliminates the unnecessary waste from the production of EOCs that end up being discarded. It also allows MA organizations and Part D sponsors additional time to develop better quality documents.

We propose to revise the language in § 422.111(a)(3) and § 423.128(a)(3) to allow the EOC to be sent to members a few months after the ANOC. We believe this provision will have minimal or no financial impact as the proposal would merely change the timing of notices that MA organizations and Part D sponsors already provide. Further, the delay in providing the EOC could result in savings as MA organizations and Part D sponsors have additional time to ensure that these documents are accurate, thus eliminating the need for updates and correction notices.

13. Effects of the Modification of the Agent/Broker Compensation Requirements

The current independent agent compensation structure (as originally published as CMS–4138–IFC2 in November 2008) is comprised of a 6-year cycle and is scheduled to end December 31, 2013. MA organizations and Part D sponsors provide an initial compensation payment to independent agents for new enrollees or unlike plan changes (Year 1), and pay a renewal rate (equal to 50 percent of the initial year compensation) for Years 2 through 6. CMS is proposing to revise this existing compensation structure. MA Organizations and PDP sponsors would have the discretion to decide, on an annual basis, whether to pay initial and/or renewal compensation payments to their independent agents. For new or unlike plan change enrollments, MA Organizations and PDP sponsors could make an initial payment that is no greater than the fair market value (FMV)

amount for such services, set annually by CMS in guidance interpreting these regulations. For renewals in Year 2 and subsequent years, the MA organization or PDP sponsor could pay up to 35 percent of the FMV amount for that year. We are proposing that recovery of compensation payments not happen when the disenrollment does not result from the agent's behavior. In addition to the agent and broker compensation structures, we are amending the training and testing requirements and setting limits on referral fees for agents and brokers.

We do not believe that any of these revisions will add additional burden or have financial impact. We are simply revising the existing compensation structure under which MA organizations may pay independent agents and believe that the total compensation amounts will generally remain unaffected. Furthermore, we believe these proposed changes would actually lessen the burden and impact on MA organizations by simplifying the compensation structure for independent agent brokers.

14. Effects of Drug Categories or Classes of Clinical Concern and Exceptions

We believe that this proposed provision to establish new criteria for identifying Part D drug categories or classes of clinical concern would generate significant Part D savings. This provision would require that Part D sponsors include all Part D drugs on their formularies in categories or classes of clinical concern that CMS specifies for a typical individual with a disease or condition treated by the drugs in the category or class meet the following proposed criteria: (1) hospitalization, persistent or significant disability or incapacity, or death likely will result if initial administration (including self-administration) of a drug in the category or class does not occur within 7 days of the date the prescription for the drug was presented to the pharmacy to be filled; and (2) more specific CMS formulary requirements will not suffice to meet the universe of clinical drug-and-disease-specific applications due to the diversity of disease or condition manifestations and associated specificity or variability of drug therapies necessary to treat such manifestations.

The expected savings to the Part D program would result from reducing the number of categories or classes of drugs for which Part D sponsors currently must include all Part D drugs on their formularies, as compared to existing requirements. Specifically, in applying the proposed criteria to all categories and classes of Part D drugs, CMS has determined that three existing categories and classes of Part D drugs would meet the new criteria and that no additional categories or classes of drugs would meet the criteria. Specifically, we determined that only the antineoplastic, antiretroviral and anticonvulsant categories and classes would meet the new criteria. This means that Part D sponsors would no longer be required to include all Part D drugs from within the antidepressant and immunosuppressant (used for transplants rejection) classes on their formularies. Relative to the antipsychotic class, however, we are deferring any change in formulary requirements for the antipsychotic class at this time and will continue to require that all drugs within the antipsychotic class be included on all Part D formularies, subject to the exceptions that get finalized in § 423.120(b)(2)(vi).

Based upon this determination, we estimated that full implementation (including the antipsychotic class) of this provision would result in federal savings to the Medicare Part D program of $720 million for the period CY 2015 through CY 2019, with most of these savings generated from the antipsychotic class (see table 14). We note this estimate is based upon the information that is available. Projected savings are based upon full implementation of the criteria and do not reflect that changes for the antipsychotic class of drugs are deferred at this time. However, there could be additional savings when new drugs enter the market and compete with each other by providing higher rebates.

A consensus panel applied our proposed criteria to determine the categories or classes of clinical concern. Our consensus panel determined that of the current six categories or classes of clinical concern, three met both of the proposed criteria, three did not, and no new drug categories or classes met both criteria. Finally, we estimated the impact on drug expenditures for those drugs that ultimately met the criteria, as well as those drug categories or classes that no longer qualify as categories or classes of clinical concern.

To arrive at the cost estimate for the implementation of the categories or classes of clinical concern, we began by putting drug spending into three groupings: (1) Drugs that were already included in the six categories or classes of clinical concern; (2) drugs with a greater likelihood of being affected by this change because formularies without them would be acceptable under our formulary review process; (3) drugs with a lesser likelihood of being affected by this statutory change because formularies without them would not be acceptable under our formulary review process; and (4) drugs in the research and development pipeline in the six categories or classes of clinical concern that would be affected by this statutory change. Because we reduced the number of categories or classes of clinical concern relative to the six for which we currently require formulary inclusion of all Part D drugs, we expect Part D sponsors' negotiating power to increase. As a result, Part D sponsors could incur lower drug costs and could lower their bids, which could result in lower premiums and co-pays. We also believe that direct savings would be generated by the increasing generic utilization by removing brand products from formularies. Although, based on other categories and classes of drugs that exhibit generic saturation, we have reason to believe that some plans would still cover the brand products. Moreover, we believe that the program would avoid future costs because some drugs in the research and development pipeline would not be required on formularies as a result of this change.

To support the panel's conclusion that our formulary checks could efficiently require adequate access to these categories and classes without requiring that every drug in them be included on Part D formularies, we compared a Part D formulary to other formularies. To accomplish this, we took an approved CY 2014 formulary containing the average number of RxNorm Concept Unique Identifiers (RxCUIs). This formulary includes the following: 23 Generic (ANDA) antidepressant drug entities, 7 brand (NDA) antidepressant drug entities, 18 generic antipsychotic drug entities, and 9 brand antipsychotic drug entities. We then reviewed the drugs comprising the previously mentioned list against our formulary review requirements standards for treatment guidelines, common Medicare drugs, and the discrimination review. We found that the formulary could have passed these checks with 9 generic antidepressant drug entities, and 6 generic antipsychotic drug entities. No brands were necessary to meet the formulary review requirements. Thus, this formulary includes an excess of 16 brand drug entities and 26 generic drug entities within these two classes of medications. Because all these products are currently required on all Part D formularies, there is significantly less need for manufacturers to restrain list prices or offer rebates to sponsors for formulary placement. In contrast, under our proposal, 100 percent of the brands

(16/16) and 63 percent of the generics (26/41) would be expected to meet or exceed the price concessions applicable to the least expensive products in those classes to remain competitive. If manufacturers increased price concessions in response, sponsors might elect to keep the products on the formulary. Otherwise, we would expect sponsors to take those products off formulary. Thus, individuals on brand versions of these drugs or on the 63 percent of generic versions would in most cases either stay on the drug at that more competitive price, or switch to an even cheaper alternative that remains on formulary. Either way, the beneficiary's drug costs and costs to the program would decrease. Moreover, to evaluate whether plans would continue to offer brand drugs (because new generic drugs would be available), and therefore whether any rebates would be available, we evaluated CY 2014 formularies for three classes of drugs that face saturation by generics. We found that even though the majority of drugs in those classes were generic, some plans continued to offer brand drugs. We also propose to establish exceptions that we believe permit Part D sponsors to apply meaningful utilization management to these drugs without compromising access. Although these exceptions are generally similar to existing policy, we propose to permit prior authorizations for drugs in the categories and classes of clinical concern to verify medically accepted indications or in Part A/B versus D situations. These lower costs could be reflected in bids submitted to CMS by Part D sponsors and could result in decreased premiums for Medicare beneficiaries.

Although Part D sponsors would be required to include all Part D drugs on their formularies in fewer categories or classes than are currently required, we believe that our formulary review processes are sufficient to ensure that the implementation of this provision would not negatively impact beneficiary access to drugs or enrollment in Part D plans. Moreover, robust transition, exceptions and coverage determination, appeals and grievances processes ensure beneficiary access in the event that they have enrolled, either self-enrolled or auto-enrolled, in a plan where their drugs are not on formulary. We also do not believe that the proposed provisions would lead to greater beneficiary confusion or any increased difficulty in making enrollment decisions. We continue to believe that overall enrollment would increase given demographic trends and the increasing cash prices for drugs paid by beneficiaries who must pay cash because they do not enroll. Accordingly, we believe Medicare beneficiaries would continue to find Part D to be a cost efficient method of obtaining robust drug coverage at a range of acceptable costs.

We plan on working closely with Part D sponsors as our guidance in this area develops to ensure that they continue to provide high quality prescription drug coverage at the most economical price. It is not clear to us whether PBMs would experience a decrease in administrative costs. On one hand, the provisions in this rule may decrease formulary maintenance expenses, such as managing a small formulary. This may result in PBMs decreasing their fees to Part D sponsors. On the other hand, these provisions may increase exception requests, appeals, prior authorizations, and outreach to Part D sponsors, thereby increasing PBMs' administrative costs. However, because these types of administrative costs exist for PBMs today, it is unclear how much of an increase we would see specifically as a result of these provisions. Similar to our ongoing communications with our Part D sponsors, we intend to work closely with the industry to minimize the likelihood of any unanticipated increases in beneficiary costs.

15. Effects of Medication Therapy Management Program (MTMP) Under Part D

Current regulations require that Part D sponsors must have established a Medication Therapy Management Program that targets beneficiaries who: (1) Have multiple chronic diseases with three chronic diseases being the maximum number a Part D plan sponsor may require for targeted enrollment; (2) are taking multiple Part D drugs, with eight Part D drugs being the maximum number of drugs a Part D plan sponsor may require for targeted enrollment; and (3) are likely to incur costs for covered Part D drugs in an amount greater than or equal to $3000, as increased by an annual percentage. We specified in guidance that while Part D sponsors are permitted to target beneficiaries with select chronic diseases, they must include at least five of nine core chronic diseases in their criteria. These provisions have generated wide variability in MTM programs. Moreover, despite opt-out enrollment, completion rates for comprehensive medication reviews (CMR) remain very low.

We propose to broaden the MTM criteria to require that Part D sponsors now target beneficiaries who have two or more chronic diseases and are taking two or more covered Part D drugs. We propose to set the annual cost threshold at an amount commensurate with the annual amount of Part D costs incurred by individuals that meet the first two criteria regarding multiple chronic conditions and use of multiple covered Part D drugs. Applying this methodology, we would set the cost threshold at $620, which is the approximate cost of filling two generic prescriptions. We propose to revise this number periodically to reflect more up-to-date information regarding the drug spending of beneficiaries that have two or more chronic conditions and use two covered Part D drugs. We estimate that 2.5 million beneficiaries are currently eligible for MTM services, 13 percent opt-out of the MTM program, and 10 percent of participating beneficiaries will receive an annual CMR. We also estimate that an average CMR requires 35 minutes to complete and the average hourly compensation (including fringe benefits, overhead, general, and administrative expenses and fee) of the MTM provider is $120 (labor cost per CMR is $70), and that it costs $0.91 to print and mail a CMR summary in CMS' standardized format. Therefore, the estimated total annual cost of providing CMRs in all settings is $15,422,925 ($70.91/CMR × 217,500 CMRs). Previously, prior to the availability of more precise opt-out and CMR rates, we estimated that the total burden associated with conducting CMRs and delivering the CMR written summary in CMS' standardized format was 1,192,429 hours with a cost of $143,363,555, including delivery of 1,896,500 CMRs in all settings under the current eligibility criteria, and implementation and mailing costs for the CMR summary in standardized format (see OMB Control No. 0938–1154). We do not currently have data or estimates to determine the costs associated with quarterly targeted medication reviews and follow-up interventions, if necessary.

We estimate that 18 million beneficiaries would be eligible for MTM services based on the proposed criteria. Using the same opt-out, CMR, and expense rates as before, the estimated total annual cost of providing CMRs in all settings is $111,045,060 ($70.91/CMR × 1,566,000 CMRs). This is below previous estimates.

Additionally, there is currently no requirement to ensure that beneficiaries in special populations receive focused targeting, outreach, or engagement for enrollment or participation in MTM. Moreover, the opt-out method of enrolling targeted beneficiaries into MTM at 42 CFR 423.153(d)(1)(v) may only partly address the increased

barriers to care faced by some beneficiaries. Without being prescriptive about what strategies must be employed, we are proposing that sponsors develop an effective strategy to ensure access to services for all MTM-eligible beneficiaries. We would expect to see details concerning sponsors' specialized strategies regarding outreach and service provisions in their bids. We believe that current plan reporting requirements, along with other CMS data sources, will be sufficient for us to evaluate the impact of such strategies.

We cannot definitively score this proposal because the portion of the administrative costs attributable to MTM is not a specific line item that can be easily extracted from the bid. Although the increase in the number of CMRs is estimated to cost $111 million, mounting evidence shows that MTM services may generate overall medical savings.

Supporting this conclusion, a recent study conducted in conjunction with the Center for Medicare and Medicaid Innovation (''CMMI MTM study'') (available at *http://innovation.cms.gov/Files/reports/MTM-Interim-Report-01-2013.pdf*) found that MTM programs effectively targeted high risk individuals who had problems with their drug-therapy regimens and had high rates of hospital and emergency room visits before enrollment as well as those that experienced a recent visit to the hospital or emergency room. The study also found that individuals enrolled in MTM programs—particularly those who received annual CMRs—experienced significant improvements in drug therapy outcomes when compared to beneficiaries who did not receive any MTM services, thus supporting the hypothesis that the annual CMR may be one of the more crucial elements of MTM. Significant cost savings associated with all-cause hospitalizations at the overall PDP and MA–PD levels were found, which may be due to MTM's comprehensive rather than disease-specific approach. This research supports statements in a recent Congressional Budget Office report that programs and services that manage the benefit well or improve prescription drug use might result in medical savings (Congressional Budget Office, ''Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services'', November 2012, available at *http://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf*).

We anticipate that many more beneficiaries will have access to MTM services under the proposed revisions to the eligibility criteria, and believe that these changes will simplify the MTM criteria and minimize beneficiary confusion when choosing or transitioning between plans. Moreover, we believe these changes will reduce disparity and allow more beneficiaries with drug therapy problems to receive MTM services. Similarly, we expect the proposed requirement that sponsors develop an effective strategy to ensure access to services for all MTM-eligible beneficiaries will help to ensure that beneficiaries in special populations receive focused targeting, outreach, or engagement for enrollment or participation in MTM.

16. Effects of Business Continuity for MA Organizations and Part D Sponsors

Proposed § 422.504(o) and § 423.505(p) would, respectively, require MA organizations and Part D sponsors to develop and maintain business continuity plans which assess risks posed by disasters and contain strategies to mitigate those risks. We also would require that essential functions—including at a minimum benefit authorization, claim adjudication, call center and supporting operations—be restored within 24 hours after such functions fail or are disrupted.

Business continuity plans are well established in the business community, and we believe that most MA organizations and Part D sponsors already have business continuity plans in place which cover the basic proposed subject areas. We estimate that 5 percent of the contracting entities (532 MA organizations and Part D sponsors in 2013), or about 27 entities, will be affected by this requirement, resulting in an initial burden of 2,080 hours.

We estimate the first year burden of an emergency management director to help design the plan would be a burden of 56,160 hours ($27 \times 2{,}080$). The estimated cost associated with such expert is the estimated number of hours multiplied by the estimated hourly rate of $36.50 (hourly rate for an emergency management director, General Medical and Surgical Hospitals, according to May 2012 wage data from Bureau of Labor Statistics Occupational Employment Statistics) plus 48 percent for fringe benefits and overhead, which equals a first year cost of $3,033,763.

In subsequent years, the burden associated with this proposed requirement would be the costs of an emergency management director working on a part time basis for an ongoing burden of 28,080 ($27 \times 1{,}040$). The estimated cost associated with such expert is the estimated number of hours multiplied by the estimated hourly rate of $36.50 plus 48 percent for fringe benefits and overhead, which equals an annual cost of $1,516,882 for subsequent years.

We do expect that the burden would, should a disaster or other disruption of business occur, ultimately result in savings from planning that would avoid even more losses, but such offsets cannot be calculated here.

Requiring business continuity plans would benefit Medicare beneficiaries in these Part C and Part D plans because planning helps to negate problems: The more prepared that MA organizations and Part D sponsors are for disasters and other disruptions to business, the more likely it would be that these organizations would address timely any problems encountered and ultimately return to regular operations and the less likely it would be that individuals would lose access to benefits as a result of disruptions. Requiring the restoration of essential functions within 24 hours after failure would help by providing a clear deadline by which priority operations must be available to beneficiaries. Our proposal to deem as essential benefit authorization certain minimum functions, including claim adjudications, and all supporting operations would benefit individuals by providing the means to ensure beneficiaries access to their Medicare benefits—and therefore health care and drugs. Designating operation of the call center as essential would provide beneficiaries real time customer support which could be critical to ensuring access to benefits in times of disaster or other disruption. For instance, if beneficiaries could not get to their regular places of business or found their claims were rejected at point of sale, customer service representatives could then send them to providers and pharmacies that could provide them with benefits or resolve questions in real time such that they would be more likely to leave pharmacies with any appropriate drugs in hand.

17. Effects of Requirement for Applicants or Their Contracted First Tier, Downstream, or Related Entities to Have Experience in the Part D Program Providing Key Part D Functions

Based on CMS' authority at section 1860D–12(b)(3)(D) of the Act to adopt additional contract terms, not inconsistent with the Part C and D statutes, that are necessary and appropriate to administer the Part D program, we are proposing at § 423.504(b)(8)(i) through (iii) that Part D organizations seeking a new Medicare contract must have arrangements in place such that either the applicant, or

a contracted entity that will be performing certain key Part D functions, has at least one full benefit year of experience providing key Part D functions. This proposal ensures that applicants take advantage of the abundant Part D industry expertise and experience that exists today in the development of their Part D program operations, rather than relying on technical assistance from CMS and having their inexperience place beneficiaries' access to prescription drugs at risk. We believe this provision will have a very minor savings impact on the federal budget, based on savings of time and effort (staff time and contracted auditor time and resources) that the government would spend on overseeing the disproportionate level of problems experienced by organizations operating Part D plans without prior Part D experience. For each inexperienced organization allowed into the program in the absence of this proposal, we would anticipate a savings of 1,000 staff hours at an average rate of $50 per hour, for a total of $50,000 in employee time, plus an additional savings of $200,000 in contractor dollars to conduct an emergency audit, for a total of $250,000. In the absence of this proposal, we would anticipate no more than two such inexperienced entities beginning Part D operations per year, for a total annual savings of $500,000.

The burden associated with this proposal on industry would be minimal, with a total estimated number of labor hours of 3.25 to submit information during the Part D application process. Using the same average hourly salary as previously mentioned, the total cost to Part D applicants would be $162.50. We do not believe there are any non-administrative costs to industry associated with this proposal, as Part D applicants are already required to have arrangements in place to perform the key Part D functions discussed in our proposal.

The main anticipated effect from this proposal is ensuring that only entities with some experience with Part D in critically important functional areas are permitted to offer new Part D contracts, thus strengthening the Part D program by enhancing the qualification criteria. We considered the alternate proposal of requiring the prior Part D experience to be tied to specific quality outcomes. We rejected the alternative because we believed it added unnecessary complexity and burden to the process, and we believe a simple experience requirement is currently sufficient.

18. Effects of Requirement for Applicants for Stand Alone Part D Plan Sponsor Contracts To Be Actively Engaged in the Business of the Administration of Health Insurance Benefits

Based on CMS' authority at section 1860D–12(b)(3)(D) of the Act to adopt additional contract terms, not inconsistent with the Part C and D statutes, that are necessary and appropriate to administer the Part D program, we proposed at § 423.504(b)(9)(i) through (ii) that organizations seeking to offer a stand-alone prescription drug plans (PDP) for the first time must have either: (i) Actively offered health insurance or health benefits coverage for 2 continuous years immediately prior to submitting an application, or (ii) actively managed prescription drug benefits for a company offering health insurance or health benefits coverage for 5 continuous years immediately prior to submitting an application. This proposal would ensure that applicants have substantial experience in administering health insurance benefits prior to becoming a Part D sponsor. We believe this provision will have a very minor savings impact on the federal budget, based on savings of time and effort (staff time and contracted auditor time and resources) that the government would spend on overseeing the disproportionate level of problems experienced by organizations operating stand-alone PDPs without prior health insurance administration experience. For each inexperienced organization not allowed into the program in the absence of this proposal, we would anticipate a savings of 1,000 staff hours at an average rate of $50 per hour, for a total of $50,000 in employee time, plus an additional savings of $200,000 in contractor dollars to conduct an emergency audit, for a total of $250,000. In the absence of this proposal, we would anticipate no more than two such inexperienced entities beginning Part D operations per year, for a total annual savings of $500,000.

The burden associated with this proposal on industry would be minimal, with a total estimated number of labor hours of 3.25 to submit information during the Part D application process. Using the same average hourly salary as previously mentioned, the total cost to Part D applicants would be $162.50. We do not believe there are any non-administrative costs to industry associated with this proposal, as Part D applicants are already required to be licensed in at least one state prior to offering Part D benefits.

The main anticipated effect from this proposal is ensuring that only entities with some experience administering health insurance benefits will be permitted to offer new stand-alone PDPs, thus strengthening the Part D program by enhancing the qualification criteria. CMS considered the alternate proposal of requiring the prior health insurance benefit administration experience to be tied to specific quality outcomes. We rejected this alternative because we believed it added unnecessary complexity and burden to the process, and we believe a simple experience requirement is currently sufficient.

19. Effects of Limit Parent Organizations to One Prescription Drug Plan (PDP) Sponsor Contract per PDP Region

This provision has no quantifiable impact because the savings that might be achieved likely will be offset by the burden necessary with the consolidation activities and legal work necessary to implement these changes.

20. Effects of Limit Stand-Alone Prescription Drug Plan Sponsors To Offering No More Than Two Plans per PDP Region

This provision has no quantifiable impact because the savings that might be achieved likely will be offset by the burden necessary with the consolidation activities and legal work necessary to implement these changes.

21. Effects of Efficient Dispensing and in Long Term Care Facilities and Other Changes

We are proposing the following specific changes to the LTC short-cycle dispensing requirements at § 423.154: (1) Add a prohibition on payment arrangements that penalize the offering and adoption of more efficient LTC dispensing techniques; (2) eliminate language that has been misinterpreted as requiring the proration of dispensing fees; (3) incorporate an additional waiver for LTC pharmacies using restock and reuse dispensing methodologies under certain conditions; and (4) make a technical correction to eliminate the requirement that Part D sponsors report on the nature and quantity of unused brand and generic drugs. Medicare Part D plan sponsors are already required to comply with the LTC short-cycle dispensing requirements.

The prohibition on payment arrangements that penalize the offering and adoption of more efficient LTC dispensing techniques is a clarification of the Congress' intent in enacting section 1860D–4(c)(3) of the Act, and we

do not believe it will impose any new costs on stakeholders. Indeed, this proposal should reduce Part D sponsors' costs by preventing Part D sponsors from penalizing the most efficient LTC dispensing techniques. The resulting reduction in brand drug costs should offset or surpass increases in dispensing fees.

22. Effects of Applicable Cost-Sharing for Transition Supplies: Transition Process Under Part D

We propose to add at § 423.120(b)(3)(vi) a paragraph clarifying that a Part D sponsor must charge cost sharing as follows: (a) For low-income subsidy (LIS) enrollees, a sponsor must not charge higher cost sharing for transition supplies than the statutory maximum copayment amounts; (b) for non-LIS enrollees, a sponsor must charge: (1) The same cost sharing for non-formulary Part D drugs provided during the transition that would apply for non-formulary drugs approved under a coverage exception; and (2) the same cost sharing for formulary drugs subject to utilization management edits provided (for example, prior authorization and step therapy) during the transition that would apply once the utilization management criteria are met.

Because increases or decreases in cost sharing during transition supplies under the various circumstances are likely to offset one another, we anticipate that there would be no cost impact on plans.

23. Effects of Medicare Coverage Gap Discount Program and Employer Group Waiver Plans

The regulation amends § 423.2325 by adding a new paragraph (h), ''Medicare Coverage Gap Discount Program and Employer Group Waiver Plans''. This new provision requires Part D sponsors to fully disclose to each employer group the projected and actual manufacturer discount payments under the Discount Program attributable to the employer group's enrollees.

We believe that the provision will have negligible regulatory impact because, in the interest of Full Disclosure requirements, the great majority of sponsors with employer group clients have likely already integrated Discount Program data into their existing client reporting. This additional reporting has enabled employer groups to begin to incorporate the manufacturer payments into their benefit packages. Also, for those few Part D sponsors that have not already incorporated the discounts into client reports, the provision creates a minimal financial burden. The requirement does not entail development or gathering of any new data as currently, Part D sponsors report beneficiary-level discounts to CMS on Prescription Drug Event (PDE) data, and report aggregated enrollee utilization to employer group clients. The new provision requires only that sponsors who have not yet modified their existing reports provide the aggregated discount amounts to each employer group, and use the existing processes for report dissemination.

In estimating the associated regulatory costs we assumed that 80 percent of the sponsors were already supplying employer group clients with Discount Program information and that 20 percent of the plans would need to modify the reports as a result of this provision. We used 2013 data to determine the number of sponsors that would be affected by this new requirement. In 2013, 131 Part D sponsors operated one or more EGWP plans. If 20 percent of these Part D sponsors were required to change their client reporting, approximately 26 sponsors would be affected. Our research indicates that it would take each sponsor employing a mid-level analyst about 2-business days to aggregate the manufacturer discounts for each client and modify the existing reports to include the discount payments. Assuming an average hourly wage and benefits of $50,[5] the cost of these 16 hours would be $50 × 16 = $800 for each Part D sponsor or a total of $800 × 26 = $20,800 for all 26 sponsors combined. In subsequent years we do not believe that there will be any incremental costs associated with the regulation as sponsors will update the discount data per their existing processes.

There is no quantifiable monetary value to CMS. Rather, requiring Part D sponsors to report amounts they receive on behalf of employer group enrollees will enable the employer group to use the payments in a way that best serves retirees.

24. Effects of Interpreting the Non-Interference Provision

We are proposing to formally interpret section 1860D–11(i) of the Act, referred to as the non-interference provision. This provision prohibits CMS from interfering with the negotiations between drug manufacturers and pharmacies and Part D sponsors, and requiring a particular formulary or instituting a price structure for the reimbursement of covered part D drugs. We have not previously interpreted the statutory provision, which has resulted in different stakeholders having different views about its scope. Consequently, we believe that a clear interpretation of the statutory provision will remove ambiguity. We do not believe there is any regulatory impact because we are codifying an existing requirement that currently prohibits CMS from interfering in certain activities between Part D sponsors, pharmacies and manufacturers without adding any new requirements.

25. Effects of Pharmacy Price Concessions in Negotiated Prices

We propose to revise the definition of negotiated prices at § 423.100 to specify that all pharmacy price concessions must be included in the negotiated price. This would preclude the differential reporting that is taking place today in the realm of reporting drug costs and price concessions from network pharmacies. This proposal would change current policy that permits sponsors to elect to take some price concessions from pharmacies in forms other than the negotiated price and report them outside the PDE. This practice currently allows price concessions to be applied disproportionately to costs that plans are liable for, and thus may shift more low-income cost-sharing subsidy and reinsurance costs to the government, as well as to manufacturers in the calculation of coverage gap discount payments. A sponsor that engages in this practice can reduce its bid and achieve a competitive advantage relative to a sponsor that applies all price concessions to the negotiated price—a competitive advantage stemming not from greater efficiency, but from a technical difference in how costs are reported to CMS. Meanwhile, the higher the negotiated price, the higher beneficiary coinsurance will be, the faster the beneficiary is moved through the benefit, and the higher government subsidies for low-income cost sharing (LICS) and reinsurance subsidies will be. Our proposal would impose consistent treatment of drug price reporting.

Our proposal to require all price concessions to be reflected in the negotiated price received by the pharmacy would not necessarily change the level of price concessions received from network pharmacies, but would impose a single consistent price concession reporting process on all Part

[5] Depart of Labor quarterly census of Employment and Wages indicates that the average 2011 wage for private health insurance plans was $74,431. To project a 2015 wage this figure was increased 3 percent per year to $83,772 in 2015. This lead to an hourly wage projection of $40.27 or with 20 percent benefits an hourly rate of $48.33, which was in turn rounded upward to derive an hourly rate of $50.

D sponsors. Therefore, it is not clear that any contractual arrangements between a subset of sponsors and network pharmacies would require renegotiation, since only the form of the price concession, rather than its level, would be affected by this proposal.

In addition, when price concessions from pharmacies are in forms other than the negotiated price, the degree of price concession that the pharmacy has agreed is no longer reflected in the negotiated prices available at point of sale or reflected on the Medicare Prescription Drug Plan Finder (Plan Finder) tool. Thus, the true price of drugs at individual pharmacies is no longer transparent to the market. Consequently, consumers cannot efficiently minimize both their costs (cost sharing) and costs to the taxpayers by seeking and finding the lowest-cost drug/pharmacy combination. This proposal would ensure that the actual level of price competition is transparent to the Part D market.

Under current policy, a sponsor may be able to offer a lower bid than its competitors and may achieve a competitive advantage stemming not from greater efficiency, but from a technical difference in how costs are reported to CMS. When this happens, such differential reporting may result in bids that are no longer comparable, and in premiums that are no longer valid indicators of relative plan efficiency. The changes we are proposing would lead to Part D bids being more accurately comparable and premiums more accurately reflecting relative plan efficiencies. The lowest premiums would more accurately direct beneficiaries to the plans that have the lowest costs to the program overall.

We do not collect sufficient detail in price concession data reported to CMS to quantify the impact of this proposed change to standardize price concession reporting. We believe that only certain sponsors are engaging in the differential reporting practices today, and these sponsors face close competition from larger competitors that do not appear to be employing the same strategies. Consequently, if the sponsors employing these tactics increase their bids to maintain margin, they could likely risk losing market share. Therefore, we would expect these sponsors to carefully consider the risk of losing market share before raising their bids in response to our regulatory proposals, particularly those that are committed to the LIS market.

We expect that the effect of our proposal to require consistent and transparent pricing would not only provide higher-quality information to the Part D market, but also promote increased price competition among network pharmacies. This expectation is consistent with economic theory that holds that increased price transparency will increase price competition. We believe pharmacies will support including the full price concession in the point-of-sale price, and fully transparent price competition will align beneficiary and taxpayer interests in minimizing costs. Our proposal would not change the level of price concessions and therefore costs under the program as a whole, but would apply consistency to how these are reported to CMS and treated in bidding and payment processes. Therefore, we anticipate that there would be no cost impact on plans.

26. Effects of Payments to PDP Plan Sponsors for Qualified Prescription Drug Coverage and Payments to Sponsors of Retiree Prescription Drug Plans

This section is not anticipated to have any significant impact since it is only a conforming change, necessary to align with the proposed definition change in another section of the regulation.

27. Effects of Preferred Cost Sharing

We propose to require that sponsors may offer reduced copayments or coinsurance for covered Part D drugs obtained through a subset of network pharmacies, as long as such preferred cost sharing is in return for consistently lower negotiated prices relative to the same drugs when obtained in the rest of the pharmacy network. Therefore, we intend to clarify that preferred cost sharing should consistently be aligned with and accurately signal lower costs. We propose that by ''consistently lower'' we mean that sponsors must offer better prices on all drugs in return for the lower cost sharing. In practice we believe this would mean that whatever pricing standard is used to reimburse drugs purchased from network pharmacies in general, a lower pricing standard must be applied to drugs offered at the preferred level of cost sharing. Our analysis shows that most sponsors offering preferred cost sharing are currently achieving these levels of savings, and therefore our proposed policy would only require a change in price concession levels or reporting for a limited number of sponsors. Our proposal would apply a consistent expectation across all sponsors to compete on the same basis on negotiated prices, including in related-party pharmacy operations.

Instead of consistently passing through lower costs available through economies of scale or steeper discounts, some (but not the majority of) sponsors are actually charging the program higher negotiated prices in some cases. In other cases, the negotiated prices offered for preferred cost sharing are only slightly lower than the prices in the rest of the network. When either higher prices or very nearly the same prices are combined with significantly lower cost sharing, such pricing increases the proportion of costs borne by the plan and the government. Moreover, the lower cost sharing provides a defective price signal that distorts market behavior. In these cases, the lower cost sharing does not incent enrollees to select pharmacies with lower prices and thus make more efficient choices in the market, but the exact opposite. This would be expected to result in higher costs to the Part D program overall. Therefore, we believe our proposed policy change to require consistently lower negotiated prices in return for preferred cost sharing may not only decrease overall price levels in certain sponsor's networks, but would also encourage beneficiaries to make drug purchase decisions that are better aligned with lower costs to the program overall. However, we do not have enough information on how negotiated prices might change—particularly in combination with the requirements for all price concessions from pharmacies to be reflected in negotiated prices, and for any-willing-pharmacy terms and conditions to include minimum price concession terms for preferred cost sharing—to predict the overall change in Part D costs.

28. Effects of Maximum Allowable Cost Pricing Standard

We are proposing a change to the regulations at § 423.505(b)(21) and § 423.505(i)(3) governing the disclosure and updating of prescription drug pricing standards used by Part D sponsors to reimburse network pharmacies to make clear that drug pricing based on maximum allowable cost (MAC) is subject to these regulations. In the final rule at 76 FR 54600 (September 1, 2011), we did not estimate a regulatory impact for Part D sponsors to comply with the prescription drug pricing standard requirements, and we do not believe these proposed changes would result in any regulatory impact. Read together, the new provisions in § 423.501, § 423.505(b)(21), and § 423.505(i)(3)(viii) require sponsors, when applicable, to include provisions in network pharmacy contracts, to address the disclosure of MAC prices themselves to be updated to the applicable pharmacies

in advance of their use for reimbursement of claims, because the source of the MAC prices is not publicly available. Addressing prices that will be paid to a subcontractor is an activity undertaken in the normal course of business. Also, whether to use MAC prices is voluntary for Part D sponsors. Finally, sponsors must have procedures, systems, and technology currently in place to use these prices for reimbursement of pharmacy claims in the normal course of business. These systems would have to be adapted to also disclose the prices to pharmacies in advance of their use, which we believe would involve negligible effort for Part D sponsors' existing employees and/or subcontractors. Therefore, we estimate the impact of these provisions to be negligible.

29. Effects of Any Willing Pharmacy Standard Terms & Conditions

Proposed changes to § 423.120(a)(8) would require Part D sponsors to offer the contract terms and conditions (T&C) for every level of cost sharing offered under a Part D plan (preferred, standard retail, mail order, etc.) to any willing pharmacy. We expect the burden for Part D sponsors to amend contracts, where necessary, to offer every level of cost sharing would be negligible. Sponsors already must meet any willing pharmacy requirements for retail and mail order cost sharing. In 2013, nearly half of non-employer group Part D sponsors were designing and marketing plans with T&C for preferred cost sharing levels. For these sponsors, the only change associated with this proposal will be to ensure that now T&C for all levels of cost sharing, including preferred, are being offered (if they are not already) to all interested pharmacies. For the other half of Part D sponsors not currently offering preferred cost sharing options, this proposal does not require them to start.

Part D sponsors already negotiate contracts regularly with pharmacies in order to meet network access requirements. We estimate that for sponsors who currently offer benefit packages with a preferred cost sharing level (approximately 500 plans), an estimated new burden of 5,000 legal hours (500 plans × 10 hours) for revising contract language and 2,000 hours (500 plans × 4 hours) for additional contract support staff time negotiating with and assisting pharmacies contracting at the preferred cost sharing level for the first time. The estimated cost associated with this change is the estimated number of hours multiplied by available average hourly rates ($62.93 per hour for a lawyer, $32.22 per hour for a financial specialist [May 2012 wage data from Bureau of Labor Statistics Occupational Employment Statistics]), plus 48 percent for fringe benefits and overhead, which equals a first year cost of $561,053.20. Once a sponsor has revised contracts to meet the proposed requirement, no extraordinary additional expenses are anticipated for subsequent years. For a plan not currently offering preferred cost sharing levels, it is expected that preferred cost sharing terms and conditions would be offered to any willing pharmacy if they ever decide to offer them.

Any new burden on pharmacies is similarly expected to be negligible, as they are already reviewing and implementing terms from contracts, often annually. Pharmacies are not being directed to choose one set of T&C over another, but rather are gaining the option to review and implement terms for preferred cost sharing, if they so choose to accept the applicable negotiated pricing terms.

Beneficiaries are expected to benefit from an increased number of pharmacies offering preferred cost sharing levels.

30. Effects of Enrollment Requirements for the Prescribers of Part D Covered

Our proposal is that prescribers must be enrolled in Medicare in order for their prescriptions to be coverable under the Part D program. This will entail Part D sponsors or their designated PBMs checking the prescriber's individual NPI to determine whether the prescriber's is validly enrolled in Medicare before paying a claim from a network pharmacy or request for reimbursement from a beneficiary.

When we promulgated the NPI PDE requirement in a final regulation published on April 12, 2012 (77 FR 22072), we estimated the impact for PBMs and plan organizations to contract for or build prescriber ID validation services. Thus, while this proposal entails a new requirement for Part D sponsors, we do not believe it would have any new or additional impact because Part D sponsors must already have prescriber validation capabilities to meet the NPI PDE requirement.

Additionally, under our proposal, we do not estimate any savings. We presume that if a beneficiary's prescriber is not enrolled or does not enroll in Medicare, the beneficiary will find a new prescriber who is enrolled, rather than go without needed medications. Therefore, we do not estimate any savings from this proposal.

31. Effects of Improper Prescribing Practices and Patterns

Our proposed revisions in § 424.530(a)(11) and § 424.535(a)(13) would likely result in additional application denials and revocations. The DEA Web site found at *http://www.deadiversion.usdoj.gov/crim_admin_actions/index.html* contains a list of physicians, eligible professionals, and pharmacies that have had their DEA Certificate of Registration suspended or revoked since 2000. Based on our review of this data, we believe that approximately 200 Medicare-enrolled physicians and eligible professionals would be affected by proposed § 424.535(a)(13). However, we do not have data available to assist us in calculating the potential costs to physicians and eligible professionals in lost potential billings or the potential costs or savings to the government arising from this provision; nor are we able to estimate the number of denials per year that would result from proposed § 424.530(a)(11).

Our proposed § 424.535(a)(14) would result in an increase in the total number of revocations under § 424.535(a). We are unable, though, to project the number of providers and suppliers that would be revoked under § 424.535(a)(14) because we do not have data available that can be used to make such an estimate. Thus, we cannot project: (1) The potential costs to providers and suppliers in lost billings, or (2) the potential costs or savings to the government arising from our proposed provision.

32. Effects of the Transfer of TrOOP Between Part D Sponsors Due to Enrollment Changes During the Coverage Year

We do not expect that codifying the requirement for Part D sponsors to report TrOOP-related data to a subsequent plan in which a beneficiary enrolls during the coverage year, and for the new plan to accept that data and use it to position the beneficiary in their benefit would generate savings or increase costs.

We expect the requirement to report TrOOP-related data and to accept and use the data to position a beneficiary in a new plan benefit when the member changes plans during the coverage year would ensure the Part D benefit is correctly administered by the new plan and prevent a beneficiary who has already moved through the initial phase(s) of the Part D benefit from starting the benefit anew as a result of the enrollment change.

33. Effects of Broadening the Release of Part D Data

We are proposing to revise our regulations governing the release of Part D data to expand the release of unencrypted prescriber, plan and pharmacy identifiers contained in prescription drug event (PDE) records to external researchers, as well as to make other changes to our policies regarding release of PDE data, as currently codified at § 423.505(f)(3) and (m). This proposal does not impose any new costs on any stakeholders. Medicare Part D plan sponsors are already required to, and do, submit the information that may be released in accordance with this proposal. Therefore, we are not including any assessment of this proposal for the regulatory impact statement.

34. Effects of Establish Authority to Directly Request Information From First Tier, Downstream, and Related Entities

Pursuant to sections 1857(d)(2) and 1860D 12(b)(3)(c) of the Act, we are now proposing to specify at § 422.504(i)(2)(ii) and § 423.505(i)(2)(ii) that HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any records directly from any first tier, downstream, or related entity. This proposed regulatory change would not grant CMS (or the MEDIC, the contractor that conducts fraud investigations on our behalf) any oversight authority beyond what we already possess.

In enabling CMS or its designee(s) to directly request information from a first tier, downstream, or related entity, we would provide a more efficient avenue to obtain necessary information. This proposal would change the current policy, which requires going through the plan sponsor in order to collect information. Our proposal would save money and time for CMS as well as the plan sponsor.

We anticipate that adoption of this proposal would result in cost savings for plan sponsors. Under the current regulatory structure, assuming that the MEDIC (the CMS contractor that typically would put forth such requests) puts forth 1000 requests per year to Part C and D sponsors, each request requires the plan sponsor to spend 5 hours developing and making the request for information from its first tier, downstream, or related entity, and communicating the results of that request back to CMS. At a rate of $55 per hour, plan sponsors may save a total of $275,000 in employee costs in the aggregate. Additionally, we believe this provision will have a very minor savings impact on the federal budget. This calculation is based on the savings in time and effort the MEDIC will experience (2 hours per information request) resulting from the ability to request information directly from first tier, downstream, and related entities. The 2 hours reflects the time the MEDIC currently spends resolving ambiguities in the request or in the information provided in response that are created by the presence of an intermediary (that is, the plan sponsor) between the requestor (MEDIC) and the custodian of the information (that is; first tier, downstream, or related entity).

In addition to cost savings, this proposed regulatory change will reduce the administrative burden on plan sponsors. The plan sponsor will no longer have to act as the gatekeeper between the MEDIC and its first tier, downstream, or related entity.

We do not anticipate any additional burden relating to the proposed requirement that we alert the plan sponsor that we are contacting its first tier, downstream or related entity since CMS will be merely copying the plan sponsor on the request.

35. Effects of Eligibility of Enrollment for Incarcerated Individuals

We are proposing to amend § 417.460(b)(2)(i), § 417.460(f)(1)(i), § 422.2, § 422.74(d)(4)(i)(A), § 422.74(d)(4)(v), § 423.4, and § 423.44(d)(5) to clarify the eligibility requirement for residing in the plan's service area related to incarceration for the purposes of enrolling into and remaining enrolled in MA, Part D, and Medicare cost plans. We expect the impact of this change to be primarily that of savings to the MA and Part D programs. In CY 2012, there were close to 50 million Medicare beneficiaries. Approximately 34.4 million of those beneficiaries were enrolled in MA plans, PDPs, or cost plans which accounts for 68.8 percent of the total Medicare population. In the same year, an average of 21,329 Medicare beneficiaries enrolled in MA or Part D plans were identified by SSA as being incarcerated.

We issued guidance to MA plans and PDPs to investigate each individual's incarcerated status and disenroll the individual for no longer residing in the plan's service area if the plan confirmed incarcerated status. If the MA plan or PDP could not confirm the incarcerated status, those plans were to continue to investigate each instance of incarceration for up to 6/12 months and disenroll the individuals at the end of that time following § 422.74(b)(4)(ii)/ § 423.44(b)(5)(ii) if they couldn't verify the incarcerated status sooner. As a result, the plan received capitated payments when the individual was ineligible to receive payment of Medicare benefits. Section 1876 Cost contracts had no such instructions to disenroll individuals who are incarcerated. By directing MA plans, PDPs, and cost plans to disenroll incarcerated individuals at the time of notification from CMS, we intend to prevent improper payment for these individuals to MA plans, PDPs, and cost plans for periods when they were ineligible to receive such services. Based on the data for capitation payments for MA and PDPs, as well as the prepayments provided to cost plans, we estimate that the disenrollment of incarcerated individuals would result in a decrease in payments made by CMS and would result in a cost savings of $70 million in 2015.

We estimate, based on the numbers mentioned previously, that this change could save the MA program approximately $27 million in 2015, increasing to $62 million in 2019, and could save the Part D program (includes the Part D portion of MA–PD plans) approximately $46 million in 2015, increasing to $90 million in 2019. As cost plans are paid based on the reasonable costs delivering Medicare-covered services to their enrollees, instead of the fixed capitation amounts paid to MA and PDPs, we believe the impact to cost plans associated with this provision to be negligible.

TABLE 11—PROJECTED NUMBER OF INDIVIDUALS DISENROLLED DUE TO INCARCERATION AND ESTIMATED SAVINGS TO THE MEDICARE ADVANTAGE PROGRAM BY PROVISION FOR CALENDAR YEARS 2015 THROUGH 2019

	2015	2016	2017	2018	2019	Totals (CYs 2105–2019)
Projected number of incarcerated beneficiaries enrolled in MA plans	6,280	7,750	9,221	10,691	12,162	46,104

TABLE 11—PROJECTED NUMBER OF INDIVIDUALS DISENROLLED DUE TO INCARCERATION AND ESTIMATED SAVINGS TO THE MEDICARE ADVANTAGE PROGRAM BY PROVISION FOR CALENDAR YEARS 2015 THROUGH 2019—Continued

	2015	2016	2017	2018	2019	Totals (CYs 2105–2019)
Projected federal impact due to incarcerated individuals disenrolled 6 months sooner	[1] – $27	[1] – $35	[1] – $43	[1] – $52	[1] – $62	[1] – $219

Note: Estimates reflect scoring by the CMS, Office of the Actuary, and 2012 incarceration data provided by the SSA.
[1] Million.

TABLE 12—PROJECTED NUMBER OF INDIVIDUALS DISENROLLED DUE TO INCARCERATION AND ESTIMATED SAVINGS TO THE MEDICARE PART D PROGRAM BY PROVISION FOR CALENDAR YEARS 2015 THROUGH 2019

	2015	2016	2017	2018	2019	Totals (CYs 2015–2019)
Projected number of incarcerated beneficiaries enrolled in Part D plans (including MA–PDs)	49,275	55,970	62,666	69,362	76,058	[1] 313,331
Projected federal impact due to incarcerated individuals disenrolled 12 months sooner	[2] – $46	[2] – $55	[2] – $65	[2] – $77	[2] – $90	[2] – $333

Note: Estimates reflect scoring by the CMS, Office of the Actuary, and 2012 incarceration data provided by the SSA.
[1] Accumulated; not unique individuals.
[2] Million.

36. Effects of Rewards and Incentives Program Regulations for Part C Enrollees

This proposal would permit plans to provide limited rewards and incentives to enrollees who participate in activities that focus on promoting improved health, preventing injuries and illness, and promoting efficient use of health care resources. While there would be a cost associated with providing rewards and incentives, we anticipate that there may be savings as a result of healthier beneficiary behavior. Because plans are not required to provide rewards and incentives and CMS does not have a means of calculating the costs and benefits of rewards/incentives at this time, we are not providing an impact analysis for this provision.

37. Effects of Expand Quality Improvement Program Regulations

The proposed regulation changes are only technical changes for the established quality improvement program requirements. These changes would clarify how MA organizations report quality improvement program information to CMS. As MA organizations are already reporting this information to CMS and the changes are only to codify the process, the changes will not increase costs for MA organizations.

38. Effects of Authorization of Expansion of Automatic or Passive Enrollment Non-Renewing Dual Eligible SNPs (D–SNPs) to Another D–SNP To Support Alignment Procedures

We propose to modify the situations in which CMS may passively enroll beneficiaries to include the situation when a Medicare Advantage Dual Eligible SNP (D–SNP) is non-renewing. More specifically, passive enrollment would be permitted for full-benefit dual eligible beneficiaries in the non-renewing D–SNP when there is another D–SNP in the service area that offers substantially similar benefits, network, and cost-sharing as the non-renewing D–SNP, and that also offers the Medicaid managed care organization in which the beneficiary is enrolled.

SNPs are due to sunset in 2014. Consequently, we are not scoring this provision for contract years 2015 through 2019.

39. Effects of Improving Payment Accuracy: Reporting Overpayments, RADV Appeals, Part D Payment Reopening, LIS Cost Sharing, and Coverage Gap Discount Program

This proposed section proposes only technical changes for overpayment reporting, RADV appeals, Part D payment reopening, LIS cost sharing, and the Coverage Gap Discount Program. These technical changes will not result in costs to MA organizations and Part D sponsors, nor do we expect the impact of these technical changes to result in savings.

40. Effects of Part C and Part D RAC Determination Appeals

In section III.B.x of this proposed rule, to establish an administrative appeals process for overpayment determinations by the Part C and Part D RACs. The cost associated with these provisions involves the preparation and submission of appeal requests by plans. We estimate this cost to be $48,343 as summarized in the following Table 13.

TABLE 13—SUMMARY OF RAC DETERMINATION APPEALS COSTS AND BENEFITS

Provision description	Costs (in $millions)	Benefits
Submission of MA plans' first level Request for Reconsideration.	0.02167	Administrative appeal rights and accuracy in recovery demands.
Submission of Part D plans' first level Request for Reconsideration.	0.02167	Administrative appeal rights and accuracy in recovery demands.
Submission of MA plans' second level Request for Review	0.00208	Administrative appeal rights and accuracy in recovery demands.

TABLE 13—SUMMARY OF RAC DETERMINATION APPEALS COSTS AND BENEFITS—Continued

Provision description	Costs (in $millions)	Benefits
Submission of Part D plans' second level Request for Review	0.00208	Administrative appeal rights and accuracy in recovery demands.
Submission of MA plans' third level Request for Review by the CMS Administrator.	0.0004	Administrative appeal rights and accuracy in recovery demands.
Submission of Part D plans' third level Request for Review by the CMS Administrator.	0.0004	Administrative appeal rights and accuracy in recovery demands.

41. Effects of Requirement To Provide High Quality Health Care

The proposal to add contractual requirements for MA plans and Part D plans to provide high quality health care proposes to include in the terms and conditions in our contracts with Part D sponsors and explicit requirement that Part D plans administer a benefit that promotes and supports high quality care. We believe that we have conveyed this expectation in other ways, such as through our performance and quality measurements and methodologies. This proposal provides a basis for enforcement or corrective action for low-performing plans. Therefore, we do not believe there is an impact associated with this proposal.

42. Effects of MA–PD Coordination Requirements for Drugs Covered Under Part D

To ensure that Part A, Part B and Part D drug benefits are coordinated by MA–PDs so that enrollees receive needed medications on a timely basis, we are proposing to add a new section (b)(7) to § 422.112 to require MA–PDs to establish adequate messaging and processing requirements with network pharmacies to ensure that appropriate payment is assigned at the point of sale (POS) and to ensure that when coverage is denied under Part D due to available coverage under Part A or Part B, that such coverage is authorized expeditiously so that the drug may be provided to the enrollee as his or her health condition requires. Our proposed regulation requires that MA–PDs have systems in place to accurately and timely adjudicate claims at the POS.

In addition, we would like to ensure that MA–PD plans are coordinating their benefits appropriately during the coverage determination process. If an MA–PD denies PDP coverage due to the availability of Part A or Part B coverage, we expect the MA organization to ensure that the decision results in authorization or provision of the drug under Part B pursuant to the requirements in parts 422 and 423, subpart M. We do not expect MA–PD enrollees to have to request an initial Part A or B versus Part D coverage determination more than once. We are soliciting comments about our proposal, as well as other possible approaches to minimizing delays in beneficiary access to needed medications caused by inadequate coordination of Part A, Part B and Part D benefits at the POS and during the coverage determination process. In particular, we would appreciate organizations sharing their expertise regarding best practices for benefit coordination at the POS and plan processes that enhance those coverage determinations. We also are soliciting comments on challenges MA–PDs currently encounter in their efforts to integrate these benefits. Under Medicare regulations MA–PD plans are already required to coordinate member coverage for both Part A and B and Part D covered drugs. It is our understanding that the majority of MA–PDs are effectively performing this activity. However, we are aware that some MA–PDs have been less successful. With this regulation we propose to identify drug coverage standards that all MA–PDs can follow that have proven to be both cost effective and efficient. This proposed regulation does impose any new requirements or costs but rather will assist low performing MA–PDs in clarifying the necessary actions to meet existing regulatory requirements for the effective coordination of Part A, Part B and Part D covered drugs.

43. Effects of Revisions to Good Cause Processes

We are proposing to revise § 417.460, § 422.74, and § 423.44 to allow an entity acting on behalf of CMS to conduct good cause reviews. Shifting responsibility for this activity from CMS to entities such as MA, Part D and cost plans would not change the number of individuals requesting reinstatement for good cause nor the number of those individuals who meet the criteria for reinstatement. While some plans may increase their bids to cover the costs to complete this work, the administrative burden to plans is negligible. Therefore, we do not expect this change to have a monetary impact to the Medicare Trust Funds or affect enrollment, as the policies permitting involuntary disenrollment for non payment of premiums and allowing beneficiaries to request reinstatement for good cause have been in existence for some time.

44. Effects of the Definition of Organization Determination

The proposed revisions at § 422.566 are intended to clarify the meaning of organization determination and to maintain consistency between the regulatory definition of organization determination and the definition used elsewhere in CMS documents and subregulatory guidance. Specifically, we are seeking to include additional types of coverage decisions that are subject to Medicare appeals processing requirements set forth in subpart M. In other words, cases where a provider under contract with an MA organization provides a service directly to an enrollee and when a contract provider refers an enrollee to a non-contract provider for an item or service. Because this proposed change codifies the existing definition of organization determination, this proposal does not represent any new burden on MA organizations or burden for small businesses, rural hospitals, states or the private sector.

45. Effects of MA Organization Extension of Adjudication Timeframes for Organization Determinations and Reconsiderations

The proposed changes to § 422.568(b), § 422.572(b), and § 422.590 would clarify the limited circumstances in which MA organizations are permitted to extend the adjudication timeframe for organization determinations and reconsiderations. We believe these proposed changes would have a minimal impact on MA organizations, because they are not likely to alter the number of coverage requests plans would receive or the required clinical resources to process each request. During audits of MA organizations, we identified cases where plans are improperly extending the applicable adjudication timeframe (for example,

where clinical documentation is needed from a contract provider or where the plan has failed to develop and review the case during the required timeframe) but we do not have data on the overall frequency with which extensions are being invoked and what percentage of those cases involve the scenarios described.

46. Effects of Two-Year Prohibition When Organizations Terminate Their Contracts

As part of a group of proposals intended to strengthen our ability to distinguish stronger applicants for Part C participation we propose to revise the regulation text at § 422.506 and § 422.512 to explicitly apply the 2-year prohibition on re-application after an organization has terminated its contract to applications for service area expansions in addition to applications for new contracts. These changes to § 422.506 and § 422.512would make the text of these regulations consistent with the language of a similar provision at § 422.503 and § 422.508 (which bans re-application for 2 years after we have terminated an organization's contract). We believe this provision will have minimal financial impact as it only affects those organizations that choose to non-renew or mutually terminate a contract with CMS. This provision will not affect current beneficiaries as it only applies when an organization is applying for a new contract or to expand the service area of its existing contract; beneficiaries who are currently enrolled in an organization's existing contracts are therefore not affected.

47. Effects of Withdrawal of Stand Alone Prescription Drug Plan Bid Prior to Contract Execution

This provision is not anticipated to have any significant impacts, as the withdrawn bids that this provision would not relate to any existing enrollees.

48. Effects of Essential Operations Test Requirement for Part D

This provision has no quantifiable impact because the requirement affects unknown individuals/entities in the future. Nevertheless, we believe this proposal to require new Part D sponsors to pass an essential operations test prior to being permitted to accept enrollments will enhance our ability to ensure that beneficiaries are permitted to choose only from among those Part D plans offered by sponsors truly qualified to administer the full range of benefits to which beneficiaries are entitled. This approach will reduce both the likelihood of disruptions in beneficiaries' access to outpatient prescription drugs and the resources CMS has to dedicate to addressing such disruptions.

49. Effects of Termination of the Contracts of Medicare Advantage Organizations Offering Part D for Failure for Three Consecutive Years To Achieve Three Stars on Both Part C and Part D Summary Star Ratings in the Same Contract Year

This provision has no quantifiable impact because this affects unknown individuals/entities in the future. We believe the proposal to authorize the termination of contracts that fail to achieve three-star ratings for both Part C and D within three years is consistent with our overall emphasis on ensuring that beneficiaries receive quality services from their plan sponsors. Eliminating poor performing contracts will promote beneficiary satisfaction with the Part C and D programs and reduce the amount of effort we must apply to overseeing and correcting the performance of organizations that consistently fail to demonstrate a commitment to quality.

50. Effects of Requirements for Urgently Needed Services

The proposed revisions of § 422.113(b)(1)(iii) removes the requirement of ''extraordinary and unusual'' for in-service-area, out-of-network coverage for urgent needed services. Typically, this will mean that enrollees with non-emergent weekend medical problems will now be covered for services furnished out of network thus eliminating the need for beneficiaries to seek out-of-network care. Many plans already contract with 24/7 walk-in clinics providing in-network coverage. Historically, the alternative to plan coverage has been emergency-room care. We therefore expect minimal cost and possible savings as a result of this change.

51. Effects of Skilled Nursing Facility Stays

Our proposal that would relocate the MA regulation language currently located at § 422.101(c), ''Requirements Related to Basic Benefits'' to § 422.102(a)(5), ''Supplemental Benefits'' is a technical change only and would have no financial impact.

52. Effects of Agent and Broker Training and Testing Requirements

At § 422.2274 and § 423.2274, we are proposing to revise § 422.2274(b) and (c) and § 423.2274(b) and (c) to remove the concept of a CMS endorsed or approved training and testing, and require instead that agents be trained and tested annually, as specified by CMS. We believe this proposed change continues to ensure that all agents/brokers selling Medicare products have a comprehensive understanding of Medicare program rules. The changes made to this regulation will not result in any additional costs for MA plans or Part D plans, or a new collection of information. We are simply revising the existing language to remove an obligation for CMS to endorse or approve a training program in favor of CMS providing such training directly.

53. Effects of Deemed Approval of Marketing Materials

At § 422.2266 and § 423.2266, CMS provides the regulatory requirements for materials that are deemed approved. It also provides the requirements for the review and distribution of marketing materials. We are proposing to move the current requirements in §§ 422.2266 and 423.2266 to §§ 422.2262(a)(2) and 423.2262(a)(2), respectively. We also propose to simplify the language in §§ 422.2266 and 423.2266 by stating if CMS does not approve or disapprove marketing materials within the specified review timeframe, the materials will be deemed approved. Deemed approved means that a MA organization or Part D sponsor may use the material. Changes to this regulation will not result in additional. We are simply revising the existing language to clarify the existing requirements for deemed approved materials.

54. Effects of Part C Disclosure Requirements

This provision would simply replace the current, incorrect, reference in § 422.111 to the marketing materials and elections form requirements at § 422.80, with the correct reference to subpart V, Medicare Advantage Marketing Requirements. This is a technical change and represents no costs or impact.

55. Effects of Managing Disclosure and Recusal in P&T Conflicts of Interest: Formulary Development and Revision by a Pharmacy and Therapeutics Committee Under Part D

We propose to revise our regulations at § 423.120(b)(1) to reorder the existing provisions and add a new paragraph (b)(1)(iv) to require that a Part D sponsor's P&T committee clearly articulates and documents processes to determine that the requirements under paragraphs (b)(1)(i), (ii), and (iii) have been met, including the determination by an objective party of whether disclosed financial interests are

conflicts of interest and that management of any recusals due to such conflicts of interest.

Because plans were previously required to have these processes in place, and we are only asking that they document them, we anticipate that there would be no cost impact on plans.

56. Effects of the Technical Changes to the Definition of Part D Drug

There is no impact associated with this provision as it is a technical change to regulation language.

57. Effects of Thirty Sixth Month Coordination of Benefits (COB) Limit

There is no impact associated with this provision as it is a technical change to regulation language.

58. Effects of Application and Calculation of Daily Cost-Sharing Rates

There is no impact associated with this provision, as it is a technical change to regulation language.

59. Effects of Technical Change To Align Regulatory Requirements for Delivery of the Standardized Pharmacy Notice

Our proposed revision to § 423.562(a)(3) is a technical change and does not represent a burden for small businesses, rural hospitals, states, or the private sector.

60. Effects of Special Part D Access Rules During Disasters

In proposed § 423.126(a), we would codify requirements similar to existing guidance that pertains to relaxing ''refill-too-soon'' (RTS) edits to permit one refill in the event of any imminent or occurring disaster or emergency that would hinder an enrollee's access to covered Part D drugs.

The proposed changes would not result in any additional costs. For one, we currently expect through guidance that sponsors will relax edits after the issuance of certain federal declarations. We also do not anticipate that providing a general framework for when sponsors must relax RTS edits would necessitate an increase in resources because it is currently not uncommon for Part D sponsors to relax edits for particular individuals under certain circumstances.

The proposed provisions would require Part D sponsors to relax ''refill-too-soon'' (RTS) edits when, as evidenced by a declaration of a disaster or emergency or its imminence by an appropriate federal, state, or local official, it is reasonable to conclude that an occurring or imminent disaster or emergency would make it difficult for beneficiaries to obtain refills of their medications. Relaxing RTS edits in these circumstances would benefit beneficiaries by better ensuring that they do not run out of their medications when a disaster is imminent or after it strikes.

61. Effects of MA Organization Responsibilities in Disasters and Emergencies

The proposed addition of section § 422.100(m) requires plan activities during disasters that are currently recommended in our guidance. Since plans are already cooperating with our recommendations we expect no impact as a result of this requirement. Additionally, we are requiring a dedicated Web page for disasters on plan Web sites. Since plans already have Web sites and technical staff supporting them, we expect minimal cost, if any, for the additional page. We are also requiring plans to annually notify enrollees about disaster preparation. Since plans, as required at § 422.111, already annually notify beneficiaries using the Evidence of Coverage template, we expect minimal cost, if any, for the additional notification about disasters.

62. Effects of the Technical Changes Regarding the Termination of a Contract, Contract Determination and Other Appeals, and Intermediate Sanctions and Civil Money Penalties Under Parts C and D

Sections III.E.13. and 14 this proposed rule include provisions making minor technical and clarifying changes. These changes include making language consistent, aligning titles and correcting references. These technical and clarifying changes will not result in additional burden to sponsors nor will they have a financial impact on sponsors.

63. Effects of Technical Change to the Restrictions on use of Information Under Part D

There is no impact associated with this provision as it is a technical change to regulation language to reflect the expansion, pursuant to section 6402(b)(1) of the Affordable Care Act, in the purposes for which HHS, its contractors, and the Attorney General, and Comptroller General may use information disclosed or obtained pursuant to section 1860D–15 of the Act.

TABLE 14—ESTIMATED [1] AGGREGATE COSTS AND SAVINGS TO THE HEALTH CARE SECTOR BY PROVISION FOR CALENDAR YEARS 2015 THROUGH 2019

Provision	Regulation section(s)	Calendar year ($ in millions)					Total ($ in millions) CYs 2015–2019
		2015	2016	2017	2018	2019	
Impacts to MA Organizations and Part D Sponsors							
A.6. Changes to Audit and Inspection	§ 422.503(d)(2), § 423.504(d)(2).	8.9	8.9	8.9	8.9	8.9	44.5
Total ($ in millions)		8.9	8.9	8.9	8.9	8.9	44.5
Federal Government (Medicare) Impacts							
A.10. Enrollment Eligibility for Individuals Not Lawfully Present in the United States [2].	§ 422.1, § 422.50, AND § 422.74; § 423.1, § 423.30, and § 423.44.	−10	−12	−13	−15	−17	−67
A.14. Drug Categories or Classes of Clinical Concern and Exceptions [3].	§ 423.102(b)(2)(v)–(vi)	0	−30	−50	−220	−420	−720
A.35. Eligibility of Enrollment for Incarcerated Individuals [4].	§ 422.74	−73	−90	−108	−129	−152	−552

TABLE 14—ESTIMATED [1] AGGREGATE COSTS AND SAVINGS TO THE HEALTH CARE SECTOR BY PROVISION FOR CALENDAR YEARS 2015 THROUGH 2019—Continued

Provision	Regulation section(s)	Calendar year ($ in millions)					Total ($ in millions) CYs 2015–2019
		2015	2016	2017	2018	2019	
Total ($ in millions)		−83	−132	−171	−364	−589	−1,339

Notes:
[1] Estimates of costs and savings reflect scoring by the CMS, Office of the Actuary. Also, only provisions with savings or cost exceeding $1,000,000 are listed. Other provisions either have no expected savings or cost, or, have a savings or cost under $1,000,000. Details on these savings and cost may be found in the RIA narrative.
[2] Supporting 2012 lawful presence data provided by SSA.
[3] Projected savings are based upon full implementation of the criteria and do not reflect that changes for the antipsychotic class of drugs are deferred at this time.
[4] Supporting 2012 incarceration data provided by the SSA.

D. Expected Benefits

1. Drug Categories or Classes of Clinical Concerns and Exceptions (§ 423.102(b)(2)(v)–(vi)

Proposed codification of the categories or classes of clinical concern provisions would assist PBMs in applying the Part D plans and managing the Part D sponsor's benefit packages more efficiently.

2. Medication Therapy Management Program under Part D

We anticipate that many more beneficiaries will have access to MTM services and believe that the proposed changes will simplify the MTM criteria and minimize beneficiary confusion when choosing or transitioning between plans. Moreover, we believe the proposed changes would reduce disparity and allow more beneficiaries with drug therapy problems to receive MTM services. Similarly, we expect the proposed requirement that sponsors develop an effective strategy to ensure access to services for all MTM-eligible beneficiaries will help to ensure that beneficiaries in special populations receive focused targeting, outreach, or engagement for enrollment or participation in MTM.

E. Alternatives Considered

1. Separating the Annual Notice of Change from the Evidence of Coverage

We considered reverting back to requirements in place prior to the 2009 contract year, which allowed issuing EOCs as late as January 31 of the applicable contract year. We determined the EOC should be received by members before the effective date of their coverage for that contract year, beginning on January 1, in order for members to have full disclosure of plan rules prior to the beginning of the contract year.

2. Modifying the Agent/Broker Compensation Requirements

In the preamble we outlined a few alternative compensation schedules. Ultimately we determined that the best approach was a two tier payment schedule, incorporating an initial payment and a continuous renewal payment.

3. Medicare Coverage Gap Discount Program and Employer Group Waiver Plans

In the preamble we outlined the alternative approaches we considered in our efforts to make sure that the discounts were used to benefit enrollees. Ultimately we determined that the best approach would be to make sure that employer groups have the information needed to incorporate the payments into their benefit packages.

4. Prescription Drug Pricing Standards and Maximum Allowable Cost

No alternatives were considered.

5. Access to Covered Part D drugs (c) Use of Standardized Technology

No alternatives were considered.

6. Any Willing Pharmacy Standard Terms & Conditions

We considered the alternative of maintaining the current process where Part D plans can limit pharmacy access to preferred cost-sharing contracts. We have observed this in practice to be limiting market competition, creating a barrier to entry, and further, not producing the savings to the program that were initially anticipated.

7. Negotiated Prices

We did not identify any alternatives that both maintained consistent reporting among sponsors leading to comparable bids, and maximized price competition.

8. Preferred Cost Sharing

We considered whether a methodology that was based on lower average costs (or any other function of costs in the rest of the network) in return for preferred cost sharing would suffice to meet the statutory requirement. While such a methodology might technically meet the requirement not to increase CMS payments to plans, whether it did so or not would be dependent on the actual negotiated prices paid and could be determined only long after a coverage year had ended and complete the PDE data was available. We believe that to promote price competition, the relative levels of negotiated prices offered for preferred cost sharing and in the rest of the network should be transparent and verifiable at the point of sale, as well as to CMS oversight at any point prior to and during a coverage year. We were unable to identify any methodology other than our proposal to accomplish these goals. We solicit comments on alternative approaches to ensuring that the offering of preferred cost sharing does not increase CMS payments. We believe that any alternative methodology must be based solely on the level of negotiated prices and thus consistent with our proposal to amend that definition. We also solicit comments on whether we should also establish standards on how much lower drug costs should be in return for preferred cost sharing.

9. Transfer of TrOOP Between Part D Sponsors Due to Enrollment Changes During the Coverage Year

No alternative proposals were considered.

10. Part D Notice of Changes

We did not consider any alternatives for the proposed provision because it proposes to codify a longstanding policy.

11. Special Part D Access Rules During Disasters or Emergencies

We did not consider alternatives to requiring Part D sponsors to lift ''refill too soon'' (RTS) edits in the event of any imminent or occurring disaster or emergency that would hinder an enrollee's access to covered Part D drugs. It is important for the well-being and health of beneficiaries that they be able to obtain their medications after disasters strike. Furthermore, given the complexities of moving large numbers of people with different health conditions to safer locations, we also believed we had no alternative but to require Part D sponsors to relax RTS edits when a disaster is imminent and access to services might be jeopardized rather than waiting for it to strike.

12. Business Continuity for MA Organizations and Part D Sponsors

We did not consider any alternatives for the initial part of the provision found in §§ 422.504(o)(1) and 423.505(p)(1) that would, respectively, require MA organizations and Part D sponsors to develop and maintain business continuity plans. Creating such a plan is an accepted business practice and we would require MA organizations and Part D sponsors to address a standard list of areas; in short, we know of no other options.

In contrast, we considered other options when drafting proposed §§ 422.504(o)(2) and 423.505(p)(2), which would require the restoration of essential functions within 24 hours after failure. We considered requiring MA organizations and Part D sponsors to restore even more functions, but decided disruptions to business would presumably limit resources and that it was important to focus on only the most vital functions. We also considered paring down the list of essential functions, but found that we could not do so without jeopardizing the mandate of the Act—to ensure access to health care and covered Part D drugs through the provision of appropriate Medicare benefits. Benefit authorization, claim adjudications, and call center operations are all essential to providing appropriate Medicare coverage for beneficiaries both living inside and outside of areas hit by disasters and other disruptions.

Lastly, we considered the option of requiring restoration of essential functions to occur for a shorter or longer time period than 24 hours after failure proposed. We decided that 12 hours might present operational challenges for MA organizations and Part D sponsors; conversely, requiring beneficiaries to wait more than 24 hours to access their coverage and therefore health care and drug benefits, seemed to pose an undue risk to both their present and possibly future health and well-being.

13. Drug Categories or Classes of Clinical Concerns and Exceptions

The critical policy decision was how broadly or narrowly to establish criteria and exceptions to those criteria pursuant to Affordable Care Act provisions. Broad criteria might easily encompass many classes of drugs and significantly increase costs to the Part D program by eliminating the need for manufacturers to aggressively rebate their products for formulary placement. Only narrow criteria would limit the number of categories or classes of clinical concern receiving additional protections under the Affordable Care Act. Similarly, broad exceptions further limit the products within those categories or classes of clinical concern that would receive additional protection under the Affordable Care Act.

14. Medication Therapy Management Program (MTM) Under Part D

We considered leaving the maximum number of multiple chronic diseases a plan may require for targeted enrollment at three, but believed this threshold significantly limited the number of beneficiaries who qualified for MTM services and was inconsistent with literature concerning the relative risk of the combination of multiple disease states and the need for access to MTM interventions. Similarly, we considered other numbers of Part D drugs less than eight, but again believed these thresholds decreased access to MTM services, contributed to beneficiary confusion, and led to racial disparities in access to MTM services. We also considered other cost thresholds less than $3,000, for example, $900 or $1,200, which roughly coincide with cost thresholds achieved by taking 3 or 4 generic drugs, and we solicit stakeholder comment on where the threshold might alternatively be set.

Relative to the requirement for sponsors to establish effective strategies for reaching all MTM-eligible beneficiaries, we do not believe it is appropriate at this time to prescribe outreach activities for Part D sponsors to effectively reach diverse, special populations of their enrolled beneficiaries. Rather, we propose that sponsors develop an effective strategy to ensure access to MTM services for all MTM-eligible beneficiaries. We will continue to monitor the efficacy of such programs and the impact of any change to the requirements and will consider other options as may be necessary.

15. Requirement for Applicants or Their Contracted First Tier, Downstream, or Related Entities To Have Experience in the Part D Program Providing Key Part D Functions

Based on CMS' authority at section 1860D–12(b)(3)(D) of the SSA to adopt additional contract terms that are necessary and appropriate to administer the Part D program, we proposed at § 423.504(b)(8)(i) through (iii) that Part D organizations seeking a new Medicare contract must have arrangements in place such that either the applicant or a contracted entity that will be performing certain key Part D functions has at least one full benefit year of experience providing the function for another Part D plan sponsor. This proposal ensures that applicants take advantage of the abundant Part D industry expertise and experience that exists today in the development of their Part D program operations, rather than relying on technical assistance from CMS and having their inexperience place beneficiaries' access to prescription drugs at risk. We believe this provision will have a very minor savings impact on the federal budget, based on savings of time and effort (staff time and contracted auditor time and resources) that the government would spend on overseeing the disproportionate level of problems experienced by organizations operating Part D plans without prior Part D experience. For each inexperienced organization allowed into the program in the absence of this proposal, we would anticipate a savings of 1,000 staff hours at an average rate of $50 per hour, for a total of $50,000 in employee time, plus an additional savings of $200,000 in contractor dollars to conduct an emergency audit, for a total of $250,000. In the absence of this proposal, we would anticipate no more than two such inexperienced entities beginning Part D operations per year, for a total annual savings of $500,000.

The burden associated with this proposal on industry would be minimal, with a total estimated number of labor hours of 3.25 to submit information during the Part D application process. Using the same average hourly salary as previously mentioned, the total cost to Part D applicants would be $162.50. We do not believe there are any non-administrative costs to industry associated with this proposal, as Part D applicants are already required to have arrangements in place to perform the key Part D functions discussed in our proposal.

The main anticipated effect from this proposal is ensuring that only entities

with some experience with Part D in critically important functional areas are permitted to offer new Part D contracts, thus strengthening the Part D program by enhancing the qualification criteria. CMS considered the alternate proposal of requiring the prior Part D experience to be tied to specific quality outcomes. CMS rejected the alternative because we believed it added unnecessary complexity and burden to the process, and we believe a simple experience requirement is currently sufficient.

F. Accounting Statement and Table

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a0004/a-4/pdf*), in Table 15, we have prepared an accounting statement showing the classification of the expenditures, costs, and savings associated with the provisions of this proposed rule for CYs 2015 through 2019.

TABLE 15—ACCOUNTING STATEMENT: CLASSIFICATIONS OF ESTIMATED COSTS AND TRANSFERS FROM CALENDAR YEARS 2015 TO 2019

[$ in millions]

Category	Transfers		
	Discount rate		Period covered
	7%	3%	
Annualized Monetized Transfers (Federal)	−$251.23	−$260.49	CYs 2015–2019.
Whom to Whom?	Federal Government, MA Organizations and Part D Sponsors		
	Costs (all other provisions)		
	Discount rate		Period covered
	7%	3%	
Annualized Costs to MA Organizations and Part D Sponsors	$8.9	$8.9	CYs 2015–2019.

Note: Monetized Figures in 2014 Dollars.

G. Conclusion

We estimate the savings to the federal government from implementing these provisions will be $83 million in CY 2015. The savings will increase annually. In CY 2019, the federal government savings from implementing these provisions will be $589 million. For the entire estimated period, CYs 2015 through 2019, we estimate the total federal government (Medicare) impact to result in savings of approximately $1.34 billion in 2014 dollars. The cost impact to MA organizations and Part D sponsors is estimated at $8.9 million annually during CYs 2015 through 2019. We note that these savings do not represent net social benefits because they consist of transfers of value from drug manufacturers, pharmacies, incarcerated individuals and individuals not lawfully present in the United States to the federal government, MA organizations, Part D sponsors and beneficiaries who continue in the programs.

List of Subjects

42 CFR Part 409

Health facilities and Medicare.

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, Reporting and record keeping requirements.

42 CFR Part 424

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and record keeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR Chapter IV as follows:

PART 409—HOSPITAL INSURANCE BENEFITS

■ 1. The authority citation for part 409 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 409.30 is amended by revising paragraph (b)(2)(ii) to read as follows:

§ 409.30 Basic requirements.

(b) * * *

(2) * * *

(ii) If, upon admission to the SNF, the beneficiary was enrolled in an M+C plan, as defined in § 422.4 of this chapter, offering the benefits described in § 422.102(a)(5) of this chapter, the beneficiary will be considered to have met the requirements described in paragraphs (a) and (b) of this section, and also in § 409.31(b)(2), for the duration of the SNF stay.

PART 417—HEALTH MAINTENANCE ORGANIZATION, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 3. 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.

■ 4. Section 417.1 is amended by revising the definition of ''service area'' to read as follows:

§ 417.1 Definitions.

* * * * *

Service area means a geographic area, defined through zip codes, census tracts, or other geographic measurements, that is the area, as determined by CMS, within which the HMO furnishes basic and supplemental health services and makes them available and accessible to all its enrollees in accordance with § 417.106(b). Facilities in which individuals are incarcerated are not included in the geographic service area of an HMO or CMP plan.

* * * * *

■ 5. Section 417.2 is amended by revising paragraph (b) to read as follows:

§ 417.2 Basis and scope.

* * * * *

(b) Subparts G through R of this part set forth the rules for Medicare contracts with, and payment to, HMOs and competitive medical plans (CMPs) under section 1876 of the Act and 8 U.S.C. 1611.

* * * * *

§ 417.420 [Amended].

■ 6. In § 417.420, paragraph (a) is amended by removing the phrase ''Individuals who are entitled to'' and adding in its place the phrase ''Eligible individuals who are entitled to''.

■ 7. Section 417.422 is amended—

■ A. In the introductory text, by removing the phrase ''any individual who—'' and adding in its place the phrase ''any individual who meets all of the following:''

■ B. In paragraphs (a) through (e), by removing the ''; '' and adding in its place ''.''.

■ C. In paragraph (f), by removing the ''; and'' and adding in its place ''.''.

■ D. Adding paragraph (h).

The addition reads as follows:

§ 417.422 Eligibility to enroll in an HMO or CMP.

* * * * *

(h) Is a United States citizen or qualified alien who is lawfully present in the United States as determined in 8 CFR 1.3.

■ 8. Section 417.460 is amended—

■ A. Revising paragraph (b)(2)(i).

■ B. In paragraph (b)(2)(iii), by removing ''; or'' and adding in its place ''; ''.

■ C. By removing the period at the end of (b)(2)(iv) and adding ''; or'' in its place.

■ D. By adding paragraph (b)(2)(v).

■ E. In paragraph (b)(3), by removing the cross-reference ''paragraphs (c) through (i)'' and adding in its place the cross-reference ''paragraphs (c) through (j)''.

■ F. By revising paragraph (c)(3).

■ G. In paragraph (c)(4), by removing the phrase ''non-payment of premiums.'' and adding in its place the phrase ''non-payment of premiums or other charges.''.

■ H. By adding new paragraphs (f)(1)(i)(A) through (C).

■ I. By adding paragraph (j).

The revisions and the additions read as follows:

§ 417.460 Disenrollment of beneficiaries by an HMO or CMP.

* * * * *

(b) * * *

(2) * * *

(i) Moves out of the HMO's or CMP's geographic area or is incarcerated.

* * * * *

(v) Loses qualified alien status or lawful presence in the United States.

* * * * *

(c) * * *

(3) *Good cause and reinstatement.* When an individual is disenrolled for failure to pay premiums or other charges imposed by the HMO or CMP for deductible and coinsurance amounts for which the enrollee is liable, CMS (or its designee) may reinstate enrollment in the plan, without interruption of coverage, if the individual shows good cause for failure to pay and pays all overdue premiums or other charges within 3 calendar months after the disenrollment date. The individual must establish by a credible statement that failure to pay premiums or other charges was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

* * * * *

(f) * * *

(1) * * *

(i) * * *

(A) *Incarceration.* The HMO or CMP must disenroll an individual if the HMO or CMP establishes, on the basis of evidence acceptable to CMS, that the individual is incarcerated per § 417.1.

(B) *Notification by CMS of incarceration.* When CMS notifies an HMO or CMP of disenrollment due to an incarceration as per § 417.1, disenrollment is effective the first of the month following the start of incarceration, unless otherwise specified by CMS.

(C) *Exception.* The exception in paragraph (f)(2) of this section does not apply to individuals who are incarcerated.

* * * * *

(j) *Loss of qualified alien status.* Disenrollment is effective the first day of the month following the last month of lawful presence or qualified alien status in the United States.

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 9. 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).

■ 10. Section 422.1 is amended by revising paragraph (a) to read as follows:

§ 422.1 Basis and scope.

(a) *Basis.* This part is based on the indicated provisions of the following:

(1) The following provisions of the Act:

1128J(d)—Reporting and Returning of Overpayments.

1851—Eligibility, election, and enrollment.

1852—Benefits and beneficiary protections.

1853—Payments to Medicare Advantage (MA) organizations.

1854—Premiums.

1855—Organization, licensure, and solvency of MA organizations.

1856—Standards.

1857—Contract requirements.

1858—Special rules for MA Regional Plans.

1859—Definitions; enrollment restriction for certain MA plans.

(2) 8 U.S.C. 1611—Aliens who are not qualified aliens ineligible for Federal public benefits

* * * * *

■ 11. Section 422.2 is amended by—

■ A. Revising the definition of ''Attestation process''.

■ B. Removing the definition of ''Initial Validation Contractor (IVC)''.

■ C. Adding the definitions of ''Parent organization'' and ''RADV appeal process''.

■ D. Removing the definition of ''RADV payment error calculation appeal process''.

■ E. Revising the definition of ''Risk adjustment data validation (RADV) audit''.

■ F. Revising introductory text of the definition of ''Service area''.

■ G. Removing the definition of ''The one best medical record for the purposes of Medicare Advantage Risk Adjustment Validation (RADV)''.

The revisions and additions read as follows:

§ 422.2 Definitions.

* * * * *

Attestation process means a CMS-developed RADV audit-related process that is part of the medical record review process that enables MA organizations undergoing RADV audit to submit CMS-generated attestations for eligible medical records with missing or illegible signatures or credentials. The purpose of the CMS-generated attestations is to cure signature and credential issues. CMS-generated attestations do not provide an opportunity for a provider or supplier to replace a medical record or for a provider or supplier to attest that a beneficiary has the medical condition.

* * * * *

Parent organization means a legal entity that owns one or more other subsidiary legal entities.

* * * * *

RADV appeal process means an administrative process that enables MA organizations that have undergone RADV audit to appeal the Secretary's medical record review determinations and the Secretary's calculation of an MA organization's RADV payment error.

* * * * *

Risk adjustment data validation (RADV) audit means a payment audit of a MA organization administered by the Secretary that ensures the integrity and accuracy of risk adjustment payment data.

* * * * *

Service area means a geographic area that for local MA plans is a county or multiple counties, and for MA regional plans is a region approved by CMS within which an MA-eligible individual may enroll in a particular MA plan offered by an MA organization. Facilities in which individuals are incarcerated, with the exclusion of Institutions for Mental Disease, are not included in the service area of an MA plan. Each MA plan must be available to all MA-eligible individuals within the plan's service area. In deciding whether to approve an MA plan's proposed service area, CMS considers the following criteria:

* * * * *

■ 12. Section 422.50 is amended—

■ A. In paragraph (a) introductory text, by removing the phrase ''if he or she—'' and adding in its place the phrase ''if he or she meets all of the following:''

■ B. In paragraphs (a)(1) and (4), by removing ''; '' and adding in its place ''.''.

■ C. In paragraph (a)(5), by removing ''; and'' and adding in its place ''.''.

■ D. By adding paragraph (a)(7).

The addition reads as follows:

§ 422.50 Eligibility to elect an MA plan.

* * * * *

(a) * * *

(7) Is a United States citizen or qualified alien who is lawfully present in the United States as determined in 8 CFR 1.3.

* * * * *

■ 13. Section 422.60 is amended by redesignating paragraphs (g) introductory text through (g)(3) as paragraphs (g)(1) through (4), and by revising newly redesignated paragraph (g)(1) to read as follows:

§ 422.60 Election process.

* * * * *

(g) * * *

(1) *Passive enrollment by CMS.* CMS may implement passive enrollment procedures (as described in paragraph (g)(2) of this section) in any of the following situations:

(i) Immediate terminations as provided in § 422.510(a)(5).

(ii) Other situations in which CMS determines that remaining enrolled in a plan poses potential harm to the members.

(iii) Situations which meet all of the following criteria:

(A) A specialized MA plan for special needs individuals in which the individual is enrolled will no longer be offered following the end of the current calendar year,

(B) The individual is a—

(*1*) Special needs individual entitled to medical assistance under a Medicaid State plan, as defined in section 1859(b)(6)(B)(ii) of the Act and § 422.2; and

(*2*) Full-benefit dual eligible beneficiary, as defined in section 1935(c) of the Act.

(C) The passive enrollment is into a specialized MA plan for special needs individuals with a network and benefits that are substantially similar, as determined by CMS, to the non-renewing plan, and where the sponsoring organization also offers the Medicaid managed care organization in which the individual is also enrolled.

* * * * *

■ 14. Section 422.74 is amended by—

■ A. Adding paragraph (b)(2)(v).

■ B. Revising paragraphs (d)(1)(v) and (d)(4)(i)(A).

■ C. Adding paragraphs (d)(4)(v)and (d)(8).

The additions and revisions read as follows:

§ 422.74 Disenrollment by the MA organization.

* * * * *

(b) * * *

(2) * * *

(v) The individual loses qualified alien status or is no longer lawfully present in the United States.

* * * * *

(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 (or its designee) 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.

* * * * *

(4) * * *

(i) * * *

(A) Out of the MA plan's service area or is incarcerated as specified in paragraph (d)(4)(v) of this section.

* * * * *

(v) *Incarceration.* (A) The MA organization must disenroll an individual if the MA organization establishes, on the basis of evidence acceptable to CMS, that the individual is incarcerated as specified § 422.2 or when notified of the incarceration by CMS as specified paragraph (d)(4)(v)(B) of this section.

(B) *Notification by CMS of incarceration.* When CMS notifies the MA organization of the disenrollment due to an incarceration as specified in § 422.2, disenrollment is effective the first of the month following the start of incarceration, unless otherwise specified by CMS.

* * * * *

(8) *Loss of qualified alien status.* Disenrollment is effective with the month following the last month of lawful presence or qualified alien status in the United States.

* * * * *

■ 15. Section 422.100 is amended by adding paragraph (m) to read as follows:

§ 422.100 General requirements.

* * * * *

(m) *Special requirements during a disaster or emergency.* (1) When a state of disaster is declared as described in paragraph (m)(2) of this section, an MA organization offering an MA plan must, until one of the conditions described in

paragraph (m)(3) of this section occurs, ensure access to benefits in the following manner:

(i) Cover Medicare Parts A and B services and supplemental Part C plan benefits furnished at non-contracted facilities subject to § 422.204(b)(3).

(ii) Waive, in full, requirements for gatekeeper referrals where applicable.

(iii) Provide the same cost-sharing for the enrollee had the service or benefit been furnished at a plan-contracted facility.

(iv) Make changes that benefit the enrollee effective immediately without the 30-day notification requirement at § 422.111(d)(3).

(2) *Declarations of disasters.* A declaration of disaster will identify the geographic area affected by the event and may be made as one of the following:

(i) Presidential declaration of a disaster or emergency under the either of the following:

(A) Stafford Act.

(B) National Emergencies Act.

(ii)(A) Secretarial declaration of a public health emergency under section 319 of the Public Health Service Act.

(B) If the President has declared a disaster as described in paragraph (m)(2)(i) or (2)(ii) of this section, then the Secretary may also authorize waivers or modifications under section 1135 of the Act.

(iii) Declaration by the Governor of a State or Protectorate.

(3) *End of the disaster.* The public health emergency or state of disaster ends when any of the following occur:

(i) The source that declared the public health emergency or state of disaster declares an end.

(ii) The CMS declares an end of the public health emergency or state of disaster.

(iii) Thirty days have elapsed since the declaration of the public health emergency or state of disaster and no end date was identified in paragraph (m)(3)(i) or (3)(ii) of this section.

(4) *MA plans unable to operate.* An MA plan that cannot resume normal operations by the end of the public health emergency or state of disaster must notify CMS.

(5) *Disclosure.* In addition to other requirements of annual disclosure under § 422.111, an organization must do all of the following:

(i) Indicate the terms and conditions of payment during the public health emergency or disaster for non-contracted providers furnishing benefits to plan enrollees residing in the state-of-disaster area.

(ii) Annually notify enrollees of the information listed in paragraphs (m)(1) through (3) and (m)(5) of this section.

(iii) Provide the information described in paragraphs (m)(1) through (3) and (m)(4)(i) of this section on its Web site.

§ 422.101 [Amended]

■ 16. Section 422.101 is amended by removing and reserving paragraph (c).

■ 17. Section 422.102 is amended by adding paragraph (a)(5) to read as follows:

§ 422.102 Supplemental benefits.

(a) * * *

(5) MA organizations may elect to furnish, as part of their Medicare covered benefits, coverage of post hospital SNF care as described in subparts C and D of this part, in the absence of the prior qualifying hospital stay that would otherwise be required for coverage of this care.

* * * * *

■ 18. Section 422.111 is amended by revising paragraphs (a)(3) and (d)(1) to read as follows:

§ 422.111 Disclosure requirements.

(a) * * *

(3) At the time of enrollment and at least annually thereafter by December 31 for the following contract year.

* * * * *

(d) * * *

(1) Submit the changes for CMS review under procedures of Subpart V of this part.

* * * * *

■ 19. Section 422.112 is amended by adding paragraph (b)(7) to read as follows:

§ 422.112 Access to services.

* * * * *

(b) * * *

(7) With respect to drugs for which payment as so prescribed and dispensed or administered to an individual may be available under Part A or Part B, or under Part D, MA–PD plans must coordinate all benefits administered by the plan and—

(i) Establish and maintain a process to ensure timely and accurate claims adjudication at the point-of-sale; and

(ii) Issue the determination and authorize or provide the benefit under Part A or Part B or as a benefit under Part D as expeditiously as the enrollee's health condition requires, in accordance with the requirements of part 422, subpart M and Part 423, subpart M, as appropriate, when a party requests a coverage determination.

* * * * *

■ 20. Section 422.113 is amended by revising paragraph (b)(1)(iii) introductory text to read as follows:

§ 422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services.

* * * * *

(b) * * *

(1) * * *

(iii) *Urgently needed services* means covered services that are not emergency services as defined in this section, provided when an enrollee is temporarily absent from the MA plan's service (or, if applicable, continuation) area (or provided when the enrollee is in the service or continuation area but the organization's provider network is temporarily unavailable or inaccessible) when the services are medically necessary and immediately required—

* * * * *

■ 21. Section 422.134 is added to subpart C to read as follows:

§ 422.134 Reward and incentive programs.

(a) *General rule.* The MA organization may create one or more programs consistent with the standards of this section that provide rewards and incentives to enrollees in connection with participation in activities that focus on promoting improved health, preventing injuries and illness, and promoting efficient use of health care resources.

(b) *Non-discrimination.* Reward and incentive programs—

(1) Must not discriminate against enrollees based on race, gender, chronic disease, institutionalization, frailty, health status or other impairments;

(2) Must be designed so that all enrollees are able to earn rewards; and

(3) Are subject to sanctions at § 422.752(a)(4).

(c) *Requirements.* (1) A rewards and incentives program must meet all of the following:

(i) Be offered in connection with completion of the entire service or activity.

(ii) Be offered to all eligible members without discrimination.

(iii) Have a monetary cap, as determined by CMS, of a value that may be expected to impact enrollee behavior but not exceed the value of the health related service or activity itself.

(iv) Otherwise comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute and civil money penalty prohibiting inducements to beneficiaries.

(2) Reward and incentive items may not—

(i) Be offered in the form of cash or other monetary rebates; or

(ii) Be used to target potential enrollees.

(3) The MA organization must make information available to CMS upon request about the form and manner of any rewards and incentives programs it offers and any evaluations of the effectiveness of such programs.

■ 22. Section 422.152 is amended as follows:

■ A. Paragraph (a) introductory text is amended by:

■ i. Removing the phrase ''for each of those plans'' and adding in its place the phrase ''for each plan''.

■ .ii. Removing the phrase ''a plan must—'' and adding in its place the phrase ''a plan must do all of the following:''

■ B. By redesignating paragraphs (a)(1) through (3) as (a)(2) through (4), respectively.

■ C. By adding a new paragraph (a)(1).

■ D. In newly redesignated paragraph (a)(2), by removing the '';'' and adding in its place ''.''.

■ E. In newly redesignated paragraph (a)(3), by removing the ''; and'' and adding in its place ''.''.

■ F. By revising paragraphs (c), (g) introductory text, and (h).

The addition and revisions read as follows:

§ 422.152 Quality improvement program.

(a) * * *

(1) Create a quality improvement program plan that sufficiently outlines the elements of the plan's quality improvement program.

* * * * *

(c) *Chronic care improvement program requirements.* (1) Develop criteria for a chronic care improvement program. These criteria must include all of the following:

(i) Methods for identifying MA enrollees with multiple or sufficiently severe chronic conditions that would benefit from participating in a chronic care improvement program.

(ii) Mechanisms for monitoring MA enrollees that are participating in the chronic improvement program and evaluating participant outcomes such as changes in health status.

(iii) Performance assessments that use quality indicators that are objective, clearly and unambiguously defined, and based on current clinical knowledge or research.

(iv) Systematic and ongoing follow-up on the effect of the program.

(2) The organization must report the status and results of each program to CMS as requested.

* * * * *

(g) *Special requirements for specialized MA plans for special needs individuals.* All special needs plans (SNPs) must be approved by the National Committee for Quality Assurance (NCQA) effective January 1, 2012 and subsequent years. SNPs must submit their model of care (MOC), as defined under § 422.101(f), to CMS for NCQA evaluation and approval, in accordance with CMS guidance. In addition to the requirements under paragraphs (a) and (f) of this section, a SNP must conduct a quality improvement program that meets all of the following:

* * * * *

(h) *Requirements for MA private-fee-for-service plans and Medicare medical savings account plans.* MA PFFS and MSA plans are subject to the requirement that may not exceed the requirement specified in § 422.152(e).

§ 422.300 [Amended]

■ 23. Section 422.300 is amended by removing the phrase ''and 1858 of the Act.'' and adding in its place the phrase ''1858, and 1128J(d) of the Act.''

■ 24. Section 422.310 is amended by:

■ A. Redesignating the text of paragraph (e) as paragraph (e)(2) and adding new paragraph (e)(1) following current paragraph (e) subject heading.

■ B. Adding new paragraph (e)(1).

■ C. Revising paragraph (g)(2).

■ D. Adding paragraph (g)(3).

The additions and revision read as follows:

§ 422.310 Risk adjustment data.

* * * * *

(e) * * *

(1) Any medical record reviews conducted by an MA organization must be designed to determine the accuracy of diagnoses submitted under § 422.308(c) and § 422.310(g).

* * * * *

(g) * * *.

(2) After the payment year is completed, CMS recalculates the risk factors for affected individuals to determine if adjustments to payments are necessary.

(i) Prior to calculation of final risk factors for a payment year, CMS allows a reconciliation process to account for risk adjustment data submitted after the March deadline until the final risk adjustment data submission deadline in the year following the payment year.

(ii) After the final risk adjustment data submission deadline, which is announced by CMS, an MA organization can submit data to correct overpayments but cannot submit diagnoses for additional payment.

(3) Submission of corrected risk adjustment data in accordance with overpayments after the final risk adjustment data submission deadline, as described in paragraph (g)(2) of this section, must be made as provided in § 422.326.

■ 25. Section 422.311 is amended as follows:

■ A. In paragraph (a), by removing the phrase ''CMS annually'' and adding in its place the phrase ''the Secretary annually''.

■ B. In paragraph (b)(2), by removing the phrase ''to CMS or its contractors'' and adding in its place the phrase ''to the Secretary''.

■ C. By removing paragraph (b)(3).

■ D. By revising paragraph (c).

The revision read as follows:

§ 422.311 RADV audit dispute and appeal processes.

* * * * *

(c) *RADV audit appeals.* (1) *Appeal rights.* MA organizations that do not agree with their RADV audit results may appeal.

(2) *Issues eligible for RADV appeals.* (i) *General rules.* MA organizations may appeal RADV medical record review determinations and the Secretary's RADV payment error calculation. In order to be eligible for RADV appeal, MA organizations must adhere to the following:

(A) Established RADV audit procedures and requirements.

(B) RADV appeals procedures and requirements.

(ii) *Failure to follow RADV rules.* Failure to follow the Secretary's RADV audit procedures and requirements and the Secretary's RADV appeals procedures and requirements will render the MA organization's request for appeal invalid.

(iii) *RADV appeal rules.* The MA organization's written request for medical record review determination appeal must specify the following:

(A) The audited HCC(s) that the Secretary identified as being in error.

(B) A justification in support of the audited HCC selected for appeal.

(iv) *Number of medical records eligible for appeal.* For each audited HCC, MA organizations may appeal one medical record that has undergone RADV review. If an attestation was submitted to cure a signature or credential-related error, the attestation may be included in the HCC appeal.

(v) *Selection of medical record for appeal.* The MA organization must select the medical record that undergoes appeal.

(vi) *Written request for RADV payment error calculation appeal.* The written request for RADV payment error calculation appeal must clearly specify the following:

(A) The MA organization's own RADV payment error calculation.

(B) Where the Secretary's RADV payment error calculation was erroneous.

(3) *Issues ineligible for RADV appeals.* (i) MA organizations' request for appeal may not include HCCs, medical records or other documents beyond the audited HCC, RADV-reviewed medical record, and any accompanying attestation that the MA organization chooses for appeal.

(ii) MA organizations may not appeal the Secretary's medical record review determination methodology or RADV payment error calculation methodology.

(iii) As part of the RADV payment error calculation appeal—MA organizations may not appeal RADV medical record review-related errors.

(iv) MA organizations may not appeal RADV errors that result from an MA organization's failure to submit a medical record.

(4) *Burden of proof.* The MA organization bears the burden of proof by a preponderance of the evidence in demonstrating that the Secretary's medical record review determination(s) or payment error calculation was incorrect.

(5) *Manner and timing of a request for RADV appeal.* (i) At the time the Secretary issues its RADV audit report, the Secretary notifies audited MA organizations of the following:

(A) That they may appeal RADV HCC errors that are eligible for medical record review determination appeal.

(B) That they may appeal the Secretary's RADV payment error calculation.

(ii) MA organizations have 30 days from date of issuance of the RADV audit report to file a written request with CMS for RADV appeal. This request for RADV appeal must specify one of the following:

(A) Whether the MA organization requests medical record review determination appeal, the issues with which the MA organization disagrees, and the reasons for the disagreements.

(B) Whether the MA organization requests RADV payment error calculation appeal, the issues with which the MA organization disagrees, and the reasons for the disagreements.

(C) Whether the MA organization requests both medical record review determination appeal and RADV payment error calculation appeal, the issues with which the MA organization disagrees, and the reasons for the disagreements.

(iii) For MA organizations that appeal both medical record review determination appeal and RADV payment error calculation appeal:

(A) The Secretary adjudicates the request for RADV payment error calculation following conclusion of reconsideration of the MA organization's request for medical record review determination appeal.

(B) MA organizations may not appeal their RADV payment error calculation until appeals of RADV medical record review determinations filed by the MA organization have been completed and the decisions are final.

(6) *Reconsideration stage.* (i) *Written request for medical record review reconsideration.* A MA organization's written request for medical record review determination reconsideration must specify the following:

(A) The audited HCC that the Secretary identified as being in error that the MA organization wishes to appeal.

(B) A justification in support of the audited HCC chosen for appeal.

(ii) *Written request for payment error calculation.* The MA organization's written request for payment error calculation reconsideration—

(A) Must include the MA organization's own RADV payment error calculation that clearly specifies where the Secretary's RADV payment error calculation was erroneous; and

(B) May include additional documentary evidence pertaining to the calculation of the payment error that the MA organization wishes the reconsideration official to consider.

(iii) *Conduct of the reconsideration.* (A) For medical record review determination reconsideration, a medical record review professional who was not involved in the initial medical record review determination of the disputed audited HCCs does the following:

(*1*) Reviews the medical record and accompanying dispute justification.

(*2*) Reconsiders the initial audited medical record review determination.

(B) For payment error calculation reconsideration, CMS ensures that a third party not involved in the initial RADV payment error calculation does the following:

(*1*) Reviews the Secretary's RADV payment error calculation.

(*2*) Reviews the MA organization's RADV payment error calculation;

(*3*) Recalculates the payment error in accordance with CMS's RADV payment error calculation procedures.

(iv) *Effect of the reconsideration official's decision.* (A) The reconsideration official issues a written reconsideration decision to the MA organization.

(B) The reconsideration official's decision is final unless the MA organization disagrees with the reconsideration official's decision.

(C) If the MA organization disagrees with the reconsideration official's decision, they may request a hearing in accordance with paragraph (c)(8) of this section.

(7) *Hearing stage.* (i) *Errors eligible for hearing.* At the time the reconsideration official issues his or her reconsideration determination to the MA organization, the reconsideration official notifies the MA organization of any RADV HCC errors or payment error-calculations that are eligible for RADV hearing.

(ii) *General hearing rules.* A MA organization that requests a RADV hearing must do so in writing in accordance with procedures established by CMS.

(iii) *Written request for hearing.* The written request for a hearing must be filed with the Hearing Officer within 30 days of the date the MA organization receives the reconsideration officer's written reconsideration decision.

(A) If the MA organization appeals medical record review reconsideration determination, the written request for RADV hearing must—

(*1*) Include a copy of the written decision of the reconsideration official;

(*2*) Specify the audited HCCs that the reconsideration official confirmed as being in error; and

(*3*) Specify a justification why the MA organization disputes the reconsideration official's determination.

(B) If the MA organization appeals the RADV payment error calculation, the written request for RADV hearing must include the following:

(*1*) A copy of the written decision of the reconsideration official.

(*2*) The MA organization's own RADV payment error calculation that clearly specifies where the Secretary's payment error calculation was erroneous.

(iv) *Designation of hearing officer.* A hearing officer will conduct the RADV hearing.

(v) *Disqualification of the hearing officer.* (A) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(B) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(C) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(D) If the hearing officer withdraws, another hearing officer conducts the hearing.

(E) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and

request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to the Secretary.

(vi) *Hearing Officer review.* The hearing officer reviews the following:

(A) For medical record review determination appeal all of the following:

(*1*) The RADV-reviewed medical record and any accompanying attestation that the MA organization selected for review.

(*2*) The reconsideration official's written determination.

(*3*) The written brief submitted by the MA organization or the Secretary in response to the reconsideration official's determination.

(B) For payment error calculation appeal all of the following:

(*1*) A copy of the written decision of the reconsideration official that clearly specifies whether the Secretary's payment error calculation was erroneous.

(*2*) Briefs addressing the reconsideration decision.

(vii) *Hearing procedures.* (A) *Authority of the Hearing Officer.* The hearing officer has full power to make rules and establish procedures, consistent with the law, regulations, and the Secretary rulings. These powers include the authority to dismiss the appeal with prejudice and take any other action which the hearing officer considers appropriate, including for failure to comply with such rules and procedures.

(B) *The hearing is on the record.* (*1*) Except as specified in paragraph (c)(viii)(B)(*2*), the hearing officer is limited to the review of the record.

(*2*)(*i*) Subject to the hearing officer's full discretion, the parties may request a live or telephonic hearing regarding some or all of the disputed medical records.

(*ii*) The hearing officer may, on his or her own-motion, schedule a live or telephonic hearing.

(*3*) The record is comprised of the following:

(*i*) Documents described at paragraphs (c)(6)(iv) and (7)(vi) of this section.

(*ii*) Written briefs from the MA organization explaining why they believe the reconsideration official's determination was incorrect.

(*iii*) The Secretary's optional brief that responds to the MA organization's brief—

(*4*) The hearing officer neither receives testimony nor accepts any new evidence that is not part of the record.

(*5*) Either the MA organization or the Secretary may ask the hearing officer to rule on a motion for summary judgment.

(viii) *Hearing Officer decision.* The hearing officer decides whether to uphold or overturn the reconsideration official's decision, and sends a written determination to CMS and the MA organization, explaining the basis for the decision.

(ix) *Computations based on hearing decision.* (A) Once the hearing officer's decision is considered final pursuant to subsection (x), a third party not involved in the initial RADV payment error calculation recalculates the MA organization's RADV payment error and issues a new RADV audit report to the appellant MA organization and CMS.

(B) For MA organizations appealing the RADV error calculation only, a third party not involved in the initial RADV payment error calculation recalculates the MA organization's RADV payment error and issues a new RADV audit report to the appellant MA organization and CMS.

(x) *Effect of the Hearing Officer's decision.* The hearing officer's decision is final unless the decision is reversed or modified by the CMS Administrator.

(8) *CMS Administrator review stage.* (i) A request for CMS Administrator review must be made in writing and filed with the CMS Administrator.

(ii) CMS or a MA organization that has received a hearing officer's decision and requests review by the CMS Administrator must do so within 30 days of receipt of the hearing officer's decision.

(iii) After receiving a request for review, the CMS Administrator has the discretion to elect to review the hearing officer's decision or to decline to review the hearing officer's decision.

(iv) If the CMS Administrator elects to review the hearing decision—

(A) The CMS Administrator acknowledges the decision to review the hearing decision in writing and notifies CMS and the MA organization of their right to submit comments within 15 days of the date of the notification; and

(B) The CMS Administrator is limited to the review of the record. The record is comprised of the following:

(*1*) The record is comprised of documents described at paragraphs (c)(6)(iv), (7)(vii), and (7)(ix) of this section.

(*2*) The hearing record.

(*3*) Written arguments from the MA organization or CMS explaining why either or both parties believe the hearing officer's determination was correct or incorrect.

(C) The CMS Administrator reviews the record and determines whether the hearing officer's determination should be upheld, reversed, or modified.

(v) The CMS Administrator renders his or her final decision in writing to the parties within 60 days of acknowledging his or her decision to review the hearing officer's decision.

(vi) The decision of the hearing officer is final if the CMS Administrator—

(A) Declines to review the hearing officer's decision; or

(B) Does not make a decision within 60 days.

■ 26. Section 422.326 is added to subpart G to read as follows:

§ 422.326 Reporting and returning of overpayments.

(a) *Terminology.* For purposes of this section—

Applicable reconciliation occurs on the date of the annual final deadline for risk adjustment data submission described at § 422.310(g), which is announced by CMS each year.

Funds means any payment that an MA organization has received that is based on data submitted by the MA organization to CMS for payment purposes, including § 422.308(f) and § 422.310.

Overpayment means any funds that an MA organization has received or retained under title XVIII of the Act to which the MA organization, after applicable reconciliation, is not entitled under such title.

(b) *General rule.* If an MA organization has identified that it has received an overpayment, the MA organization must report and return that overpayment in the form and manner set forth in this section.

(c) *Identified overpayment.* The MA organization has identified an overpayment if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the existence of the overpayment. An MA organization must exercise reasonable diligence to determine the accuracy of information it receives that an overpayment may exist.

(d) *Reporting and returning of an overpayment.* An MA organization must report and return any overpayment it received no later than 60 days after the date on which it identified it received an overpayment.

(1) *Reporting.* An MA organization must notify CMS, of the amount and reason for the overpayment, using a notification process determined by CMS.

(2) *Returning.* An MA organization must return identified overpayments in a manner specified by CMS.

(3) *Enforcement.* Any overpayment retained by an MA organization after the 60-day deadline for reporting and returning is an obligation under 31 U.S.C. 3729(b)(3).

(e) *Look-back period.* An MA organization must report and return any overpayment identified for the 6 most recent completed payment years. Overpayments resulting from fraud are not subject to this limitation of the look-back period.

§ 422.502 [Amended]

■ 27. Section 422.502(b)(3) is amended by removing the phrase ''CMS may deny an application based on the applicant's'' and adding in its place the phrase ''CMS may deny an application for a new contract or service are expansion based on the applicant's''.

■ 28. Section 422.503 is amended by—

■ A. Adding paragraph (b)(4)(vi)(C)(*3*).

■ B. Adding and reserving paragraph (b)(4)(vi)(G)(4).

■ C. Revising paragraph (b)(4)(vi)(G)(*5*).

■ D. In paragraph (d)(2) introductory text, removing the phrase ''has the right to:'' and adding in its place the phrase ''has the right to timely do all of the following:''.

■ E. In paragraph (d)(2)(i), removing the ''; '' and adding in its place a ''.''.

■ F. In paragraph (d)(2)(ii), removing the ''; and'' and adding in its place a ''.''.

■ G. Adding paragraph (d)(2)(iv).

The revisions and additions are as follows:

§ 422.503 General provisions.

* * * * *

(b) * * *

(4) * * *

(vi) * * *

(C) * * *

(*3*) An MA organization must require all of its first tier, downstream and related entities to take the CMS training and accept the certificate of completion of the CMS training as satisfaction of this requirement. MA organizations are prohibited from developing and implementing their own training or providing supplemental training materials to fulfill this requirement.

* * * * *

(G) * * *

(*5*) Not accept, or share a corporate parent organization with an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.

(d) * * *

(2) * * *

(iv) CMS may require that the MA organization hire an independent auditor to conduct full or partial program audits or to provide CMS with information to determine if deficiencies found during an audit or inspection have been corrected and are not likely to recur. The independent auditor must work in accordance with CMS specifications and must be willing to attest that a complete and full independent review has been performed.

* * * * *

■ 29. Amend § 422.504 by:

■ A. Adding paragraphs (a)(3)(iv) and (a)(19).

■ B. Redesignating paragraph (i)(2)(ii) as (i)(2)(iii).

■ C. Adding new paragraph (i)(2)(ii) and paragraphs (1)(5) and (o).

§ 422.504 Contract provisions.

* * * * *

(a) * * *

(3) * * *

(iv) Such benefits and access in a manner that provides good quality health care demonstrated by scores of three or higher on CMS performance standards for patient outcomes, intermediate outcomes, process, patient experience, and patient access to care.

* * * * *

(19) That it will not submit a bid for the same type of MA plan that is non-renewed under § 522.506(b)(1)(iv) in the service area of the non-renewed plan for 2 years.

* * * * *

(i) * * *

(2) * * *

(ii) HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any records under (i)(2)(i) of this section directly from any first tier, downstream, or related entity.

* * * * *

(l) * * *

(5) *Certification of accuracy of data for overpayments.* The CEO, CFO, or COO must certify (based on best knowledge, information, and belief) that the information provided for purposes of reporting and returning of overpayments under § 422.326 is accurate, complete, and truthful.

* * * * *

(o) *Business continuity.* (1) The MA organization agrees to develop, maintain, and implement a business continuity plan containing policies and procedures to ensure the continuation of business operations during disruptions to business operations which would include natural or man-made disasters, system failures, emergencies, and other similar circumstances and the threat of such occurrences. To meet the requirement, the business continuity plan must, at a minimum, include the following:

(i) *Risk assessment.* Identify threats and vulnerabilities that might affect business operations.

(ii) *Mitigation strategy.* Design strategies to mitigate hazards. Identify essential functions in addition to those specified in paragraph (o)(2) of this section and prioritize the order in which to restore all other functions to normal operations. At a minimum, each MA organization must do the following:

(A) Identify specific events that will activate the business continuity plan.

(B) Develop a contingency plan to maintain, during any business disruption, the availability and, as applicable, confidentiality of communication systems and essential records in all forms (including electronic and paper copies). The contingency plan must do the following:

(*1*) Ensure that during any business disruption the following systems will operate continuously or, should they fail, be restored to operational capacity on a timely basis:

(*i*) Information technology (IT) systems including those supporting claims processing at point of service.

(*ii*) Provider and enrollee communication systems including telephone, Web site, and email.

(*2*) With respect to electronic protected health information, comply with the contingency plan requirements of the Health Insurance Portability and Accountability Act of 1996 Security Regulations at 45 CFR 160 and 164, Subparts A and C.

(C) Establish a chain of command.

(D) Establish a business communication plan that includes emergency capabilities and procedures to contact and communicate with the following:

(*1*) Employees.

(*2*) First tier, downstream, and related entities.

(*3*) Other third parties (including pharmacies, providers, suppliers, and government and emergency management officials).

(E) Establish employee and facility management plans to ensure that essential operations and job responsibilities can be assumed by other employees or moved to alternate sites as necessary.

(F) Establish a restoration plan including procedures to transition to normal operations.

(G) Comply with all applicable Federal, State, and local laws.

(iii) *Testing and revision.* On at least an annual basis, test and update the business operations continuity plan to ensure the following:

(A) That it can be implemented in emergency situations.

(B) That employees understand how it is to be executed.

(iv) *Training.* On at least an annual basis, educate all employees, including contract staff about the business

continuity plan and their own respective roles.

(v) *Records.* (A) Develop and maintain records documenting the elements of the business continuity plan described in paragraphs (o)(1)(i) through (iv) of this section.

(B) Make the information specified in paragraph (o)(1)(v)(A) of this section available to CMS upon request.

(2) *Restoration of essential functions.* Every MA organization must restore essential functions within 24 hours after any of the essential functions fail or otherwise stop functioning as usual. In addition to any essential functions that the MA organization identifies under paragraph (o)(1)(ii) of this section, for purposes of this paragraph (o)(2) of the section essential functions include, at a minimum, the following:

(i) Benefit authorization (if not waived), adjudication, and processing of health care claims for services furnished at a hospital, clinic, provider office or other place of service.

(ii) Operation of an enrollee exceptions and appeals process including coverage determinations.

(iii) Operation of call center customer services.

■ 30. Section 422.506 by revising paragraphs (a)(4) and (b)(1)(iv) to read as follows:

§ 422.506 Nonrenewal of contract.

(a) * * *

(4) If an MA organization does not renew a contract under this paragraph (a) of this section, CMS may deny an application for a new contract or a service area expansion from the MA organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS. This prohibition may apply regardless of the product type, contract type or service area of the previous contract.

* * * * *

(b) * * *

(1) * * *

(iv) The contract must be non-renewed as to an individual MA plan if that plan does not have a sufficient number of enrollees to establish that it is a viable independent plan option.

* * * * *

■ 31. Section 422.508 is amended by revising paragraphs (c) and (d) introductory text to read as follows:

§ 422.508 Modification or termination of contract by mutual consent.

* * * * *

(c) *Agreement to limit new MA applications.* As a condition of the consent to a mutual termination CMS requires, as a provision of the termination agreement, language prohibiting the MA organization from applying for new contracts or service area expansions for a period of 2 years, absent circumstances warranting special consideration. This prohibition may apply regardless of the product type, contract type or service area of the previous contract.

(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 does not contract with an organization whose covered persons also served as covered persons for the mutually terminating sponsor. This prohibition may apply regardless of the product type, contract type or service area of the previous contract. A ''covered person'' as used in this paragraph means one of the following:

* * * * *

■ 32. Amend § 422.510 as follows;

■ A. By redesigating paragraphs (a)(4) through (15) as paragraphs (a)(4)(i) through (xii).

■ B. By adding new paragraph (a)(4) introductory text.

■ C. In newly redesignated paragraphs (a)(4)(ii), (v), (vi), and (viii) by removing the term ''fails'' and adding in its place the term ''failed''.

■ D. In newly redesignated paragraphs (a)(4)(iii), (iv), (vii), (ix), and (x), by removing the term ''Fails'' and adding in its place the term ''Failed''.

■ E. By revising newly redesignated paragraphs (a)(4)(xi) and (xii).

■ F. In paragraph (b)(1)(i), by removing the phrase ''90 days'' and adding in its place the phrase ''at least 45 calendar days''.

■ G. By revising paragraph (b)(1)(iii) and the heading for paragraph (b)(2).

■ H. In paragraph (b)(2)(i)(C), by removing the cross-reference ''(a)(4) of this section'' and adding in its place the cross reference ''(a)(4)(i) of this section''.

■ I. In paragraph (c)(2)(iii), by removing the cross reference ''(a)(4) of this section'' and adding in its place the cross reference ''(a)(4)(i) of this section''.

The additions and revisions read as follows:

§ 422.510 Termination of Contract by CMS.

* * * * *

(a) * * *

(3) * * *

(4) CMS may make a determination under paragraph (a)(1), (2), or (3) of this section if the MA organization has had one or more of the following occur:

* * * * *

(xi) Achieves a Part C summary plan rating of less than 3 stars for 3 consecutive contract years. Plan ratings issued by CMS before September 1, 2012, are not included in the calculation of the 3–year period.

(A) Holds a MA contract that does not include a Part D addendum and achieves a Part C summary plan rating of less than 3 stars for 3 consecutive contract years.

(B) Holds a MA contract that includes a Part D addendum and fails for three consecutive years to achieve both Part C and D summary ratings of 3 or more stars in the same year.

(xii) Has failed to report MLR data in a timely and accurate manner in accordance with § 422.2460 or that any MLR data required by this subpart is found to be materially incorrect or fraudulent.

* * * * *

(b) * * *

(1) * * *

(i) CMS notifies the MA organization in writing at least 45 calendar days before the intended date of the termination.

(ii) The MA organization notifies its Medicare enrollees of the termination by mail at least 30 calendar days before the effective date of the termination.

(iii) The MA organization notifies the general public of the termination at least 30 calendar days before the effective date of the termination by releasing a press statement to news media serving the affected community or county and posting the press statement prominently on the organization's Web site.

(2) Immediate termination of contract by CMS.

* * * * *

■ 33. Section 422.512 is amended by revising paragraph (e)(1) to read as follows:

§ 422.512 Termination of contract by the MA organization.

* * * * *

(e) * * *

(1) CMS may deny an application for a new contract or a service area expansion from an MA organization that has terminated its contract within the preceding 2 years unless there are circumstances that warrant special consideration, as determined by CMS. This prohibition may apply regardless of the contract type, product type, or service area of the previous contract.

* * * * *

■ 34. Amend § 422.566 by revising paragraphs (b) introductory text, and (b)(1) through (3) and adding paragraph (b)(6) to read as follows:

§ 422.566 Organization determinations.

* * * * *

(b) *Actions that are organization determinations.* The following actions by an MA organization are organization determinations:

(1) Any determination with respect to payment for temporarily out of the area renal dialysis services, emergency services, post-stabilization care, or urgently needed services.

(2) Any determination with respect to payment for any other health services furnished by a provider other than the MA organization that the enrollee believes—

(i) Are covered under Medicare; or

(ii) If not covered under Medicare, should have been furnished, arranged for, or reimbursed by the MA organization.

(3) Any determination by the MA organization not to provide or pay for services, in whole or in part, including the type, level or duration of services, that the enrollee believes should be furnished or arranged for by the MA organization.

* * * * *

(6) Any determination by the MA organization to provide or pay for an item or service, including the initial or continued provision of an item or service by a contract provider of the MA organization.

* * * * *

■ 35. Section 422.568 is amended by revising paragraph (b) to read as follows:

§ 422.568 Standard timeframes and notice requirements for organization determinations.

* * * * *

(b) *Timeframe for requests for service.* Except as provided in paragraph (b)(1) of this section, when a party has made a request for a service, the MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination.

(1) *Extensions.* The MA organization may extend the timeframe by up to 14 calendar days if—

(i) The enrollee requests the extension;

(ii) The extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or

(iii) The extension is justified due to extraordinary, exigent, or other non-routine circumstances and is in the enrollee's interest.

(2) *Notice of extension.* When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

* * * * *

■ 36. Section 422.572 is amended by revising paragraph (b) to read as follows:

§ 422.572 Timeframes and notice requirements for expedited organization determinations.

* * * * *

(b) *Extensions.* (1) The MA organization may extend the 72-hour deadline by up to 14 calendar days if—

(i) The enrollee requests the extension;

(ii) The extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or

(iii) The extension is justified due to extraordinary, exigent, or other non-routine circumstances and is in the enrollee's interest.

(2) *Notice of extension.* When the MA organization extends the deadline, it must notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

* * * * *

■ 37. Section 422.590 is amended as follows:

■ A. By revising paragraph (a)(1).

■ B. In paragraph (d)(1), by removing the cross reference ''(d)(2)'' and adding in its place the cross-reference ''(e)''.

■ C. By removing paragraph (d)(2).

■ D. By redesignating paragraphs (d)(3) through (5) as paragraphs (d)(2) through (4), respectively.

■ E. By redesignating paragraphs (e) through (g) as paragraphs (f) through (h), respectively;

■ F. By adding new paragraph (e).

The additions and revisions read as follows:

§ 422.590 Timeframes and responsibility for reconsiderations.

(a) * * *

(1) Except as provided in paragraph (e) of this section, if the MA organization makes a reconsidered determination that is completely favorable to the enrollee, the MA organization must issue the determination (and effectuate it in accordance with § 422.618(a)) as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration.

* * * * *

(e) *Extensions.* (1) As described in paragraphs (e)(1)(i) through (e)(1)(iii) of this section, the MA organization may extend the standard or expedited reconsideration deadline by up to 14 calendar days if—

(i) The enrollee requests the extension; or

(ii) The extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or

(iii) The extension is justified due to extraordinary, exigent or other non-routine circumstances and is in the enrollee's interest.

(2) *Notice of extension.* When the MA organization extends the deadline, it must notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

* * * * *

§ 422.618 [Amended]

■ 38. In paragraph (a), removing the cross-reference ''§ 422.590(a)(1)'' and adding in its place the cross-reference ''§ 422.590(e)''.

§ 422.619 [Amended]

■ 39. In paragraph (a), removing the cross-reference ''§ 422.590(d)(2)'' and adding in its place the cross-reference ''§ 422.590(e)''.

■ 40. Amend § 422.641 by revising paragraphs (b) and (c) to read as follows:

§ 422.641 Contract determinations.

* * * * *

(b) A determination not to authorize a renewal of a contract with an MA organization in accordance with § 422.506(b).

(c) A determination to terminate a contract with an MA organization in accordance with § 422.510(a).

* * * * *

■ 41. Amend § 422.644 by revising paragraphs (a), (b)(1), and (c)(1) to read as follows:

§ 422.644 Notice of contract determination.

* * * * *

(a) When CMS makes a contract determination under § 422.641, it gives the MA organization written notice.

(b) * * *

(1) Reasons for the determination; and

* * * * *

(c) * * *

(1) *General rule.* Except as provided in (c)(2) of this section, CMS mails notice to the MA organization 45 calendar days before the anticipated effective date of the termination.

* * * * *

■ 42. Amend § 422.660 by revising paragraphs (a)(2), (a)(3), and (b)(4) to read as follows:

§ 422.660 Right to a hearing, burden of proof, standard of proof, and standards of review.

* * * * *

(a) * * *

(2) An MA organization whose contract has been terminated in accordance with § 422.510.

(3) An MA organization whose contract has not been renewed in accordance with § 422.506.

(b) * * *

(4) During a hearing to review the imposition of an intermediate sanction as described at § 422.750, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.752(a) and (b).

* * * * *

■ 43. Amend § 422.752 by adding paragraphs (a)(9) through (12) and revising paragraphs (c)(1) and (c)(2)(ii) to read as follows:

§ 422.752 Basis for imposing intermediate sanctions and civil money penalties

(a) * * *

(9) Except as provided under § 423.34 of this chapter, enrolls an individual in any plan under this part without the prior consent of the individual or the designee of the individual.

(10) Transfers an individual enrolled under this part from one plan to another without the prior consent of the individual or the designee of the individual or solely for the purpose of earning a commission.

(11) Fails to comply with marketing restrictions described in subpart V or applicable implementing guidance.

(12) Employs or contracts with any individual, agent, provider, supplier or entity who engages in the conduct described in paragraphs (a)(1) through (11) of this section.

* * * * *

(c) * * *

(1) *CMS.* In addition to, or in place of, any intermediate sanctions, CMS may impose civil money penalties in the amounts specified in the following:

(i) Section 422.760(b) for any of the determinations at § 422.510(a), except § 422.510(a)(4)(i).

(ii) Section 422.760(c) for any of the determinations at § 422.752(a) except § 422.752(a)(5).

(2) * * *

(ii) Determinations made under § 422.510(a)(4)(i).

■ 44. Amend § 422.756 by revising paragraphs (a)(2), (b)(4), and (d) to read as follows:

§ 422.756 Procedures for imposing intermediate sanctions and civil money penalties.

(a) * * *

(2) *Opportunity to respond.* CMS allows the MA organization 10 calendar days after receipt of the notice to provide a written rebuttal. CMS considers receipt of the notice as the day after the notice is sent by fax, email, or submitted for overnight mail.

(b) * * *

(4) The MA organization must follow the right to a hearing procedure as specified in subpart N of this part.

* * * * *

(d) *Non-renewal or termination by CMS.* In addition to or as an alternative to the sanctions described in § 422.750, CMS may—

(1) Decline to authorize the renewal of an organization's contract in accordance with § 422.506(b); or

(2) Terminate the contract in accordance with § 422.510.

* * * * *

■ 45. Amend 422.760 by revising paragraph (a)(3) and the heading of paragraph (b) and adding paragraph (c) to read as follows:

§ 422.760 Determinations regarding the amount of civil money penalties and assessment imposed by CMS.

(a) * * *

(3) The adverse effect to enrollees which resulted or could have resulted from the conduct of MA organization;

(b) *Amount of penalty imposed by CMS.* * * *

* * * * *

(c) *Amount of penalty imposed by CMS or OIG.* CMS or the OIG may impose civil money penalties in the following amounts for a determination made under § 422.752(a):

(1) Civil money penalties of not more than $25,000 for each determination made.

(2) With respect to a determination made under § 422.752(a)(4) or (a)(5)(i), not more than $100,000 for each such determination, except with respect to a determination made under § 422.752(a)(5), an assessment of not more than the amount claimed by such plan or MA organization based upon the misrepresentation or falsified information involved.

(3) Plus with respect to a determination made under § 422.752(a)(2), double the excess amount charged in violation of such paragraph (and the excess amount charged must be deducted from the penalty and returned to the individual concerned).

(4) Plus with respect to a determination made under § 422.752(a)(4), $15,000 for each individual not enrolled as a result of the practice involved.

■ 46. Amend § 422.1016 by revising the first sentence of paragraph (b)(1) to read as follows:

§ 422.1016 Filing of briefs with the Administrative Law Judge or Departmental Appeals Board, and opportunity for rebuttal.

* * * * *

(b) * * *

(1) The other party will have 20 calendar days from the date of mailing or in person filing to submit any rebuttal statement or additional evidence. * * *

* * * * *

■ 47. Amend § 422.1020 by revising paragraph (a)(2) to read as follows:

§ 422.1020 Request for hearing.

(a) * * *

(2) The MA organization or its legal representative or other authorized official must file the request, in writing, to the appropriate Departmental Appeals Board office, with a copy to CMS, within 60 calendar days after receipt of the notice of initial determination, to request a hearing before an ALJ to appeal any determination by CMS to impose a civil money penalty.

* * * * *

■ 48. Amend § 422.2262 by adding paragraph (a)(2) to read as follows:

§ 422.2262 Review and Distribution of marketing materials.

(a) * * *

(2) If CMS does not approve or disapprove marketing materials within the specified review timeframe, the materials will be deemed approved. Deemed approved means that the MA organization may use the material.

* * * * *

§ 422.2266 [Removed and Reserved]

■ 49. Section 422.2266 is removed and reserved.

■ 50. Amend § 422.2274 by:

■ A. Revising the introductory text.

■ B. Redesignating paragraphs (a) through (f) as (b) through (g).

■ C. Adding new paragraph (a).

■ D. Revising newly redesignated paragraphs (b) through (d).

■ E. Adding paragraph (h).

The revisions and addition read as follows:

§ 422.2274 Broker and agent requirements.

If an MA organization uses agents and brokers to sell its Medicare plans, the following requirements in this section are applicable:

(a) *Definitions.* For purposes of this section, the following definitions are applicable:

Compensation (1) Includes monetary or non-monetary remuneration of any kind relating to the sale or renewal of a policy including, but not limited to—

(i) Commissions;

(ii) Bonuses;

(iii) Gifts;

(iv) Prizes or Awards; or

(v) Referral or Finder fees.

(2) Does not include—

(i) Payment of fees to comply with State appointment laws, training, certification, and testing costs;

(ii) Reimbursement for mileage to, and from, appointments with beneficiaries; or

(iii) Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

Like plan type means one of the following:

(1) PDP replaced with another PDP.

(2) MA or MA–PD replaced with another MA or MA–PD.

(3) Cost plan replaced with another cost plan.

Unlike plan type means one of the following:

(1) PDP replaced with a MA–PD or a MA–PD replaced with a PDP.

(2) PDP replaced with a cost plan or a cost plan replaced with a PDP.

(3) MA–PD replaced with a cost plan or a cost plan replaced with a MA–PD.

Plan year means the year beginning January 1 and ending December 31.

Renewal year means all years following the initial enrollment year in a like plan type.

(b) *Compensation rules.* A MA organization must compensate independent brokers and agents, if compensation is paid, only according to the following rules in this section.

(1) *Compensation amounts.* (i) For an initial year enrollment of a Medicare beneficiary into an MA plan, the compensation must be at or below the fair market value of such services, published annually as a cut-off amount by CMS.

(ii) For renewal years, compensation may be up to 35 percent of the current fair market value cut-off amounts published annually by CMS.

(2) *Aggregate compensation.* (i) An entity must not provide aggregate compensation to its agents or brokers greater than the renewal compensation payable by the replacing plan on renewal policies if an existing policy is replaced with a like plan at any time.

(ii) An agent or broker must not receive aggregate compensation greater than the renewal compensation payable by the replacing plan on renewal policies if an existing policy is replaced with a like plan type at any time.

(iii) The initial compensation is paid for replacements between unlike plan types.

(3) *Compensation payment and payment recovery.* (i) Compensation may only be paid for the enrollee's months of enrollment during a plan year.

(ii)(A) Subject to paragraph (b)(3)(iii) of this section, compensation payments may be made at one time for the entire current plan year or in installments throughout the year.

(B) Compensation may not be paid until January 1 of the compensation year and, if paid at all, must be paid in full by December 31 of the compensation year.

(iii) When a beneficiary disenrolls from an MA plan, compensation paid to agents and brokers must be recovered for those months of the plan year for which the beneficiary is not enrolled. For disenrollments occurring within the first 3 months, the entire compensation must be recovered when the disenrollment was the result of agent or broker behavior.

(4) *Compensation structure.* (i) The MA organization must establish a compensation structure for new and replacement enrollments and renewals effective in a given plan year. Compensation structures must be in place by the beginning of the plan marketing period, October 1.

(ii) Compensation structures must be available upon CMS request including for audits, investigations, and to resolve complaints.

(c) *Annual training.* The MA organization must ensure that all agents and brokers selling Medicare products are trained annually on the following:

(1) Medicare rules and regulations.

(2) Details specific to the plan products they intend to sell.

(d) *Annual testing.* It must ensure that all agents and brokers selling Medicare products are tested annually, to ensure the following:

(1) Appropriate knowledge and understanding of Medicare rules and regulations.

(2) Details specific to the plan products they intend to sell.

* * * * *

(h) *Finder's (referral) fees.* Finder's (referral) fees paid to all agents and brokers—

(1) May not exceed an amount CMS determines could reasonably be expected to affect enrollee behavior while not exceeding the value of the health-related service or activity itself; and

(2) Must be included in the total compensation not to exceed the fair market value for that calendar year.

Subpart Y—[Reserved]

■ 51. Part 422 is amended by adding reserved subpart Y.

■ 52. Part 422 is amended by adding subpart Z to read as follows:

Subpart Z—Part C Recovery Audit Contractor Appeals Process

Sec.

Subpart Z—Part C Recovery Audit Contractor Appeals Process

§ 422.2600 Payment appeals.

If the Part C RAC did not apply its stated payment methodology correctly, an MA organization may appeal the findings of the applied methodology. The payment methodology itself is not subject to appeal.

§ 422.2605 Request for reconsideration.

(a) *Time for filing a request.* The request for reconsideration must be filed with the designated independent reviewer within 60 calendar days from the date of the demand letter received by the MA organization.

(b) *Content of request.* (1) The request for reconsideration must be in writing and specify the findings or issues with which the MA organization disagrees.

(2) The MA organization must include with its request all supporting documentary evidence it wishes the independent reviewer to consider.

(i) This material must be submitted in the format requested by CMS.

(ii) Documentation, evidence, or substantiation submitted after the filing of the reconsideration request will not be considered.

(c) *CMS rebuttal.* CMS may file a rebuttal to the MA organization's reconsideration request.

(1) The rebuttal must be submitted within 30 calendar days of the review entity's notification to CMS that it has received the MA organization's reconsideration request.

(2) CMS sends its rebuttal to the MA organization at the same time it is submitted to the independent reviewer.

(d) *Review entity.* An independent reviewer conducts the reconsideration. The independent reviewer reviews the demand for repayment, the evidence and findings upon which it was based and any supporting documentation that the MA organization or CMS submitted in accordance with this section.

(e) *Notification of decision.* The independent reviewer informs the CMS and the MA organization of its decision in writing.

(f) *Effect of decision.* A reconsideration decision is final and binding unless the MA organization requests a hearing official review in accordance with § 422.2610.

(g) *Right to hearing official review.* An MA organization that is dissatisfied with the independent reviewer's reconsideration decision is entitled to a hearing official review as provided in § 422.2610.

§ 422.2610 Hearing official review.

(a) *Time for filing a request.* A MA organization must file with CMS a request for a hearing official review within 15 calendar days from the date of the independent reviewer's issuance of a reconsideration determination.

(b) *Content of the request.* (1) The request must be in writing and must specify the findings or issues in the reconsideration decision with which the MA organization disagrees and the reasons for the disagreements.

(2) The MA organization must submit with its request all supporting documentation, evidence, and substantiation that it wants to be considered.

(3) No new evidence may be submitted.

(4) Documentation, evidence, or substantiation submitted after the filing of the request will not be considered.

(c) *CMS rebuttal.* CMS may file a rebuttal to the MA organization's hearing official review request.

(1) The rebuttal must be submitted within 30 calendar days of the MA organization's submission of its hearing official review request.

(2) CMS sends its rebuttal to the MA organization at the same time it is submitted to the hearing official.

(d) *Conducting a review.* A CMS-designated hearing official conducts the hearing on the record.

(1) The hearing is not to be conducted live or via telephone unless the hearing official, in his or her sole discretion, requests a live or telephonic hearing.

(2) In all cases, the hearing official's review is limited to information that meets one or more of the following:

(i) The Part C RAC used in making its determinations.

(ii) The independent reviewer used in making its determinations.

(iii) The MA organization submits with its hearing request.

(iv) CMS submits in accordance with paragraph (c) of this section.

(3) Neither the MA organization nor CMS may submit new evidence.

(e) *Hearing official decision.* The CMS hearing official decides the case within 60 days and sends a written decision to the MA organization and CMS, explaining the basis for the decision.

(f) *Effect of hearing official decision.* The hearing official's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with § 422.2615.

§ 422.2615 Review by the Administrator.

(a) *Request for review by Administrator.* If an MA organization is dissatisfied with the hearing official's decision, it may request that the CMS Administrator review the decision.

(1) The request must be filed with the CMS Administrator within 15 calendar days of the date of the hearing official's decision.

(2) The request must provide evidence or reasons to substantiate the request.

(b) *Content of request.* The MA organization must submit with its request all supporting documentation, evidence, and substantiation that it wants to be considered.

(1) Documentation, evidence, or substantiation submitted after the filing of the request will not be considered.

(2) Neither the MA organization, nor CMS may submit new evidence.

(c) *Discretionary review.* After receiving a request for review, the CMS Administrator has the discretion to review the hearing official's decision in accordance with paragraph (e) of this section or to decline to review said decision.

(d) *Notification of decision whether to review.* The Administrator notifies the MA organization within 45 days of receiving the MA organization's hearing request of whether he or she intends to review the hearing official's decision.

(1) If the Administrator agrees to review the hearing official's decision, CMS may file a rebuttal statement within 30 days of the Administrator's notice to the plan that the request for review has been accepted. CMS sends its rebuttal statement to the plan at the same time it is submitted to the Administrator.

(2) If the CMS Administrator declines to review the hearing official's decision, the hearing official's decision is final and binding.

(e) *CMS Administrator's review.* If the CMS Administrator agrees to review the hearing official's decision, he or she determines, based upon this decision, the hearing record, and any arguments submitted by the MA organization or CMS in accordance with this section, whether the determination should be upheld, reversed, or modified. The Administrator furnishes a written decision, which is final and binding, to the MA organization and to CMS.

PART 423—MEDICARE PROGRAM; MEDICARE PRESCRIPTION DRUG PROGRAM

■ 53. 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).

■ 54. Amend § 423.1 by adding new references in numerical order to paragraph (a)(1) and by adding paragraph (a)(3) to read as follows:

§ 423.1 Basis and scope.

(a) * * *

(1) * * *

1128J(d). Reporting and Returning of Overpayments.

* * * * *

1860D–14A. Medicare coverage gap discount program.

* * * * *

1860D–43. Condition for coverage of drugs under this part.

* * * * *

(3) Section 8 of the United States Code regarding aliens who are not qualified aliens ineligible for Federal public benefits.

* * * * *

■ 55. Section 423.10 is added to subpart A to read as follows:

§ 423.10 Prohibition on intervention in negotiations with manufacturers.

(a) *General rule.* CMS promotes fair private market competition in the market for Part D drugs.

(b) *No interference in negotiations.* (1) Except as necessary to enforce CMS requirements, CMS is not—

(i) A party to discussions between drug manufacturers and pharmacies or

between prescription drug manufacturers and Part D sponsors; nor

(ii) An arbiter of the meaning of or compliance with the terms and conditions of agreements reached between these parties.

(2) Nothing in paragraph (b)(1) of this section limits CMS's authority to—

(i) Require documentation of and access to all agreements referenced in paragraph (b)(1)(ii) of this section; or

(ii) Require inclusion of terms and conditions in such agreements when necessary to implement requirements under the Act.

(c) *No establishment of formulary drug product selection.* CMS does not determine the specific drug products to be included on Part D sponsor formularies or any tier placement of such products, except as necessary to comply with § 423.120(b)(1)(v) or § 423.272(b)(2).

(d) *No establishment of Part D drug price reimbursement methodologies.* (1) CMS does not establish specific drug product pricing standards (as defined in § 423.505(b)(21)) or the dollar amount of price concessions at any stage in the drug distribution channel for Part D drugs.

(2) Nothing in this section limits CMS authority to require full disclosure or uniform treatment and reporting of drug costs, prices, or price concessions consistent with rules established by CMS.

■ 56. Amend § 423.30 as follows:

■ A. In paragraph (a)(1) introductory text, by removing the phrase ''if he or she:'' and adding in its place the phrase ''if he or she does all of the following:''.

■ B. In paragraph (a)(1)(i), by removing ''; and'' and adding in its place ''.''.

■ C. By adding paragraph (a)(1)(iii).

The addition reads as follows:

§ 423.30 Eligibility and enrollment.

(a) * * *

(1) * * *

(iii) Is a United States citizen or qualified alien who is lawfully present in the United States as determined in 8 CFR 1.3.

* * * * *

§ 423.44 [Amended]

■ 57. Amend § 423.44 as follows:

■ A. By adding paragraph (b)(2)(vi).

■ B. In paragraph (d)(1)(vi), by removing the phrase ''CMS may reinstate'' and adding in its place the phrase ''CMS (or its designee) may reinstate''.

■ C. By adding paragraph (d)(8).

The additions read as follows:

§ 423.44 Involuntary disenrollment from Part D coverage.

* * * * *

(b) * * *

(2) * * *

(vi) The individual loses qualified alien status or is no longer lawfully present in the United States.

* * * * *

(d) * * *

(8) *Loss of qualified alien status.* Disenrollment is effective with the month following the last month of lawful presence or qualified alien status in the United States.

* * * * *

§ 423.100 [Amended]

■ 58. Amend § 423.100 as follows:

■ A. By revising the definition of ''Daily cost-sharing rate''.

■ B. By revising the definition of ''Negotiated prices''.

■ C. By removing the definition of ''Non-preferred pharmacy''.

■ D. In the definition of ''Part D drug''—

■ i. By revising paragraph (1) introductory text.

■ ii. By adding paragraph (1)(vii).

■ iii. In paragraph (2) introductory text, by removing the phrase ''Does not include—'' and adding in its place the phrase ''Does not include any of the following:''

■ iv. In paragraph (2)(i), by removing ''; and'' and adding in its place ''.''.

■ vi. By adding paragraph (2)(iii).

■ E. By adding the definition of ''Preferred cost sharing''.

■ F. By removing the definition of ''Preferred pharmacy''.

The additions and revisions read as follows:

§ 423.100 Definitions.

* * * * *

Daily cost-sharing rate means, as applicable, the established—

(1) Monthly copayment under the enrollee's Part D plan, divided by the number of days in the approved month's supply for the drug dispensed and rounded to the nearest cent; or

(2) Coinsurance percentage under the enrollee's Part D plan.

* * * * *

Negotiated prices means prices for covered Part D drugs that meet all of the following:

(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug.

(2) Are inclusive of all price concessions and any other fees charged to network pharmacies; and

(3) Include any dispensing fees; but

(4) May exclude additional contingent amounts, such as incentive fees, only if these amounts increase prices and cannot be predicted in advance.

(5) May not be rebated back to the Part D sponsor (or other intermediary contracting organization) in full or in part.

* * * * *

Part D drug * * *

(1) Unless excluded under paragraph (2) of this definition, any of the following, or any FDA-approved combinations of the following, if used for a medically accepted indication (as defined in section 1860D–2(e)(4) of the Act).

* * * * *

(vii) A combination product approved and regulated by the FDA as a drug, vaccine, or biologic (or any approved combinations of these) described in paragraphs (i), (ii), (iii), or (v) of the Part D drug definition.

(2) Does not include any of the following:

* * * * *

(iii) Medical foods, defined as a food that is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation, and that are not regulated as drugs under section 505 of the Federal Food, Drug, and Cosmetic Act.

* * * * *

Preferred cost sharing means lower cost sharing for certain covered Part D drugs at certain network pharmacies offered in accordance with the requirements of § 423.120(a)(9).

* * * * *

■ 59. Amend 423.120 by:

■ A. Revising paragraphs (a)(3), (8), and (9).

■ B. Redesignating paragraphs (b)(1)(iv) through (x) as (b)(1)(v) through (xi), respectively.

■ C. Adding a new paragraph (b)(1)(iv).

■ D. Revising paragraphs (b)(2)(v), (vi)(B), and (C).

■ E. Adding new paragraphs (b)(2)(vi)(D) through (G) and (3)(vi).

■ F. Redesignating paragraphs (c)(5)(i) through (v) as paragraphs (c)(5)(i)(A) through (E), respectively.

■ G. Adding paragraph (c)(5)(i) introductory text.

■ H. In newly resdesignated paragraphs (c)(5)(i)(A) and (B), removing the cross-reference ''(c)(5)(iii) of this section'' and adding in its place the cross-reference ''(c)(5)(i)(C) of this section''

■ I. In newly redesignated paragraph (c)(5)(i)(D), removing the cross-reference

''(c)(5)(ii) and (iii) of this section'' and adding in its place the cross-reference ''(c)(5)(i)(B) and (C) of this section''.

■ J. Adding a new paragraph (c)(5)(ii).

■ K. Adding paragraph (c)(6).

The revisions and additions read as follows:

§ 423.120 Access to covered Part D drugs.

* * * * *

(a) * * *

(3) *Access to non-retail pharmacies.* A part D sponsor's contracted pharmacy network may be supplemented by non-retail pharmacies, including pharmacies offering home delivery via mail order and institutional pharmacies, provided the requirements of paragraph (a)(1) of this section are met. Sponsors that contract with mail order pharmacies, and pharmacies offering home delivery via mail order, must ensure that the pharmacies meet the following fulfillment standards:

(i) For prescriptions adjudicated and filled without requiring additional review, the time of shipment must not be more than 3 business days from order receipt by the mail order pharmacy.

(ii) For prescriptions requiring additional review before shipping, the time of shipment must not be more than 5 business days from order receipt by the mail order pharmacy.

* * * * *

(8) *Pharmacy network contracting requirements.* In establishing its contracted pharmacy network, a Part D sponsor offering qualified prescription drug coverage must comply with all of the following requirements:

(i) Must offer and publicly post standard terms and conditions for network participation for each type of pharmacy in the network, subject to paragraphs (a)(8)(ii) and (iii) of this section.

(ii) May not require a pharmacy to accept insurance risk as a condition of participation in the Part D sponsor's contracted pharmacy network.

(iii) Must offer payment terms for every level of cost sharing offered under the sponsor's plans consistent with CMS limitations on the number and type of cost sharing levels (preferred, standard, extended day), and for every type of similarly situated retail pharmacy.

(iv) Must contract with any willing pharmacy able to meet one set of the terms and conditions offered by that plan for that type of pharmacy.

(9) *Preferred cost-sharing in network pharmacies.* A Part D sponsor offering a Part D plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs obtained through a subset of network pharmacies, as long as such preferred cost sharing is offered in accordance with the requirements of § 423.120(a)(8) and for Part D drugs with consistently lower negotiated prices than the same Part D drugs when obtained in the rest of the pharmacy network.

* * * * *

(b) * * *

(1) * * *

(iv) Clearly articulates and documents processes to determine that the requirements under paragraphs (b)(1)(i) through (iii) of this section have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts.

* * * * *

(2) * * *

(v) Effective contract year 2015, except as provided in paragraph (b)(2)(vi) of this section, a Part D sponsor's formulary must include without restriction at point of sale all Part D drugs in a category or class that CMS has determined for a typical individual with a disease or condition treated by the drugs in the category or class meets the all of the following criteria:

(A) Hospitalization, persistent or significant disability or incapacity, or death will likely result if initial administration (including self-administration) of a drug in the category or class does not occur within 7 days of the date the prescription for the drug was presented to the pharmacy to be filled.

(B) More specific CMS formulary requirements will not suffice to meet the universe of clinical drug-and-disease-specific applications due to the diversity of disease or condition manifestations and associated specificity or variability of drug therapies necessary to treat such manifestations.

(vi) * * *

(B) Drug products that are primarily covered under Medicare Part A or B.

(C) Part D Compounds as described in § 423.120(d).

(D) Fixed combination dosage form prescription drugs other than antiretrovirals, including co-packaged drug products, as defined by 21 CFR 300.50.

(E) Certain types of Part D drugs, including the following:

(*1*) Multisource brands of the identical molecular structure.

(*2*) Extended-release products when the immediate-release product is included.

(*3*) Products that have the same active ingredient or moiety.

(*4*) Dosage forms that do not provide a unique route of administration (for example, tablets and capsules versus tablets and transdermals).

(F) Point-of-sale utilization management safety edits consistent with the FDA approved label.

(G) Prior authorization requirements used to verify a drug is being used for a medically accepted indication (as defined in § 423.100) or to verify a drug is not covered under Medicare Parts A or B as prescribed and dispensed or administered.

(3) * * *

(vi) A Part D sponsor must charge cost sharing for a temporary supply of drugs provided under its transition process such that the following conditions are met:

(A) For low-income subsidy (LIS) enrollees, a sponsor must not charge higher cost sharing for transition supplies than the statutory maximum copayment amounts.

(B) For non-LIS enrollees, a sponsor must charge—

(*1*) The same cost sharing for non-formulary Part D drugs provided during the transition that would apply for non-formulary drugs approved through a formulary exception in accordance with § 423.578(b); and

(*2*) The same cost sharing for formulary drugs subject to utilization management edits provided during the transition that would apply once the utilization management criteria are met.

* * * * *

(c) * * *

(5)(i) Before January 1, 2015—

* * * * *

(ii) Beginning January 1, 2015—

(A) A Part D sponsor must deny or must require its PBM to deny a pharmacy claim for a Part D drug if an active and valid physician or eligible professional (as defined in section 1848(k)(3)(B)(i) or (ii) of the Act) National Provider Identifier is not contained on the claim.

(B) A Part D sponsor must deny or require its PBM to deny a pharmacy claim for a Part D drug if the physician or eligible professional—

(*1*) Is not enrolled in the Medicare program in an approved status; and

(*2*) Does not have a valid opt-out affidavit on file with an A/B MAC.

(C) To receive payment for a drug, a beneficiary's request for reimbursement from a Part D sponsor must be for a Part D drug that was dispensed in accordance with a prescription written by a physician or, when permitted under applicable State law, other eligible professional (as defined in section 1848(k)(3)(B)(i) or (ii) of the Act) who—

(*1*) Is identified by his or her legal name in the request; and

(*2*)(*i*) Is enrolled in Medicare in an approved status; or

(*ii*) Has a valid opt-out affidavit on file with an A/B MAC.

* * * * *

(6)(i) In order for a Part D sponsor to submit to CMS a prescription drug event record, the PDE must pertain to a claim for a Part D drug that was dispensed in accordance with a prescription written by a physician or, when permitted under applicable State law, an eligible professional (as defined in section 1848(k)(3)(B)(i) or (ii) of the Act) who is either of the following:

(A) Is enrolled in Medicare in an approved status.

(B) Has a valid opt-out affidavit on file with an A/B MAC.

(ii) To receive payment for a drug, a beneficiary's request for reimbursement from a Part D sponsor must be for a Part D drug that was dispensed in accordance with a prescription written by a physician or, when permitted, other eligible professional (as defined in section 1848(k)(3)(B)(i) or (ii) of the Act) who—

(A)(*1*) Is identified by his or her legal name in the request; and

(*2*) Is enrolled in Medicare in an approved status; or

(B) Has a valid opt-out affidavit on file with an A/B MAC.

(iii) A Part D sponsor must deny or must require its PBM to deny the following:

(A) A pharmacy claim for a drug, if the claim does not meet the requirements of paragraph (c)(6)(i) of this section.

(B) A request for reimbursement from a Medicare beneficiary for a drug, if the request does not meet the requirements of paragraph (c)(6)(ii) of this section.

* * * * *

■ 60. Section 423.126 is added to read as follows:

§ 423.126 Special access rules during disasters or emergencies.

(a) *Special access rules during disasters or emergencies.* A Part D sponsor must relax ''refill-too-soon'' (RTS) edits to allow an enrollee to obtain one early refill of each covered Part D drug he or she is taking in the event of an anticipated or actual disaster or emergency, as evidenced by a declaration of a disaster or emergency issued by an appropriate Federal, State, or local official, and it is reasonable to conclude that such disaster or emergency or preparation therefore would make it difficult for beneficiaries to obtain refills of their medications because the disaster or emergency or anticipation thereof has affected, or will affect, their ability to have timely access to their usual pharmacies.

(b) *Duration of relaxed edits.* A Part D sponsor must continue to relax the RTS edits as described in paragraph (a) of this section until the 30 days after the date of the triggering emergency or disaster declaration.

■ 61. Amend § 423.128 by revising paragraph (a)(3) and adding paragraph (g) to read as follows:

§ 423.128 Dissemination of Part D information.

* * * * *

(a) * * *

(3) At the time of enrollment, and at least annually thereafter by December 31 for the following contract year.

* * * * *

(g) *Changes in rules.* If a Part D sponsor intends to change its rules for a Part D plan, it must do all of the following:

(1) Submit the changes for CMS review under the procedures of Subpart V of this part.

(2) For changes that take effect on January 1, notify all enrollees at least 15 days before the beginning of the Annual Coordinated Election Period as defined in section 1860D–1(b)(1)(B) of the Act.

(3) Provide notice of all other changes in accordance with notice requirements as specified in Part 423.

■ 62. Amend § 423.153 by revising paragraphs (b)(4), (d)(1)(v), and (d)(2)(i) through (iii) to read as follows:

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

* * * * *

(b) * * *

(4)(i) *Daily cost sharing rate.* Subject to paragraph (b)(4)(ii) of this section, establishes a daily cost-sharing rate (as defined in § 423.100) and applies it to a prescription presented to a network pharmacy for a covered Part D drug that is dispensed for a supply less than 30 days, if the drug is in the form of a solid oral dose and may be dispensed for a supply less than 30 days under applicable law.

(ii) *Exceptions.* The requirements of paragraph (b)(4)(i) of this section do not apply to either of the following:

(A) Solid oral doses of antibiotics.

(B) Solid oral doses that are dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance.

(iii) *Cost-sharing*—(A) *Copayments.* In the case of a drug that would incur a copayment, the Part D sponsor must apply cost-sharing as calculated by multiplying the applicable daily cost-sharing rate by the days' supply actually dispensed when the beneficiary receives less than a 30 days' supply.

(B) *Coinsurance.* In the case of a drug that would incur a coinsurance percentage, the Part D sponsor must apply the coinsurance percentage for the drug to the days' supply actually dispensed.

* * * * *

(d) * * *

(1) * * *

(v) Must do both of the following:

(A) Have an outreach strategy designed to effectively engage at-risk beneficiaries enrolled in the plan.

(B) Enroll targeted beneficiaries using an opt-out method of enrollment only.

* * * * *

(2) * * *

(i) Have two or more chronic diseases. At least one of the chronic diseases must be one from the following list of core chronic diseases:

(A) Cardiovascular disease

(B) Diabetes.

(C) Dyslipidemia.

(D) Respiratory disease.

(E) Bone disease-arthritis.

(F) Mental health.

(G) Alzheimer's disease.

(H) End-stage renal disease.

(ii) Are taking two or more covered Part D drugs.

(iii) Are likely to incur annual costs for covered Part D drugs that are commensurate with the drug spending of beneficiaries with two or more chronic diseases that take two covered Part D drugs.

* * * * *

■ 62. Amend § 423.154 by:

■ A. Revising paragraphs (a)(2) and (c).

■ B. Removing paragraph (e).

■ D. Redesignating paragraph (f) as (e).

■ E. Adding a new paragraph (f).

The revisions and addition read as follows:

§ 423.154 Appropriate dispensing of prescription drugs in long-term care facilities under PDPs and MA–PD plans.

(a) * * *

(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.

* * * * *

(c) *Waivers.* CMS waives the requirements under paragraph (a) of this section for any of the following:

(1) Pharmacies when they service intermediate care facilities for the mentally retarded (ICFs/IID) and

institutes for mental disease (IMDs) as defined in § 435.1010 of this chapter.

(2) I/T/U pharmacies (as defined in § 423.100).

(3)(i) Institutional pharmacies that—

(A) Subject to paragraph (c)(3)(iii) of this section, exclusively use a dispensing technique that returns all unused medications to stock for reuse;

(B) Issues full credit of the ingredient costs of unused medication to the Part D sponsor; and

(C) For drugs that cannot be returned to stock for reuse under applicable law use a dispensing methodology that results in the delivery of no more than a 14 days' supply of a drug at a time.

(ii) The waiver in paragraph (c)(3)(i) of this section does not apply to a pharmacy organization that is contracted to use this dispensing technique at some of its pharmacies, but only to the qualifying pharmacies themselves.

* * * * *

(f) *Prohibition on proration of dispensing fees.* A Part D sponsor must not, or must require its intermediary contracting organization not to, do the following:

(1) Not penalize long-term care facilities' choice of more efficient uniform dispensing techniques described in paragraph (a)(1)(ii) of this section by prorating dispensing fees based on days' supply or quantity dispensed.

(2) Ensure that any difference in payment methodology among long-term care pharmacies incentivizes more efficient dispensing techniques.

■ 64. Amend § 423.265 as follows:

■ A. By redesignating paragraph (b)(3) as (b)(4).

■ B. By adding a new paragraph (b)(3).

■ C. In newly redesignated paragraph (b)(4), by adding a paragraph heading.

The additions read as follows:

§ 423.265 Submission of bids and related information.

* * * * *

(b) * * *

(3) *Number of bids.* Starting with bids submitted during 2015 for plans to be offered during coverage year 2016, CMS will not accept more than two bids for a coverage year from a stand-alone PDP sponsor in each PDP region.

(4) *Declining a bid.* * * *

* * * * *

■ 65. Section 423.294 is added to subpart F to read as follows:

§ 423.294 Collections of premiums and cost sharing.

(a) *Refunds of incorrect collections*—(1) *Definitions.* As used in this section the following definitions are applicable:

Amounts incorrectly collected. (i) Means amounts that exceed the monthly beneficiary Part D premium limits under § 423.286 or exceed permissible cost-sharing amounts as specified § 423.104(d) through (f); and

(ii) Includes amounts collected from an enrollee who was believed to be entitled to Medicare benefits but was later found not to be entitled.

Other amounts due means amounts due for covered Part D drugs that were—

(i) Accessed at an out-of-network pharmacy in accordance with the requirements at § 423.124; or

(ii) Initially denied but, upon appeal, found to be covered Part D drugs the enrollee was entitled to have provided by the Part D plan.

(2) *General rule.* A Part D plan must refund all amounts incorrectly collected from its Medicare enrollees, or from others on behalf of the enrollees, and to pay any other amounts due the enrollees or others on their behalf within the timeframe specified at § 423.466(a).

(3) *Refund methods*—(i) *Lump-sum payment.* The Part D plan must use lump-sum payments for the following:

(A) Amounts incorrectly collected that were not collected as premiums.

(B) Other amounts due.

(C) All amounts due if the Part D plan is going out of business or terminating its Part D contract for a prescription drug plan(s).

(ii) *Premium adjustment, lump-sum payment, or both.* If the amounts incorrectly collected were in the form of premiums, or included premiums as well as other charges, the Part D plan may refund by adjustment of future premiums or by a combination of premium adjustment and lump-sum payments.

(iii) *Refund when enrollee has died or cannot be located.* If an enrollee has died or cannot be located after reasonable effort, the Part D plan must make the refund in accordance with State law.

(4) If the Part D plan does not make the refund required under this section within the timeframe specified at § 423.466(a), the Part D plan may receive compliance notices from CMS or, depending on the significance of the non-compliance, be the subject of an intermediate sanction (for example, suspension of marketing and enrollment activities) in accordance with part 423, subpart O.

(b) *Retroactive collection of cost-sharing amounts*—(1) *General rule.* A Part D plan must make a reasonable effort to collect cost sharing from a beneficiary or to bill cost sharing to another appropriate party.

(2) *Timeframe.* Recovery efforts must be initiated in accordance with the timeframe specified at § 423.466(a).

(c) *Reduction or waiver of premiums and cost sharing*—(1) *General rule.* Part D plans, directly, or indirectly through related entities as defined at § 423.501, are prohibited from reducing or waiving the collection of enrollee premiums or cost sharing or both.

(2) *Failure to collect premiums and cost sharing.* Failure to collect premiums, collect cost sharing at the time the service is provided, or attempt to collect cost sharing from a beneficiary or to bill cost sharing to another appropriate party after the fact, is in violation of the uniform benefit provisions set forth in § 423.104(b).

■ 66. Amend § 423.308 by revising the definition of ''Actually paid'' to read as follows:

§ 423.308 Definitions and terminology.

* * * * *

Actually paid means that the costs must be actually incurred by the Part D sponsor and must be net of any direct or indirect remuneration (including discounts, incentive payments, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any source other than pharmacies (including manufacturers, enrollees, or any other person) that would serve to decrease (or increase) the costs incurred under the Part D plan.

(1) Direct and indirect remuneration includes discounts, incentive payments, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers or similar entities obtained by an intermediary contracting organization with which the Part D plan sponsor has contracted, regardless of whether the intermediary contracting organization retains all or a portion of the direct and indirect remuneration or passes the entire direct and indirect remuneration to the Part D plan sponsor and regardless of the terms of the contract between the plan sponsor and the intermediary contracting organization.

(2) Direct and indirect remuneration may include additional payments to pharmacies, such as for incentive payments, but may not include any other price concessions from pharmacies.

* * * * *

■ 67. Amend § 423.322 by revising paragraph (b) to read as follows:

§ 423.322 Requirement for disclosure of information.

* * * * *

(b) *Restrictions on use of information.* (1) Officers, employees, and contractors of the Department of Health and Human Services may use the information disclosed or obtained in accordance with the provisions of this subpart for the purposes of, and to the extent necessary—

(i) In carrying out this subpart, including, but not limited to, determination of payments, and payment-related oversight and program integrity activities.

(ii) In conducting oversight, evaluation, and enforcement under Title XVIII of the Act.

(2) The United States Attorney General and the Comptroller General of the United States may use the information disclosed or obtained in accordance with the provisions of this subpart for purposes of, and to the extent necessary in, carrying out health oversight activities.

(3) The restrictions described in paragraphs (b)(1) and (2) of this section do not limit either of the following:

(i) OIG's authority to fulfill the Inspector General's responsibilities in accordance with applicable Federal law.

(ii) CMS' ability to use data regarding drug claims in accordance with section 1848(m) of the Act.

§ 423.329 [Amended]

■ 68. Amend § 423.329 (d)(1), by removing the phrase ''the amount described in § 423.782.'' and adding in its place the phrase ''the difference between the Part D cost-sharing for a non-low-income subsidy eligible beneficiary under the Part D plan and the statutory cost-sharing for a low-income subsidy eligible beneficiary.''

■ 69. Section 423.346 is amended by revising paragraphs (a) through (c) to read as follows:

§ 423.346 Reopening.

(a) CMS may reopen an initial final payment determination (including a determination on the final amount of direct subsidy described in § 423.329(a)(1), final reinsurance payments described in § 423.329(c), the final amount of the low income subsidy described in § 423.329(d), or final risk corridor payments as described in § 423.336) one time within 5 years after the date of the notice of the initial determination to the Part D sponsors.

(b) CMS may reopen the Coverage Gap Discount Reconciliation (as described at § 423.2320 (b), one time within 5 years after the date of the notice of the Coverage Gap Discount Reconciliation to the Part D sponsors.

(c) CMS does not reopen as a result of a change in legal interpretation or administrative ruling upon which the final determination was made.

* * * * *

■ 70. Amend § 423.350 as follows:

■ A. In paragraph (a)(1)(iii), by removing ''; or'' and adding in its place ''.''.

■ B. In paragraph (a)(1)(iv), by removing '').'' adding in its place ''.''.

■ C. By adding paragraph (a)(1)(v).

■ D. By revising paragraph (a)(2).

■ E. By adding paragraph (b)(1)(iv).

§ 423.350 Payment appeals.

(a) * * *

(1) * * *

(v) The reconciled coverage gap discount payment under § 423.2320(b).

(2) *Payment information not subject to appeal.* Payment information submitted to CMS under § 423.322 and reconciled under § 423.343 or submitted and reconciled under § 423.2320(b) is final and may not be appealed nor may the appeals process be used to submit new information after the submission of information necessary to determine retroactive adjustments and reconciliations.

(b) * * *

(1) * * *

(iv) For the Coverage Gap Discount Program, the date of the final reconciled payment under § 423.2320(b).

* * * * *

■ 71. Section 423.360 is added to subpart G to read as follows:

§ 423.360 Reporting and returning of overpayments.

(a) *Definitions.* For the purposes of this section the following definitions are applicable:

Applicable reconciliation means the later of either the annual deadline for submitting—

(i) PDE data for the annual Part D payment reconciliations referred to in § 423.343(c) and (d); or

(ii) Direct and indirect remuneration data.

Funds for purposes of this section, means any payment that a Part D sponsor has received that is based on data submitted by the Part D sponsor to CMS for payment purposes, including data submitted under § 423.329(b)(3), § 423.336(c)(1), § 423.343, and data provided for purposes of supporting allowable costs as defined in § 423.308 which includes data submitted to CMS regarding direct or indirect remuneration.

Overpayment means funds that a Part D sponsor has received or retained under title XVIII of the Act to which the Part D sponsor, after applicable reconciliation, is not entitled under such title.

(b) *General rule.* If a Part D sponsor has identified that it has received an overpayment, the Part D sponsor must report and return that overpayment in the form and manner set forth in this section.

(c) *Identified overpayment.* A Part D sponsor has identified an overpayment if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the existence of the overpayment. A Part D sponsor must exercise reasonable diligence to determine the accuracy of information it receives that an overpayment may exist.

(d) *Reporting and returning of an overpayment.* A Part D sponsor must report and return any overpayment it received no later than 60 days after the date on which it identified it received an overpayment.

(1) *Reporting.* A Part D sponsor must notify CMS of the amount and reason for the overpayment, using the notification process determined by CMS.

(2) *Returning.* A Part D sponsor must return identified overpayments in a manner specified by CMS.

(3) *Enforcement.* Any overpayment retained by a Part D sponsor after the 60-day deadline for reporting and returning is an obligation under 31 U.S.C. 3729(b)(3).

(e) *Look-back period.* A Part D sponsor must report and return any overpayment identified within the 6 most recent completed payment years. Overpayments resulting from fraud would not be subject to this limitation.

■ 72. Amend § 423.464 as follows:

■ A. In paragraph (f)(2)(i) introductory text, by removing the phrase ''a Part D plan must—'' and adding in its place ''a Part D plan must do all of the following:''.

■ B. In paragraph (f)(2)(i)(A), by removing ''; and'' and adding in its place ''.''.

■ C. By adding paragraph (f)(2)(i)(C).

The addition reads as follows:

§ 423.464 Coordination of benefits with other providers of prescription drug coverage.

* * * * *

(f) * * *

(2) * * *

(i) * * *

(C) Report, accept and apply benefit accumulator data in a timeframe and manner determined by CMS.

* * * * *

§ 423.466 [Amended]

■ 73. Amend § 423.466(b) by removing the phrase ''a period not to exceed 3 years'' and adding in its place the phrase ''a period of 3 years''.

■ 74. Amend § 423.501 by a adding a definition for ''prescription drug pricing standard'' to read as follows:

§ 423.501 Definitions.

* * * * *

Prescription drug pricing standard means any methodology or formula for varying the pricing of a drug or drugs during the term of a pharmacy reimbursement contract that is based on the cost of a drug, which includes, but is not limited to, drug pricing references and amounts based on any of the following:

(1) Average wholesale price.

(2) Wholesale average cost.

(3) Average manufacturer price.

(4) Average sales price.

(5) Maximum allowable cost.

(6) Other cost, whether publicly available or not.

* * * * *

■ 75. Amend § 423.503 by revising paragraph (a)(1) and adding paragraphs (a)(3), (c)(4), and (d) to read as follows:

§ 423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.

(a) * * *

(1) With the exception of evaluations conducted under paragraph (b) of this section, CMS evaluates an entity's application solely on the basis of information contained in the application itself and any additional information that CMS obtains through on-site visits and an essential operations test.

* * * * *

(3) CMS may not approve an application when it would result in the applicant's parent organization, directly or through its subsidiaries, holding more than one PDP sponsor contract in the PDP Region for which the applicant is seeking qualification as a PDP sponsor. A parent organization is an entity that exercises a controlling interest in the applicant.

* * * * *

(c) * * *

(4) *Nullification of approval of application.* If CMS discovers through any means that an applicant is not qualified to contract based on information gained subsequent to application approval (for example, failure of an essential operations test, absence of required employees), CMS gives the applicant written notice indicating that the approval issued under § 423.503(c)(1) is nullified and the applicant no longer qualifies to contract as a Part D plan sponsor.

(i) This determination is not subject to the appeals provisions in subpart N of this part.

(ii) This provision only applies to applicants that have not previously entered into a Part D contract with CMS and neither it, nor another subsidiary of the applicant's parent organization, is offering Part D benefits during the current year.

(d) Withdrawal of application and bid in a previous year. An applicant that withdraws its application and corresponding bid after the release of the low income subsidy benchmark is not eligible to be approved as a Part D plan sponsor for the 2 succeeding annual contracting cycles.

■ 76. Amend § 423.504 as follows:

■ A. By adding paragraphs (b)(4)(vi)(C)(*4*) and (b)(8) through (10).

■ B. In paragraph (d)(2) introductory text, by removing the phrase ''has the right to—'' and adding in its place the phrase ''has the right to timely do all of the following:''.

■ C. In paragraph (d)(2)(i), by removing ''; '' and adding in its place a ''.''.

■ D. In paragraph (d)(2)(ii), by removing ''; and'' and adding in its place a ''.''.

■ E. By adding paragraph (d)(2)(iv).

The additions read as follows:

§ 423.504 General provisions.

* * * * *

(b) * * *

(4) * * *

(vi) * * *

(C) * * *

(*4*) A Part D plan sponsor must require all of its first tier, downstream and related entities to take the CMS training and accept the certificate of completion of the CMS training as satisfaction of this requirement. Part D plan sponsors are prohibited from developing and implementing their own training or providing supplemental training materials to fulfill this requirement.

* * * * *

(8) If neither the applicant, nor its parent or another subsidiary of the same parent, holds a Part D sponsor contract that has been in effect for at least 1 year at the time it submits an application, the applicant must have arrangements in place such that the applicant and its contracted first tier, downstream, or related entities, in combination, have at least 1 full-benefit year of experience within the 2 years preceding the application submission performing at a minimum all of the following functions in support of the operation of another Part D contract:

(i) Authorization, adjudication, and processing of prescription drug claims at the point of sale.

(ii) Administration and tracking of enrollees' drug benefits in real time, including automated coordination of benefits with other payers.

(iii) Operation of an enrollee appeals and grievance process.

(9) For organizations applying to offer stand-alone prescription drug plans, the organization, its parent, or a subsidiary of the organization or its parent, must have either of the following:

(i) For 2 continuous years immediately prior to submitting an application, actively offered health insurance or health benefits coverage, including prescription drug coverage, as a risk-bearing entity in at least one State.

(ii) For 5 continuous years immediately prior to submitting an application, actively managed prescription drug benefits for an organization that offers health insurance or health benefits coverage, including at a minimum, all of the services listed in paragraph (b)(8) of this section.

(10) Effective contract year 2015, pass an essential operations test prior to the start of the benefit year. This provision only applies to new sponsors that have not previously entered into a Part D contract with CMS when neither it, nor another subsidiary of the applicant's parent organization, is offering Part D benefits during the current year.

* * * * *

(d) * * *

(2) * * *

(iv) CMS may require that the Part D Plan sponsor hire an independent auditor to conduct full or partial program audits or to provide CMS with information to determine if deficiencies found during an audit or inspection have been corrected and are not likely to recur. The independent auditor must work in accordance with CMS specifications and must be willing to attest that a complete and full independent review has been performed.

* * * * *

■ 77. Amend § 423.505 as follows:

■ A. By revising paragraphs (b)(18) and (21).

■ B. By adding paragraphs (b)(27) and (28).

■ C. In paragraph (f)(3)(v), by removing '','' and adding in its place ''.''.

■ D. In paragraph (f)(3)(vi), by removing ''; and'' and adding in its place ''.''.

■ E. By adding paragraph (f)(3)(viii).

■ F. In paragraph (i)(2)(i), by removing the phrase ''audit, evaluate and inspect'' and adding in its place ''audit, evaluate, collect, and inspect''.

■ G. By redesignating paragraph (i)(2)(ii) as paragraph (i)(2)(iii).
■ H. By adding a new paragraph (i)(2)(ii).
■ I. By revising paragraph (i)(3)(viii).
■ J. By adding paragraph (k)(7).
■ K. By adding a paragraph (m) subject heading.
■ L. By revising paragraphs (m)(1)(iii) introductory text, (m)(1)(iii)(A) and (B).
■ M. By removing paragraph (m)(1)(iii)(C).
■ N. By redesignating (m)(1)(iii)(D) as paragraph (m)(1)(iii)(C).
■ O. By revising newly redesignated (m)(1)(iii)(C)(*1*) and (3).
■ P. By revising paragraph (m)(3).
■ Q. By adding paragraph (p).

The revisions and additions read as follows:

§ 423.505 Contract provisions.

* * * * *

(b) * * *

(18) To agree to have standard contracts that meet the requirements described in § 423.120(a)(8) with reasonable and relevant terms and conditions of participation for each type of pharmacy in its network whereby any willing pharmacy may access all relevant contract(s) to participate as a network pharmacy.

* * *

(21)(i) Update any prescription drug pricing standard (as defined in § 423.501) based on the cost of the drug used for reimbursement of network pharmacies by the Part D sponsor on January 1 of each contract year and not less frequently than once every 7 days thereafter;

(ii) Indicate the source used for making any such updates; and

(iii) Disclose all individual drug prices to be updated to the applicable pharmacies in advance of their use for reimbursement of claims, if the source for any prescription drug pricing standard is not publicly available.

* * * * *

(27) A Part D sponsor is required to administer a Part D Benefit that provides good quality health care demonstrated by scores of three or higher on CMS performance standards for patient outcomes, intermediate outcomes, process, patient experience, and patient access to care.

(28) Effective contract year 2015, pass an essential operations test prior to the start of the benefit year. This provision only applies to new sponsors that have not previously entered into a Part D contract with CMS and neither it, nor another subsidiary of the applicant's parent organization, is offering Part D benefits during the current year.

* * * * *

(f) * * *

(3) * * *

(viii) Supporting program integrity purposes, including coordination with the States.

* * * * *

(i) * * *

(2) * * *

(ii) HHS, the Comptroller General or their designees have the right to audit, evaluate, collect, and inspect any records under (i)(2)(i) directly from any first tier, downstream, or related entity.

* * * * *

(3) * * *

(viii) If applicable, provisions addressing the drug pricing standard requirements of § 423.505(b)(21).

* * * * *

(k) * * *

(7) *Certification of accuracy of data for overpayments.* The CEO, CFO, or COO must certify (based on best knowledge, information, and belief) that the information provided for purposes of reporting and returning of overpayments under § 423.360 is accurate, complete, and truthful.

* * * * *

(m) *Release of data.*

(1) * * *

(iii) Subject, in certain cases, to encryption of beneficiary identifiers and aggregation of cost data to protect beneficiary confidentiality and commercially sensitive data of Part D sponsors, in accordance with all of the following principles:

(A) Subject to the restrictions in this paragraph, all elements on the claim are available to HHS, other executive branch agencies, and the States.

(B) Cost data elements on the claim generally are aggregated for releases to other executive branch agencies, States, and external entities. Upon request, CMS excludes sales tax from the aggregation at the individual level if necessary for the project.

(C) * * *

(*1*) Beneficiary identifier elements on the claim generally are encrypted for release, except in limited circumstances, such as the following:

(*i*) If needed, in the case of release to other HHS entities, Congressional oversight agencies, non-HHS executive agencies and the States.

(*ii*) If needed to link to another dataset, in the case of release to external entities. Public disclosure of research results will not include beneficiary identifying information.

* * * * *

(3)(i) CMS must make available to Congressional support agencies (the Congressional Budget Office, the Government Accountability Office, the Medicare Payment Advisory Commission, and the Congressional Research Service when it is acting on behalf of a Congressional committee in accordance with 2 U.S.C. 166(d)(1)), all information collected under paragraph (f)(3) of this section for the purposes of conducting congressional oversight, monitoring, making recommendations, and analysis of the Medicare program.

(ii) The Congressional Research Service is considered an external entity when it is not acting on behalf of a Congressional committee in accordance with 2 U.S.C. 166(d)(1) for the purposes of paragraph (m)(1) of this section.

* * * * *

(p) *Business continuity.* (1) The Part D sponsor agrees to develop, maintain, and implement a business continuity plan containing policies and procedures to ensure the continuation of business operations during disruptions to business operations which would include natural or man-made disasters, system failures, emergencies, and other similar circumstances and the threat of such occurrences. To meet the requirement, the business continuity plan must, at a minimum, include the following:

(i) *Risk assessment.* Identify threats and vulnerabilities that might affect business operations.

(ii) *Mitigation strategy.* Design strategies to mitigate hazards. Identify essential functions in addition to those specified in paragraph (p)(2) of this section and prioritize the order in which to restore all other functions to normal operations. At a minimum, each Part D sponsor must do the following:

(A) Identify specific events that will activate the business continuity plan.

(B) Develop a contingency plan to maintain, during any business disruption, the availability and, as applicable, confidentiality of communication systems and essential records in all forms (including electronic and paper copies). The contingency plan must do the following:

(*1*) Ensure that during any business disruption the following systems will operate continuously or, should they fail, be restored to operational capacity on a timely basis:

(*i*) Information technology IT systems including those supporting claims processing at point of service.

(*ii*) Provider and enrollee communication systems including telephone, Web site, and email.

(*2*) With respect to electronic protected health information, comply with the contingency plan requirements of the Health Insurance Portability and Accountability Act of 1996 Security

Regulations at 45 CFR 160 and 164, Subparts A and C.

(C) Establish a chain of command.

(D) Establish a business communication plan that includes emergency capabilities and procedures to contact and communicate with the following:

(*1*) Employees.

(*2*) First tier, downstream, and related entities.

(*3*) Other third parties (including pharmacies, providers, suppliers, and government and emergency management officials).

(E) Establish employee and facility management plans to ensure that essential operations and job responsibilities can be assumed by other employees or moved to alternate sites as necessary or both.

(F) Establish a restoration plan including procedures to transition to normal operations.

(G) Comply with all applicable Federal, State, and local laws.

(iii) *Testing and revision.* On at least an annual basis, test and update the business operations continuity plan to ensure the following:

(A) That it can be implemented in emergency situations.

(B) That employees understand how it is to be executed.

(iv) *Training.* On at least an annual basis, educate all new and existing employees about the business continuity plan and their own respective roles.

(v) *Records.* (A) Develop and maintain records documenting the elements of the business continuity plan described in paragraph (p)(1)(i) through (p)(1)(iv) of this section.

(B) Make the information specified in paragraph (p)(1)(v)(A) of this section available to CMS upon request.

(2) *Restoration of essential functions.* Every Part D sponsor must restore essential functions within 24 hours after any of the essential functions fail or otherwise stop functioning as usual. In addition to any essential functions that the Part D sponsor identifies under paragraph (p)(1)(ii) of this section, for purposes of this paragraph (p)(2) of this section essential functions include at a minimum, the following:

(i) Benefit authorization (if not waived), adjudication, and processing of prescription drug claims at the point of sale.

(ii) Administration and tracking of enrollees' drug benefits in real time, including automated coordination of benefits with other payers.

(iii) Provision of pharmacy technical assistance.

(iv) Operation of an enrollee exceptions and appeals process including coverage determinations.

(v) Operation of call center customer services.

■ 78. Amend § 423.509 as follows:

■ A. By redesignating paragraphs (a)(4) through (a)(14) as paragraphs (a)(4)(i) through (a)(4)(xi).

■ B. By adding paragraph (a)(4) introductory text.

■ C. In newly redesignated paragraphs (a)(4)(ii), (iv), (v) introductory text, (vi), and (vii), by removing the term ''fails'' and adding in its place the term ''failed''.

■ D. In newly redesignated paragraphs (a)(4)(iii), (viii), and (ix), by removing the term ''fails'' and adding in its place the term ''failed''.

■ E. By revising newly redesignated paragraphs (a)(4)(x) and (xi).

■ F. By adding paragraph (a)(4)(xii).

■ G. By revising paragraphs (b)(1)(i) through (iv) and (b)(2)(i)(C).

■ H. In paragraph (b)(2)(ii), by removing the phrase ''MA organization'' and adding in its place the phrase ''Part D plan sponsor''.

■ I. In paragraph (c)(2)(iii), by removing the cross-reference ''(a)(4) of this section'' and adding in its place the cross-reference ''(a)(4)(i) of this section''.

■ J. In paragraph (d), by removing the cross-reference ''§ 423.642'' and adding in its place the cross-reference ''subpart N of this part''.

The additions and revisions read as follows:

§ 423.509 Termination of a contract by CMS.

(a) * * *

(4) CMS may make a determination under paragraph (a)(1), (2) or (3) of this section if the Part D Plan sponsor has had one or more of the following occur:

* * * * *

(x) Achieves a Part D summary plan rating of less than 3 stars for 3 consecutive contract years. Plan ratings issued by CMS before September 1, 2012 are not included in the calculation of the 3-year period.

(xi)(A) Has failed to report MLR data in a timely and accurate manner in accordance with § 423.2460; or

(B) That any MLR data required by this subpart is found to be materially incorrect or fraudulent.

(xii) Failure of an essential operations test before the start of the benefit year by an organization that has entered into a Part D contract with CMS when neither it, nor another subsidiary of the organization's parent organization, is offering Part D benefits during the current year.

* * * * *

(b) * * *

(1) * * *

(i) CMS notifies the Part D plan sponsor in writing at least 45 calendar days before the intended date of the termination.

(ii) The Part D plan sponsor notifies its Medicare enrollees of the termination by mail at least 30 calendar days before the effective date of the termination.

(iii) The Part D plan sponsor notifies the general public of the termination at least 30 calendar days before the effective date of the termination by releasing a press statement to news media serving the affected community or county and posting the press statement prominently on the organization's Web site.

(iv) CMS notifies the general public of the termination no later than 30 calendar days after notifying the plan of CMS's decision to terminate the Part D plan sponsor's contract by releasing a press statement.

(2) * * *

(i) * * *

(C) The contract is being terminated based on the grounds specified in paragraphs (a)(4)(i) and (xii) of this section.

* * * * *

§ 423.562 [Amended]

■ 79. Amend § 423.562(a)(3) by removing the phrase ''request an exception if they disagree with the information provided by the pharmacist.'' and adding in its place the phrase ''request an exception.''.

§ 423.642 [Amended]

■ 80. Amend § 423.642(c)(1) by removing the phrase ''90 calendar days'' and adding in its place ''45 calendar days''.

§ 423.650 [Amended]

■ 81. Amend § 423.650 as follows:

■ A. In paragraph (a)(2), by removing the term ''under'' and adding in its place the phrase ''in accordance with''.

■ B. In paragraph (a)(4), by removing the cross-reference ''§ 423.752(a) and (b)'' and adding in its place the cross-reference ''§ 423.752(a) and (b)''.

■ 82. Amend § 423.752 as follows:

■ A. By adding paragraphs (a)(7) through (10).

■ B. By revising paragraph (c)(1).

■ C. In paragraph (c)(2)(ii), by removing the phrase ''pursuant to 423.509(a)(4)'' and adding in its place the phrase ''pursuant to § 422.510(a)(4)(i)''.

The additions and revision read as follows:

§ 423.752 Basis for imposing intermediate sanctions and civil money penalties

* * * * *

(a) * * *

(7) Except as provided under § 423.34, enrolls an individual in any plan under this part without the prior consent of the individual or the designee of the individual.

(8) Transfers an individual enrolled under this part from one plan to another without the prior consent of the individual or the designee of the individual or solely for the purpose of earning a commission.

(9) Fails to comply with marketing restrictions described in subpart V or applicable implementing guidance.

(10) Employs or contracts with any individual, agent, provider, supplier or entity who engages in the conduct described in paragraphs (a)(1) through (9) of this section.

* * * * *

(c) * * *

(1) *CMS.* In addition to, or in place of, any intermediate sanctions, CMS may impose civil money penalties in the amounts specified in either of the following:

(i) Section 423.760(b) for any of the determinations at § 423.509(a), except § 423.509(a)(4)(i).

(ii) Section 423.760(c) for any of the determinations in paragraph (a) of this section except § 422.752(a)(5).

* * * * *

■ 83. Amend § 423.756 as follows:

■ A. In paragraph (a)(2), by removing the phrase ''days from receipt'' and adding in its place ''days after receipt''.

■ B. In paragraph (b)(4), by removing the cross-reference ''§ 423.650 through § 423.662 of this part.'' and adding in its place ''Subpart N of this part.''.

■ C. In paragraph (c)(3)(ii) introductory text, by removing the phrase ''In instances where marketing or enrollment or both intermediate sanctions have been imposed,'' and adding in its place the phrase ''In instances where intermediate sanctions have been imposed,''.

■ D. Adding paragraph (c)(3)(ii)(C).

■ E. Revising paragraph (d).

The addition and revision read as follows:

§ 423.756 Procedures for imposing intermediate sanctions and civil money penalties.

* * * * *

(c) * * *

(3) * * *

(ii) * * *

(C) During the limited time period, sanctioned Part D plan sponsors under the benchmark that would normally participate in the annual and monthly auto enrollment process for enrollees receiving the low income subsidy will not be allowed to receive or process these types of enrollments.

(d) *Non-renewal or termination by CMS.* In addition to or as an alternative to the sanctions described in § 423.750, CMS may decline to authorize the renewal of an organization's contract in accordance with § 423.507(b), or terminate the contract in accordance with § 423.509.

* * * * *

■ 84. Amend § 423.760 as follows:

■ A. In paragraph (a) introductory text, by removing the phrase ''under 423.752(c)(1), CMS will consider as appropriate:'' and adding in its place the phrase ''under § 423.752(c)(1), CMS considers the following as appropriate:''.

■ B. In paragraphs (a)(1) and (2), by removing ''; '' and adding in its place ''.''.

■ C. Revising paragraph (a)(3).

■ D. In paragraph (a)(4) by removing ''; '' and adding in its place ''.''.

■ E. In paragraph (a)(5), by removing ''; and'' and adding in its place ''.''.

■ F. Adding paragraph (c).

The revision and addition read as follows:

§ 423.760 Determinations regarding the amount of civil money penalties and assessment imposed by CMS.

(a) * * *

(3) The adverse effect to enrollees which resulted or could have resulted from the conduct of the Part D sponsor.

* * * * *

(c) *Amount of penalty imposed by CMS or OIG.* CMS or the OIG may impose civil money penalties in the following amounts for a determination made under § 423.752(a):

(1) Civil money penalties of not more than $25,000 for each determination made.

(2) With respect to a determination made under § 423.752(a)(4) or 423.752(a)(5)(i), not more than $100,000 for each such determination except with respect to a determination made under § 423.752(a)(5), an assessment of not more than the amount claimed by such plan or PDP sponsor based upon the misrepresentation or falsified information involved.

(3) Plus with respect to a determination made under § 423.752(a)(2), double the excess amount charged in violation of such paragraph (and the excess amount charged must be deducted from the penalty and returned to the individual concerned).

(4) Plus with respect to a determination made under § 423.752(a)(4), $15,000 for each individual not enrolled as a result of the practice involved.

■ 85. Amend § 423.882 by revising the definition of ''Actually paid'' to read as follows:

§ 423.882 Definitions.

* * * * *

Actually paid means that the costs must be actually incurred by the qualified retiree prescription drug plan and must be net of any direct or indirect remuneration (including discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any manufacturer or similar entity that would serve to decrease the costs incurred under the qualified retiree prescription drug plan.

* * * * *

■ 86. Amend § 423.1016 by revising the first sentence in paragraph (b)(1) to read as follows:

§ 423.1016 Filing of briefs with the Administrative Law Judge or Departmental Appeals Board, and opportunity for rebuttal.

* * * * *

(b) * * *

(1) The other party will have 20 calendar days from the date of mailing or in person filing to submit any rebuttal statement or additional evidence. * * *

* * * * *

■ 87. Amend § 423.1020 by revising paragraph (a)(2) to read as follows:

§ 423.1020 Request for hearing.

(a) * * *

(2) The Part D sponsor or its legal representative or other authorized official must file the request, in writing, to the appropriate Departmental Appeals Board office, with a copy to CMS, within 60 calendar days after receipt of the notice of initial determination, to request a hearing before an ALJ to appeal any determination by CMS to impose a civil money penalty.

* * * * *

■ 88. Amend § 423.2262 by adding paragraph (a)(2) to read as follows:

§ 423.2262 Review and distribution of marketing materials.

(a) * * *

(2) If CMS does not approve or does not disapprove marketing materials within the specified review timeframe, the materials are deemed approved and the Part D sponsor may use the material.

* * * * *

§ 423.2266 [Removed and Reserved]

■ 89. Section 423.2266 is removed and reserved.

■ 90. Amend § 423.2274 by:
■ A. Revising the introductory text.
■ B. Redesignating paragraphs (a) through (f) as (b) through (g).
■ C. Adding new paragraph (a).
■ D. Revising newly redesignated paragraphs (b) through (d).
■ E. Adding paragraph (h).

The revisions and additions read as follows:

§ 423.2274 Broker and agent requirements.

If a Part D sponsor uses agents and brokers to sell its Part D plans, the following requirements in this section are applicable.

(a) *Definitions.* For purposes of this section, the following definitions are applicable:

Compensation (1) Includes monetary or non-monetary remuneration of any kind relating to the sale or renewal of a policy including, but not limited to—

(i) Commissions;

(ii) Bonuses;

(iii) Gifts;

(iv) Prizes or Awards; or

(v) Referral or Finder fees.

(2) Does not include—

(i) Payment of fees to comply with State appointment laws, training, certification, and testing costs;

(ii) Reimbursement for mileage to, and from, appointments with beneficiaries; or

(iii) Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

Like plan type means one of the following:

(1) PDP replaced with another PDP.

(2) MA or MA–PD replaced with another MA or MA–PD.

(3) Cost plan replaced with another cost plan.

Unlike plan type means one of the following:

(1) PDP replaced with a MA–PD or a MA–PD replaced with a PDP

(2) PDP replaced with a cost plan or a cost plan replaced with a PDP

(3) MA–PD replaced with a cost plan or a cost plan replaced with a MA–PD

Plan year means the year beginning January 1 and ending December 31.

Renewal year means all years following the initial enrollment year in a like plan type.

(b) *Compensation rules.* An Part D sponsor must compensate independent brokers and agents, if compensation is paid, only according to the following rules in this section.

(1) *Compensation amounts.* (i) For an initial year enrollment of a Medicare beneficiary into a Part D plan, the compensation must be at or below the fair market value of such services, published annually as a cut-off amount by CMS.

(ii) For renewal years, compensation may be up to 35 percent of the current fair market value cut-off amounts published annually by CMS.

(2) *Aggregate compensation.* (i) An entity must not provide aggregate compensation to its agents or brokers greater than the renewal compensation payable by the replacing plan on renewal policies if an existing policy is replaced with a like plan at any time.

(ii) An agent or broker must not receive aggregate compensation greater than the renewal compensation payable by the replacing plan on renewal policies if an existing policy is replaced with a like plan type at any time.

(iii) The initial compensation is paid for replacements between unlike plan types.

(3) *Compensation payment and payment recovery.* (i) Compensation may only be paid for the enrollee's months of enrollment during a plan year.

(ii)(A) Subject to paragraph (b)(3)(iii) of this section, compensation payments may be made at one time for the entire current plan year or in installments throughout the year.

(B) Compensation may not be paid until January 1 of the compensation year and, if paid at all, must be paid in full by December 31 of the compensation year.

(iii) When a beneficiary disenrolls from an MA plan, compensation paid to agents and brokers must be recovered for those months of the plan year for which the beneficiary is not enrolled. For disenrollments occurring within the first 3 months, the entire compensation must be recovered when the disenrollment was the result of agent or broker behavior.

(4) *Compensation structure.* (i) A Part D sponsor must establish a compensation structure for new and replacement enrollments and renewals effective in a given plan year. Compensation structures must be in place by the beginning of the plan marketing period, October 1.

(ii) Compensation structures must be available upon CMS request including for audits, investigations, and to resolve complaints.

(c) *Annual training.* The Part D sponsor must ensure that all agents and brokers selling Medicare products are trained annually on the following:

(1) Medicare rules and regulations.

(2) Details specific to the plan products they intend to sell.

(d) *Annual testing.* The Part D sponsor must ensure that all agents and brokers selling Medicare products are tested annually, to ensure the following:

(1) Appropriate knowledge and understanding of Medicare rules and regulations.

(2) Details specific to the plan products they intend to sell.

* * * * *

(h) *Finder's (referral) fees.* Finder's (referral) fees paid to all agents and brokers—

(1) May not exceed an amount CMS determines could reasonably be expected to affect enrollee behavior while not exceeding the value of the health-related service or activity itself; and

(2) Must be included in the total compensation not to exceed the fair market value for that calendar year.

■ 91. Amend § 423.2320 by adding paragraph (c) to read as follows:

§ 423.2320 Payment processes for Part D sponsors.

* * * * *

(c) In the event that a manufacturer declares bankruptcy, as described in Title 11 of the United States Code and, as a result of the bankruptcy, does not pay the quarterly invoices described in § 423.2315(b)(10) by the time of the Coverage Gap Discount Reconciliation described in paragraph (b) of this section, CMS adjusts the Coverage Gap Discount Reconciliation amount of each of the affected Part D sponsors to account for the total unpaid quarterly invoiced amount owed to each of the Part D sponsors in the contract year being reconciled.

■ 92. Amend § 423.2325 by adding paragraph (h) to read as follows:

§ 423.2325 Provision of applicable discounts.

* * * * *

(h) *Treatment of employer group waiver plans.* (1) Beginning 2014, Part D sponsors offering employer group waiver plans must provide applicable discounts to employer group waiver plan enrollees as determined consistent with the defined standard benefit.

(2)(i) Part D sponsors offering employer group waiver plans must report to each employer or union group client projected and actual aggregate manufacturer payments attributable to the EGWPs enrollees, at least annually or upon request.

(ii) CMS may request documentation that notice as described in paragraph (h)(2)(i) of this section has been provided by the Part D sponsor and received by the employer or union group.

Subpart Y [Reserved]

■ 93. Part 423 is amended by adding reserved subpart Y.

■ 94. Part 423 is amended by adding subpart Z to read as follows:

Subpart Z—Recovery Audit Contractor Part C Appeals Process

Sec.

Subpart Z—Recovery Audit Contractor Part C Appeals Process

§ 423.2600 Payment appeals.

If the Part D RAC did not apply its stated payment methodology correctly, a Part D plan sponsor may appeal the findings of the applied methodology. The payment methodology itself is not subject to appeal.

§ 423.2605 Request for reconsideration.

(a) *Time for filing a request.* The request for reconsideration must be filed with the designated independent reviewer within 60 calendar days from the date of the demand letter received by the Part D plan sponsor.

(b) *Content of request.* (1) The request for reconsideration must be in writing and specify the findings or issues with which the Part D plan sponsor disagrees.

(2) The Part D plan sponsor must include with its request all supporting documentary evidence it wishes the independent reviewer to consider.

(i) This material must be submitted in the format requested by CMS.

(ii) Documentation, evidence, or substantiation submitted after the filing of the reconsideration request will not be considered.

(c) *CMS Rebuttal.* CMS may file a rebuttal to the Part D plan sponsor's reconsideration request.

(1) The rebuttal must be submitted within 30 calendar days of the review entity's notification to CMS that it has received the Part D plan sponsor's reconsideration request.

(2) CMS sends its rebuttal to the Part D plan sponsor at the same time it is submitted to the independent reviewer.

(d) *Review entity.* An independent reviewer conducts the reconsideration. The independent reviewer reviews the demand for repayment, the evidence and findings upon which it was based, and any evidence that the Part D plan sponsor or CMS submitted in accordance with this section.

(e) *Notification of decision.* The independent reviewer informs CMS and the Part D plan sponsor of its decision in writing.

(f) *Effect of decision.* A reconsideration decision is final and binding unless the Part D plan sponsor requests a hearing official review in accordance with § 423.2610.

(g) *Right to hearing official review.* A Part D plan sponsor that is dissatisfied with the independent reviewer's reconsideration decision is entitled to a hearing official review as provided in § 423.2610.

§ 423.2610 Hearing official review.

(a) *Time for filing a request.* A Part D plan sponsor must file with CMS a request for a hearing official review within 15 calendar days from the date of the independent reviewer's issuance of a determination.

(b) *Content of the request.* (1) The request must be in writing and must provide evidence or reasons or both to substantiate the request.

(2) The Part D plan sponsor must submit with its request all supporting documentation, evidence, and substantiation that it wants to be considered.

(3) No new evidence may be submitted.

(4) Documentation, evidence, or substantiation submitted after the filing of the request will not be considered.

(c) *CMS rebuttal.* CMS may file a rebuttal to the Part D plan sponsor's hearing official review request.

(1) The rebuttal must be submitted within 30 calendar days of the Part D plan sponsor's submission of its hearing official review request.

(2) CMS sends its rebuttal to the Part D plan sponsor at the same time it is submitted to the hearing official.

(d) *Conducting a review.* A CMS-designated hearing official conducts the hearing on the record.

(1) The hearing is not to be conducted live or via telephone unless the hearing official, in his or her sole discretion, requests a live or telephonic hearing.

(2) In all cases, the hearing official's review is limited to information that meets one or more of the following:

(i) The Part D RAC used in making its determinations.

(ii) The independent reviewer used in making its determinations.

(iii) The Part D plan sponsor submits with its hearing request.

(iv) CMS submits in accordance with paragraph (c) of this section.

(3) Neither the Part D plan sponsor nor CMS may submit new evidence.

(e) *Hearing official decision.* The CMS hearing official decides the case within 60 days and sends a written decision to the Part D plan sponsor and CMS, explaining the basis for the decision.

(f) *Effect of hearing official decision.* The hearing official's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with § 423.2610.

§ 423.2615 Review by the Administrator.

(a) *Request for review by Administrator.* If a Part D plan sponsor is dissatisfied with the hearing official's decision, it may request that the CMS Administrator review the decision.

(1) The request must be filed with the CMS Administrator within 15 calendar days of the date of the hearing official's decision.

(2) The request must provide evidence or reasons to substantiate the request.

(b) *Content of request.* The Part D plan sponsor must submit with its request all supporting documentation, evidence, and substantiation that it wants to be considered.

(1) Documentation, evidence, or substantiation submitted after the filing of the request will not be considered.

(2) Neither the Part D plan sponsor nor CMS may submit new evidence.

(c) *Discretionary review.* After receiving a request for review, the CMS Administrator has the discretion to review the hearing official's decision in accordance with paragraph (e) of this section or to decline to review said decision.

(d) *Notification of decision whether to review.* The CMS Administrator notifies the Part D plan sponsor within 45 days of receiving the Part D plan sponsor's hearing request of whether he or she intends to review the hearing official's decision. If the Administrator agrees to review the hearing official's decision, CMS may file a rebuttal statement within 30 days of the Administrator's notice to the plan sponsor that the request for review has been accepted. CMS sends its rebuttal statement to the plan sponsor at the same time it is submitted to the Administrator. If the CMS Administrator declines to review the hearing official's decision, the hearing official's decision is final and binding.

(e) *Administrator review.* If the CMS Administrator agrees to review the hearing official's decision, he or she determines, based upon this decision, the hearing record, and any arguments submitted by the Part D plan sponsor or CMS in accordance with this section, whether the determination should be upheld, reversed, or modified. The CMS Administrator furnishes a written decision, which is final and binding, to the Part D plan sponsor and to CMS.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 95. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 96. Amend § 424.530 by adding paragraph (a)(11) to read as follows:

§ 424.530 Denial of enrollment in the Medicare program.

(a) * * *

(11) *Prescribing authority.* (i) A physician or eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration to dispense a controlled substance is currently suspended or revoked; or

(ii) The applicable licensing or administrative body for any State in which a physician or eligible professional practices has suspended or revoked the physician or eligible professional's ability to prescribe drugs, and such suspension or revocation is in effect on the date physician or eligible professional submits his or her enrollment application to the Medicare contractor.

* * * * *

■ 97. Amend § 424.535 by revising the section heading and adding paragraphs (a)(13) and (14) to read as follows:

§ 424.535 Revocation of enrollment in the Medicare program.

(a) * * *

(13) *Prescribing authority.* (i) The physician or eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration is suspended or revoked; or

(ii) The applicable licensing or administrative body for any state in which the physician or eligible professional practices suspends or revokes the physician or eligible professional's ability to prescribe drugs.

(14) *Improper prescribing practices.* CMS determines that the physician or eligible professional has a pattern or practice of prescribing Part D drugs that falls into one of the following categories:

(i) The pattern or practice is abusive and represents a threat to the health and safety of Medicare beneficiaries. In making this determination, CMS considers the following factors:

(A) Whether there are diagnoses to support the indications for which the drugs were prescribed.

(B) Whether there are instances when the necessary evaluation of the patient for whom the drug was prescribed could not have occurred (for example, the patient was deceased or out of state at the time of the alleged office visit).

(C) Whether the physician or eligible professional has prescribed controlled substances in excessive dosages that are linked to patient overdoses.

(D) The number and type(s) of disciplinary actions taken against the physician or eligible professional by the licensing body or medical board for the State or States in which he or she practices, and the reason(s) for the action(s).

(E) Whether the physician or eligible professional has any history of ''final adverse actions'' (as that term is defined in § 424.502).

(F) The number and type(s) of malpractice suits that have been filed against the physician or eligible professional related to prescribing that have resulted in a final judgment against the physician or eligible professional or in which the physician or non-physician practitioner has paid a settlement to the plaintiff(s) (to the extent this can be determined).

(G) Whether any State Medicaid program or any other public or private health insurance program has restricted, suspended, revoked, or terminated the physician or eligible professional's ability to prescribe medications, and the reason(s) for any such restriction, suspension, revocation, or termination.

(H) Any other relevant information provided to CMS.

(ii) The pattern or practice of prescribing fails to meet Medicare requirements. In making this determination, CMS considers the following factors:

(A) Whether the physician or eligible professional has a pattern or practice of prescribing without valid prescribing authority.

(B) Whether the physician or eligible professional has a pattern or practice of prescribing for controlled substances outside the scope of the prescriber's DEA registration.

(C) Whether the physician or eligible professional has a pattern or practice of prescribing drugs for indications that were not medically accepted—that is, for indications neither approved by the FDA nor medically accepted under section 1860D–2(e)(4) of the Act— and whether there is evidence that the physician or eligible professional acted in reckless disregard for the health and safety of the patient.

* * * * *

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

Dated: October 21, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Dated: December 11, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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