



FEDERAL REGISTER

Vol. 79

Friday,

No. 100

May 23, 2014

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, 423, *et al.*

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, 423, and 424

[CMS-4159-F]

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: Final rule.

SUMMARY: The final rule will revise the Medicare Advantage (MA) program (Part C) regulations and prescription drug

benefit program (Part D) regulations to implement statutory requirements; improve program efficiencies; and clarify program requirements. The final rule also includes several provisions designed to improve payment accuracy.

DATES: Effective Dates: These regulations are effective on July 22, 2014 except for the amendment in instruction 27 to § 423.100, the amendment in instruction 30 to § 423.501, and the amendment in instruction 34 to § 423.505, which are effective on January 1, 2016.

Applicability Dates: In the **SUPPLEMENTARY INFORMATION** section of this final rule, we provide a table (Table 1) which lists key changes in this final rule that have an applicability date other than the effective date of this final rule.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Table 1 lists key changes that have an applicability date other than 60 days after the date of publication of this final rule. The applicability dates are discussed in the preamble for each of these items.

TABLE 1—APPLICABILITY DATE OF KEY PROVISIONS OTHER THAN 60 DAYS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE

Preamble section	Section title	Applicability date
III.A.4	Reducing the Burden of the Compliance Program Training Requirements (§§ 422.503(b)(4)(vi)(C) and § 423.504(b)(4)(vi)(C)).	01/01/2016
III.A.7	Agent/Broker Compensation Requirements (§§ 422.2274 and 423.2274)	01/01/2015
III.A.20	Enrollment Requirements for the Prescribers of Part D Covered Drugs (§ 423.120(c)(6))	06/01/2015
III.A.24	Eligibility of Enrollment for Incarcerated Individuals (§§ 417.1, 417.460(b)(2)(i), 417.460(f)(1)(i)(A) through (C), 422.74(d)(4)(i)(A), 422.74(d)(4)(v), 423.44(d)(5)(iii) and (iv)).	01/01/2015

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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
 DUA Data Use Agreement
 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
 ICL Initial Coverage Limit
 ICR Information Collection Requirement

ID Identification
 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
 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 of 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
 NWS National Weather Service
 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
 SCORM Sharable Content Object Reference Model
 SEP Special Election 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 final 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. This final rule is necessary to—(1) clarify various program participation requirements; (2) improve payment accuracy; and (3) make other clarifications and technical changes.

B. Summary of the Major Provisions

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

The former regulatory compensation structure was comprised of a 6-year cycle that ended December 31, 2013. Under that structure, MA organizations and Part D sponsors provided an initial compensation payment to independent agents for new enrollees (Year 1), and paid a renewal rate (equal to 50 percent of the initial year compensation) for Years 2 through 6. MA organizations and Part D sponsors had the option to pay the 50 percent renewal rate for CY2014 (year 1). This compensation structure proved to be complicated to implement and monitor, and also created an incentive for agents to move beneficiaries as long as the fair market value (FMV) continued to increase each year. To resolve these issues, we proposed to revise the compensation structure. Under our proposal, MA organizations and Part D sponsors would continue to have the discretion to decide, on an annual basis, whether or not to use independent agents. Also, for new enrollments, MA organizations and Part D sponsors could determine what their initial rate would be, up to the CMS designated FMV amount. For renewals in Year 2 and subsequent years, with no end date, the MA organization or Part D sponsor could pay up to 35 percent of the current FMV amount for that year. We believed 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 was appropriate based on a couple of factors. First, we believed 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 was 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 proposed to amend the training and testing requirements as well as setting limits on referral fees (\$100) for agents and brokers.

We received more than 140 comments from agents, health plans, and trade associations opposing the 35 percent renewal rate, and instead suggesting that CMS maintain the 50 percent renewal rate. A number of commenters expressed concerns that the proposed reduction in compensation would represent a significant decrease from the current compensation limit, and a rate set at 50 percent of FMV would be in line with industry standard. They noted that the higher compensation amount would be particularly important for stand-alone prescription drug plans, as 35 percent would be insufficient to cover an agent's costs associated with the renewal transaction and could discourage agents from assisting in the annual evaluation of a Medicare beneficiary's options. Commenters also stated that, compared to current practice, the proposed 35 percent renewal rate is a reduction since a number of MA plans began offering a renewal rate of 50 percent for 10 years or more at the end of the 6-year cycle (2013). The majority of commenters also stated that agents play an important role in educating beneficiaries about Medicare and the proposed reduction in the renewal rate could reduce the level and quality of services provided to beneficiaries, thereby resulting in less information sharing and poorer plan choices by beneficiaries. Many commenters also stated that agents spend a significant amount of time in training, preparing, and educating beneficiaries and that the compensation

is already low relative to the hours spent. Some commenters also expressed concern that the lower compensation rate would discourage new agents from entering the MA market. Many agents stated they would have to stop selling MA products and instead sell other more profitable products. No plans strongly supported the 35 percent renewal rate. Therefore, we are modifying the compensation renewal rate from up to 35 percent to up to 50 percent. These changes will be applicable for enrollments effective January 2015. Because the proposed rate is similar to previous regulatory requirements, present CMS guidance, and industry practice, we believe this implementation timeframe is reasonable and appropriate. We are not finalizing the proposed changes to agent and broker training and testing at this time. We are finalizing limits on referral fees for agents as proposed.

2. Drug Categories or Classes of Clinical Concern

We are not finalizing any new criteria and will maintain the existing six protected classes.

3. Improving Payment Accuracy—Implementing Overpayment Provisions of Section 1128J(d) of the Social Security Act (§§ 422.326 and 423.360)

These proposed regulatory provisions codify the Affordable Care Act requirement establishing section 1128J(d) of the Act that MA organizations and Part D sponsors report and return identified Medicare overpayments.

We proposed to adopt the statutory definition of overpayment for both Part C and Part D, which means any funds that an MA organization or Part D sponsor has received or retained under Title XVIII of the Act to which the MA organization or Part D sponsor, after applicable reconciliation, is not entitled under such title. To reflect the unique structure of Part C and Part D payments to plan sponsors, we also propose to define two terms included in the statutory definition of overpayments: “funds” and “applicable reconciliation.” We proposed 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. For Part C we proposed that applicable reconciliation occurs on the annual final risk adjustment data submission deadline. For Part D, we proposed that applicable reconciliation occurs on the date that 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.

In addition, we proposed to state in regulation that an 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. An MA organization or Part D sponsor must report and return any identified overpayment it received no later than 60 days after the date on which it identified it received an overpayment. 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. Finally, we proposed a look-back period with an exception for overpayments resulting from fraud, whereby MA organizations and Part D sponsors would be held accountable for reporting overpayments within the 6 most recent completed payment years for which the applicable reconciliation has been completed.

We received approximately 30 comments from organizations and individuals. Generally, commenters supported establishing separate applicable reconciliation dates for Part C and Part D. Many commenters questioned when the 60-day period for reporting and returning begins, and what activities constitute reporting and returning an overpayment to CMS, including questions about estimating an amount of overpayment. A number of commenters also requested to clarify the standards for “identifying” an overpayment, including questions about the meaning of reasonable diligence. Finally, a few commenters recommended that we impose the same limitation on the look-back period for all overpayments, even those relating to fraud.

We are finalizing the provisions at §§ 422.326 and 423.360, with the following modifications. First, we add at the end of paragraph § 422.326(d) the phrase “unless otherwise directed by CMS for the purpose of § 422.311.” Also, to increase clarity we revise §§ 422.326(c) and 423.360(c) regarding identified overpayments. Finally, we strike the following sentence in the proposed paragraphs on the 6-year look-back period: “Overpayments resulting from fraud are not subject to this limitation of the lookback period.”

4. Risk Adjustment Data Requirements

We proposed several amendments to § 422.310 to strengthen existing regulations related to the accuracy of

risk adjustment data, including: (1) A requirement that medical record reviews, if used, be designed to determine the accuracy of diagnoses submitted under §§ 422.308(c)(1) and 422.310(g)(2); (2) a revision in the deadlines for submission of risk adjustment data; and (3) a limitation on the type and purpose of late data submissions. We also proposed a restructuring of subparagraph (g)(2) as

part of the revisions. We received approximately 25 comments from organizations and individuals regarding these proposals; many of the comments were concerned and critical of the proposals, highlighting vagueness and the potential for operational instability. For reasons discussed in more detail below in section III.B.2 of the preamble, we are not finalizing the proposed amendment regarding the scope of

medical reviews and we are not finalizing at this time the proposal to change the date for final risk adjustment data submission. We are finalizing as proposed the restructuring of §§ 422.310(g)(2) and the 422.310(g)(2)(ii) provision to prohibit submission of diagnoses for additional payment after the final risk adjustment data submission deadline.

C. Summary of Costs and Benefits

TABLE 2—SUMMARY OF COSTS AND BENEFITS

Provision description	Total costs	Transfers
Modifying the agent/broker requirements, specifically agent/broker compensation.	N/A	N/A
Improving Payment Accuracy Eligibility of Enrollment for Incarcerated Individuals.	N/A	N/A We estimate that this change could save the MA program up to \$27 million in 2015, increasing to \$103 million in 2024 (total of \$650 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 \$153 million in 2024 (total of \$965 million over this period).

II. Background

A. General Overview and Regulatory History

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, in 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.

B. Issuance of a Notice of Proposed Rulemaking

In the proposed rule titled “Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs,” which appeared in the January 10, 2014 **Federal Register** (79 FR 1918), we proposed to 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 included several provisions designed to improve payment accuracy.

C. Public Comments Received in Response to the CY 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Proposed Rule

We received approximately 7,600 timely pieces of correspondence containing multiple comments on the CY 2014 proposed rule. While we are finalizing several of the provisions from the proposed rule, there are a number of provisions from the proposed rule (for example, enrollment eligibility criteria for individuals not lawfully present in the United States) that we intend to address later and a few which we do not intend to finalize. We also note that some of the public comments were outside of the scope of the proposed

rule. These out-of-scope public comments are not addressed in this final rule. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments are set forth in the various sections of this final rule under the appropriate heading. However, we note that in this final rule we are not addressing comments received with respect to the provisions of the proposed rule that we are not finalizing at this time. Rather, we will address them at a later time, in a subsequent rulemaking document, as appropriate.

D. Provisions Not Finalized in This Final Rule

As noted previously, some of the provisions of the proposed rule will be addressed later and, therefore, are not being finalized in this rule. Table 3 lists the provisions that were proposed but are not addressed at this time. We note that several provisions that were proposed are not being finalized in this rule and are effectively being withdrawn; those provisions are not listed in Table 3.

TABLE 3—PROVISIONS NOT FINALIZED AT THIS TIME

Proposed rule section	Topic
Clarifying Various Program Participation Requirements	
III.A.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)).
III.A.6	Changes to Audit and Inspection Authority (§ 422.503(d)(2) and § 423.504(d)(2)).
III.A.9	Collections of Premiums and Cost Sharing (§ 423.294).
III.A.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).
III.A.11	Part D Notice of Changes (§ 423.128(g)).
III.A.12	Separating the Annual Notice of Change (ANOC) from the Evidence of Coverage (EOC) (§ 422.111(a)(3) and § 423.128(a)(3)).
III.A.14	Exceptions to Drug Categories or Classes of Clinical Concern (§ 423.120(b)(2)(vi)).
III.A.15	Medication Therapy Management Program (MTMP) under Part D (§ 423.153(d)(1)(v)(A))—outreach strategies.
III.A.16	Business Continuity for MA Organizations and PDP Sponsors (§ 422.504(o) and § 423.505(p)).
III.A.21	Efficient Dispensing in Long Term Care Facilities and Other Changes (§ 423.154).
III.A.23	Medicare Coverage Gap Discount Program and Employer Group Waiver Plans (§ 423.2325).
III.A.26	Payments to PDP Plan Sponsors For Qualified Prescription Drug Coverage (§ 423.308) and Payments to Sponsors of Retiree Prescription Drug Plans (§ 423.882).
III.A.32	Transfer of TrOOP Between PDP Sponsors Due to Enrollment Changes during the Coverage Year (§ 423.464).
III.A.37	Expand Quality Improvement Program Regulations (§ 422.152).
III.A.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).
Improving Payment Accuracy	
III.B.2	Determination of Payments (§ 423.329).
III.B.3	Reopening (§ 423.346).
III.B.4	Payment Appeals (§ 423.350).
III.B.5	Payment Processes for Part D Sponsors (§ 423.2320).
III.B.6	Risk adjustment data requirements—proposal regarding annual deadline for MAO submission of final risk adjustment data (§ 422.310(g)(2)(ii)).
Strengthening Beneficiary Protections	
III.C.1	Providing High Quality Health Care (§ 422.504(a)(3) and § 423.505(b)(27)).
III.C.2	MA-PD Coordination Requirements for Drugs Covered Under Parts A, B, and D (§ 422.112).

TABLE 3—PROVISIONS NOT FINALIZED AT THIS TIME—Continued

Proposed rule section	Topic
III.C.3	Good Cause Processes (§ 417.460, § 422.74 and § 423.44).
III.C.4	Definition of Organization Determination (§ 422.566).
III.C.5	MA Organizations May Extend Adjudication Timeframes for Organization Determinations and Reconsiderations (§ 422.568, § 422.572, § 422.590, § 422.618, and § 422.619).
Strengthening Our Ability to Distinguish Stronger Applicants for Part C and D Program Participation and to Remove Consistently Poor Performers	
III.D.1	Two-Year Prohibition When Organizations Terminate Their Contracts (§§ 422.502, 422.503, 422.506, 422.508, and 422.512).
III.D.2	Withdrawal of Stand-Alone Prescription Drug Plan Bid Prior to Contract Execution (§ 423.503).
III.D.3	Essential Operations Test Requirement for Part D (§§ 423.503(a) and (c), 423.504(b)(10), 423.505(b)(28), and 423.509).
III.D.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).
Implementing Other Technical Changes	
III.E.1	Requirements for Urgently Needed Services (§ 422.113).
III.E.2	Skilled Nursing Facility Stays (§§ 422.101 and 422.102).
III.E.3	Agent and Broker Training and Testing Requirements (§§ 422.2274 and 423.2274).
III.E.4	Deemed Approval of Marketing Materials (§ 422.2266 and § 423.2266).
III.E.5	Cross-Reference Change in the Part C Disclosure Requirements (§ 422.111).
III.E.6	Managing Disclosure and Recusal in P&T Conflicts of Interest: [Formulary] Development and Revision by a Pharmacy and Therapeutics Committee under PDP (§ 423.120(b)(1)).
III.E.8	Thirty-Six-Month Coordination of Benefits (COB) Limit (§ 423.466(b)).
III.E.9	Application and Calculation of Daily Cost-Sharing Rates (§ 423.153).
III.E.10	Technical Change to Align Regulatory Requirements for Delivery of the Standardized Pharmacy Notice (§ 423.562).
III.E.12	MA Organization Responsibilities in Disasters and Emergencies (§ 422.100).
III.E.14	Technical Changes to Align Part C and Part D Contract Determination Appeal Provisions (§§ 422.641 and 422.644).
III.E.15	Technical Changes to Align Parts C and D Appeal Provisions (§§ 422.660 and 423.650).
III.E.17	Technical Change to the Restrictions on use of Information under Part D (§ 423.322).

III. Provisions of the Proposed Regulations and Analysis of and Responses to Public Comments

A. Clarifying Various Program Participation Requirements

1. Closing Cost Contract Plans to New Enrollment (§ 422.503(b)(4))

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 proposed to revise paragraph § 422.503(b)(4)(vi)(G)(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 proposed to add the definition of “parent organization” to § 422.2 of the MA program definitions, specifying that, “Parent organization means a legal entity that owns one or more other subsidiary legal entities.” 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. We requested comments on whether a parent organization with less than a 100 percent interest in a subsidiary legal entity should trigger the prohibition we proposed with the amendment at § 422.503(b)(4).

During the public notice and comment process, a handful of commenters provided their input on our proposal. Some of the respondents included multiple comments. The comments and our responses follow.

Comment: A commenter supported the proposal, stating that it would prevent possible shifting of sicker enrollees to cost plans and should result in Medicare savings.

Response: We thank the commenter for the support.

Comment: A commenter stated that there is no evidence of complaints about the current situation and thus no change in current policy is necessary.

Response: The intention of our initial rule was to ensure that situations not arise in which an entity was able to move an enrollee from one of its plans to another plan in the same area based on financial or other reasons that may not be in the enrollee’s best interest. The current regulations limit this possibility to some extent, but, without the

proposed changes, would leave open the possibility that legal entities controlled by a shared parent organization could move enrollees from one plan to another, based on something other than the enrollee’s best interest.

Comment: A commenter stated that risk-adjusted payments for MA plans eliminate any incentive for an entity to move sicker enrollees from an MA plan to a cost plan.

Response: While risk adjusted payments do help to account for costs associated with sicker enrollees, it may still be advantageous for an organization to move an enrollee from an MA plan to a cost plan. Even with risk adjustment, there are other reasons an organization might want to move enrollees from one plan to another to include enrollment and other interests based on the organization’s business model.

Comment: A commenter stated that, because cost plan cost-sharing and premiums must be equal to the actuarial value of Medicare fee-for-service cost-sharing, cost plan enrollees with high health care needs would have high relative costs resulting in higher premiums for the cost plan, thus removing any incentive for moving sicker enrollees from an entity’s MA plan to the cost plan.

Response: MA plans also have constraints with respect to cost-sharing that affect premiums, and out-of-pocket payments by enrollees. We believe, as a result, that any difference in cost plan and MA premiums or cost-sharing is negligible and does little to remove the incentives for organizations to move enrollees from one of their plans to another.

Comment: A couple of commenters requested that, at minimum, the provision not be applied to entities that have both a cost plan and dual eligible special needs plan (D-SNP). One of the commenters states that: (1) cost plans would likely have a premium and cost sharing that would make it unattractive for dual eligibles; and (2) the regulation could eliminate D-SNPs that “participate in longstanding dual eligible integrated plans,” and thus the proposal “could have the effect of hurting a major initiative of the Administration.”

Response: As we have addressed elsewhere in the comments on this issue, we do not believe that any premium and cost-sharing differences in cost plans and MA plans necessarily reduce the incentives an organization may have for moving an individual from one of its plans to another. We believe this is also the case for D-SNPs and, that in the case of D-SNPs, which are frequently made up of enrollees that are sicker and frailer than the general Medicare population, there may be even greater incentive to move these enrollees to a cost contract plan.

Comment: A commenter requested that we not finalize the proposal because cost plan enrollees will already be subject to dwindling cost plan enrollment options as a result of the cost plan competition statute. The commenter stated that if we do finalize the proposal, we should grant an exception and not require cost plans affected by the cost plan competition requirements to close to new enrollment.

Response: It isn't clear at this point what kind of overlap there might be between cost plans affected by the cost plan competition requirements and those cost plans that would have to stop accepting enrollment because of sharing a parent organization with an MA plan. However, we do not believe that a significant number of cost plans will be affected by expanding the requirement to include a shared parent organization, as the requirement is largely prospective and designed to prevent a situation that we did not originally account for, but which we believe could lead to potential harm for enrollees.

Comment: A commenter stated that “the test should not only be whether entities have the same parent but also whether the two entities are affiliated, including if one entity is the parent of the other (rather than shares a parent).”

Response: We agree with the commenter with respect to the specific example cited and have included language in the final rule that will also trigger a prohibition on new enrollment in a cost plan in situations in which a parent organization and its subsidiary have a cost contract and MA plan in the same service area. In addition to the proposed language that MA organizations “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,” we are adding to § 422.503 (b)(4)(vi)(G)(5)(ii) that MA organizations “Not accept, as either the parent organization owning a controlling interest of or subsidiary of 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.” The language from the initial proposal along with the additional language will now be contained in § 422.503 (b)(4)(vi)(G)(5)(i) and (ii).

Comment: A few commenters stated that CMS should define a parent organization as an entity that “exercises a controlling interest in the applicant.” Other commenters stated that we should limit the definition of “parent organization” to the context of this provision only as our proposed definition could create inconsistencies in the Part C and D polices and guidance or have “unanticipated implications that are difficult to identify at this time.” One of the commenters, who asked us to limit the application of the “parent organization” definition to this provision only, stated that it would support our proposal if we clarified that the parent organization must have a “controlling interest” in the subsidiary legal entities in question.

Response: In the proposed rule, we specifically solicited comments on whether the requirement should be applied to a parent organization with less than 100 percent interest in the affected cost contract and MA plan. We agree that a controlling interest is a reasonable standard that is consistent with our intention to prevent an organization from having control over both a cost contract and MA plan in the same service area. We also agree that the threshold for determining when the prohibition should be applied is best established in the context of this provision and thus are not finalizing the

definition of “parent organization” in § 422.2. Instead, we are including the threshold for the prohibition in modifications in § 422.503(b)(4)(vi)(G)(5)(i) and (ii). These sections will now state that any entity seeking to contract as an MA organization—

- Not accept, or share a corporate parent organization owning a controlling interest in 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.
- Not accept, as either the parent organization owning a controlling interest of, or subsidiary of, 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.

We are finalizing the provisions of the proposed rule with the revisions and additions discussed in this section III.A.1 of this final rule.

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

Sections 1857(a) and 1860D–12(b)(1) of the Act provided the Secretary with the authority to enter into contracts with MA organizations, and Part D sponsors (respectively). Section 1857(g)(1) of the Act provided a list of contract violations and the corresponding enforcement responses (intermediate sanctions (sanctions) and/or civil money penalties (CMPs)) are listed under section 1857(g)(2) of the Act (section 1860D–12(b)(3)(E) applied these provisions to Part D contracts).

We proposed two changes to our existing authority to impose sanctions and CMPs based on section 6408 of the Affordable Care Act (Pub. L. 111–148). The provisions of section 6408 provided CMS with the authority to impose intermediate sanctions or CMPs for violations of the Part C and D marketing and enrollment requirements. As well as, 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. Additionally, we proposed 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).

Comment: A commenter expressed concern and stated that MA organizations and Part D sponsors should be given the opportunity to refute marketing or other allegations of

non-compliance prior to sanctions and/or CMPs being imposed.

Response: Enforcement actions are only typically taken based on substantiated, well documented instances of non-compliance and in the case of both a sanction and a CMP, even after they are issued, MA organizations and Part D sponsors are given an opportunity to rebut or appeal CMS' determination through a formal appeals process.

Comment: A few commenters requested clarification regarding the new sanction authority, specifically the language that would allow CMS 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. The commenters requested that CMS clarify that this would not apply to organizations that perform facilitated or auto-enrollment, passive enrollment, seamless enrollment or requests from Employer Group Waiver Plans (EGWPs).

Response: In the proposed rule, we proposed to amend the regulation text at §§ 422.752 and 423.752 by adding (a)(9), and (a)(7), respectively, which read: ". . . 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." Section 423.34 specifically refers to enrollment of individuals who receive the low income subsidy (LIS) and are therefore subject to facilitated or auto-enrollment. Therefore, we believe that the proposed regulation text already makes clear that this provision would not apply to those organizations that are performing facilitated enrollment of LIS beneficiaries. Additionally, passive enrollment and use of the seamless enrollment option are initiated or approved by CMS, respectively. Therefore, an organization who is contacted by CMS to receive passive enrollment would not be considered to have performed enrollment without prior consent. As for the seamless enrollment option, as these proposals must be submitted to and approved by CMS, as long as organizations are following CMS' enrollment guidance in Chapter 2, § 40.1.4, an organization, again, would not be considered as enrolling without prior consent and would, therefore, not be considered for a possible sanction. Finally, an organization who is accepting group or individual enrollment requests from EGWPs must follow CMS' enrollment guidance in Chapter 2, § 40.1.6. As long as CMS enrollment guidance is being followed with respect to processing

these enrollments, CMS would not consider MA and Part D organizations in violation of the new requirement.

Comment: One commenter stated that only one organization, either CMS or OIG should have CMP authority and that there should be no overlapping authority. They went on to state that if CMS proposed to allow overlapping CMP authority that CMS agree that the total amount of the CMPs issued not exceed what either CMS or OIG could impose separately.

Response: It is not CMS' intent to create overlapping CMP authority, simply to clarify our existing CMP authority. However, to the extent CMS or OIG were planning on pursuing a CMP, we have internal mechanisms in place to ensure that the other entity within the department is not simultaneously pursuing a CMP for the same or similar conduct. If we were to determine that OIG was pursuing a CMP for similar conduct, we would coordinate with the OIG so that only one CMP action would move forward.

Comment: One commenter requested that CMS not finalize this provision because they believe the current division of authority to impose CMPs should remain unchanged, with the authority to CMP for certain violations remaining with OIG, instead of adding to CMS' existing CMP authority, as this approach ensures a natural division of power and oversight expected from government agencies.

Response: CMS has always had the statutory authority to impose CMPs for the violations currently designated as belonging solely to the OIG in the regulation. However, CMS agrees that there are certain violations that should be retained solely by OIG for purposes of imposing CMPs, which is why the proposed rule states that the authority to impose CMPs for violations listed at §§ 422.752(a)(5) and 423.752(a)(5), involving misrepresentation or falsification of information furnished to CMS, an individual, or other entity, will continue to reside solely with the OIG.

Comment: One commenter, in addition to expressing support for our proposal, stated that CMS should authorize use of monies collected from CMPs to allow states to contract with, or grant funds to entities, provided that the funds are used for CMS approved projects to protect or improve SNF services for residents.

Response: We thank the commenter for their support and we will explore in the future if such arrangements are allowed within our current statutory authority.

Comment: We received several comments that supported the new

proposed sanction authority for marketing and enrollment violations.

Response: We thank the commenters for their support.

After careful consideration of all of the comments we received, we are finalizing these proposals without modification.

3. 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 provided us with the authority to terminate a Part C or D sponsoring organization's contract. Sections 1857(h)(1)(B) and 1860D–12(b)(3)(F) of the Act provided us with the procedures necessary to facilitate the termination of those contracts. We proposed three revisions to our existing regulations that relate to contract termination.

First, we proposed to clarify the scope of our authority to terminate Part C and D contracts under §§ 422.510(a) and 423.509(a) by modifying the language at §§ 422.510(a) and 423.509(a) to separate the statutory bases for termination from our examples of specific violations which meet the standard for termination established by the statute. We proposed to effectuate this change by renumbering the list of bases contained in §§ 422.510(a) and 423.509(a).

Second, we proposed 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 Part D sponsoring organization's contract, we must notify the organization in writing 90 days before the intended date of termination. We proposed to shorten the notification timeframe from 90 days to 45 days. Additionally, in an effort to respond to changes in the media and information technology landscape, we proposed a slight modification to the termination notification provision for the general public at §§ 422.510(b)(1)(iii) and 423.509(b)(1)(iii) which includes the contracting organizations 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 instead of publishing the notice in applicable newspapers.

Finally, we proposed 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 proposed to replace the word "fails" with "failed" so that it reads consistently throughout §§ 422.510 and 423.509.

Comment: Several commenters opposed our proposal to shorten the notification period for contract termination from 90 days to 45 days. Commenters made several arguments supporting their opposition to the shortened notification timeframe, but most stated that it is not enough time to ensure members' needs are adequately addressed, specifically noting the difficulty in effectively communicating the change with their members and ensuring their members were effectively transitioned to a new plan. Other commenters stated that the timeframe was too short to provide adequate notice to affected providers and vendors. Yet another commenter stated that the shortened timeframe did not allow enough time for a plan to appeal the termination. A final commenter noted that the shortened timeframe would increase costs to the contracting organization if the termination period is reduced.

Response: After carefully considering the commenters' concerns, we respectfully disagree that these concerns outweigh the need to protect beneficiaries and have them moved from a plan that is in such substantial non-compliance with our regulations that CMS would proceed with termination. Plans that receive a notice of termination from CMS are instructed that they must provide notice to their affected beneficiaries at least 30 days prior to the effective date of the termination. If CMS provides their notice of termination to contracting organizations 45 days before the effective date of the termination, this affords plans 15 days to issue their notice to enrollees while still complying with the existing 30-day beneficiary notification requirements. While we do request that terminated plans work with the receiving plan to transition enrollee data and records, it is not expected that these tasks would be completed by the effective date of the termination, but would instead begin upon transfer of the enrollees once the termination was actually effective.

As for adequate notification to affected vendors and providers, it is the responsibility of the contracting organization to design their contracts with their providers and vendors in a manner that recognizes possible contract actions, such as termination, that could be taken by CMS. For example, all plans that have a contract with CMS could ultimately be subject to immediate termination if they are found in such substantial non-compliance by CMS that it poses an imminent and serious risk to Medicare enrollees. Therefore, most, if not all plans, likely

have clauses in their provider and vendor contracts that allow them to terminate these contracts expeditiously with the affected entities in the event of a contract termination by CMS.

We also do not agree that the shortened timeframe in any way affects a contracting organization's ability to appeal. Contracting organizations who are subject to a contract termination in §§ 422.510(b) or 423.509(b) must file their request for a hearing within 15 days from the date of receipt of the notice of termination. A timely filed request for hearing effectively stays the termination proceeding until a hearing decision is reached. Consequently, shortening the notice of termination from 90 to 45 days should have no impact on a contracting organization's ability to file an appeal of the contract termination.

Finally, we do not agree that the shortened notice timeframe to effectuate a termination would result in increased costs to an organization. We already have the ability to prorate its payment to an organization for terminations that are effective in the middle of a month; consequently we do not agree that shortening the notification timeframe would in any way change the CMS's current approach to payment or recoupment of capitated payments in these circumstances.

Comment: One commenter suggested that CMS should have different notification timeframes for termination. They recommended that 90 day notice be provided to all post-acute care (PAC) providers as well as to beneficiaries in PAC. They stated that 45 days for notice may be sufficient for non-post-acute care beneficiaries, but not for people in a short stay setting. They also suggested that MA plans that are serving full dual eligible beneficiaries should be required to provide 180 day notice to individuals and providers.

Response: CMS' proposal to shorten the notification of termination from 90 days to 45 days affects the amount of notice that CMS must give to an MA or Part D organization prior to moving forward with a termination action. The timeframe in which that organization must then notify their beneficiaries, which is currently 30 days, is not being changed in this proposal. While we appreciate the commenter's suggestion, we believe that it would be incredibly burdensome to organizations and confusing to our beneficiaries to implement such a striated notification process for our beneficiaries during a termination. Additionally, if we were to adopt the commenter's suggestion of a 90 day notice period for beneficiaries in a PAC setting or 180 day notice for dual

eligible beneficiaries, this would require that we give organizations even more advance notice of our intent to terminate than we do currently, which is contrary to the ultimate goal of our proposal, which is to remove beneficiaries as quickly as possible from a plan with such significant noncompliance issues that CMS is pursuing termination. Consequently, we plan to proceed with our proposed change.

Comment: Several commenters supported CMS' proposed revisions to the contract termination authority (§§ 422.510 and 423.509) and stated that these measures will help enforce consumer protections and enhance plan accountability.

Response: We thank the commenters for their support.

After consideration of the public comment(s) received, we are finalizing these proposals without modification. We note that the amendatory instruction to the regulation text in this final rule more precisely describes the redesignation of subparagraph (a)(4) of § 423.509 than that found in the proposed rule.

4. 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) and section 1860D-12(b)(1) of the Act provided the Secretary with the authority to enter into contracts with MA organizations and Part D sponsors (respectively). 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. We first established that all Part C and Part D contracting organizations have 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)(vi). We later 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). 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 continued 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 19688).

Consequently, we proposed in this rule to require that all contracting organizations accept a certificate of completion of the CMS developed training as satisfaction of this general compliance program training requirement. We proposed 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 first-tier, downstream and related entities.

Comment: One commenter questioned if there would be a fee associated with the CMS mandated training.

Response: There is no fee to take the CMS Standardized General Compliance Program Training; it is provided free of charge.

Comment: Multiple commenters stated that Part C and Part D contracting organizations should have the option of using the CMS Standardized General Compliance Program Training and Education Module. The commenters wrote that there should be flexibility in meeting the proposed training requirement, and that CMS should consider allowing plan sponsors to utilize their own training or the training developed by established training companies to meet the requirement.

Response: The CMS Standardized General Compliance Program Training and Education Module was created to reduce the burden on sponsors and FDRs. If we continue to allow sponsors to modify or utilize their own training in lieu of using the CMS Compliance training, it will no longer ensure the elimination of the prior duplication of effort that so many FDRs stated was creating a huge burden on their operation. This is why CMS proposed that only our training can be used, as it is the only means to ensure that duplication of effort is avoided for FDRs who hold contracts with multiple Part C and Part D contracting organizations.

Comment: One commenter raised concerns over the significant amount of time required to complete the current CMS Compliance training and stated that it may take time away from other areas of training the organization has deemed necessary through their own

internal risk assessments. They suggested CMS consider modifying the requirement to allow the longer training initially and developing a shorter “refresher” version that could be taken annually thereafter.

Response: We will not modify the existing CMS Standardized General Compliance Program Training at this time. However, we recognize the commenter’s concern and will take under consideration the development of a refresher training module for future use.

Comment: A few commenters recommended that CMS establish a single centralized electronic location where FDRs could obtain this training, and that the centralized location would also serve as a repository to hold attestations of training completion accessible to Part C and Part D contracting organizations for compliance oversight purposes. Commenters suggested it be searchable or that CMS provide updates, one suggesting daily reports be pushed to each MA organization and Part D sponsor so that they could track compliance with the training requirement. One other commenter suggested that the training be provided in a Sharable Content Object Reference Model (SCORM) format for downloading into various organizations’ systems.

Response: The training is in a centralized location on the Medicare Learning Network. All who take the training will be able to print out a certificate of completion to prove they have completed the training. It is the responsibility of Part C and Part D contracting organizations to determine how to best retrieve and catalog this information from their FDRs. CMS is unable, at this time, to provide the capacity for a publicly searchable database of users who have completed that training or a system that would allow reports to be sent to the various contracting organizations regarding the training status of various FDR organizations. We will consider and determine if our training module could be available for download into the format suggested by commenters, but we would need to ensure that the content could not be modified to ensure the integrity and completeness of the training module.

Comment: One commenter suggested CMS leverage the existing Compliance Training, Education & Outreach (CTEO) site to support this initiative and to interactively execute the training and collect and track the required attestations.

Response: When we developed the Standardized General Compliance Program Training, the CTEO Web site was not yet in existence. We will take the commenter’s suggestion under consideration and further explore that Web site’s capability to determine if it actually exceeds the current capability of the Medicare Learning Network, where the training is currently housed.

Comment: A few commenters recommended maintaining the current policy of allowing flexibility in how the training requirement is met. These commenters stated the current training requirements meet their needs because it allows options and reduces the burden on various sectors of the industry. They stated that various organizations had already invested resources to become compliant and to develop efficient means of both delivering and tracking the training. The flexibility in the current regulations allows plan sponsors to work in concert with FDRs to develop effective training for those specific entities and their existing learning models.

Response: We recognize that the current compliance program training requirement does meet the needs of some contracting organizations. However, based on public feedback received previously, as well as in response to this proposed change, we continue to believe that the proposed approach is most efficient and effective for the majority of FDRs and contracting organizations.

Comment: Many commenters requested clarification regarding who is required to take the training: Providers, brokers, FDRs, and/or internal employees.

Response: The compliance and fraud, waste, and abuse (FWA) training and education requirement applies to all delegated entities (which may include agents/brokers) whom the Part C or Part D contracting organization qualifies as an FDR using the definition at 42 CFR §§ 422.500(b) and 423.500. Whether a Part C or Part D contracting organization identifies a certain entity or individual provider as an FDR depends on the contractual relationship and/or written agreement between the entity/individual and the contracting organization. The compliance and FWA training is not intended to be mandatory for the employees of those contracting organizations.

Comment: Several commenters wanted to know if this training would satisfy the FWA and Compliance training requirements.

Response: There is both a FWA and a Compliance training module available on the Medicare Learning Network,

FDRs must take both modules in order to satisfy the entire training requirement.

Comment: A few comments requested clarification regarding who was deemed for purposes of the FWA training requirement (for example, is it just the provider participating in Medicare FFS or also all of the employees that work in his office, similarly with a hospital participating in Medicare, does it extend to their employees). Commenters also requested if CMS was exploring deeming status for providers in the Part D program.

Response: This question is outside of the scope of this regulation. We did not propose any changes to the FWA training module or the associated deeming requirements. Therefore, we are unable to address your question at this time.

Comment: Several commenters had questions regarding the one-pager that contracting organizations can provide with organization specific information, and requested whether this meets the requirements for distributing their codes of conduct (COC) or standards of conduct (SOC) located in Chapter 9 of Pub. 100–18, Medicare Prescription Drug Manual, and Chapter 21 of Pub. 100–16 of the Medicare Advantage Manual. Some commenters inquired if this new proposal could be construed to forbid them from distributing their COC/SOC to their FDRs.

Response: We intend that the standardized FWA and Compliance Training modules will cover the basic training requirements. We recognize that each contracting organization has specific information that must be shared with their FDRs regarding the organization's specific operations. The one-pager was suggested for organizations to communicate unique information that is usually shared in FWA/Compliance such as relevant organization contact information (for example, Web site address, hotline/ethics phone numbers) the Compliance Officer's contact information, the Compliance Department staff, and possibly even online access to the COC/SOC or disciplinary policies. Our experience has shown that many contracting organizations issue their COC/SOC electronically (internally and externally) and/or create Web sites designated for their FDRs to locate the information mentioned previously. Contracting organizations must continue to distribute their COC/SOC to all of their employees, FDRs, board members, etc. Nothing in this regulation should be interpreted to preclude organizations from satisfying the seven elements of the compliance program requirements.

Comment: The commenters suggested that feedback should be solicited from the plans to assist with improving the content of the training, specifically including more examples that are relevant to FDRs, as commenters mentioned the modules examples are often organization-centric.

Response: We always welcome feedback from contracting organizations and FDRs with respect to improving our training products. Organizations, entities or individuals who have suggestions should submit them to the following mailbox: Parts_C_and_D_CP_Guidelines@cms.hhs.gov.

Comment: Some commenters stated that CMS should consider how it can implement this proposal in a way that reduces administrative burdens on contracting organizations and FDRs, as new processes to collect and track attestations may be difficult and time consuming. Many suggested that a January 1, 2015 effective date was an insufficient amount of time to set up such elaborate processes and recommended that these provisions be effective no earlier than January 1, 2016.

Response: CMS recognizes the administrative burden imposed on the contracting organizations and their FDRs. The primary goal of this proposal is to reduce that administrative burden by instituting a uniform compliance training module and we believe that contracting organizations are in the best position to determine the most effective way to collect and track compliance amongst their FDRs. However, we recognize that setting up these new processes may take time, along with potentially updating contracts to reflect the new requirements. Therefore, we will delay the implementation of this provision to January 1, 2016.

Comment: The largest number of commenters represented FDRs that wrote in support of the proposed compliance training program requirements and use of the CMS Standardized General Compliance Program Training, agreeing that it would greatly reduce burden on FDRs.

Response: We thank the commenters for their support.

After careful consideration of all of the comments received, we are finalizing this proposal with the one modification discussed previously, with a delayed applicability date of January 1, 2016.

5. 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.

We proposed to expand the potential applicability of the test period requirement to three types of intermediate sanctions by modifying the existing rules 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. Second, we proposed to clarify the enrollment parameters for sanctioned sponsoring organizations offering Part D plans to include language specifying that a sanctioned plan is not available to receive automatically assigned beneficiaries for the entire duration or a portion of the testing period. We proposed to modify the regulation text at §§ 422.756 and 423.756 to reflect these changes.

Comment: One commenter questioned clarification on what CMS considers a contract violation of marketing requirements and requested if violations would be based solely on allegations of misconduct.

Response: Marketing standards for MA organizations and Part D sponsors are codified in subpart V of parts 422 and 423. The current Medicare Marketing guidelines are located in Chapter 3 of Pub. 100–16, Medicare Managed Care Manual, and Chapter 3 of Pub. 100–18, The Medicare Prescription Drug Manual, which should provide sponsors with guidance regarding current marketing requirements. With respect to contract violations being based on unsubstantiated allegations of wrongdoing, enforcement actions are only taken based on substantiated, well documented instances of non-compliance. Additionally, MA organizations and Part D sponsors that are sanctioned are given an opportunity to rebut or appeal our determination through a formal appeals process.

Comment: One commenter suggested the prohibition on auto-enrollment into plans under a test period should also apply to passive enrollment. Specifically, the commenter stated that

Medicare-Medicaid eligible individuals should not be passively enrolled into an MA or an MA Special Needs Plan (SNP) that is under sanction or under sanction and in a test period as part of a demonstration or a state developed integrated plan product.

Response: Plans that are under a sanction are not eligible to receive enrollments. However, we have the discretion to require a sanctioned plan to market or accept enrollments for a limited period to assist in making a determination as to whether the bases for imposing the sanction have been fully corrected and are not likely to recur. As stated previously, sanctioned sponsoring organizations offering a Part D benefit would not be eligible to receive automatically assigned beneficiaries during the test period. During a “test period” the sanction(s) remain in effect.

Comment: One commenter requested that we extend the proposal to also not allow passive enrollment into plans that are coming off of sanction or are currently in a test period until we have determined they are ready.

Response: CMS has determined that it is legally permissible to provide for enrollment in an MA or Part D plan under a passive enrollment request process in specific, limited circumstances generally associated with either immediate plan terminations or in other situation where CMS determines that remaining enrolled in the plan would pose potential harm to members. We determine when passive enrollment is appropriate. In evaluating whether such CMS-directed enrollee movements are appropriate, a key factor is the determination as to whether the receiving plan is essentially equivalent to (or better than) the current plan from an overall perspective.

Therefore, in situations where passive enrollment is determined permissible, like an immediate plan termination, CMS would factor in a number of criteria, including the receiving plan’s current premium, benefit and formulary structure, as well as plan past performance. In any event, our goal would be to ensure that those affected members suffered as little disruption as possible during their transition. Plans that were under sanction at the time of a passive enrollment would not be considered a viable option for affected enrollees and it is unlikely that sponsors under a test period would either. However, if a sponsor who was removed from sanction and was under a test period met several other criteria for receiving passive enrollment (that is, plan’s benefit and formulary structure was largely the same and their premium

was not significantly higher), we may consider them among the group of available plans to receive passive enrollment.

Comment: A few commenters requested clarification regarding the new sanction authority, specifically the language that would allow CMS 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. The commenters asked that CMS clarify that this would not apply to organizations that perform facilitated or auto-enrollment, passive enrollment, seamless enrollment or group or individual enrollment requests from EGWPs.

Response: In the proposed rule, we proposed to amend the regulation text at §§ 422.752 and 423.752 by adding subparagraph (a)(9), which reads: “. . . 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.” Section 423.34 specifically refers to enrollment of individuals who receive the low income subsidy (LIS) and are therefore subject to facilitated or auto-enrollment. Therefore, we believe that the proposed regulation text already makes clear that this provision would not apply to those organizations that are performing facilitated enrollment of LIS beneficiaries. Additionally, passive enrollment and use of the seamless enrollment option are initiated or approved by CMS, respectively. Therefore, an organization who is contacted by CMS to receive passive enrollment would not be considered to have performed enrollment without prior consent. As for the seamless enrollment option, as these proposals must be submitted to and approved by CMS, as long as organizations are following CMS’ enrollment guidance in Chapter 2, § 40.1.4, and have received CMS’ approval, an organization again would not be considered as enrolling without prior consent and would therefore not be considered for a possible sanction. Finally an organization who is accepting enrollment requests for an employer or union sponsored plan using the group enrollment mechanism must follow CMS’ enrollment guidance in Chapter 2, § 40.1.6.1. As long as CMS enrollment guidance is being followed with respect to processing these enrollments, CMS would not consider MA and Part D organizations in violation of the new requirement. However, we expect that requests for enrollment into an

employer or union sponsored plan outside of the group enrollment process (that is, beneficiary initiated enrollment requests) follow all requirements, including prior consent, applicable to any other individual enrollment request.

Comment: Several commenters expressed support for our proposal to expand the use of the “test period” requirement to all intermediate sanctions, and support the proposal that previously sanctioned below-the-benchmark Part D plans not be allowed to receive or process auto-enrollments or reassignments until they are determined to be ready by CMS.

Response: We thank the commenters for their support.

After careful consideration of the comments received, we are finalizing these proposals without modification. We inadvertently failed to include proposed regulation text for § 423.756 that corresponds to this proposal. In this final rule, we finalize amendments to §§ 422.756 and 423.756 that are virtually identical to implement this proposal.

6. 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. 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.

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 proposed 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.

Therefore, we proposed 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 would 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 believed 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 solicited 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 received the following comments and our response follows:

Comment: A few commenters questioned why we proposed turnaround times of 3 and 5 days if we list in preamble that standard turnaround times are 7 to 10 days for delivery.

Response: The preamble discussion surrounding delivery of prescriptions within 7 to 10 days is from the perspective of the beneficiary; listing the total time from when a medication is ordered to the time it is delivered. Importantly, this includes shipping time. The proposed fulfillment standards were specific to mail order pharmacy processing times and did not include actual time in shipping. In other words, the 3 to 5-day turnaround time only refers to the timeframe from when the pharmacy receives the order until the pharmacy ships the order.

Comment: Many commenters expressed concerns that 5 business days is too short of a time frame to require mail order pharmacies to resolve some issues when they arise (such as manufacturer drug shortages), many of which are outside the control of the pharmacy. Many commenters noted unique timeline concerns specific to specialty medications, such as cold chain shipping and needing to contact the beneficiary to coordinate delivery. Multiple commenters suggested that additional leeway is also needed to accommodate issues such as natural disasters. Multiple commenters suggested that mail order pharmacies should contact beneficiaries as a good customer service practice when any delay in filling will prevent an order from shipping within 5 days. Many commenters noted that they currently would be able to meet a 3-day turnaround standard for filling orders

not requiring follow up contact with the beneficiary or prescriber.

Response: We recognize that some interventions may require more than 5 business days to resolve. In those cases, we agree with the suggestion from multiple commenters that mail order pharmacies should contact beneficiaries as a good customer service practice when any delay in filling will prevent an order from shipping within 5 days. However, in light of the comments received regarding a variety of situations that we had not considered, including some outside of the pharmacy's control that could create delays longer than 5 days, we are not finalizing the proposal to establish fulfillment standards for mail order. Instead, we will continue analysis on mail order fulfillment time frames, including evaluating the impact of the implementation of the auto-ship beneficiary consent policy finalized in the 2014 Call Letter. In addition, Part D sponsors are expected to follow best practices by making clear their expected delivery turnaround times in their beneficiary materials, consistently meeting such delivery time frames, and having contingency plans for when they cannot, such as allowing retail access at mail order cost sharing levels if necessary. The volume of complaints that we receive related to mail order delivery suggests that beneficiary expectations are not consistently being met. We will increase our monitoring of mail order pharmacies, and will consider the need to establish standards and requirements in the future. Based on the comments submitted, additional consideration may be necessary surrounding specialty medications and their delivery, especially when there are cold chain or other shipping considerations. We reviewed the information provided on how specialty pharmacy differs from other mail order deliveries, and agree that additional consideration should be given to these pharmacies and medications in any future guidance. Additionally, we will clarify existing guidance about exception processes and coverage denials to ensure that mail order pharmacies provide beneficiaries notice of non-fulfillment of a prescription as expeditiously as possible. Current guidance on disaster responses and drug shortages still apply, and we encourage sponsors to communicate with their enrollees when unique situations like these arise.

Comment: A few commenters suggested that mail order turnaround times are best left to state Boards of Pharmacy to monitor, instead of being set in regulation.

Response: We proposed specifying parameters for timely mail order fulfillment, consistent with the authority given to the Secretary to specify additional contract terms not inconsistent with the Part D statute. However, we had not considered the potential conflict or duplication with state-based requirements and appreciate the comments. We will take this under consideration as we consider establishing requirements for Part D sponsors offering a mail order benefit in the future.

Comment: Some commenters wrote that turnaround times would be better defined in guidance or incorporated in star ratings or other quality metrics.

Response: We appreciate the suggestion. As we will not be finalizing the proposed fulfillment standards in this final rule, we are exploring alternatives for ensuring consistent and predictable access to medications for beneficiaries in a plan offering a mail order benefit. As part of this effort, we are currently developing a study of how mail order benefits are used within the Part D benefit. The comments received on the proposed rule and the results of this study will be considered when determining whether fulfillment standards should be included in future star ratings measures, as well as used to inform the need for future guidance or rulemaking. Additionally, we will increase our monitoring and analysis of mail order-related complaints in the CTM and explore setting a threshold for the volume or severity of complaints triggering a review by CMS. We remain very concerned by the high level of complaints received relating to mail order, and take seriously the issues raised by beneficiaries. We are also exploring how fulfillment of plan-designated turnaround times listed in marketing or other beneficiary materials could be included within the audit framework.

Comment: One commenter wrote in with concerns that the methodology used in two CMS studies cited in another provision were problematic and stated that no regulation proposals relating to mail order should be finalized until corrected and reexamined.

Response: The studies noted by the commenter were not used when designing the proposal specific to timely delivery of mail order prescriptions.

Comment: Some commenters suggested that the policy announced in the CMS 2014 Call Letter that pharmacies obtain beneficiary consent prior to shipping any medications that the beneficiary did not affirmatively order directly affects the timeline for

order fulfillment and any defined turnaround times for delivery should be adjusted accordingly.

Response: We recognize that the CMS 2014 Call Letter auto-ship policy necessitates an increased level of coordination with the beneficiary for some pharmacies, when filling prescriptions that the beneficiary did not directly request (such as new orders submitted directly by the provider or refills prompted by an automatic delivery program). We will not be finalizing the proposed fulfillment standards in this final rule, but encourage all plan sponsors to consider the need for coordination with the beneficiary when establishing and marketing average turnaround time estimates for their members.

Comment: A few commenters suggested that beneficiaries should be allowed to fill their medications at the retail pharmacy of their choice, at the same cost sharing level as mail order, if a mail order pharmacy encounters any delays, or delays extending beyond 5 days.

Response: While this was not a part of our proposal, and we will not be finalizing any new requirements at this time, we do agree with commenters that this would be an important beneficiary protection. We believe that best practices for addressing a lost or delayed order would include plan sponsors providing clear and timely guidance to the beneficiary in the event of a lost or delayed order, including a list of options for obtaining a medication. Part D sponsors should have contingencies in place when issues are encountered that lead to a delay and potentially a gap in therapy. This could include offering beneficiaries the ability to fill a delayed mail order prescription at a retail pharmacy and pay no more than what they would have been charged by a mail order pharmacy. The need to prevent gaps in therapy for beneficiaries relying on mail order pharmacies remains a significant concern to us.

In summary, we are not finalizing any fulfillment standards for mail order prescriptions, in light of the concerns raised. We will use the information gained from our mail order study and from the public comments submitted to explore the need for additional guidance or rulemaking in the future. The need to ensure consistent access to and prevent gaps in therapy for enrollees relying on mail order for their medications continues to be a significant concern.

We additionally solicited 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 received the following comments and our response follows:

Comment: Many commenters stated that additional requirements for beneficiary materials would enhance mail order services and that this would be a positive change for beneficiaries. These commenters noted that clear definitions of requirements are needed to resolve issues, ensure consistent access, and ensure no gaps in therapy.

Response: We appreciate the comments. We intend to conduct a study of mail order benefits offered by Part D sponsors and will use this, and the information received from public comments, to inform changes to beneficiary materials relating to mail order. At a minimum, we expect sponsors offering mail order services to follow best practices by clearly listing estimated delivery times in their marketing and beneficiary materials. In the event of a failure to meet plan-designated timeframes for delivery, as a best practice sponsors should be prepared to take the steps necessary to provide their enrollee the medication in a timely manner in order to avoid gaps in therapy. This could include offering enrollees the option to obtain delayed medications at a retail pharmacy at the same cost sharing level as mail order.

We also welcomed 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 uninterrupted 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. We received the following comments and our response follows:

Comment: A few commenters agreed that mail order is not an appropriate venue for filling 30 day supplies of medications.

Response: We appreciate the comments and will explore how often mail order is used for short days' supplies of medications as a part of the current study on mail order benefits.

Comment: Some commenters noted that specialty pharmacies often dispense medications by mail order in an amount lasting 1 month or less.

Response: We agree with the comments that noted some specialty medications may be best supplied, when supplied by mail order, in quantities less than a 3 month supply, due to frequent dose titrations, financial concerns, or applicable controlled substance laws.

We did not propose any specific regulatory requirements to mail order for 30-day supplies or less. We are currently analyzing the types of prescriptions filled by mail order pharmacies and will use the information gained from this to explore the need for future guidance or rulemaking that could help ensure consistent timely access for Part D beneficiaries opting to use mail order for both short and extended days' supplies.

7. 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 554226), which, among other things, established the current compensation structure for agents and brokers as it applies to 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 necessary 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 (CY) 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 (FMV). (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 first 6-year cycle ended at the end of CY 2013, on December 31, 2013. The first year, CY 2009, was considered to be the first renewal year for those already enrolled, effectively making CY 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 final 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. In our NPRM, dated January 10, 2014, we provided a detailed example of the complexities of the current compensation structure. Summarizing the current complexities, every MA organization or Part D sponsor 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 for the current contract year. For new members, 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.

In addition to its complexity, we remain 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. In our NPRM, we discussed and expanded upon our example of how the current system results in different payments when a beneficiary moves from one like plan to another like plan in different organizations. 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, an incentive exists for the agent to move beneficiaries from one parent organization to another. (See §§ 422.2274(a)(3) and 423.2274(a)(3)).

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 required levels of compensation or the timing of compensation, there could be an uneven 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 proposed simpler agent/broker compensation regulations to 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 proposed 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 renewal year payment changes 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 is currently the case, 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.

When we proposed the 35 percent renewal rate, we also discussed 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 extend past year 7. 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 beneficiary ages for an initial enrollment, as well as life expectancy. In the analysis, a 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.

In our NPRM, we stated that we believed 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 was appropriate based on several factors. First, we stated that a two-tiered (initial and renewal) payment system would be significantly less complicated than a three-tiered system

(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 was based on the existing commission structure basing renewal commissions on the starting year initial commission amount and not the current year FMV amount.

In order to implement the changes in the identical Part C and Part D regulations at §§ 422.2274 and 423.2274, our NPRM first proposed to revise the introductory language for each section and then define "compensation" in paragraph (a)(1) and to restate the fair market value limit on compensation for the initial year as paragraph (b)(1)(i). Second, we proposed 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 proposed 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 proposed 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 proposed 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 to 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 proposed 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 who perform services similar to agents and brokers.

We welcomed comments on both the amount of the renewal payment, as well as the proposed indefinite time frame, which are discussed in depth as follows. In summary, we received a number of comments supporting our efforts to simplify agent/broker compensation calculation. These comments were primarily from plans and industry trade groups. We will be finalizing the rule to implement a two-tiered (initial and renewal) payment system using the FMV in the current year for renewal calculations.

We received numerous comments from agents, brokers, plans and trade associations overwhelmingly opposing the 35 percent renewal rate. Based on the comments received, we will finalize the amendment to the regulations with a cap of 50 percent of the current FMV for renewals.

In response to the comments received, we also determined that some clarifications were necessary. For renewals, the payment is based on the current FMV and not the initial enrollment year FMV. For example, assume a beneficiary enrolls in an MA plan in CY 2013. The plan pays the initial FMV for CY 2013, which is \$413. In CY 2015, assume the FMV is \$420. The plan chooses to pay 50 percent of the FMV for renewals. The maximum renewal payment for this member for CY 2015 would be \$210 ($\$420 * .50$) instead of \$207 ($\$413 * .50$). For all enrollments, MA organizations and Part D Sponsors should calculate the renewal rate based on the FMV of the enrollment year. We are also clarifying that our proposed and final regulations do not require an indefinite payment of 50 percent of the FMV. The final rule would permit up to 50 percent of the current FMV to be paid by an MA organization or Part D sponsor. CMS currently requires that plans inform CMS as to whether they are using independent agents. Contracts between MA organizations and Part D Sponsors, on one hand, and their independent agents and/or downstream entities on the other hand, such as Field Marketing Organizations, are not exhaustively regulated by CMS. Therefore, MA organizations and Part D sponsors may decide the duration of their contract with agents, number of applicable renewals, and the actual rate for renewals for each year, subject to the limits in this final rule.

Current regulations at §§ 422.2274(a)(4) and 423.2274(a)(4),

which we proposed to redesignate as part of paragraph (b), address the timing of plan payments, as well as recoupment of payments when a beneficiary disenrolls from a plan. Specifically, current paragraph (a)(4) states that compensation may only be paid for the beneficiary's months of enrollment during the year (January through December). Under our proposal, the new subparagraph (a) would more clearly define a plan year for purposes of compensation. The annual compensation amount covers January 1 through December 31 of each year. Our proposal also clarified that the payment made to an agent must be for January 1 through December 31 of the year and may not span calendar years. For example, a renewal payment cannot be made for the period of November 1, 2013 through October 31, 2014. These proposed revisions represented clarifications rather than new proposals and were necessary based on our findings that some plans have been paying compensation based on a rolling year cycle, rather than a calendar year cycle. Therefore, we are implementing the provision defining "plan year" and, at subparagraph (b)(3)(i), limiting payments to the months of enrollment during the calendar year, as proposed. Comments concerning this provision are discussed later in this section.

Currently, regulations at § 422.2274(a)(4)(i) permit payments to be made at one time or in installments and at any time. In order to reduce the number of payments that need to be recouped based on changes made during the annual coordinated election period (AEP), which runs from October 15 through December 7, CMS proposed, in new subparagraph (b)(3)(ii), changing the timing of payments to require that payments may not be made until January 1 of the enrollment year and must be paid in full by December 31 of the enrollment year. We stated that this proposal was appropriate given that the beneficiary's final application during the AEP becomes the effective enrollment. This would reduce the number of recoupments required when an enrollee signed more than one application during the AEP. We received several comments opposing the requirement that MA organizations and Part D plans may not make AEP payments until January 1 of the following year, but do not find these arguments sufficiently compelling to outweigh the simplification that would be gained by establishing the January deadline. We also received comments regarding our proposed requirement that payments be completed by December

31. MA organizations and industry associations stated that accurate payments, especially for enrollments effective on December 1, would be difficult to operationalize by the end of the year. However, we would expect enrollment requests for a December 1 effective date to be relatively low, as only individuals newly eligible to Medicare Advantage and those with a special election period would be able to enroll for that date. Moreover, organizations and sponsors are already required to process most post-enrollment activities within two weeks. Therefore, we continue to believe that the December 31 deadline is in the best interest of the program and are finalizing subparagraph (b)(3)(ii) as proposed.

Current regulations at §§ 422.2274(4)(ii)(A) and 423.2274(4)(ii)(A) require MA organizations and Part D sponsors to recoup compensation paid to agents when a beneficiary disenrolls from a plan within the first 3 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 recoup compensation, even though the beneficiary was enrolled in the plan for less than 3 months. In such circumstances, since the disenrollment decision could not be based on agent or broker behavior, we believe it to be appropriate and in the best interest of the Medicare program for the agent to receive the compensation based on the number of months that beneficiary was enrolled in the plan. While the plan would not recoup the compensation for those months, it would recoup any compensation paid for the months after the date of disenrollment.

CMS proposed to combine current paragraphs (a)(4)(ii)(A) and (a)(4)(ii)(B) into a revised paragraph (b)(3)(iii), which included new text to require plans to recover compensation for only the months that the beneficiary is not enrolled, unless the disenrollment took place within the first 3 months. In our proposed rule, paragraph (b)(3)(iii) would require recoupment of all compensation in cases where the disenrollment was the result of agent or broker behavior. We received few but compelling comments on this proposal, which stated that it would be extremely difficult for MA organizations and Part D Sponsors to determine whether the disenrollment was a result of agent behavior, potentially resulting in

compensation either being inappropriately recouped or not recouped when necessary. Based on these comments, we are not finalizing our proposal for subparagraph (b)(3)(iii) but are finalizing regulation text to state that the entire compensation must be recouped if a disenrollment occurs during the first 3 months unless CMS determines that recoupment is not in the best interest of the Medicare program. We intend for this standard to be applied as we have implemented this aspect of the current regulation in past, with certain 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) not triggering the recoupment requirement. We will continue to provide exceptions to the requirement in sub-regulatory guidance by applying the standard we are finalizing today.

We also proposed, to be codified at §§ 422.2274(h) and 423.2274(h), to codify existing sub-regulatory guidance regarding referral (finder's) fees. We released a memorandum on October 19, 2011 addressing excessive referral fees, noting that referral fees should not exceed \$100. We have 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 referral fees paid to others are part of the total compensation. This creates an uneven 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 for whether plan benefits meet the beneficiaries' health care needs. Therefore, we proposed 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 form, to a reasonable amount, as determined by CMS, which is currently \$100, for CY 2013 and CY 2014. The entire proposal concerning agent and broker compensation was discussed in the context of our concern that agents and brokers not be influenced by payments from MA organizations and Part D sponsors to steer beneficiaries to plans that do not meet the beneficiaries' needs. We note that this proposal was clearly identified in the preamble, 79 FR 1936, but the proposed regulation text, 79 FR 2060 and 2071, mistakenly included language discussing enrollee behavior and the value of health-related activities.

Furthermore, under §§ 422.2274(h)(2) and 423.2274(h)(2), CMS proposed that that referral fees paid to independent agents and brokers must be part of total compensation not to exceed the FMV for that calendar year. Although a few comments were received concerning our proposals on referral fees, we are implementing this proposal substantively as described in the preamble. However, we believe that use of the phrase “. . . while not exceeding the value of the health-related service or activity itself” was an error in the proposed regulation text. Therefore, we are finalizing text at subparagraph (h)(1) by removing that error and more clearly providing that CMS will set an annual threshold for finder fees based on a determination about amounts that would improperly incentivize agents and brokers to steer beneficiaries. We are finalizing subparagraph (h)(2) as proposed. Comment details and our responses may be found as follows.

We are finalizing the regulations with additional regulation text for a technical correction. One entity commented that the proposal eliminated §§ 422.2274(a)(1)(iv) and 423.2274(a)(1)(iv). Our proposal was not to remove these provisions concerning the applicability of compensation to third party entities and the regulation text should have included the substance of current subparagraph (a)(1)(iv). We have inserted the text from the regulation prior to the proposal at §§ 422.2274(b)(1)(iii) and 423.2274(b)(1)(iii) of this final rule.

Finally, we are not finalizing the change to the introductory language to §§ 422.2274 and 423.2274 in favor of deleting the existing introductory language (which forms the substantive basis for the new paragraph (a) definitions); the introductory language we proposed seems unnecessary to establish the scope of each regulation.

Comment: We received more than 140 comments concerning the level of renewal payments, proposed at 35 percent. A few of the comments appreciated the simplification and briefly discussed the 35 percent but neither strongly supported the amount or strongly opposed the amount. A few commenters believed renewal compensation should increase. The vast majority (over 95 percent) of the comments did not support the proposed renewal rate of 35 percent for years two and beyond with a few clearly stating that the renewal rate should be 50 percent. Commenters included agents, brokers, plans, and industry trade associations. One major trade association representing 37 plans stated that 35 percent was overly restrictive

and 50 percent is in line with industry standards, especially concerning PDPs where the 35 percent renewal would not cover the agent's costs to ensure members are in the best plans for them. The commenters provided various reasons why the 35 percent should not be implemented. The majority of commenters stated that agents play an important role in educating beneficiaries and the reduced level of compensation would result in a negative impact on beneficiaries, as it would reduce the level and quality of services provided to beneficiaries, resulting in less information and poor plan choices made by beneficiaries and would also result in agents leaving the MA marketplace. Many commenters stated that agents spend a significant amount of time in training, preparing, and testing in order to properly educate beneficiaries about plan choices. A number of commenters stated that their overhead costs (travel, postage, facility costs) were significant and a reduction in compensation would affect this aspect of their business. Commenters also stated that the lower compensation would discourage new agents from entering the MA market.

Response: Based on the comments received, we are modifying our proposed regulations to permit the renewal payment to be up to 50 percent of FMV. MA organizations and Part D sponsors may still determine how much will be paid, up to 50 percent of the current FMV, and retain the authority to specify the details of their contracts with agents, including how many years renewal payments will be made. We believe that this increased percentage meets the statutory standard of “ensur[ing] 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.”

Comment: We received one comment from an individual who misunderstood our proposal. It appears that the commenter thought our proposal would allow two different payment options.

Response: We have reviewed this comment and are not taking action based on an incorrect understanding of the proposal. Our proposal actually discussed two options that we considered for the renewal compensation.

Comment: We received two comments from individuals who suggested alternative agent payment strategies. One commenter suggested modifying Medicare.gov to track agents for enrollments processed through the Web site for payment by plans. The commenter also proposed paying agents

on a monthly basis, coinciding with the months the beneficiary is in a plan, eliminating the need to commission reversals. Another commenter proposed that plans submit compensation schedules to CMS for review and approval.

Response: These recommendations entail significant changes with numerous operational implications. Therefore, we are not implementing the suggestions from these comments at this time. With respect to the comment regarding the frequency of payments, we did not propose to modify the existing regulatory permission for MA organizations and Part D sponsors to determine whether payments would be made at one time or in installments; therefore the comment is outside the scope of this proposed rule.

Comment: We received a few comments regarding the requirement that payments be made between January 1 and December 31 of the enrollment year. One commenter supported the proposal. A few commenters did not support the January 1 date because agents would have to wait 3 to 4 months for compensation for those enrolling during the AEP. One of these commenters also noted that getting the commission assures agents that the beneficiary was enrolled. A few plans were concerned about timely payment of December 1 effective enrollees.

Response: Our proposal is aimed at simplifying compensation while ensuring an even playing field. As explained previously, using a January 1 through December 31 payment timeframe limits the recoupment of payments made when a beneficiary makes more than one election during the AEP. Therefore, we are implementing this provision as proposed.

Comment: We received one comment stating that regulating the payment of only independent agents was unfair and that employed agents should also be regulated.

Response: We have reviewed this comment and have determined that the regulation of only independent agents is still appropriate. Our initial regulations were promulgated to ensure that agents/brokers do not steer beneficiaries into plans due to the agent's/broker's financial or other interest; we continue to be concerned about such steering on the part of independent agents, since they often sell multiple products, with varying levels of compensation. In contrast, employed agents work for only one company and therefore do not have an incentive to move a member into a plan offered by a different organization

or sponsor in exchange for a higher commission.

Comment: We received a comment from a trade association recommending that CMS consider changes from cost plans to MA plans as “like” plan changes, rather than “unlike” plan changes for compensation purposes. The commenter stated beneficiaries evaluate cost plans similar to MA plans and that treating these as unlike plan types encourages churning.

Response: We have received this comment and declined to implement such this change from our proposal; we believe that this is outside the scope of the proposed rule. Our proposal did not address what constitutes “like” and “unlike” plan types, but instead simply referenced “like” and “unlike” plan types, using the existing regulation standards on this point, because CMS re-designated and revised certain portions of the existing regulation for simplification.

Comment: We received a few comments regarding referral fees. One commenter recommended that the referral fee for enrollments be limited to FMV instead of \$100. Other commenters requested that CMS not allow referral fees to be paid.

Response: We reviewed these comments and are finalizing our proposal as described in the preamble to the proposed rule, with the changes to the regulation text at subparagraph (h)(1) as explained previously. Referral fees are applicable to employed, captive, and independent agents, and permitting the referral fee to be as high as the Fair Market Value (FMV) would increase the potential for steerage among different types of agents and thus plans. The \$100 cap, which is required to be part of the total compensation, is an added protection to ensure financial interests of agents do result in misleading beneficiaries. Our proposal did not address whether referral fees should be permitted, only whether such fees should be capped and, if so, at what level. We do not believe that it is appropriate to prohibit or eliminate referral fees without additional rule-making that is specific on that question.

Comment: One plan requested clarification as to whether the renewal rate of the “current” FMV meant the year in which the renewal commission is being paid.

Response: We intend, for purposes of renewal rates, that the “current” FMV be the FMV for the enrollment year. For example, an agent would be paid 50 percent of Contract Year (CY) 2015’s FMV for a renewal member who is enrolled in CY 2015.

Comment: One plan requested clarification as to whether CMS would require payments to be retroactive or if the existing regulations would continue until member’s current 6-year cycle ended. One trade organization wanted to know whether the requirements will be effective for January 1, 2015 enrollments and how the new regulations will affect members currently in the existing 6-year cycle.

Response: As part of this final rule, the new compensation requirements will be implemented for all members for CY2015. One of CMS’ intentions was to simplify the regulations and create an even playing field. We would not be able to accomplish these goals if we were to wait to implement these new requirements until all members finish their current 6-year cycle. However, we note that the final provides flexibility to MA organizations and Part D sponsors so long as payments are within the thresholds established in the rule. To the extent that an MA organization or Part D sponsor wishes to continue payment using a cycle system, negotiates that payment structure with its agents and brokers, and that cycle system complies with the limits and requirements of this final rule, the MA organization or Part D sponsor may do so.

Comment: We received a few comments concerning recoupment of compensation when a member disenrolls within the first three months of enrollment. One plan requested a better definition of “broker behavior.” One trade association stated that there would be significant challenges in determining whether disenrollments were due to independent agent/broker conduct. The trade association is concerned that plans could face significant disputes with agents/brokers about these decisions.

Response: We have reviewed these comments and determined that the current situation should remain unchanged based on these concerns that our proposed revisions would hamper MA organizations’ and Part D sponsors’ ability to determine which enrollments should be fully recouped, with the result that compensation is either inappropriately recouped or not recouped when necessary. Therefore, we are finalizing the regulation to require full recoupment of compensation when a member disenrolls within the first three months unless CMS determines that the recoupment is not in the best interests of the Medicare program. CMS will apply this standard and specify exceptions in sub-regulatory guidance. Our current guidance is consistent with

this standard and will remain applicable.

Comment: We received a few comments regarding the implementation date of the regulations. One trade association stated that it typically took nine months to make systems changes to accommodate new requirements.

Response: We understand that systems changes may take time to implement. Because of necessary industry systems changes, and because the rule provides for a payment structure applicable by calendar year, these compensation changes do not take effect until enrollments effective January 2015. Therefore, organizations and sponsors will have approximately seven months to make such changes. Other than simplifying how FMV applies to renewal rates, the new compensation structure is similar to industry practice and present guidance. Therefore, we did not make any changes to this section of the regulation.

Comment: One trade organization commented that many MA organizations and Part D sponsors currently operate on a “rolling year” basis, such that, if an enrollment is effective February 1, the compensation covers the period starting on February 1 and continuing through January 31 of the following year. The association said that these were well-established processes and a change could disrupt systems and require a significant re-design effort.

Response: Our position has always been that organizations and sponsors were required under the existing rules to pay compensation on a calendar year basis, not a “rolling” year basis. When we encountered situations where organizations and sponsors have not implemented these requirements correctly, we have required the organization to adjust its processes to comply and they have done so in a timely manner. We decided to clarify this requirement in our regulations to ensure that all plans fully understand the CMS definition of an enrollment year. Therefore, we will not be making any modification based on this comment.

Comment: One trade association stated that the NPRM appears to have eliminated the current provisions at §§ 422.2274(a)(1)(iv) and 423.2274(a)(1)(iv), which address compensation requirements for Third Party Entities.

Response: We thank the commenter for this observation. These provisions were inadvertently eliminated from the current provisions. We have revised the regulation text accordingly.

Comment: We received one comment from a trade association that was concerned about CMS' requirement to recover commissions if an enrollee disenrolls in the middle of the year. They suggested that CMS require MA organizations and Part D sponsors to take "commercially reasonable efforts" to recover funds.

Response: The requirement to recover funds when a member disenrolls mid-year remains the same; we did not propose to change this requirement. Organizations and sponsors have the ability to make payments yearly, quarterly, monthly, or in other frequencies. Therefore, they could pay monthly, rather than on a yearly or quarterly basis, and thereby limit the need to recoup funds for disenrollments that occur at mid-year. Therefore, we will not be making any changes to the regulation.

Comment: We received a few comments recommending that CMS provide a mandatory plan comparison form. Agents/Brokers would be required to fill this out and provide to the beneficiary for review.

Response: These comments are outside the scope of our proposed rule, but we will consider this suggestion for future changes.

Comment: We received a few comments from beneficiary advocacy groups stating that MA organizations and Part D sponsors slow down, artificially delay, or dispute the payment of compensation, which ultimately encourages agents and brokers to take their business to another plan.

Response: These comments are outside the scope of our proposed rule, but we believe that our new requirement that compensation be paid within the enrollment year will address some of these issues.

After consideration of the public comments received, we are finalizing our proposal at §§ 422.2274(a), (b) and (h) and 423.2274(a), (b), and (h) with the following modifications as previously discussed:

- Deleting the introductory text to the regulation section.
- Raising the renewal compensation rate from 35 percent to (up to) 50 percent of the current fair market value cut-off amounts published annually by CMS.
- Removing the proposed recoupment standard for rapid disenrollments by reverting to the status quo where subregulatory guidance describes activities not triggering recoupments (rather than requiring recoupments based on "agent or broker behavior"; implementing a standard based on the

best interests of the Medicare program to identify disenrollments that do not require recoupment.

- Incorporating existing regulation text about compensation to Field Marketing Organizations.
- Clarifying the CMS standard for applying the limit on referral fees.

8. Drug Categories or Classes of Clinical Concern (§ 423.120(b)(2)(v))

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 exceptions that permit a Part D sponsor to exclude from its formulary a particular Part D drug that is otherwise required to be included in the formulary in a drug category or class of clinical concern (or otherwise limit access to such a drug, including through prior authorization or utilization management). The Affordable Care Act amendments to section 1860D–4(b)(3)(G) of the Act specified that until such time as the Secretary establishes through rulemaking 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 proposed 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) to specify: (1) the criteria the Secretary will use to identify drug categories or classes of clinical concern; and (2) exceptions that permit Part D sponsors to exclude a particular Part D drug from within a category or class of clinical concern that is otherwise required to be included in the formulary (or to otherwise limit access to such a drug, including through utilization management or prior authorization restrictions). We also proposed to specify which drug categories or classes met the proposed criteria and explained the process we used for making these determinations.

We proposed 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 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.

We were concerned that requiring essentially open coverage of certain categories and classes of drugs presents both patient welfare concerns and financial disadvantages for the Part D program as a result of increased drug prices and overutilization. We also believed 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 took the opportunity to propose to codify criteria for identifying categories or classes of drugs that are of clinical concern, we believed that the requirements of section 3307 of the Affordable Care Act should be implemented taking into consideration the other protections available to beneficiaries. Otherwise, we believed 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 needed to take the other beneficiary access protections into account. We detailed five such protections: formulary transparency, formulary requirements, reassignment formulary coverage notices, transition supplies and notices, and the coverage determination and appeals processes. Taken together, we believed these requirements were comprehensive

enough that additional access safeguards would be needed only in those situations where a Part D beneficiary's clinical needs cannot be more efficiently met.

We received the following comments, and our response follows:

Comment: We received strong support for our entire proposal from some commenters who agreed, as they stated, with "all of the reasons" underlying the proposal, but we received no supportive comments explicitly directed toward our proposed criteria for identifying categories and classes of clinical concern. However, we did receive significant opposition to our proposed criteria. Several commenters generally stated that the criteria themselves were flawed, much less their application to the drug categories and classes in our analysis. Although the statute did not provide individual criteria, some commenters stated that the criteria were more restrictive than statutory intent and insufficiently accounted for patient complexity. Other commenters stated that application of overly restrictive criteria set a dangerous precedent, and other commenters raised related concerns that other categories and classes of clinical concern could be eliminated in the future or that they could be incorrectly applied to other disease states whose guidelines indicate the use of these drugs. For example, many commenters expressed concern that if immunosuppressants for transplant rejection no longer received the additional protections under section 3307, patients with multiple sclerosis who use immunosuppressants may face access issues. Additionally, although it was mentioned as a source of savings in our RIA, some commenters opposed the idea that future drugs in a particular category or class, representing advances in therapy, may not be covered, believing this jeopardized beneficiary health. Indeed, many commenters stated that the application of these criteria would be life-threatening.

Response: We thank the commenters for bringing their concerns to our attention. We attempted to embrace the principle of balancing access and cost through optimal formulary management inherent in the design of the Part D benefit in proposing to establish criteria pursuant to section 3307 of the Affordable Care Act. However, based on the comments received, we have concluded that our proposed criteria did not strike the balance among beneficiary access, quality assurance, cost-containment, and patient welfare that we were striving to achieve. Thus, we are not finalizing our proposal to establish new criteria for the categories

and classes of clinical concern. Accordingly, we are maintaining the existing six categories and classes of clinical concern listed in the statute and are amending the regulation at § 423.120(b)(2)(v) to reflect that the categories and classes of clinical concern will be as specified in section 1860D-4(b)(3)(G)(iv) of the Act until we undertake rulemaking to specify criteria to identify the categories and classes of clinical concern.

During our annual formulary review and approval process, regardless of a drug's placement in a category or class of clinical concern, to the extent that a treatment guideline speaks to a specific category or class of drugs, we look for representation from that category or class of drugs on the formulary. Moreover, if the treatment guidelines address specific drugs, we would review formularies to ensure inclusion of those specific drugs. Thus, although a category or class of clinical concern is immunosuppressants for transplant rejection, to the extent that the treatment guidelines for multiple sclerosis indicate the use of immunosuppressants, we still would look for representation of these drugs on the formulary during our treatment guidelines review for multiple sclerosis.

After consideration of the public comments we received, we are finalizing a technical change to § 423.120(b)(2)(v) to reflect the existing categories and classes of clinical concern. Because the existing regulation at § 423.120(b)(2)(v) is obsolete in light of the Affordable Care Act, we are making a technical change to specify that until such time as we undertake rulemaking to establish criteria to identify, as appropriate, categories and classes of drugs for which we determine are of clinical concern, the categories and classes of clinical concern shall be as specified in section 1860D-4(b)(3)(G)(iv) of the Act.

9. 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 belief that more than 25 percent of enrollees will benefit from MTM services.

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. In the proposed rule, we cited a number of studies which discussed the following: there may be racial disparities in meeting the eligibility criteria, the current eligibility criteria and variability are restricting access to MTM services, and MTM enrollees with certain chronic diseases, 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, and cost savings.

We believe the studies support the necessity to reduce variability and racial disparity in eligibility criteria among plans and improve access to beneficial MTM services. We proposed changes to the eligibility requirements regarding multiple chronic diseases, multiple Part D drugs, and the annual cost threshold.

a. Multiple Chronic Diseases

Under the statute, one of the three criteria that are used to target beneficiaries for MTM services is whether a Part D beneficiary has 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 proposed 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 also proposed 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. In addition, we proposed 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 proposed list of core chronic diseases became cardiovascular disease, diabetes, dyslipidemia, respiratory disease, bone disease—arthritis, mental health, Alzheimer’s disease, and end stage renal disease.

b. Multiple Part D Drugs

The second of the three statutory criteria for identifying targeted beneficiaries is whether a Part D beneficiary is taking multiple covered Part D drugs. We proposed 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. We also proposed to restrict the flexibility previously available to sponsors by requiring that they consider any Part D covered drug. In the proposed rule, we cited literature that supported the idea that patients with multiple diseases and taking at least two drugs are more likely to have drug therapy problems and need MTM.

c. Annual Cost Threshold

The final statutory requirement for targeting Part D beneficiaries for MTM services is that the beneficiary be identified as likely to incur costs for covered Part D drugs that exceed a level specified by the Secretary. 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. We previously codified a \$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 \$3,017 in 2014. However, 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 \$3,017, 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 proposed setting the annual amount in Part D drug costs at an amount that represents the intersection of multiple conditions and multiple drugs. Specifically, we proposed setting the threshold at \$620 which is the estimated annual total drug cost for a beneficiary filling two generic prescriptions, based on an analysis of prescription drug event (PDE) data.

We are not finalizing these proposals. We will engage in new notice and comment rulemaking on this issue as warranted in the future.

We received a large number of comments related to our proposal to revise § 423.153(d)(2)(i) through (iii) to expand MTM program eligibility and our response follows.

Comment: Many commenters were supportive of MTM in general and CMS’ goals. These commenters were supportive of the proposed changes to expand access to MTM services, shared CMS’ concerns regarding restrictive and variable eligibility criteria established by some sponsors, and endorsed the proposals to revise the eligibility criteria to increase uniformity. This included support for and clarifying questions regarding the revised definitions for “multiple chronic diseases,” with the addition of “cardiovascular disease” to the list of core diseases, and “multiple

Part D drugs.” Some commenters stated that CMS should post MTM eligibility rates on the CMS Web site or make plan-reported data more available for research. Other commenters, who supported the proposed changes to expand access to MTM, provided information on return on investment, outcomes, or individual experiences in improving quality and lowering costs through MTM provided by community pharmacists who have close relationships with the beneficiaries and local prescribers. A large number of commenters also stated that, to date, variability in plan offerings and limited compensation has made the provision of MTM in the community setting difficult in a consistent, scalable and timely manner.

A significant number of commenters also were strongly opposed to the broad expansion of eligibility. They questioned the effectiveness of expansion under the current infrastructure as delivered by drug plans with limited incentives and a lack of care coordination, and they commented that the clinical evidence did not support the proposed changes. We received many comments that the proposed changes would significantly increase costs (both administrative and beneficiary premiums), reduce the quality of programs delivered to beneficiaries who most need MTM, and could overwhelm limited resources. Many commenters requested that the proposed changes be withdrawn, and some commenters offered alternative eligibility criteria for CMS to consider in the future. These included: delay the proposed changes or implement the changes incrementally, alternative criteria for the minimum thresholds for eligibility, alternative eligibility criteria based on risk factors, and requiring MTM at transition of care.

Response: We thank these commenters for their thoughtful and supportive comments. MTM has been shown to improve drug therapy outcomes and lower costs, and we agree that the use of community-based resources for providing MTM services shows promise in improving access and quality. We still have concerns that many sponsors are applying restrictive criteria to narrow the pool of targeted beneficiaries for MTM rather than optimizing the eligibility criteria to offer MTM to beneficiaries who will most benefit from these services. These programs are not living up to our expectations. As we discussed in the regulatory impact analysis for the proposed rule (79 FR 2036), we estimate that only 2.5 million beneficiaries (8 percent) are eligible for MTM services,

13 percent opt-out of the MTM program, and 10 percent of participating beneficiaries receive an annual CMR. That means that less than 220,000 Part D enrollees receive CMRs, which studies have shown is a crucial element of MTM to improve drug therapy outcomes and lower costs. Not enough is being done by sponsors to provide sufficient access to MTM services and engage beneficiaries and providers in this process. We will consider publicly posting the MTM program eligibility rates for each Part D contract, similar to how we display MTM program CMR rates, and explore ways to make the plan-reported data available for public use.

Despite the persuasive comments from those who support the proposed changes in eligibility criteria, we also take into account the comments that the timeline for implementing the proposed changes may be too aggressive and could negatively affect existing MTM programs. While our goal was to increase eligibility and access to MTM, we do not want to do it at the expense of sacrificing any quality with existing programs. Therefore, we are not finalizing our proposed changes to the eligibility criteria. But, we will continue to evaluate information on MTM programs and monitor sponsors' compliance in accordance with the MTM requirements established by § 423.153, with the goal of proposing other revisions to criteria in future rulemaking that will help expand the program. We believe that Part D sponsors can target more beneficiaries for MTM under the existing criteria. We plan to closely scrutinize sponsors that may be abusing the flexibility provided to them in establishing the eligibility criteria, which may have contributed to the racial disparity, variability, and beneficiary confusion with respect to MTM eligibility that we identified in the proposed rule. We will consider the commenters' suggestions for alternative criteria and may consider revisions to MTM eligibility criteria for future rulemaking. We may also consider changes to the definitions for "multiple chronic diseases," including the core chronic diseases, and "multiple Part D drugs" in the future.

10. 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.

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 proposed 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 MA 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 2 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.

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. 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.

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 proposed to require Part D experience in only three critical areas in which beneficiaries are particularly vulnerable should the sponsor demonstrate significant non-compliance. The three areas for which we proposed 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.

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.

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. In 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.

While our proposal did not require the Part D experience to be current at the time of an application to become a Part D sponsor, we proposed that the experience be recent (that is, within the past 2 years) and have lasted for at least one full benefit year. 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 proposed to amend § 423.504(b) accordingly. 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.

We received the following comments and our response follows:

Comment: We received strong statements of support from many commenters. We received only one suggestion of not finalizing the policy, but the commenter did not provide any details or rationale to support its comment.

Response: We appreciate the widespread support for this proposal.

Comment: We received one recommendation to consider a less stringent standard for employer groups seeking to act as Employer Group Waiver Plan (EGWP) sponsors.

Response: We expect all sponsors, including EGWP sponsors, to meet our experience and capability requirements. We have an obligation to ensure that all beneficiaries receive their benefits from experienced Part D sponsors.

Comment: One commenter that supported the policy suggested that CMS should also address the problem of applicants not having the skills or capacity to even oversee their experienced FDRs.

Response: We share the concern that applicants may not have experience overseeing FDRs, which is why, in addition to the current requirements and standards in place for administration and management, we are finalizing at section A.III.11. of this final rule our proposed requirement that new PDP sponsor applicants have immediately prior to the date of the application submission 2 years' experience administering health insurance benefits directly or 5 years' experience providing certain prescription drug benefit management services to a health insurer. We also have procedures and mechanisms in place to monitor a Part D sponsor's administration and management of its contract, including the option of

conducting an audit of a sponsor's operations prior to the start of the contract year to confirm that it is prepared to oversee the delivery of Part D benefits to its members.

Given the near universal support for this proposal we are finalizing this provision without modification.

11. 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.

To address this problem, we proposed, 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.10. of this final 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 proposed to codify at § 423.504(b)(9), 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 MA organizations offering Part D through an MA-PD plan. We proposed 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 that 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.

While relatively few sponsors fit this profile each year, they have caused disproportionate problems for beneficiaries and CMS. 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.

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. 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. We proposed that new applicants have 2-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. We believe that requiring 2-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. Therefore, we proposed 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 5-continuous years of 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.10. of this final rule. The three areas that we proposed 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 proposed 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. Therefore, we 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 5-continuous years, rather than merely 2.

We intend to implement this proposal through our existing Part D contract qualification application process, and we proposed to amend § 423.504(b) accordingly.

We received the following comments and our response follows:

Comment: We received strong statements of support from several commenters.

Response: We appreciate the support for this proposal.

Comment: We received one recommendation to consider a less stringent standard for employer groups seeking to act as EGWP sponsors.

Response: We are not persuaded by this comment because, in general, we expect that all sponsors, including EGWP sponsors, meet all of our

experience and capability requirements. EGWP sponsors perform the same core functions as sponsors of individual market PDPs, including claims processing, formulary administration, operation of an appeals and grievance process, and coordination of benefits. Therefore, the same concerns that led us to adopt the requirement that new PDP sponsors have experience in these areas applies to EGWP sponsors as well as sponsors of individual market plans.

Given the universal support for this proposal, we are finalizing this provision without modification.

12. 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. We proposed, 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.

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. 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. We oppose the inefficiencies of duplicate contracts and

the gaming duplicate contracts can support. That said, we welcomed 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. 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.

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 Part D program and provide a means by which the integrity and reliability of our star ratings system can be compromised. Therefore, we proposed 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, we will deny all of the parent organization's applications.

We received the following comments and the response follows:

Comment: The comments of several beneficiary advocacy organizations contained expressions of support for our proposal, citing in particular the role it will play in preserving the integrity of CMS' star ratings system.

Response: We appreciate the expressions of support for our proposal.

Comment: Several commenters stated their opposition to our proposal on the basis that it would limit their business opportunities and reduce competition in the Part D market by reducing the number of plan sponsors participating in a given PDP region.

Response: We note that the commenters did not describe or provide examples of the nature of the business opportunities that Part D sponsors and their parent organizations would be denied should this provision go into effect. Also, we believe that to properly assess the level of competition in the Part D market, it is important to consider not just the number of plan sponsors offering benefits, but also whether all of those sponsors truly have incentives to compete against one another. As we noted in our preamble discussion to the proposed rule, additional plan sponsors controlled by entities that already participate in the Part D market do not promote improved plan options since subsidiaries of the same parent cannot be said to be truly in competition with each other. In a truly competitive market, multiple entities develop and promote products

to capture as large a share of that market as possible at the expense of other market participants. It is our experience that two or more subsidiaries of the same parent organization are ultimately accountable to the same set of shareholders and are administered by the same senior management team. In such an arrangement, we believe there is little incentive for the parent organization to manage one PDP contract in a way that would attempt to take enrollees away from, or prevent beneficiaries from electing, plans offered by the related entity operating a second contract. We also note that none of the commenters provided an explanation as to how related entities would truly compete in the same PDP region.

Comment: Several plan sponsors that have recently acquired other plan sponsor contracts expressed their concern that the new policy would jeopardize their right to maintain two or more contracts during a transition period following the acquisition.

Response: We assure the commenters that our proposal has no effect on our application of the regulatory provision at § 423.272(b)(3), which provides acquiring organizations an exemption from the meaningful differences standard normally applied to a sponsor's (or its parent organization's) bids for a 2-year period following the acquisition of or merger with another Part D sponsor. We have allowed acquiring sponsors to maintain the separate acquired contract during the authorized 2-year period, and we will continue to apply that policy after the adoption of this provision.

Comment: Some plan sponsors that currently hold more than one PDP sponsor contract in a PDP region commented that they were concerned that the proposed provision would require them to consolidate their operations into one contract.

Response: We note that the proposal only addressed our intention to deny applications for new contracts submitted by entities related to organizations that already hold a PDP sponsor contract in a particular region. As we discussed in the preamble to the proposed regulation, we will continue to encourage such organizations to consolidate their contracts, but we are not requiring organizations to take such action at this time.

Comment: One commenter requested that CMS revise the proposal to allow a parent organization to hold two contracts in the same PDP region if one of those contracts is maintained solely for the purpose of offering employer group waiver plans (EGWPs). The

commenter explained that because EGWPs operate differently than individual market plans (for example, different enrollment processes, the need to coordinate with non-Part D supplemental coverage), it may reduce the complexity of a parent organization's Part D operations if it is permitted to keep its EGWP business under a separate contract. Moreover, since EGWP plans are not offered to individual beneficiaries, these contracts would not be subject to the same incentives that might encourage sponsors to game their star rating performance to attract enrollments.

Response: We do not believe the commenter's arguments support special treatment under our proposal for organizations offering EGWPs. While it is true that CMS affords EGWPs, through the application of our statutory waiver authority, flexibility in meeting Part D requirements, the resulting differences in requirements are not so significant that a separate EGWP-only contract is necessary for an organization to administer such plans successfully. In fact, the resulting differences do not represent conflicting requirements that might create the need for a separate contract held by a different legal entity to administer EGWPs. Rather, the EGWP requirements are a result of our completely waiving certain requirements (for example, pharmacy access standards, prior approval of marketing materials) or modifying other requirements (for example, enrollment limited to employer group members), and a single plan sponsor can meet these if it is already offering individual market PDPs. In fact, it is common for a PDP sponsor to sign a stand-alone PDP contract with CMS that includes an EGWP addendum through which the single entity offers both individual market plans and EGWPs (that is, "800 series" plans). Our experience in administering the Part D program indicates that a properly managed single legal entity is capable of complying with multiple sets of Part D requirements. Also, while sponsors may not have the same incentives to game the star rating system to attract EGWP enrollments as they do to attract individual beneficiaries, that fact alone would not support allowing sponsors to maintain separate EGWP contracts. We believe the single contract rule is necessary to maintain the integrity of the star ratings that are reported to the public. As we stated earlier in the preamble discussion of our proposal, star ratings are intended to reflect all aspects of the PDP operations controlled by a unique contracting entity, including the

administration of EGWP products. Allowing a parent organization to maintain a separate EGWP contract would mean that the star ratings associated with each of its PDP contracts contract would provide an incomplete picture of the organization's performance. We believe that all members of the public, including those who make plan elections on behalf of employer group members as well as individual beneficiaries, benefit from star ratings information that clearly indicates the quality of all Part D operations under one organization's control.

After consideration of the public comments we received, we are finalizing our proposal without modification, with the exception of a technical edit which changes the proposed phrase "may not approve" to "does not approve" to clarify that CMS will deny all applications that meet the criteria stated in the provision.

13. 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 continued with this proposal 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 that 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 covered 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.

Despite these developments, many sponsors continue to submit three bids per region each year. We believe 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.

While the incremental closure of the coverage gap continues until 2020, we believe 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. 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 affirmatively 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 believed it was urgent that we adopt the proposed policy as soon as possible so that we could bring an end to this bidding practice. We solicited comments on whether there is any real need for more than two standalone plan options per PDP sponsor.

Therefore, we proposed to amend the Part D regulations at § 423.265 to add a revised subsection (b)(3), which would state 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.

In addition to proposing to limit PDP sponsors to submitting one basic and one enhanced bid per coverage year, we

also stated that we were 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 policy goal, based on our interpretation of current law, 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 stated that we were considering three options, including a proposal, based on a reinterpretation of section 1860D–11(b) and (c) of the Act, that enhanced alternative coverage 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. We solicited 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. We received the following comments and our response follows:

Comment: Several commenters expressed support for our proposal to limit sponsors to offering no more than two plans per PDP region. They agree that beneficiaries can be overwhelmed by the number of plan choices, which can cause them to avoid even considering exploring during the annual election period plan options that might better meet their needs.

Response: We appreciate the expressions of support for our proposal.

Comment: A number of commenters stated their opposition to the proposal to limit sponsors to offer no more than two plans per PDP region. Among the assertions made by the commenters was

that the regulatory authority already in place will produce shortly the improvements in bid submissions that CMS seeks and that no further authority is required. The commenters stated that CMS’ application of the meaningful differences standard to its review of bids and its authority to non-renew plans that do not meet minimum enrollment standards already place effective limits on a given sponsor’s number of plan offerings. They stated that the continued application of those authorities, combined with the upcoming closure of the coverage gap, will eventually reduce the room for plan variation to the point of effectively creating the two-plan limit that CMS sought with its proposal. Commenters also expressed opposition to our three options for preventing risk segmentation in plan bidding, with the option requiring enhanced benefits to be offered as a supplement to a sponsor’s basic plan benefit package being particularly disfavored. Commenters that addressed the “supplement” option stated that such a bidding structure would result in less generous enhanced benefits because there would be less opportunity to spread the costs associated with such benefits. They also stated that such a bidding structure would limit formulary options available to beneficiaries because sponsors would have to offer the same formulary for both the sponsor’s basic benefit plan and its enhanced/supplemental option.

Response: We appreciate the comments. We believe that the commenters overstate the effectiveness of the tools already at our disposal to prevent risk segmentation and to make further strides in ensuring that beneficiaries have access to an array of plan options that represent real choice. We have been conservative in our use of the low enrollment non-renewal authority as demonstrated by our adoption of enrollment thresholds that ensure that only the plans that attract negligible interest from the market are non-renewed, so few additional non-renewals are likely to occur under this authority in the coming years. Also, we measure meaningful differences on a relative basis, generally using a 95 percentile threshold to arrive at the annual limits. As plan sponsors reduce the additional value offered in their benefit packages, the 95 percentile threshold will be expected to converge toward the value of basic plans. Consequently, we will need to explore alternative methodologies to ensure meaningful differences remain among a plan sponsor’s PDP offerings.

Nevertheless, the comments have given us reason to conduct further analysis of this issue and continue our

close observation of the developments in the Part D market. Therefore, we are not finalizing this proposal. It may be, as the commenters suggest, that as the coverage gap closes, the problems of risk segmentation and large numbers of plan options may solve themselves. Should that not turn out to be the case, we may revisit the issues of plan number limits and changes to basic and enhanced bid structures, keeping in mind the comments we received in response to this proposal. In the event that we make this or a similar proposal again, we would only do it as part of a new rulemaking process, during which we would solicit public comment once more before deciding whether to publish final regulations.

After consideration of the public comments we received, we are not finalizing our proposal to limit PDP sponsors to offering no more than two bids per PDP region.

14. 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 because it can result in beneficiaries paying different cost sharing for formulary drugs subject to utilization management edits (such as prior authorization or step therapy) during transition than specified in their 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.

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 proposed 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.

Comment: We received numerous comments that this clarification in regulation will simplify the rules for transition policy and reduce beneficiary confusion.

Response: We agree with these commenters that this provision will simplify the rules for transition cost sharing and reduce beneficiary confusion. We believe this requirement will help ensure more consistent treatment of transition cost sharing for formulary and non-formulary drugs across all Part D plans and removes any ambiguity that Part D sponsors may have had with respect to transition cost

sharing for formulary drugs that would otherwise be subject to utilization management edits.

Comment: One commenter wrote that this requirement will further complicate an already complex policy surrounding transition fills.

Response: We disagree with this commenter. This provision removes the ambiguity surrounding the allowable cost sharing when utilization management edits are overridden during transition for formulary drugs, and ensures that beneficiaries will pay the same cost sharing for such formulary drugs during transition and after transition if the utilization management criteria are met. There has been a great deal of confusion from both sponsors and beneficiaries with respect to the proper cost sharing that should apply in these situations during transition and both we and many commenters believe this provision provides the necessary clarification.

In light of the overwhelmingly positive comments on this proposal, we are finalizing this provision without modification.

15. 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 proposed 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. Consequently, as an initial matter, in light of our interpretation of the general purpose of section 1860D–11(i) of the Act, we proposed 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. We outlined aspects of the complex process of private market competition for prescription drugs 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](http://www.cbo.gov/)) to support our reading of the distinctly different types of negotiations between the three parties in “between drug manufacturers and pharmacies and PDP sponsors”. 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, 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, but rather under section 1860D–11(i)(2), as discussed in this section.

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 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. 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. Therefore, in our proposed rule we stated that 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. In hindsight, given the strong reaction of most commenters a better way to have articulated CMS’ long-standing position would have been to focus on what “interfere” means and to interpret it to mean a sort of hindering or influence beyond the implementation and enforcement of statutory requirements.

This is the case because 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. Consequently, we believe 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. So we believe it is clear that such involvement could not be what the Congress intended to prohibit. Therefore, we proposed 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 proposed 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 believe the first part of section 1860D–11(i)(2) of the Act would 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 formulary drug product 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. Therefore, we proposed a provision prohibiting establishment of formulary drug product selection at § 423.10(c) that would specify 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 stated our view that the phrase “price structure” refers 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 (on 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 proposed 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 our proposed regulation would have limited our authority to require full disclosure or uniform treatment and reporting of drug costs and prices.

We received numerous comments on this proposed interpretation, both supportive and strongly critical. Different commenters asserted different “plain readings” of the statute. The wide variation in interpretations of the statutory prohibition evidenced in these comments, in our view, confirms our belief that this provision is not consistently understood by all stakeholders. Although the interpretation we proposed to codify is the same interpretation we have been operating under in managing the Part D program since before the beginning of the Part D program, many commenters perceived our proposal as a change in interpretation. And as noted previously, in hindsight we could have better articulated our policy rationale than by stating that the prohibition in section 1860D–1(i)(1) did not apply to negotiations between sponsors and pharmacies. These widely differing reactions to our proposal to codify our current interpretation lead us to understand that additional work needs to be done to better explain our policy, as well as to address the concerns and arguments advanced by numerous commenters. Consequently, we will not finalize the proposed regulatory provision at § 423.10 in this final rule, and do not intend to codify this provision without issuing an additional future notice of proposed rulemaking.

Comment: Some commenters supported our interpretation and regulatory proposal; others supported the interpretation but did not believe there was any need to codify our interpretation in regulation. One commenter supported our intent to clarify and specify the limits of our authority, but was very concerned about the proposed exceptions to the limitations on our authority and requested greater specificity around the particular CMS requirements that would invoke the exceptions.

Response: We appreciate the supportive comments, and can understand the desire for greater specificity in some areas.

Comment: Several commenters stated that our interpretation violated the plain reading of the statute, and then offered differing interpretations of the plain meaning of the statute. In particular, many commenters asserted that the phrase “between drug manufacturers and pharmacies and PDP sponsors” essentially had the plain meaning of prohibiting any and all negotiations between any two of the parties. Other commenters agreed with our interpretation and that it represented the plain meaning.

Response: These differing interpretations of the statute confirm our belief that the statutory language is not universally understood in the same way by all parties and would ultimately benefit from formal interpretation and codification in regulation.

Comment: Numerous commenters understood us to be proposing that we could now interfere in negotiations between Part D sponsors and pharmacies that we had previously avoided.

Response: We intended to explain how we could reconcile the distinct sets of negotiations in the private market between manufacturers and pharmacies, between manufacturers and plan sponsors, and between plan sponsors and pharmacies with both the non-interference provision and within the context of the rest of the statute. Since the statute establishes numerous requirements that CMS must implement concerning access to network pharmacies and negotiated prices, we sought to make that distinction in the proposed rule by proposing that a CMS role in negotiations between plan sponsors and pharmacies is not prohibited under section 1860D–11(i)(1) of the Act, but rather under section 1860D–11(i)(2) of the Act. The strong reaction of many commenters to this interpretation has persuaded us that a better way to have articulated this distinction would have been to focus on what “interfere” means and to interpret it to mean a sort of hindering or influence beyond the implementation and enforcement of statutory requirements. The Congress has provided many contractual requirements for CMS to enforce between sponsors and pharmacies, and 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. In other words, we sought to explain that we could not involve ourselves in negotiations between plan sponsors and pharmacies except as necessary to fulfill our requirements established under the statute. From the many comments we received on this issue, we conclude that our explanation on this point in the proposed rule conveyed the wrong impression.

Comment: Numerous commenters characterized our proposal as a change in policy. These commenters frequently cited examples of our previous invocation of the prohibition on interference in private market negotiations as evidence of this alleged change. For instance, commenters cited a CMS response to a 2008 OIG report in

which CMS did not concur with several OIG recommendations on the basis that to do so would violate the non-interference clause. This report, “Review of Medicare Part D Contracting for Contract Year 2006” (A–06–07–00082) is available at: http://oig.hhs.gov/reports-and-publications/archives/oas/cms_archive.asp.

Response: The interpretation put forth in our proposed rule was intended to represent the interpretation that the Part D program has been operating under since before the beginning of the Part D program. We believe the examples cited by commenters can all be traced back to specific situations and topics that are consistent with our proposal. For instance, in the case of the 2008 OIG report, the specific recommendations with which CMS did not concur on the basis of interference were recommendations that violated that provision in exactly the way we proposed to prohibit in our proposed rule. Specifically, we disagreed with requiring Part D sponsors to disclose to pharmacies the data source, basis, and methodology used to develop reimbursement rates, or to reveal to pharmacies criteria for receiving higher reimbursement rates available to certain categories of pharmacies, and with CMS determining whether reimbursement rates for extended days’ supplies are adequate. In other words, we disagreed with CMS becoming a party to discussions between Part D sponsors and pharmacies on price structures or the arbiter of the adequacy of reimbursement methodologies. Thus, in our view, our responses to the OIG report were entirely consistent with our proposed regulation. (We note that section III.A.17 of this final rule addresses changes to the prescription drug pricing standard requirements established under MIPPA, but still does not require disclosure of data source, basis, and methodology used to develop reimbursement rates.) We believe that the perception of a change in interpretation arises from both the lack of a common understanding of the statutory prohibition, and from the absence of any discussion of how our previous statements on the record on this topic do or do not conform to our proposals. The numerous examples provided by commenters will be very helpful in developing such an explanation in any future rulemaking on this policy.

16. 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. 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. Therefore, we proposed changes to rectify this concern.

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 at § 423.100 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 was published on May 16, 2008 in the **Federal Register**, 73 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 with respect to how 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.

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. Therefore, they cannot 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 proposed 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 proposed 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.

We received the following comments on our proposed revisions and our responses follow.

Comment: We received a significant number of comments in support of this provision based on the improved transparency of pharmacy price concessions. One commenter stated the belief that PDPs and their contracted PBMs are circumventing the Medicare Modernization Act by hiding pharmacy charge backs as overall administrative surcharges. These commenters stated that amounts charged to pharmacies in the form of “administrative fees,” “network access fees” or rebates of dispensing fees appeared to be vehicles for price concessions. Another commenter believed that the proposed provision would alleviate the complexity of tracking actual drug reimbursement and help ensure that reimbursement structures are not actually increasing Medicare costs. Several commenters stated that inclusion of accurate costs in the Plan Finder tool would be of benefit to consumers, and added that drug prices must be accurate and transparent to help seniors compare plan costs.

We also received some comments in opposition to the proposed provision. These commenters stated that some price concessions that benefit the Part D program do not lend themselves to inclusion in negotiated prices. A few commenters stated that savings from lower point-of-sale prices would be reflected in higher enrollee premiums and increased premium subsidies. Other commenters stated that payments received from pharmacies to PBMs were for services provided and should not be considered price concessions. One commenter stated that just because pharmacies pay for and benefit from services from PBMs does not necessarily make the fees price concessions. A few commenters opposed the provision on the grounds that it would place new limitations on the terms sponsors will

be able to negotiate with network pharmacies and stated that CMS is limiting the tools available to sponsors to offer varied incentive-based agreements such as providing additional compensation for increased dispensing of generic medicines or superior customer service. Other commenters thought that Part D sponsors and PBMs should be able to retain the flexibility to determine which concessions to pass through to beneficiaries through drug prices or lower premiums. To bolster this argument one commenter quoted from our 2009 rule in which we stated that the statute says prices will “take into account” price concessions not include them all, and that a “plain reading of this demonstrates the Congress’ intent to be permissive of Part D sponsors to choose how much of their negotiated price concessions to pass through to Part D beneficiaries at the point of sale”.

One of the commenters who opposed the provision suggested that, as an alternative, CMS use its existing authority to require plans to disclose both in the bid pricing tool (BPT) and through DIR, specific line-item reporting of performance-based DIR received from network pharmacies. Several commenters urged CMS to use its existing DIR reporting authority to capture price concessions attributable to risk-based performance measures, which often require retrospective performance review and therefore cannot be captured in negotiated prices. The commenters argued that the DIR process must be used to allow sponsors to maintain innovative payment arrangements that yield efficient and quality pharmacy networks. One of these commenters voiced support for “a competitive and level playing field for all sponsors” and urged CMS to create clear and comprehensive regulatory guidance with respect to pharmacy price concessions.

Response: We appreciate the detailed comments we received in response to our proposal. We continue to believe it is critical that negotiated prices reported on PDEs have a consistent meaning across the Part D program in order to preserve a level playing field in bidding and cost reporting. As we stated in the proposed rule, we intended clause 2 of the existing definition of negotiated price 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. Our proposal to require all pharmacy price concessions

be included in the negotiated price would ensure that negotiated prices have a consistent meaning, provide for increased transparency in cost reporting to CMS, and allow for meaningful price comparisons between Part D sponsors.

While we recognize that some pharmacy price concessions are contingent upon risk or incentive based arrangements, we provided an illustration of how such price concessions could adjust future negotiated prices, rather than adjusting the current quarter’s prices downward through DIR reporting. Consequently, we did not believe that our proposal would limit Part D sponsors’ ability to enter into such contracting relationships with their network pharmacies. We did not propose placing additional restrictions around such arrangements, only that their resulting costs must be transparent to all concerned.

Nevertheless, we are persuaded by the comments that there may be some price concessions from pharmacies that are based upon contingencies that cannot be known at the point-of-sale and that these price concessions should be distinguished from all other pharmacy price concessions and continue to be reported as direct or indirect remuneration. This would be also be consistent with the commenter who pointed out the statutory language that negotiated prices will “take into account” price concessions. While we had proposed including all price concessions from pharmacies in the negotiated price to provide maximum price transparency, we believe that there is room for further discussion with industry to determine whether there are specific types of arrangements that do not lend themselves to accurate inclusion in the negotiated prices. As long as all types of price concessions are consistently “taken into account” in the same way by each sponsor in preparing bids and reporting costs, bids and point-of-sale negotiated prices can remain comparable. Therefore, in response to comments we are revising our proposed definition of negotiated price to allow a narrow exception to the requirement that all pharmacy price concession be included in the negotiated price for those contingent pharmacy price concessions that cannot reasonably be determined at the point-of-sale. We intend to identify in our DIR reporting guidance which types of price concessions from pharmacies would meet the standard for this exception, and we intend to consult with industry in developing our guidance in this area. Any contingent pharmacy price concessions or incentive payments that

can be determined at the point-of-sale must be included in negotiated prices.

We agree with the commenter who pointed out that not all fees that pharmacies pay to PBMs are price concessions. But as discussed in the NPRM, when such fees take the form of deductions from payments to pharmacies for Part D drugs dispensed, 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. Standard treatment of all price concessions will bring improved transparency to pharmacy payments. We disagree that this change is inconsistent with the MMA because the MMA established Medicare Part D as a voluntary, private-market-based program what 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. While Part D sponsors may lose some flexibility in deciding how much of the price concessions should be applied to beneficiaries at the point of sale or through reduced premium, consistency in how specific types of price concessions are “taken into account” in negotiated prices is necessary in order to preserve reliance on market competition between plans, which is a cornerstone of the Medicare Part D program.

Comment: A few commenters questioned CMS’ authority to implement the proposed change and some asserted that the non-interference provision prohibits CMS from defining negotiated prices.

Response: We disagree with these comments. We have the authority to interpret the provisions of section 1860D–2(d)(1)(B) and believe our interpretation is appropriate. We also have a history of regulating on cost and price concession reporting. We established detailed guidance for accurate and consistent cost and price concession reporting through both PDE and DIR guidance and other payment reconciliation rules, and have twice before regulated the definition of negotiated price and how it is to be treated in Part D benefit administration and in payment reconciliation. In the original Part D rule, negotiated prices were mainly defined as “prices for covered Part D drugs that were available to beneficiaries at the point of sale at network pharmacies”. This definition permitted sponsors or their intermediaries to include PBM spread in the price. Therefore, on January 12,

2009 we published in the **Federal Register** the final rule with comment entitled, “Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions” (74 FR 4131), to clarify that negotiated prices must be the amounts actually received by the pharmacy for the drug. We are now once again revising the definition.

Comment: Several commenters addressed the effective date of the proposed rule. Commenters advocated for a prospective implementation only, or expressed the hope that the rule could be delayed until 2016. They stated that time was needed to allow collaboration with the industry, enable CMS to capture the changes in detailed guidance, and give Part D sponsors time to revise their pharmacy network contracts.

Response: In response to these comments we are postponing implementation of this provision until the 2016 contract year and will use this time to work with the industry to develop guidance on when the exception previously described applies.

After considering comments received, we are finalizing the provision as proposed with modification to require that negotiated prices be inclusive of all price concessions from network pharmacies except contingent price concessions that cannot reasonably be determined at the point-of-sale. We also modified the language in paragraph (4) by clarifying that additional contingent amounts, such as incentive fees, that increase prices are always excluded from the negotiated price by removing the word “may,” and we also replaced “cannot be predicted in advance” with “cannot reasonably be determined at the point-of-sale” to parallel paragraph (2). Finally, we have modified the effective date of this provision to 2016 to avoid disruption of the existing regulation which will be applicable for the rest of 2014 and 2015.

17. 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 and 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 final 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.”

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.

Therefore, we proposed 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 proposed 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 proposed 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. We welcomed comments on alternative approaches to ensuring that the offering of preferred cost sharing does not increase our payments. We proposed 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.15. of this final 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 requested 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 solicited 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 solicited 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 solicited 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 proposed a clarification in terminology to better describe the application of the policy to a sponsor’s approved Part D pharmacy network. Specifically, we proposed 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 solicited comment on whether any further clarifications of terminology are needed for this policy proposal.

We received the following comments and our responses follow:

Comment: Many commenters strongly supported our proposal to require consistently lower negotiated prices at pharmacies offering preferred cost sharing. These commenters found it troubling that some Part D plans’ negotiated prices were not lower for some drugs at pharmacies offering preferred cost sharing and stated that the alignment of preferred cost sharing with lower negotiated prices is necessary to ensure that arrangements with pharmacies to offer preferred cost sharing do not cost the government more and provide savings for

beneficiaries. The commenters assert that the current framework is not transparent and allows PBMs to maximize profits by moving as much volume as possible to their mail order pharmacies with little, if any, savings for the beneficiary, and even the possibility that the beneficiary could pay more than they would at a pharmacy without preferred cost sharing.

However, other commenters strongly opposed our proposal to require consistently lower negotiated prices at pharmacies offering preferred cost sharing. While no commenters dispute that benefit designs that provide preferred cost sharing at some network pharmacies must not increase payment to Part D plans, many dispute our proposal to make this determination based entirely upon negotiated prices. They assert that the reference in the statute to “an increase in payments” does not refer solely to negotiated prices but must also take into consideration the direct subsidy, reinsurance subsidies, end of year reconciliation, and beneficiary premiums. Several commenters said that we do not have the authority to implement this proposal because it violates the section 1860D–11(i) statutory non-interference provision that prohibits CMS from instituting a price structure for the reimbursement of Part D drugs. One commenter said that while they share our objectives for preferred cost sharing arrangements to lower costs for the Part D program and beneficiaries, they believe these arrangements can be beneficial if the price concessions are reflected in prices at the pharmacies and/or used to lower premiums. Commenters also stated that requiring lower negotiated prices for every drug will restrict the flexibility that Part D sponsors need to negotiate discounts with pharmacies, which will lead to increased prices and beneficiary disruption. Moreover, commenters argue that savings from preferred cost sharing cannot be determined at the individual drug level because that does not account for different drug mixes at different pharmacies that could better be determined by actuarially sound aggregate methods of comparison. One commenter recommended that we implement a “fixed basket of drugs” approach similar to our Out-of-Pocket (OOPC) tools used for determining meaningful differences between basic and enhanced plans. A number of commenters also contend that such a consistently-lower-price requirement is unworkable because their contracts frequently have a “lesser of” provision

to ensure they only pay the pharmacies’ usual & customary prices when such prices are lower than the negotiated rate and they would have no way to ensure that pharmacy usual & customary prices are never lower at pharmacies that do not offer preferred cost sharing. Finally, most commenters opposed CMS establishing standards on how much lower drug costs should be in return for preferred cost sharing.

Response: We appreciate the significant support we received for the proposal and continue to believe that the proposal would provide a transparent mechanism for ensuring compliance with the statutory requirement that prohibits benefit designs with preferred cost sharing at certain network pharmacies from increasing payments to plans. While we agree that basing increased payments to plans entirely on negotiated prices is not the only possible interpretation of the statutory requirement, we believe it is a reasonable interpretation that would allow us to uniformly apply the statutory requirement while also providing price transparency to beneficiaries and maximizing price competition.

Nevertheless, we premised this proposal on our related proposal to change the definition of “Part D Negotiated Price” to include all pharmacy price concessions. If we are going to use negotiated prices as the sole basis for determining increased payments to plans for purposes of section 1860D–4(b)(1)(B) of the Act, then all pharmacy price concessions must be in the negotiated price because the price would need to have the same meaning at every network pharmacy. Consequently, because we are finalizing a different definition of negotiated price than originally proposed, one that will allow for the exclusion of some pharmacy price concessions from the negotiated price, we will not be finalizing our proposal to require consistently lower negotiated prices at pharmacies offering preferred cost sharing. Clearly if some price concessions are not reflected in the negotiated price, a higher negotiated price may not result in increased payments to plans. We also are not finalizing an alternative requirement at this time, in light of the comments that suggested different approaches because we intend to consider them further as we determine how best to ensure, in a transparent manner, that preferred cost sharing does not increase payments to plans. While we are not finalizing the proposal, we disagree with the commenter who stated that CMS does not have the authority to implement

such a requirement because it is consistent with our obligation to implement and enforce many statutory requirements under the Part D program that directly or indirectly affect negotiations between pharmacies and Part D sponsors, in particular section 1860D–4(b)(1)(B) of the Act, and including several other closely related statutory provisions contained in section 1860D–4(b)(1) of the Act. For example, we have previously established retail and non-retail pharmacy network adequacy requirements under this authority to ensure convenient pharmacy access as required under section 1860D–4(b)(1)(C) of the Act.

Comment: Some commenters asserted that our April 2013 study (“Negotiated Pricing between Preferred and Non-Preferred Pharmacy Networks”, posted at: <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/>.

Downloads/PharmacyNetwork.pdf) that we cited as showing some negotiated prices for drugs were higher at pharmacies offering preferred cost sharing than the rest of the network was flawed. Therefore, they contend that our rationale for the proposal was flawed. They point out that this study only looked at prescription drug event (PDE) data and did not take into consideration any direct or indirect remuneration. They claim that even if you accept the results of this study as stated, it shows only that drug prices were “slightly higher” and only in “a few” preferred networks in “some plans”. In addition, commenters raised methodological concerns because the CMS study was not normalized for different drug mix and utilization between plans, which they said will bias the results and lead to incorrect conclusions that will contribute to higher costs for beneficiaries and the Part D program.

Response: We appreciate the detailed comments regarding the validity of our study and the conclusions that we drew. However, we disagree with the assertion that our study was flawed and believe some commenters misinterpreted our findings. Specifically, despite the comments, we did not conclude that our findings showed that some pharmacies with preferred cost sharing were more expensive than some other pharmacies that were not offering preferred cost sharing. We acknowledge that this study did not take into consideration price concessions reported as DIR or differences in drug mix, and therefore agree that one cannot make that conclusion given the current definition of negotiated price and variability among plans on what is included in the

price. Nevertheless, we believe the findings of some higher negotiated prices at some pharmacies offering preferred cost sharing demonstrates that we cannot assume point-of-sale negotiated prices are always lower at pharmacies offering preferred cost sharing and, therefore cannot assume that benefit designs with some pharmacies offering preferred cost sharing never increase payments to plans. Instead, we believe our study highlighted this vulnerability and the need for us to propose a transparent and consistent method for ensuring these benefit designs do not increase payments to plans.

Comment: Some commenters strongly supported our proposal to remove the definitions of preferred and non-preferred pharmacies and replace them with a definition of preferred cost sharing. These commenters agreed that the term “preferred pharmacy” is confusing for beneficiaries who sometimes interpret this to mean non-preferred pharmacies are out-of-network. Other commenters opposed the proposal because they believe the change in terminology will be confusing for beneficiaries. They note that under the current framework plans may already refer to non-preferred pharmacies as “other network pharmacies” and, therefore, there is no need for this change. Moreover, some commenters opposed removing the term “preferred pharmacy” because they believe it refers not only to lower cost sharing but also quality of services. Another commenter who was supportive of the proposed change also raised concerns about beneficiary confusion from the change in terminology and urged CMS to consider education and outreach efforts to help beneficiary understand the new terminology and add related language to Medicare & You.

Response: We appreciate the comments we received on this proposal. We agree with supporters that this change will help avoid confusion regarding pharmacy network status and more accurately reflect what is meant by preferred. While any change has the potential to initially create some confusion, we disagree that substantively this change will be more confusing to beneficiaries going forward. In addition, we are perplexed by the comments that said their identification of preferred pharmacies also takes into consideration the quality of pharmacy services because that was never part of the regulatory definition. Nevertheless, we are not finalizing this proposal because it is so closely tied to the other preferred cost sharing proposal

to revise § 423.120(a)(9) that is not being finalized as a result of changes to the definition of negotiated price in this final rule (as described in section III.A.25 of this final rule).

After considering of the public comments received, we are not finalizing the proposed changes to §§ 423.120(a)(9) and 423.100. We will undertake notice and comment rulemaking if we are going to make changes to these provisions in the future.

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

We proposed 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 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. Specifically, 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. 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”).

We stated in the preamble to the September 2011 final rule that a “prescription drug pricing standard” is an accepted methodology based on published drug pricing. In the preamble

to the proposed rule, we explained that this was because we were unaware at the time that there is at least one standard based, at least in part, on costs of the drugs that is not based strictly on published drug pricing, which is maximum allowable cost prices. Now that we have become aware of these types of pricing standards, we wish to amend 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 section 173 of MIPPA indicates the provision’s purpose—Part D sponsors must update their prescription drug pricing standards regularly “to accurately reflect the market price of acquiring 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, including in cases when the reimbursement is based upon maximum allowable cost prices.

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 we compare 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 this and other reasons detailed in the preamble to the proposed regulation, as well as in response to comments received on the proposed regulation, we are defining “prescription drug pricing standard” in regulation. Specifically, in § 423.501 a “prescription drug pricing standard” is now defined as “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 acquisition cost, average manufacturer price, average sales price, maximum allowable cost, or other cost, whether publicly available or not.” In addition, we are finalizing the following technical changes to make the regulations on prescription drug pricing standards easier to reference: (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. Also, we are moving the current requirement to indicate the source used for making any such updates to (b)(21)(ii) from § 423.505(i)(3)(viii)(B), 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), we are finalizing a new requirement and not a technical change, 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 have to convey to network pharmacies the actual maximum allowable cost prices to be changed in advance. We are requiring that the actual maximum allowable cost 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 eliminating 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 duplicative to language in 423.505(b)(21). As a result of the changes described previously, there would be no paragraphs (A) and (B) of § 423.505(i)(3)(viii) (which we note will be redesignated as § 423.505(i)(3)(vii) due to other changes in this final rule), and this provision simply requires 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 changes will make the regulation text easier to reference and understand.

Comment: We received a very significant number of supportive comments for our proposal. These commenters asserted that maximum allowable cost prices are a source of deep and ongoing concern for pharmacies. Specifically, these commenters assert that PBMs update maximum allowable cost prices of drugs for which the drug costs are declining in a timely manner, but do not do so when the drug costs are increasing. These commenters asserted in particular that there were significant spikes in the acquisition costs for certain generic drugs in Fall 2013, but that PBMs did not update their maximum allowable cost prices accordingly. These commenters also offered specific examples of maximum allowable cost prices of drugs that they asserted resulted in reimbursement that was below pharmacy acquisition costs for the drugs, yet the drugs were not available on the market at lower prices. These commenters stated that pharmacies were forced not to stock certain drugs due to inadequate reimbursement based on maximum allowable cost prices of drugs, sometimes creating access issues for patients. These commenters further

stated that the pharmacies are even in danger of going out of business altogether due to the low maximum allowable cost prices for drugs, and that if pharmacies are forced to close their doors for this reason, there would be even greater health care access issues in many communities.

The supportive comments stated that greater transparency in maximum allowable cost prices of drugs would not only give pharmacies the ability to shop for more cost-effective versions of generic drugs, but would improve pharmacies’ ability to evaluate Medicare Part D plan contract proposals, plan their business staffing levels and potential capital investments, and monitor claims reimbursements and appeal when it appears that there has been a reimbursement error.

Conversely, some other commenters opposed our proposal. One commenter asserted that our proposal was based upon anecdotal complaints from pharmacies. This commenter stated that PBMs make their most utilized maximum allowable cost list available upon request to any pharmacy that asks for it, and that pharmacies almost never make such a request.

Response: We thank the commenters for their supportive comments of our proposal. Given the voluminous number of supportive comments we received, we disagree with the commenter that stated that our proposal was based upon anecdotal pharmacy complaints. However, we were surprised to learn that pharmacies do not routinely request PBMs’ most utilized maximum allowable cost lists, and wonder if pharmacies do not realize that they are available upon request. We agree with the supportive commenters that greater drug price transparency will further increase competition in the drug market which can lead to even lower drug prices. Therefore, we encourage pharmacies to make requests for the most utilized maximum allowable cost lists from the PBMs with which they do business, and thank the commenter for this suggestion.

Comment: Many commenters support our proposal out of concern that the uncertainties surrounding current maximum allowable cost prices for drugs fall more heavily on smaller rural and community pharmacies and may limit beneficiary access. Additionally, these commenters expressed support for greater drug price transparency for Medicare beneficiaries.

Response: We thank the commenters for their support of our proposal.

Comment: Some commenters opposed our proposal, asserting that it would increase costs by requiring a specific

time period (which many commenters interpreted to be 7 days advance notice) for advance notice, as generic drug costs generally decrease over time. It also appeared that some commenters asserted that requiring *any* advance notice of maximum allowable cost prices would increase costs, including one who made a general assertion that it would permit pharmacies and drug manufacturers to “game the system” by modifying the timing of their various transactions in a manner that capitalizes on the pricing changes. Other commenters stated that the proposal would interfere with a mechanism that incentivizes pharmacies to purchase the least expensive generic drug available. Finally, some commenters opposed the requirement, asserting that requiring price updates at least every 7 days is redundant of the frequent updates that are inherent in a maximum allowable cost pricing mechanism and only adds administrative cost.

Conversely, many commenters requested that PBMs be required to give at least 7 days prior notice before a maximum allowable cost price change. One commenter opposed the proposal, but recommended as an alternative that maximum allowable cost prices be updated every 7 business days, and not necessarily beginning on January 1 of each year. Another commenter opposed the proposal, but recommended as an alternative that the no-less-than-7 day update requirement for maximum allowable cost prices be extended to no less than every 14 days.

Response: This requirement does not specify any particular time period for advance notice of maximum allowable cost prices to network pharmacies. The requirement is that maximum allowable cost prices of drugs must be updated at least every 7 days and disclosed in advance of their use, if the source for any prescription drug pricing standard is not publicly available. Also, if generic prices generally decrease over time, updating maximum allowable cost prices for drugs at least every 7 days generally should have a downward pressure on overall drug costs. Therefore, we do not agree with the commenters that the requirement will necessarily increase costs. Also, maximum allowable cost prices currently must be disclosed at point-of-sale (POS) in order for a drug claim to process, so we do not believe that mere advance notice changes the drug claims processing system so significantly as to permit gaming of the system, particularly since the commenter that raised this concern provided no detail to back up its assertions about how any such gaming would occur. Furthermore,

we do not understand the argument for the status quo—that disclosing maximum allowable cost prices only at POS better incentivizes pharmacies to purchase the least expensive generic drugs compared to requiring some advance notice of those prices to the pharmacies. We think pharmacies will still be incentivized to acquire a drug at the lowest cost possible regardless of whether disclosed maximum allowable cost prices are declining or increasing.

We further were not persuaded by the argument that the requirement is redundant, as it seems to suggest that the Part D sponsors/PBMs will frequently update maximum allowable cost prices anyway and disclose them at POS, but requiring them to be updated at least every 7 days and disclosed in advance adds significant administrative costs. In fact, we think just the opposite—that negligible administrative costs will be incurred by Part D sponsors due to this requirement, since they are using and updating maximum allowable cost prices for reimbursement of drug claims already and must make minimal changes to that current system to comply with this requirement. In other words, so long as Part D sponsors are updating maximum allowable cost prices as frequently as commenters asserted that the prices change and using them for reimbursement, then the new updating and disclosure requirement changes nothing for that sponsor, other than that the sponsor must now disclose the maximum allowable cost prices to its network pharmacies in advance of their use (rather than just at point-of-sale) in a way that enables the pharmacy to connect a claim to the correct drug price at the appropriate point in time in order to validate the price. However, we acknowledge that to the extent the assertions of some commenters are true—that PBMs update maximum allowable cost prices only when drug prices are declining, but not when they are increasing—then we would agree that this requirement may also result in more updating for PBMs.

In addition, we note that the requirement to update prescription drug pricing standards every 7 days beginning on January 1 of each year is a statutory one. We do not have the authority to implement different update timing requirements, nor to disregard the January 1 start date every year.

Comment: Some commenters stated that our proposal was operationally infeasible, as there are different maximum allowable cost lists for different pharmacies, types of pharmacies, types of programs (commercial, Medicare D, TRICARE,

etc.) and over 100,000 drugs are subject to maximum allowable cost prices, (sometimes daily). Some other commenters stated that sending network pharmacies a stream of continuous maximum allowable cost pricing updates would be a nuisance and distraction and not helpful to network pharmacies. One commenter did not object to our proposal, as long the requirement can be met in a manner that is efficient, such as on a look-up basis through a secure internet site that network pharmacies can access at any time to obtain the most current maximum allowable cost pricing for a particular drug.

One commenter requested that we require maximum allowable cost prices to be disclosed via a certain consistent format layout and delivery method and include industry standard drug identifiers, such as Generic Pricing Indicators (GPI), and that the data format allow for efficient data analysis such as MS Excel, or a text document that could be converted to Excel.

Response: We were not persuaded by the commenters that stated our proposal was operationally infeasible. It does not make sense to us that Part D sponsors/PBMs can manage the complexity in pharmacy reimbursement described in the comments, but cannot manage to modify that existing system in order to disclose the prices in advance of their use to network pharmacies, and update them at least every 7 days. Rather, we were persuaded by the commenter that described one option for meeting the requirement—through a secure internet site that allowed network pharmacies to look up their drug prices. This option would be compliant with the prescription drug pricing standard requirement, so long as the site or other delivery method to convey maximum allowable cost prices enables pharmacies to connect a claim to the correct drug price at the appropriate point in time in order to validate the price. We decline to require a certain format layout and delivery method for disclosure of maximum allowable cost prices, but note these matters can be addressed by the parties in their negotiations.

Comment: Some commenters asserted that requiring the disclosure of maximum allowable cost methodology would increase Part D program costs by revealing competitive information. Many other commenters requested that we require PBMs to disclose the specific NDCs used to compute maximum allowable cost prices on drugs.

Response: Our proposal did not require Part D sponsors/PBMs to disclose their maximum allowable cost

methodology, nor the proprietary data source or basis used to develop reimbursement rates. We note that 423.505(b)(21)(ii) will require a Part D sponsor to indicate the source for making updates to a prescription drug pricing standard. In the case of publicly available standards, the sponsor would identify the standard. In the case of maximum allowable cost pricing that is not publicly available, the sponsor would indicate that the standard is maximum allowable cost pricing to meet this particular requirement. We also decline to require Part D sponsors to disclose the specific NDCs used to compute maximum allowable cost prices. However, we note that these matters can be addressed in contractual negotiations.

Comment: Some commenters asserted that maximum allowable cost prices are not a prescription drug pricing standard, and that CMS is exceeding its statutory authority in making it one. One commenter asserted that the Congress' intent in enacting section 173 of MIPPA was to ensure that pricing standards are timely adjusted when market prices fluctuate and not to ensure that pharmacies have current data on reimbursement amounts. This commenter also stated that when a payment methodology uses non-public costs for setting prices, payment amounts may have no direct relationship to fluctuations in acquisition costs. Many commenters specifically supported the language "includes, but is not limited to" in the proposed definition of prescription drug pricing standard, stating that without this language, PBMs will shift to a different drug claim reimbursement mechanism over time and assert that the new mechanism is not subject to the prescription drug pricing standard regulation. Another commenter helpfully pointed out that our proposed definition of "prescription drug pricing standard" mistakenly referred to "wholesale average cost" instead of "wholesale acquisition cost."

Response: We thank the commenters for their supportive comments and note that we are finalizing the definition of "prescription drug pricing standard" as proposed, with the exception of changing "wholesale average cost" to "wholesale acquisition cost." We disagree with the commenters that maximum allowable cost prices are not a prescription drug pricing standard, and we disagree that we are exceeding our authority in specifying in regulation that maximum allowable cost prices, like other prescription drug standards, must be updated in accordance with the statutory requirements. In our view, it is

clear that Congress believed that if a standard is based on the cost of a drug (whether directly or indirectly), it must be updated to accurately reflect the market price of acquiring the drug. Since the statutory language of section 173 of MIPPA does not exclude maximum allowable cost prices from the term "prescription drug pricing standard," and maximum allowable cost prices are based on the cost of the drug and thus fluctuate and are updated, we believe it is reasonable to interpret the term, "prescription drug pricing standard," to include maximum allowable cost prices. As such, they must be treated as any other prescription drug pricing standard under the statutory and regulatory requirements. In the case of published prescription drug pricing standards, the standards themselves provide pharmacies with current data on reimbursement amounts. In the case of non-published ones, disclosing the prices themselves in advance of their use provides this data. We agree with the commenter who asserted that MIPPA section 173 is intended to ensure that prices are adjusted timely, but we disagree that it necessarily follows that the Congress did not intend to ensure that pharmacies had access to current data on reimbursement amounts. We believe that the requirement for timely updating of reimbursement standards must include sufficient transparency so that pharmacies can determine that the updating requirement is being fulfilled. The disclosure requirements we are finalizing here are consistent with the updating requirement, and are appropriate to ensure sufficient transparency.

Comment: Many commenters stated that having current data on the amount of reimbursement pharmacies can expect in turn impacts costs that plan sponsors submit to CMS, as well as prices displayed on Medicare Prescription Drug Plan Finder (MPDFP). Other commenters asserted that the MPDFP is updated every 2 weeks with pricing that is effectively a month old, and that the validity of estimated prices on the MPDFP does not depend on the ability of pharmacies to verify the prices shown, and that this responsibility is on Part D sponsors. One commenter stated that our requirement would necessitate more frequent updating of the MPDFP.

Response: We thank the commenters for their supportive comments of our similar assertions in the preamble to the proposed rule. Our proposal does not affect the current process for Part D sponsors to submit drug price for the MPDFP. Our point about the MPDFP in

the preamble to the proposed rule was that this requirement will enable pharmacies to validate maximum allowable cost prices in the MPDFP. While we agree with the commenters that the MPDFP is not a real-time information system, but rather reflects drug prices at a point in time, we note that these prices should be the correct prices for that point in time. Currently, however, pharmacies have no ready way to validate the prices in the MPDFP that are based on maximum allowable cost prices if they choose to do so. Once maximum allowable cost prices are disclosed to pharmacies in a way that enables pharmacies to connect a claim to the correct drug price at the appropriate point in time, they will be able to validate prices in the MPDFP and alert sponsors, or CMS, to any issues.

Comment: A few commenters requested a delay in the effective date for implementation of this requirement until January 1, 2016. This delay would provide for more preparation time.

Response: We were persuaded by comments to delay the effective date of this proposal until 2016 to give Part D sponsors time to consider the format layout and delivery method for conveying maximum allowable cost prices to network pharmacies in a manner that allows the pharmacies to connect a claim to the correct drug price at the appropriate point in time in an efficient way.

Comment: Many commenters requested that we include a definition for which drugs can be included on a maximum allowable cost list, and requirements for an appeals process for challenging maximum allowable cost prices and for standards related to pharmacy audits. One commenter stated that it sends 200 requests per month to PBMs to increase their maximum allowable cost reimbursement rates to be closer to pharmacy acquisition costs and that very few are ever responded to, and fewer still are ever adjusted.

Response: These comments are out of scope of our proposal.

In light of all the comments received, we are finalizing this proposal without change, except for correcting the error in the definition for prescription drug pricing standard previously noted and delaying the effective date until January 1, 2016.

19. 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 plan's 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 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 proposed 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 are referred to as standard cost sharing levels. Cost sharing levels offered at retail pharmacies at the preferred T&C are referred to as preferred cost sharing levels.

We have 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 and 176 at <http://www.cms.gov/Medicare/Health-Plans/MedicareAdvgtgSpecRateStats/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 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) and (B) of the Act to reduce barriers is not only permissible, but also 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.

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.

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 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.

We proposed 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 proposed 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. We proposed 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 proposed to limit long term care, specialty, and infusion pharmacy cost sharing to the standard monthly rate, as is industry practice today. Second, we proposed 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 proposed 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 solicited 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).

In summary, we proposed 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 proposed 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 proposed 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 solicited 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. We believe these proposals would 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. We received more than 4,000 comments on these proposals and our response follows:

Comment: This proposal received significant support from commenters citing an interest in expanding access to preferred cost sharing and creating a more level playing field for small and independent pharmacies. Many reported that the lower cost sharing at a limited number of pharmacies offering preferred cost sharing leads many beneficiaries to drive sometimes great distances to access these savings, even when they have a stated preference to stay with a local pharmacy, or one where they have a long-term history with the pharmacist. Many other commenters reported that some current marketing practices are mistakenly interpreted as suggesting that only pharmacies offering preferred cost sharing can be used by enrollees of that plan, also leading many beneficiaries to leave their preferred choice of where to access pharmacy services.

Response: We appreciate the strong support we received for this proposal. We agree with many of the commenters who wrote that beneficiaries should be able to choose where they obtain their pharmacy services, and we are very concerned to hear that the current incentives (and potentially current marketing of pharmacies offering preferred cost sharing) lead many beneficiaries to believe that only those pharmacies offering preferred cost sharing can be used. We are also concerned by the many comments reporting that beneficiaries are now driving 30–60 miles to the nearest pharmacy offering preferred cost sharing, or are feeling forced into using mail-order services, despite a preference to stay with a local pharmacy. We share the concerns of commenters who suggest that current contracting practices by sponsors, only extending preferred cost sharing T&C with select pharmacies, are being interpreted by Medicare beneficiaries as a violation of the Any Willing Pharmacy provision in statute. While the Any Willing Pharmacy provision applies only to participation in a plan’s pharmacy network, not the subset of pharmacies offering preferred cost sharing, many commenters reported that access to preferred cost sharing does not align with beneficiaries’ expectation for choice of pharmacy service provider. That is, if a plan offers preferred cost sharing, beneficiaries assume they will be able to access that cost sharing at their own “preferred” pharmacy.

Comment: Some commenters asserted that requiring plan sponsors to allow any willing pharmacy to accept publicly disclosed terms and conditions to offer preferred cost sharing to plan enrollees, in exchange for requisite drug price discounts, would limit sponsors' ability to negotiate significant discounts from a more limited number of pharmacies. Some of these commenters stated that they did not believe CMS had the authority to make this change. A few commenters suggested that CMS use its current authority to respond to plan offerings that we determine to be discriminatory in the availability and access they provide to preferred cost sharing, and to reject plans failing to offer fair access. Many of the opponents of this proposal objected to publicly posting contract T&C, as potentially undermining price competition. These commenters suggested that this change would ultimately result in higher drug costs, as a higher number of pharmacies offering preferred cost sharing would lead to a decrease in the volume of enrollees electing to use any one of these pharmacies, and as a result pharmacies would not be as willing to negotiate deeply discounted drug prices without the promise of a high volume of enrollees. Some commenters submitted economic analyses in support of their claims. Some, but not all opponents questioned CMS' assumption that pharmacies currently offering preferred cost sharing would not elect to discontinue offering preferred cost sharing if such terms and conditions were available to any willing pharmacy.

Response: We continue to believe that reduced preferred cost sharing offered to plan enrollees should be aligned with reduced drug prices charged to the program, aligning the cost sharing price signals with high value plans offering reduced drug pricing. 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 may be necessary to restore price competition in these networks. We disagree with the comments suggesting that this provision violates the non-interference provision. Expanding access to preferred cost sharing aligns with the authority to establish rules defining convenient access within a Part D network, combined with the authority to interpret the any willing pharmacy requirements. We believe the network access provisions in section 1860D-4(b)(1)(A) of the Act support expanding § 423.120(a)(8) to establish access standards for all levels of cost sharing offered under a sponsor's benefit plans,

and that this expansion aligns with Congressional intent to have open competition between plans based on negotiated price.

Numerous comments from opponents of the provision cited published analyses that predate Part D on the elimination of selective contracting practices at the state level and higher drug expenditures noted after this change. However, we are concerned that traditional analyses that study drug expenditures after an expansion of a previously limited network may not be directly relevant to the Part D market. While we recognize the general parallels between the studies submitted for consideration and the any willing pharmacy proposal, any attempt to generalize these studies to the Part D benefit would need to incorporate multiple other variables, especially given the revenue streams other than point-of-sale pricing that may distort other economic incentives. The studies submitted offer only limited explanation of what trends in utilization, pricing, and care management surrounded the state-level changes, and without that context we do not consider these analyses persuasive. Further supporting our concerns, one commenter provided alternative economic analysis that supported our assumption that within the Part D market expanding access to any willing pharmacy may not affect drug prices.

While we continue to believe that there are benefits in increasing transparency and in permitting pharmacies willing to charge reduced prices in exchange for offering preferred cost sharing, in light of these comments we believe it is necessary to further analyze the potential impacts on the Part D market. Considering the conflicting comments and analyses submitted, and the potential consequences of implementing any changes based on incorrect assumptions, we believe it is important to wait and to spend additional time considering the evidence for potential financial impacts within the Part D benefit. We will be closely studying preferred cost sharing practices, including the associated point-of-sale drug pricing, going forward. In response to the comments suggesting that CMS use its current authority to respond to plan offerings that we determine to be discriminatory in its proposed availability and access to preferred cost sharing, we will further explore our authority in this area. In addition, we plan to closely monitor beneficiaries' access to preferred cost sharing, as well as drug pricing by pharmacies offering preferred cost sharing, to determine

whether future rulemaking in this area is necessary.

In summary, pending further study, we are not finalizing the any willing pharmacy contracting proposed provision changes to § 423.120(a)(8) or 423.505(b)(18), nor the proposed changes to limit the authorized levels of cost sharing. We will engage in further notice and comment rulemaking on this issue as warranted in the future.

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

To improve our ability to oversee the Medicare Part D program, we proposed 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 be prescribed by a physician or eligible professional (as defined at section 1848(k)(3)(B) of the Act (42 U.S.C. 1395w-4(k)(3)(B))) who is enrolled in the Medicare program pursuant to section 1866(j) of the Act (42 U.S.C. 1395cc(j)). We generally proposed in revised § 423.120(c)(5) and new paragraph (6) that a prescriber of Part D drugs must have (1) an approved enrollment record in the Medicare program, or (2) a valid opt-out affidavit on file with a Part A/Part B Medicare Administrative Contractor (A/B MAC) in order for a prescription to be eligible for coverage under the Part D program. More specifically, we proposed the following:

- Under § 423.120(c)(5)(ii)(A) and (B), a Part D sponsor must deny or must require its PBM to deny a pharmacy claim for a Part D drug if: (1) An active and valid physician or eligible professional National Provider Identifier (NPI) is not contained on the claim; or (2) the physician or eligible professional (i) is not enrolled in the Medicare program in an approved status, and (ii) does not have a valid opt-out affidavit on file with an A/B MAC.

- Under § 423.120(c)(5)(ii)(C) and (c)(6)(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 eligible professional who: (1) Is identified by his or her legal name in the request; and (2) is either enrolled in Medicare in an approved status or has a valid opt-out affidavit on file with an A/B MAC.

- Under § 423.120(c)(6)(i), in order for a Part D sponsor to submit to CMS a prescription drug event (PDE) 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 eligible professional who is either (1) enrolled in Medicare under an approved status, or (2) has a valid opt-out affidavit on file with an A/B MAC.

- Under § 423.120(c)(6)(iii), a Part D sponsor must deny or must require its PBM to deny a pharmacy claim for a drug (or a request for reimbursement from a Medicare beneficiary for a drug) if the claim does not meet the requirements of § 423.120(c)(6)(i) or (ii), respectively.

The overriding purpose of these provisions is to help ensure that Part D drugs are prescribed only by physicians and eligible professionals who are qualified to do so under state law and under the requirements of the Medicare program.

Our proposed enrollment deadline of January 1, 2015 was intended to give physicians and eligible professionals at least 6 months after the publication of a final rule to complete the Medicare enrollment process. We solicited comments regarding the propriety of this effective date.

The Medicare 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. The enrollment application collects identifying information about the applicant and his or her credentials, such as licensure status. We have been concerned about instances where unqualified individuals are prescribing Part D drugs. In fact, 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).) There have also 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 these and similar vulnerabilities by verifying the credentials of prescribers through either the Medicare enrollment process or their submission of a valid opt-out affidavit.

With respect to the latter, we note that under section 1802(b) of the Act and the implementing regulations at § 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 such contracts, these individuals do not bill the Medicare

program for non-emergency services they furnish to beneficiaries.

Under our proposal, in short, the prescriptions of a physician or eligible professional who is not enrolled in Medicare and does not have a valid opt-out affidavit on file with an A/B MAC would not be covered under the Part D program. As explained in the proposed rule, CMS would furnish or make available to Part D sponsors a list of physicians and eligible professionals who have an approved Medicare enrollment record or who have a valid opt-out affidavit on file with an A/B MAC.

We also solicited comments on the following issues:

- Whether all pharmacies should be required to enroll in Medicare in order to dispense covered Part D drugs. (Alternatively, we sought comment on whether requiring Medicare 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.)

- Whether doctors of dental surgery or dental medicine, including family dentists, should be required to enroll in Medicare in order to prescribe covered Part D drugs. (Note that we did not propose to exclude dentists from our requirements. Sections 423.120(c)(5) and (6) were intended to apply to dentists.)

We received a significant number of comments regarding these proposed provisions. Summaries of the comments as well as our responses follow:

Comment: A number of commenters opposed our proposed changes to § 423.120(c)(5) and the addition of § 423.120(c)(6). Several commenters were concerned that these requirements would disrupt Medicare beneficiaries’ current relationships with their physicians or otherwise prevent patients from seeing certain physicians, hence denying them care. One commenter stated that it appears that state licensure alone is no longer sufficient for an individual to prescribe drugs, and that § 423.120(c)(5) and (6) would inappropriately limit one’s ability to prescribe when he or she is otherwise permitted to do so under state law. The requirement to enroll is particularly disconcerting, the commenter added, considering that the prescribing individual (as opposed to the pharmacy) is not even receiving reimbursement from Medicare for the prescribed drug. Another commenter stated that medication should be based on a patient’s needs, rather than on whether a physician is in the Medicare system. Several commenters also requested

further clarification regarding the intent of our proposed revisions.

Response: The central purpose of our changes to § 423.120(c), as alluded to previously, is to ensure that we can verify that the prescriber is appropriately licensed and certified, is not excluded or debarred from Medicare, and is otherwise qualified under Medicare regulations to prescribe Part D drugs. Again, we have been concerned that unqualified individuals are prescribing such drugs, and the previously-referenced OIG report bears this out. The enrollment process will help ensure that Medicare beneficiaries and the Trust Funds are protected, which is why we intend to proceed with our proposal. We note further that these changes are fully consistent with our requirement in § 424.507 that physicians and eligible professionals who order or certify certain services and items are either enrolled in Medicare or have a valid opt-out affidavit on file with an A/B MAC.

Comment: Several commenters contended that Medicare should not require physicians who do not participate in or take Medicare to enroll in the program.

Response: Our changes to § 423.120(c) permit a physician or eligible professional who has a valid opt-out affidavit on file with an A/B MAC to prescribe Part D drugs.

Comment: Many commenters, some of whom supported our proposed changes, expressed concern about the proposed January 1, 2015 date. Several of them requested that the implementation of § 423.120(c)(5) and (6) be delayed until 2016 or even 2017 to give CMS, prescribers, and plan sponsors adequate time to prepare and to address all operational and system challenges. Other commenters suggested that CMS utilize a phased-in approach, similar to that which was used for CMS’ implementation of § 424.507. These commenters asserted that this would help ensure that patient care is not interrupted, that all information regarding prescribers’ enrollment statuses is correct, that appropriate system testing is done, that CMS engages in regular communication with all affected stakeholders, and that CMS can more accurately report the number of physicians and eligible professionals who will be affected by our proposal. Additional commenters recommended that any revised implementation date be on January 1 so as to coincide with the beginning of the new plan year.

Response: We agree with these commenters regarding the need to allow adequate time to prepare. Therefore, we are revising § 423.120(c)(5) and (6) to

establish an effective date of June 1, 2015. We understand the commenters' desire for a January 1 date, but we do not believe a delay until January 1, 2016 is feasible given our aforementioned program integrity concerns. A June 1, 2015 date, we believe, strikes an appropriate balance between the need to have sufficient time to prepare and the need to ensure that only qualified individuals are prescribing Part D drugs.

We wish to assure plan sponsors, prescriber and supplier organizations, and beneficiary advocacy groups that we will regularly communicate with them in the months leading up to the June 1, 2015 effective date to address whatever concerns they have and to keep them abreast of CMS' preparations for implementation.

Plan sponsors, prescribers, beneficiaries, and other affected parties should note that existing policies that will be superseded by our changes remain intact (and should continue to be adhered to) through May 31, 2015.

In order to: (1) Help ensure that stakeholders can effectively determine which provisions apply to them before and after June 1, 2015, (2) simplify and consolidate our proposed changes to § 423.120(c), and (3) eliminate potential duplication between the provisions we proposed in (c)(5)(ii) and in (c)(6), we are making several technical revisions. The existing version of paragraph (c)(5) will remain intact with the exception of the addition of the "Before June 1, 2015, the following are applicable" language at the very beginning of the paragraph. We are not finalizing our proposed changes to paragraph (c)(5)(ii), but are instead merging them with our addition of paragraph (a)(6). Hence, our final version of new paragraph (c)(6) will read as follows:

"(6) Beginning June 1, 2015, the following are applicable—

(i) A Part D sponsor must deny, or must require its pharmaceutical benefit manager (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 (NPI) is not contained on the claim.

(ii) A Part D sponsor must deny, or must require its PBM to deny, a pharmacy claim for a Part D drug if the physician or eligible professional (when permitted to write prescriptions by applicable State law)—

(A) Is not enrolled in the Medicare program in an approved status; and

(B) Does not have a valid opt-out affidavit on file with an A/B Medicare Administrative Contractor (MAC).

(iii) A Part D sponsor must deny, or must require its PBM to deny, a request for reimbursement from a Medicare beneficiary for a drug if the request is not for a Part D drug that was dispensed in accordance with a prescription written by a physician or, when permitted by applicable State law, other eligible professional (as defined in section 1848(k)(3)(B)(i) or (ii) of the Act) who—

(A) Is identified by his or her legal name in the request; and

(B)(1) Is enrolled in Medicare in an approved status; or

(2) Has a valid opt-out affidavit on file with an A/B MAC.

(iv) In order for a Part D sponsor to submit to CMS a prescription drug event (PDE) record, the PDE must contain an active and valid individual prescriber NPI and 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 by applicable State law, an eligible professional (as defined in section 1848(k)(3)(B)(i) or (ii) of the Act) who:

(A) Is enrolled in Medicare in an approved status; or

(B) Has a valid opt-out affidavit on file with an A/B MAC.

We note that in our final version of § 423.120(c)(6)(iv), we have included the language "must contain an active and valid individual prescriber NPI." This is not a new mandate, for a PDE must currently have the required NPI under § 423.120(c)(5)(i). We are simply clarifying that this requirement continues on and after June 1, 2015.

Again, these are merely technical revisions. They do not involve any changes to our proposed policies.

Comment: A commenter stated that proposed § 423.120(c)(5) and (6) reflect CMS' continued efforts to protect the Medicare program from inappropriate payments for prescription drugs.

Response: We appreciate the commenter's support.

Comment: A commenter requested that CMS furnish sub-regulatory guidance concerning the following issues related to § 423.120(c)(5) and (6): (1) the pharmacy's capability at point of service (POS) to verify that the prescriber's NPI and Medicare enrollment are valid; (2) whether plan sponsors will be expected to deny at the point of service if the beneficiary's prescriber has not completed either the enrollment process or an opt-out affidavit; (3) how CMS will disseminate relevant information to plan sponsors on a timely basis to enable sponsors to set up point of service edits and prevent negative beneficiary impacts; (4) whether CMS will require sponsors to

allow pharmacies to override these denials, similar to other Prescriber ID edits; (5) which party (assuming CMS requires sponsors to pay claims at point of service and investigate post-claim payment) will be financially responsible when it is subsequently confirmed that the prescriber is not enrolled or has not validly opted-out; and (6) how CMS and sponsors will ensure that beneficiaries' access to needed Medicare-covered drugs are not delayed or denied due to this new process. Other commenters requested clarification regarding whether § 423.120(c)(5) and (6) establish any new responsibilities for plan sponsors or pharmacies.

Response: We anticipate disseminating, as deemed necessary, sub-regulatory or other guidance to address the topics raised by the commenter and any new requirements for plan sponsors and pharmacies. Furthermore, and as already stated, we will regularly communicate with plan sponsors, prescriber and supplier associations, and beneficiary organizations prior to the June 1, 2015 effective date to address their concerns.

Comment: A commenter expressed concern that there would be a flood of CMS-855 enrollment application forms or opt-out affidavit submissions by physicians and practitioners. The commenter asserted that this could cause application processing delays and, consequently, the denial of claims for drugs prescribed by practitioners whose applications could not be processed to completion before the implementation date. Another commenter requested information regarding the process and timeline for Medicare enrollment. Another commenter suggested that CMS could give a grace period to accept PDEs for physicians and eligible professionals who have applied for enrollment but are still awaiting the outcome of their application submission. Yet another commenter stated that the large number of revalidation applications being submitted could delay the processing of prescribers' CMS-855 applications.

Response: We believe that our extension of the effective date to June 1, 2015 will give physicians and eligible professionals plenty of time to submit their enrollment applications or opt-out affidavits to their A/B MACs and to have the latter process these materials to completion before § 423.120(c)(6) is implemented. Therefore, we do not believe that the grace period suggested by the third commenter is or will be necessary. As we stated in the proposed rule, we believe that the number of prescribers who are neither Medicare-enrolled nor have validly opted-out is

very low in any event, given that many physicians and eligible professionals furnish or order Part B services. Nevertheless, we will monitor this situation as June 1, 2015 approaches, and will communicate with plan sponsors, prescriber and supplier organizations, and beneficiary advocacy groups about progress in physician and eligible professional enrollment in Medicare pursuant to the requirements of § 423.120(c)(6).

Information on the general provider enrollment process and the timeframes for application processing can be found on CMS' Web site at <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html>.

Comment: Several commenters questioned the accuracy of the verification process, specifically as it relates to PECOS. The commenters stated that PECOS may not capture all enrolled individuals and that the information in the system may either be inaccurate or inconsistent with the data in NPPES. Another commenter requested that CMS permit enrollment via PECOS or a contractor's legacy system.

Response: We are continuously enhancing PECOS and are confident that all enrolled and opted-out prescribers will be accurately reflected in the system. In addition, all current enrollments have been transitioned to the PECOS system and all new enrollments are directly entered into PECOS.

Comment: A number of commenters requested information about how plan sponsors and pharmacies will be able to determine that a prescription was written by a prescriber who is enrolled or has opted-out. One commenter recommended that CMS clarify whether the NPI would be used as the primary identifier of whether a particular physician or practitioner is enrolled. Other commenters requested further clarification regarding: (1) How our proposal will be operationalized; (2) whether the proposed list will include all enrolled and opt-out prescribers and will be sufficiently complete; (3) whether or how often CMS will update the list; (4) how plan sponsors will have access to the file; (5) when CMS will define the standard format; (6) whether there will be start and end-dates in the file; (7) whether there will be an indicator for physicians who are in a pending status; (8) the extent to which NPPES will be used in prescriber validation; (9) whether plan sponsors will still be required to review the OIG/System Access Management ((SAM); formerly GSA) databases; (10) how

deceased prescribers and taxonomy data will be handled; and (11) how plan sponsors and pharmacists will identify revoked or limited supplier statuses.

Response: As already indicated, we will make available to plan sponsors and pharmacies a complete list of prescribers who are either enrolled in Medicare or who have opted-out. The list will be regularly updated. The NPI will be one of several identifiers that can or will be used. We will, as deemed necessary, elaborate further on the verification process, the specific contents of the aforementioned list, the specific frequency with which the list will be updated, and various operational aspects of our requirements via sub-regulatory or other guidance.

Comment: One commenter encouraged CMS to include a review of the prescriber's taxonomy code to confirm prescribing authority as part of the Medicare enrollment process for physicians and other eligible professionals.

Response: We appreciate this suggestion and will take it under advisement as we continue our efforts to enhance the provider enrollment process.

Comment: A commenter requested clarification concerning whether an individual who enrolls in Medicare solely to prescribe Part D drugs will be required to revalidate his or her enrollment every 5 years per § 424.515. Another commenter sought clarification regarding whether enrollment pursuant to § 423.120(c)(5) and (6) would subject the enrollee to all of the enrollment requirements outlined in §§ 424.500 through 424.570 (such as revalidation, deactivation, retention of medical documentation).

Response: We reserve the right to apply applicable requirements in §§ 424.500 through 424.570 to individuals enrolled in Medicare solely to prescribe Part D drugs. This would include the requirement in § 424.515 to revalidate one's enrollment every 5 years.

Comment: A commenter requested that CMS conduct a formal analysis to determine the percentage of prescribers with an active enrollment status by comparing the prescriber NPIs submitted on the PDEs to the Medicare enrollment records. The commenter was concerned that if the unenrolled prescribers disproportionately reflect certain supplier types or geographic areas, this could cause disruptions. The commenter also stated that CMS should develop a process for allowing prescribers who are authorized under state law to prescribe but are not eligible to be enrolled in Medicare to still

prescribe Part D drugs that would be covered.

Response: Prior to the June 1, 2015 date, we will, as deemed necessary, share information with plan sponsors regarding the numbers and percentages of prescribers who are enrolled in Medicare. As for the final comment, the prescriber must either opt-out of the Medicare program or otherwise comply with all Medicare enrollment requirements. We cannot enroll a prescriber who is ineligible to enroll in Medicare regardless of the individual's status under state law, for we are bound by our established enrollment procedures. Consequently, we cannot establish the exception process envisioned by the commenter.

Comment: To limit POS denials that could affect beneficiary access and compromise patient care, a commenter made several recommendations regarding § 423.120(c)(5) and (6). First, the prescriber enrollment files provided by CMS should be the single and authoritative source of prescriber enrollment for all federal health care programs. This would eliminate duplication of effort, streamline the enrollment process for prescribers, ensure the consistent application of CMS requirements, and eliminate the need to review NPPES, the DHHS OIG List, and the SAM. Second, a CMS and industry task force should be developed to establish data integrity criteria, identify the minimum necessary data elements, establish file dissemination frequency to support real-time validations, and ensure that appropriate information is communicated to the pharmacy and patient. Third, a process should be developed to address changes in a prescriber's enrollment status (and to notify beneficiaries of such changes) after the most recent files have been disseminated and before the next update will be available. Fourth, there should be changes to the PDE to support and accept multiple Submission Clarification Codes, as well as a process for CMS to convey more accurate information to the A/B MACs to update their files. Fifth, a CMS call center should be established to support prescriber and beneficiary inquiries on the prescriber's enrollment status. Sixth, there should be a CMS prescriber outreach and education effort to emphasize the importance of enrollment and to address various prescriber questions.

Response: We appreciate the commenter's suggestions and address them as follows.

Regarding the first recommendation, the aforementioned list will be the authoritative list of prescribers who are

enrolled in Medicare or have opted-out. However, it will not contain information regarding said individuals' enrollment in other federal health care programs. We do not believe such an all-encompassing list is feasible at the present time due to the differing requirements and standards of these various programs.

We will continue to work with the health care industry to ensure that the files CMS disseminates contain the information necessary for plan sponsors, pharmacies, and prescribers to enforce and comply with all CMS requirements. This will include appropriate updates to reflect changes in a prescriber's status, as alluded to in the commenter's third suggestion.

We will consider making changes to the PDE as deemed necessary to facilitate the appropriate implementation of and adherence to § 423.120(c)(6). We will also, as deemed necessary, furnish guidance regarding: (1) appropriate information for prescribers and beneficiaries concerning the enrollment status of prescribers; (2) the importance of enrollment; and (3) vehicles for addressing prescriber inquiries.

Comment: A commenter recommended that in order to stop fraud on a prepayment basis and to ensure that Medicare beneficiaries are protected from physicians and eligible professionals who prescribe controlled substances without a valid DEA registration number, CMS should revise § 423.120(c)(6) to require Part D plan sponsors to make payments to a pharmacy or Medicare beneficiary when a Part D controlled substance is prescribed by a physician or eligible professional who has a valid and active DEA registration number.

Response: We do not believe this revision is necessary, for we will be able to revoke an individual's ability to prescribe such drugs under § 424.535(a)(13) (as explained in more detail later in this section). We believe that § 423.120(c)(6) as currently crafted (aside from the effective date) will achieve our goal of ensuring that only qualified physicians and eligible professionals can prescribe Part D drugs. We further note that having a DEA certificate does not necessarily mean that a prescriber is in compliance with all Medicare requirements.

Comment: A commenter requested clarification regarding whether, if a claim is rejected at the POS, a plan will be required to provide beneficiaries with a list of prescribers that are enrolled in the Medicare program.

Response: No. This will not be required.

Comment: A commenter stated that § 423.120(c)(5) and (6) do not take into account the thousands of patients currently serviced by interns and residents who are yet to be licensed but are authorized by state governments to examine, treat and prescribe for their patients provided they function under the supervision of an attending physician. The commenter sought clarification concerning whether these as yet unenrolled individuals would be able to order prescriptions. Another commenter requested that CMS furnish guidance: (1) On how situations in which a resident's enrollment status has changed should be handled; and (2) for teaching hospitals regarding the importance of ensuring that residents comply with Medicare enrollment rules (including updating enrollment data as needed).

Response: Section 423.120(c)(6) does not prohibit interns and residents from prescribing Part D drugs to the extent that these individuals are otherwise qualified to prescribe such drugs under applicable law and regulations and to either enroll in Medicare or validly opt-out of the program.

We will, as deemed necessary, issue guidance concerning the importance of complying with Medicare enrollment rules.

Comment: A number of commenters requested additional clarification regarding the number of physicians who are not enrolled in Medicare.

Response: Although a sizable majority of physicians nationwide are enrolled in Medicare, we do not have a precise number.

Comment: Several commenters recommended that CMS make available for Medicare Advantage plans and other stakeholders access to national, real-time data—preferably in a single file—to use in identifying excluded, non-enrolled, and opt-out suppliers. One commenter added that any opt-out file should have the physician's NPI and specialty, as well as the expiration date of his or her opt-out agreement.

Response: The file alluded to earlier that will be distributed to plan sponsors will be updated regularly. Specific information regarding the frequency of the updates and the contents of the file will, as deemed necessary, be disseminated via sub-regulatory or other guidance.

Comment: A commenter questioned whether there is evidence of higher levels of fraud, waste, or abuse by suppliers who are not enrolled in the Medicare program versus those who are enrolled, and whether increasing the number of enrolled suppliers per §§ 423.120(c)(5) and (6) will provide an

avenue for unscrupulous but unenrolled prescribers to defraud Medicare.

Response: The enrollment process, as explained earlier, is designed to ensure that we can verify that a supplier meets all CMS requirements, such as licensure. Without this process, unqualified and fraudulent suppliers would be able to enter Medicare and bill the program, resulting in billions of dollars being improperly paid to such individuals and organizations. We maintain that CMS' enrollment process reduces the amount of potential fraud, waste and abuse. Furthermore, we do not see how § 423.120(c)(6) will provide an avenue for unscrupulous persons to defraud Medicare. To the contrary, it will protect the Medicare program by ensuring that only qualified and legitimate individuals can prescribe Part D drugs.

Comment: A commenter disagreed with CMS' proposal to allow a physician who has opted-out of the Medicare program to prescribe Part D drugs to Medicare beneficiaries. The commenter stated that CMS does not have the legal authority to revoke the prescribing privileges of a physician or eligible professional who has been convicted of health care fraud but is in an opt-out status or is practicing via private contract.

Response: Section 1802(b) of the Act is clear that certain physicians and practitioners may opt-out of the Medicare program and enter into private contracts with Medicare beneficiaries. We believe that to require such individuals to enroll in Medicare would be inconsistent with this statutory provision.

Comment: A commenter suggested that CMS purge all opt-out affidavits if they are more than 2 years old and establish a systematic process to purge all opt-out affidavits on a regular basis.

Response: We appreciate this suggestion and will take it under advisement as we continue our efforts to enhance the integrity of the Medicare program.

Comment: Several commenters stated that numerous other federal requirements (for example, DEA certificate) and state regulations (for example, state medical licensing boards) already exist to ensure that medications are only prescribed by qualified individuals. Rather than implement another bureaucratic hurdle, the commenters contended that these other federal and state regulations should be tightened as needed. One commenter stated that because there are multiple safeguards currently in place through the OIG, there is no need for § 423.120(c)(5) and (6). Other

commenters stated that § 423.120(c)(5) and (6) are unnecessary because (i) Part D sponsors are already required to review NPDES to verify a prescriber's NPI and other data; (ii) states already license and regulate prescribers; and (iii) pharmacists are responsible for determining that prescriptions are written by licensed individuals.

Response: We disagree with these commenters. Data lists that are prepared, administered and updated by agencies outside of CMS frequently do not capture the information we need to confirm that a supplier meets Medicare requirements. The CMS enrollment process is the most practical, thorough, and effective means of securing and verifying all necessary information on physicians and eligible professionals.

Comment: Several commenters expressed support for our proposed provisions but sought assurances that plans would not be penalized for filling prescriptions if, at the time the drug was dispensed, the plan did not know of the prescriber's termination. Another commenter did not believe there should be retroactive enrollment terminations; this would eliminate recoupment of payment from pharmacies or Part D sponsors for prescribers who were shown as enrolled by the most current information available at the time the prescription was filled. Another commenter requested clarification as to whether there would be performance-score safeguards established for plans that appropriately deny drugs based on the information available to them through the MACs or other parties responsible for maintaining said list. Another commenter expressed concern about the impact that these requirements would have on plan performance measures due to an increased number of complaints from beneficiaries relating to prescriptions that could not be filled, or with respect to which payment would be denied.

Response: It is important to note that our requirements are directed specifically at individuals who prescribe Part D drugs. Individuals who prescribe are required to enroll in Medicare (or validly opt-out of Medicare) in order to do so. As such, plan sponsors would be required to pay only for those prescriptions written by physicians or eligible professionals who, according to CMS, are enrolled in Medicare in an approved status or who have validly opted-out of Medicare. We will, as deemed necessary, further address these issues via sub-regulatory or other guidance.

Comment: Several commenters believed that the administrative burden of these provisions would outweigh any

potential benefits in deterring fraud, waste and abuse; this would be especially true for plan sponsors that would have to verify a particular prescriber's enrollment or opt-out status. The commenters requested that CMS more closely study the potential administrative impact of these provisions.

Response: We have studied the impact of these provisions and believe that the benefits to Medicare beneficiaries, the Medicare Trust Funds, and the program as a whole of confirming that physicians and eligible professionals are qualified to prescribe Part D drugs far outweigh the burden to prescribers of completing the enrollment process or submitting an opt-out affidavit. Besides, as mentioned in the proposed rule, a large majority of physicians and eligible professionals who prescribe Part D drugs are already enrolled in Medicare; hence, our provisions will have no impact on these individuals. Furthermore, those who are impacted will have ample time to complete the enrollment or opt-out process due to the extension of the compliance date to June 1, 2015.

Comment: A commenter suggested that CMS issue warnings to prescribers for a 6 to 12-month period prior to rejecting claims that fail to meet the necessary criteria.

Response: We appreciate this suggestion. We are exploring various means of alerting prescribers who are neither enrolled in Medicare nor have submitted a valid opt-out affidavit of the need to comply with the requirements of § 423.120(c)(6).

Comment: A commenter suggested that CMS consider using technology that already exists within the pharmacy industry for validating prescriber data, for this would (when compared to the batch processes): (1) Improve patient access to care as the most timely data is made available at the time of prescription drug dispensing; (2) decrease costs associated with audits and recovery of funds resulting from out-of-date data; and (3) increase consistency of data among the multiple MACs and pharmacies. Another commenter stated that CMS should avoid using a PDF file similar to that which exists for the current ordering/certifying edits and instead create a database containing this information.

Response: We are contemplating various formats in which the previously-discussed list might be disseminated to plan sponsors.

Comment: A commenter requested clarification as to: (1) Whether CMS is proposing a new provider enrollment process for Part D in addition to the

current enrollment process for obtaining Medicare billing privileges; and (2) how a Part D revocation would impact Part B billing by the same practitioner.

Response: The provider enrollment process under § 423.120(c)(6) will be the same as that which is used for physicians and eligible professionals enrolling in Medicare in order to comply with § 424.507. A revocation under § 424.535(a) would eliminate the individual's ability to prescribe covered Part D drugs because he or she would no longer be enrolled in Medicare; hence, the requirements of § 423.120(c)(6) would no longer be met.

Comment: Several commenters requested that CMS exclude dentists from proposed § 423.120(c)(5) and (6)'s application because the provisions would place an unnecessary burden on dentists and their Medicare-eligible patients, and would not address CMS' desire to stop fraud and abuse. One commenter added that it is unaware of high-billing levels associated with prescriptions written by dentists for Medicare-eligible patients, yet the administrative burden on dentists would be significant. Another commenter expressed concern that the proposal could negatively impact plan members, in that members who receive prescriptions written by dentists not enrolled in the program would be financially responsible for such prescriptions because they would no longer be covered. Another commenter noted that Medicare beneficiaries enrolled in dual eligible SNPs may receive comprehensive dental benefits, including certain invasive procedures. Dentists may prescribe antibiotics in these circumstances, and these drugs should be covered under Medicare Part D. However, since dentists are not typically enrolled in Medicare, our proposal could interfere with this coverage. Other commenters recommended that CMS exclude from § 423.120(c)(5) and (6)'s purview those suppliers who do not normally see Medicare beneficiaries or receive Medicare payment (including psychiatrists and Veterans' Administration (VA) doctors) and enable them to (after a grace period) register with Medicare in a limited capacity to enable them to write prescriptions for Medicare beneficiaries.

Response: While we recognize the concerns of these commenters, we do not believe dentists, psychiatrists, VA physicians, or any other physicians or eligible professionals should be granted special exemptions from § 423.120(c)(6). The issue of primary concern to us is not the typical volume of drugs these individuals prescribe but the need to

ensure and confirm that Medicare payments are only made for Part D drugs that are prescribed by qualified physicians and eligible professionals. This is precisely the concern that the OIG expressed in its previously-referenced report. Moreover, we believe that our extension of the effective date to June 1, 2015 will afford these individuals more than adequate time to complete the enrollment or opt-out process, hence easing the burden on them.

Comment: One commenter: (1) Favored requiring dentists to enroll in Medicare (or have a valid opt-out affidavit on file) in order to prescribe Part D drugs; and (2) believed that a January 1, 2015 effective date was reasonable.

Response: We agree with this commenter's first comment and intend to apply § 423.120(c)(6) to dentists. While we appreciate the commenter's second comment, we believe that a June 1, 2015 effective date is more appropriate.

Comment: A commenter requested clarification concerning how these provisions would be enforced in cases of out-of-network benefits, which permit plan enrollees to receive healthcare items and services (including prescription medicines) across the country. Another commenter stated that if CMS allows point of service overrides, the Prescription Drug Events (PDEs) should be accepted and final, with no requirement for plans/sponsors to provide a retroactive look back. Other commenters suggested that CMS should: (1) Require plans to hold beneficiaries harmless from the consequences of non-coverage for a non-compliant supplier for at least one fill of the prescription; (2) require plans to reach out to the beneficiary and the supplier to explain the issue, allowing sufficient time for the beneficiary to see another supplier or for the supplier to correct his or her enrollment status; and (3) reach out to policy makers in the states that permit foreign prescriptions, to determine what kind of alternate supplier credential checking might be available to ensure that beneficiaries who spend portions of the year in other countries can access their medications without interruption or the unneeded expense of additional physician visits.

Response: We will, as deemed necessary, address these matters via sub-regulatory guidance or future rulemaking.

Comment: A commenter requested clarification as to whether § 423.120(c)(6) applies even if a physician or eligible professional is

state-licensed but is neither Medicare-enrolled nor has opted-out.

Response: Yes, it applies.

Comment: A commenter requested information as to the following: (1) Whether plan sponsors would remain responsible for ensuring that a prescriber is properly enrolled in Medicare; (2) whether prescriber validation should occur at the point-of-sale and whether plan sponsors are not permitted to "flow down" the responsibility for this verification process to their network pharmacies; and (3) whether CMS could prohibit Part D plans from reversing pharmacy claims with prescriber verification errors found in audits if the prescriber enrollment verification found by that plan was later found to be inaccurate.

Response: We will, as deemed necessary, address these matters via sub-regulatory guidance or future rulemaking.

Comment: A commenter stated that because the vast majority of prescribing physicians and other practitioners are already enrolled as Medicare suppliers, §§ 423.120(c)(5) and (6) should not impose a great burden on prescribers. However, the commenter encouraged CMS to make any requirements for beneficiary requests for reimbursement from Part D sponsors as clear and concise as possible for beneficiaries. Prescribers should be able to quickly generate forms for patients who want to submit them to their plan sponsors directly.

Response: We agree with the commenter's first statement, and will attempt to ensure that beneficiaries understand the requirements for requesting reimbursement.

Comment: A commenter urged CMS to require plans to cover the costs associated with the charge-back if there is an error in the claim related to Medicare enrollment, and that the cost for verification and correction of any claims be borne by the plan through their administrative costs.

Response: We are not prepared in this final rule to issue a definitive statement regarding costs associated with charge-backs. Any such statement will, as deemed necessary, be addressed via sub-regulatory or other guidance.

Comment: A commenter urged CMS to explore options to reduce member disruptions and to allow plans to manage prescribers not meeting these requirements. Such options could include: (1) Allowing a period of "soft edits" to effectively track and manage potential future disruptions; (2) applying our requirements only to new fills; or (3) allowing prescriptions to be

grandfathered up to a year after the effective date.

Response: We believe that our extension of the effective date to June 1, 2015, as well as CMS' outreach efforts, will greatly reduce the potential for coverage disruptions. However, we will monitor the progress of the implementation of § 423.120(c)(6) to ensure that such disruptions do not occur.

Comment: A commenter stated that the proposed rule did not address how Part D beneficiaries in the U.S. territories would be impacted by proposed § 423.120(c)(5) and (6).

Response: We anticipate conducting outreach, as needed, for beneficiaries in U.S. territories regarding how they may be affected by these provisions.

Comment: A commenter expressed concern that CMS had proposed to no longer allow Part D coverage for foreign prescriptions.

Response: We did not propose to deny coverage for foreign prescriptions. We simply proposed to require that all prescribers of Part D drugs be enrolled in Medicare or in a valid opt-out status. We may, as deemed necessary, further address this issue via sub-regulatory guidance.

Comment: Several commenters requested clarification concerning whether plan sponsors would be able to accept a pharmacy claim for an automatically-generated refill prescription if the prescriber is not enrolled in Medicare. The commenters also recommended that § 423.120(c)(5) and (6) only be applied to new prescriptions.

Response: The pharmacy claims described by the commenters will not 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, regardless of whether the prescription is new or a refill.

Comment: A number of commenters opposed the notion of requiring pharmacies to enroll in Medicare in order to distribute Part D drugs. They expressed concern about the burden and cost involved for pharmacies, and the potential disruption to the Part D program that would result if thousands of pharmacies were required to enroll. One commenter stated that Part D sponsors or their PBMs have direct contractual relationships with pharmacies and perform their own credentialing and verifications before allowing pharmacies into their networks; sponsors have the necessary experience and expertise to identify and remove unlicensed, fraudulent or otherwise unqualified pharmacies from their networks.

Response: Because we concur with these contentions, we do not intend to apply § 423.120(c)(6) to pharmacies at this time.

Comment: A commenter requested clarification concerning whether the pharmacy requirement for enrollment refers to Part B DMEPOS supplier enrollment for drugs.

Response: Our earlier reference to pharmacy enrollment pertains to Part D drugs. However, as stated previously, we are not applying § 423.120(c)(6) to pharmacies at this time.

Comment: One commenter supported the notion of requiring pharmacy enrollment.

Response: We appreciate this comment. However, as already stated, we do not intend to apply § 423.120(c)(6) to pharmacies at this time.

Given this, we are finalizing our proposed provisions in § 423.120(c) with several exceptions. First, the January 1, 2015 effective date is changed to June 1, 2015. Second, the existing version of paragraph (c)(5) will remain intact with the exception of the addition of the “Before June 1, 2015, the following are applicable” language at the very beginning of the paragraph. Third, we are not finalizing our proposed changes to paragraph (c)(5)(ii), but are instead merging them with our addition of paragraph (a)(6). Our final version of new paragraph (c)(6) will thus read as follows:

“(6) Beginning June 1, 2015, the following are applicable—

(i) A Part D sponsor must deny, or must require its pharmaceutical benefit manager (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 (NPI) is not contained on the claim.

(ii) A Part D sponsor must deny, or must require its PBM to deny, a pharmacy claim for a Part D drug if the physician or eligible professional (when permitted to write prescriptions by applicable State law)—

(A) Is not enrolled in the Medicare program in an approved status; and
(B) Does not have a valid opt-out affidavit on file with an A/B Medicare Administrative Contractor (MAC).

(iii) A Part D sponsor must deny, or must require its PBM to deny, a request for reimbursement from a Medicare beneficiary for a drug if the request is not for a Part D drug that was dispensed in accordance with a prescription written by a physician or, when permitted by applicable State law, other eligible professional (as defined in

section 1848(k)(3)(B)(i) or (ii) of the Act) who—

(A) Is identified by his or her legal name in the request; and

(B)(1) Is enrolled in Medicare in an approved status; or

(2) Has a valid opt-out affidavit on file with an A/B MAC.

(iv) In order for a Part D sponsor to submit to CMS a prescription drug event (PDE) record, the PDE must contain an active and valid individual prescriber NPI and 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 by applicable State law, an eligible professional (as defined in section 1848(k)(3)(B)(i) or (ii) of the Act) who:

(A) Is enrolled in Medicare in an approved status, or

(B) Has a valid opt-out affidavit on file with an A/B MAC.

These revisions to our proposed paragraph (c)(6) do not involve any changes from our proposed policy. They are merely technical changes designed to better fit the existing regulatory text.

21. Improper Prescribing Practices (§§ 424.530 and 424.535)

a. Background and Program Integrity Concerns

We stated in the preamble to the proposed rule that notwithstanding our proposed provisions in § 423.120(c), additional program safeguard enhancements were necessary to protect the Medicare Trust Funds from fraud, waste and abuse, and to ensure that Part D drugs are prescribed only by qualified suppliers. Along with the aforementioned OIG report (“Medicare Inappropriately Paid for Drugs Ordered by Individuals Without Prescribing Authority” (OEI-02-09-00608)), we cited another OIG report titled, “Prescribers with Questionable Patterns in Medicare Part D” (OEI-02-09-00603). 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;

- An Ohio physician ordered more than 400 drugs each for 13 of his 665 beneficiaries; and
- 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 hydromorphone HCl.

The OIG has 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 are inappropriately prescribed in dangerously excessive amounts. We share this concern, particularly as we continue to receive reports of improper prescribing practices. The difficulty, as we explained in the proposed rule, is that CMS does not possess the legal authority to take administrative action against the prescriber. This means, in many cases, that the individual can continue prescribing drugs that will be covered under Part D and, if he or she is enrolled in Medicare, remain so enrolled to furnish medical services. We believe this is inconsistent with: (1) The OIG’s recommendations in its various Part D reports; and (2) our goals of protecting and promoting the health and safety of Medicare beneficiaries and of safeguarding the Medicare Trust Funds.

To this end, and as we explain in this section, we proposed several changes to Part 424, subpart P.

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.

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. Indeed, we are concerned that a physician or eligible professional's improper prescribing practices may be duplicated in the Medicare program. To address these issues, we proposed the following:

- Adding 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 such suspension or revocation is in effect on the date he or she submits his or her enrollment application to the Medicare contractor.
- Adding 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 his or her ability to prescribe drugs. Again, this approach is consistent with our requirement that suppliers maintain compliance with all applicable licensure and certification requirements.

(We also solicited comments on whether our proposed additions of §§ 424.530(a)(11) and 424.535(a)(13) should be expanded to include pharmacy activities.)

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. We also believe that our proposed provisions were consistent with the OIG's recommendations and, equally important, are necessary to protect Medicare beneficiaries and the Trust Funds.

We received a number of comments related to our proposal. Summaries of the comments and our responses are as follows:

Comment: Several commenters expressed support for §§ 424.530(a)(11) and 424.535(a)(13), stating that these provisions would help reduce abusive prescribing.

Response: We appreciate the support of these commenters.

Comment: Various commenters recommended that CMS: (1) Verify a DEA registration number submitted on the CMS-855I or the CMS-855O with the DEA prior to enrolling a physician or eligible professional into Medicare; (2) require physicians and eligible professionals to report a change (voluntary termination, revocation, suspension) in their DEA registration number within 30 days of the change; (3) modify the CMS-855I and CMS-855O to require that physicians and eligible professionals report a DEA registration number suspension or revocation within 30 days; (4) require that a physician or eligible professional have a DEA number for each state in which the physician or eligible professional is prescribing controlled substances; (5) require its Part D sponsors to establish the necessary edits to deny a prescription for a controlled substance when the physician or eligible professional does not maintain a validly issued and active DEA registration number in the state where the prescription was written; (6) refer to the DEA the name and NPI of any physician or eligible professional who is enrolled in Medicare in multiple states and who is only using a single DEA registration number to prescribe controlled substances to Medicare beneficiaries; and (7) establish a data matching agreement with the DEA to verify the DEA registration numbers assigned by the DEA for all physicians and eligible professionals enrolled in Medicare. Another commenter suggested that CMS establish a 3-year reenrollment bar under § 424.535(c) for any physician or eligible practitioner who is revoked pursuant to § 424.535(a)(13), or at least identify in the final rule what the reenrollment bar length will be. The commenter also recommended that the reenrollment bar apply to Medicare Advantage Organizations, not simply the Part B Medicare program and Part D drugs.

Response: We appreciate these suggestions and will take them into consideration as part of our ongoing efforts to strengthen payment safeguards in the Medicare program.

Comment: Several commenters recommended that CMS allow physicians and eligible professionals to self-report a DEA license revocation or suspension (or a state licensing body revocation or suspension associated

with prescribing drugs) within 30 days of the revocation, suspension, or voluntary surrender of their DEA registration.

Response: We do not believe that a physician or eligible professional should be permitted to evade § 424.535(a)(13) and the subsequent reenrollment bar merely by reporting the DEA certificate suspension or revocation to CMS. The issues of concern to us are the certificate revocation or suspension itself and the consequent need to protect Medicare beneficiaries and the Trust Funds, and not so much the physician or eligible professional's voluntary revelation of the revocation or suspension.

Comment: A commenter requested that CMS furnish two lists to Part D sponsors: (1) A list of physicians and eligible professionals who have a DEA registration number that CMS has confirmed with the DEA; and (2) a list of physicians and eligible professionals who do not have a valid and active DEA registration number. The data on these lists, the commenter suggested, could be broken down by state.

Response: We appreciate this suggestion and will take it under advisement as we continue our efforts to strengthen the integrity of the Part D program.

Comment: Several commenters requested clarification concerning whether CMS intends to implement § 424.535(a)(13) retrospectively and revoke the Medicare billing privileges of physicians and eligible professionals who have had their DEA number suspended or revoked. One commenter opposed a retroactive application of our proposal.

Response: We retain the discretion to revoke the billing privileges of an enrolled physician or eligible professional whose DEA certificate is suspended or revoked at the time § 424.535(a)(13) becomes effective.

Comment: A commenter requested CMS' rationale for permitting an individual to enroll in Medicare after the DEA has: (1) Denied him or her a DEA certificate of registration; or (2) suspended or revoked a DEA registration number and the suspension or revocation is still in force.

Response: In the commenter's second scenario, we would be able to deny the individual's enrollment under § 424.530(a)(11). As for the first scenario, our focus in preparing our proposed rule was on individuals who had active DEA certificate suspensions or revocations. We nonetheless appreciate the commenter's apparent suggestion and may consider addressing it in future rulemaking.

Comment: Several commenters recommended that § 424.535(a)(13) not be applied in cases where a physician's DEA number was suspended due to substance abuse issues and the physician is in counseling.

Response: We do not believe that a blanket exemption from § 424.535(a)(13)'s potential application for such individuals is warranted or justified. However, we note that § 424.535(a)(13), like most other revocation reasons in § 424.535, is discretionary, meaning that CMS is not required to exercise its revocation authority. Although we have the discretion to invoke § 424.535(a)(13) regardless of the grounds for the DEA certificate revocation or suspension, we would also be able to take into account the circumstances surrounding the suspension or revocation prior to making a final determination.

Comment: Several commenters requested clarification as to whether: (1) Proposed § 424.535(a)(13) applies to non-controlled substances; and (2) whether a voluntary surrender of a DEA certificate (for instance, a semi-retired physician wishes to prescribe only non-controlled substances) would invoke § 424.535(a)(13). The commenters believed that non-controlled substances should be excluded from § 424.535(a)(13)'s purview if the prescriber otherwise maintains the legal authority to prescribe such drugs, is in good standing with a state professional licensing board, and has not engaged in abusive prescribing. At a minimum, one commenter suggested, CMS should refer a potential case to the state for review prior to making a decision.

Response: We explained in the proposed rule that a DEA certificate of registration is not required to dispense non-controlled substances. Thus, if one's DEA certificate is suspended or revoked, he or she would still be able to prescribe non-controlled substances absent some other restrictive action taken by the DEA or the state (although his or her billing privileges could still be revoked under § 424.535(a)(13)). Yet we note that § 424.535(a)(13) can be invoked if the applicable licensing or administrative body for any state in which the individual practices suspends or revokes his or her ability to prescribe drugs. Therefore, if the state rescinds the person's ability to prescribe any drugs, the individual (should § 424.535(a)(13) be invoked) would be prohibited from prescribing Part D controlled and non-controlled drugs.

The voluntary surrender of a DEA certificate would not constitute grounds for revocation under § 424.535(a)(13). The provision as written is limited to

certificate revocations and suspensions. However, we may consider addressing this issue via future rulemaking.

Comment: Several commenters recommended that CMS: (1) Explain how it will obtain information from the DEA regarding registration numbers that are valid, approved, revoked, suspended, voluntarily surrendered, etc.; (2) make available to Part D sponsors the information necessary to deny a Part D claim for controlled substances when a physician or eligible professional does not have a valid and active DEA registration number in the state in which the prescription is written; and (3) explain whether this data will be in the file that is to be used for the enforcement of §§ 423.120(c)(5) and (6).

Response: We will, as deemed necessary, address these issues via sub-regulatory or other guidance.

Comment: Several commenters requested clarification concerning whether a physician would be able to reenroll in Medicare after the suspension or revocation of his or her DEA registration is lifted.

Response: If we revoke a physician's billing privileges under § 424.535(a)(13), the physician would be able to submit a CMS-855 application for enrollment upon the expiration of his or her reenrollment bar.

Comment: A commenter recommended that CMS clarify whether physicians and eligible professionals have 30 days to report a DEA registration number revocation per § 424.516(d).

Response: The individual would be required to report this information to CMS under § 424.516(d) to the extent the CMS-855 mandates that such information be disclosed on the application.

Comment: A commenter suggested that CMS revise and update item B1 in section 3 of the CMS-855I and the CMS-855O, which states "Any revocation or suspension of a license to provide health care by any state licensing authority; this includes the surrender of such a license while a formal disciplinary proceeding was pending before a state licensing authority," to read as follows: "Any revocation or suspension of a license to provide health care by any state licensing authority or Drug Enforcement Administration Registration number. This includes the surrender of such a license while a formal disciplinary proceeding was pending before a state licensing authority." The commenter also sought clarification regarding whether CMS will indeed treat a DEA

registration number denial or revocation as a final adverse legal action.

Response: We appreciate this suggestion and will take it under advisement as we continue our efforts to strengthen the integrity of the Part D and Part B programs.

At this stage, CMS does not have the legal authority to treat a DEA certificate revocation or suspension as a final adverse action because the current definition of the latter term in § 424.502 does not specifically include DEA actions. However, we may address this issue through future rulemaking.

Comment: A commenter supported our proposal to require Part D physicians and eligible professionals who prescribe controlled substances to obtain and maintain a valid DEA certificate of registration as a condition of enrollment. Yet the commenter recommended that the provision apply only to those individuals who prescribe controlled substances; this would avoid impacting the ability of practitioners providing services solely in local public health departments to prescribe non-controlled medications.

Response: As stated previously, if one's DEA certificate is suspended or revoked, he or she would still be able to prescribe non-controlled substances absent some other restrictive action taken by the DEA or a state (although his or her billing privileges could still be revoked under § 424.535(a)(13)). However, if the state in which the individual practices suspends or revokes his or her ability to prescribe any drugs, the individual (should § 424.535(a)(13) be invoked) would be prohibited from prescribing Part D controlled and non-controlled drugs.

Comment: Several commenters opposed our proposed addition of § 424.535(a)(13), stating that a suspended DEA certificate or state license does not necessarily reflect one's inability to treat Medicare patients safely and at a high standard. This is particularly true, one commenter contended, considering that many DEA certificate or licensure revocations, suspensions, or restrictions are due to the physician or practitioner's medical illness, usually drug abuse and dependence. Such individuals generally complete treatment programs successfully and should be given a second chance. At a minimum, the commenter maintained, CMS should take into account such situations in determining whether to invoke § 424.535(a)(13).

Response: As explained earlier, § 424.535(a)(13) is a discretionary authority, and CMS can use its discretion to take into account the

individual's particular circumstances in determining whether a revocation is warranted. But we caution that we are not required to do so, and there may be instances in which we decide that the certificate revocation or suspension alone, on its face, is sufficient to justify invoking § 424.535(a)(13).

For the reasons stated in this section, we are finalizing our proposed additions of §§ 424.530(a)(11) and 424.535(a)(13).

c. Patterns or Practices of Prescribing

We also proposed 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 chose not to define “abusive” and “threat to the health and safety of Medicare beneficiaries” in the proposed rule, primarily because the myriad of questionable situations that could warrant the possible application of § 424.535(a)(14) requires that CMS have the flexibility to address each case on its own merits. We believed that the sounder approach was to propose a list of criteria that we 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, we proposed 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 in § 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, we proposed to 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.

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. As such, we proposed 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 relevant factors. 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 noted further that CMS, rather than the Part D plans or the A/B MACs, 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 received a high volume of comments regarding proposed § 424.535(a)(14). Comment summaries and our responses are as follows.

Comment: A number of commenters opposed our proposed addition of § 424.535(a)(14). They generally stated that this revocation reason would negatively impact Medicare beneficiaries by restricting access to important medications and disrupting current care plans, hence creating a chilling effect on the practice of medicine. They asserted that the proposed provision could dissuade physicians from appropriate prescribing. What may be considered excessive prescribing for the general population, they added, could be clinically appropriate given a patient's individual circumstances, particularly in pain management; many “off-label” uses are clinically appropriate and represent the standard of care, especially with cancer patients. Several commenters also stated that the process of finding the right medication for a particular individual may involve trial and error over the course of months, if not years; decisions about specific medications to prescribe must be based on clinical observations, knowledge of past history, awareness of side effects, and a process of collaboration between doctor and patient. One commenter stated that policies that markedly limit the use of substances to treat chronic pain could increase the suicide rate.

Response: We appreciate these comments and fully recognize the commenters' concerns. We certainly understand that each patient is different, as is: (1) His or her specific medical condition; (2) the setting in which he or she is being treated; and (3) the types and doses of medications that may legitimately be required. As alluded to in the proposed rule and as we more emphatically state here, we only intend to invoke § 424.535(a)(14) in very limited and exceptional circumstances. For this reason, we do not believe that § 424.535(a)(14) will have a chilling effect on physician or practitioner prescribing activities or will restrict beneficiaries' access to medications. Indeed, it will become clear to honest and legitimate prescribers (once § 424.535(a)(14) becomes effective and is implemented) that our focus is restricted to cases of improper prescribing that are so egregious that the physician or practitioner's removal from the Medicare program is needed to protect Medicare beneficiaries.

Comment: Many commenters contended that state medical licensing boards are the appropriate bodies to review prescribing practices; one such commenter stated that prescription restrictions under Part D should only be imposed if the state board finds a pattern of negligence in prescribing practices. Other commenters recommended that CMS, in lieu of utilizing § 424.535(a)(14), refer cases of improper prescribing to the applicable state board for its review and disposition, with one commenter adding that CMS could then decide whether to take action based on the state's findings. This commenter stated that such investigatory actions should be left to the state; having both CMS and the state undertake separate investigations would be duplicative and redundant, perhaps slowing down both investigations in the process.

Response: We recognize the leading position of state medical boards in monitoring the practice of medicine. However, such bodies operate independently of CMS. They play no role in overseeing the Medicare program, a responsibility that rests exclusively with CMS. As such, we must be able to rapidly take steps on our own volition (without having to wait for possible action by state licensing boards or other bodies) to protect Medicare beneficiaries and the Trust Funds from abusive behavior.

Comment: Several commenters asserted that CMS lacks the statutory authority for § 424.535(a)(14).

Response: We disagree. As we stated in the proposed rule, sections 1102 and 1871 of the Act give the Secretary the authority to establish requirements for the efficient administration of the Medicare program. We believe that § 424.535(a)(14) is necessary to help ensure the integrity and efficiency of the Medicare program.

Comment: Several commenters opposed the use of § 424.535(a)(14)(i)(F), which addresses prescription-related malpractice suits, as a criterion. One commenter contended that CMS' assertion that the existence of such a lawsuit is somehow equivalent to liability is incorrect. The commenter, as well as others, stated that many liability insurers settle cases with little or no merit. Another commenter stated that it would be difficult for CMS to verify the existence of such suits and settlements, while another commenter contended that certain physician specialties at high risk for malpractice suits could be unfairly targeted under § 424.535(a)(14).

Response: We did not assert in the proposed rule (and do not in this final

rule) that such a lawsuit automatically equates to liability. We realize that certain cases are settled with no admission or even existence of liability. Nonetheless, it would be inappropriate and even irresponsible for CMS to completely disregard situations where a physician or practitioner has, for example, been sued several times for prescription-related malpractice and has either settled one of the cases or has had at least one final judgment against him or her.

We stress that § 424.535(a)(14)(i)(F) will represent only one of several factors in our § 424.535(a)(14) determinations, and it will not in and of itself be dispositive.

With respect to the next-to-last comment, we included the language "to the extent this can be determined" at the end of proposed § 424.535(a)(14)(i)(F) based on our recognition that it may occasionally be difficult to ascertain the specific outcome of such suits.

Regarding the last comment, and as already stated: (1) We only intend to invoke § 424.535(a)(14) in very limited and exceptional circumstances; (2) we will account for the patient's particular situation and setting in determining whether a § 424.535(a)(14) revocation is warranted; and (3) § 424.535(a)(14)(i)(F) is only one of a number of factors we will consider.

Comment: Several commenters stated that CMS' proposal is duplicative of current safety mechanisms, ignores the long history of states regulating the licensure process, adds yet another layer of regulatory burden and administrative costs to the program, and gives the federal government an excessive amount of latitude without furnishing clear objectives. They added that CMS has stepped outside its statutory authority and into regulating the practice of medicine, and has also usurped the authority of state boards to regulate the practice of medicine. They requested that CMS work with the medical community through pre-rulemaking activities, such as listening sessions, town halls, and the issuance of requests for information (RFI), to better develop any future proposals to address the agency's concerns. Another commenter stated that CMS should focus on preventing individuals who do not have the authority to prescribe (such as massage therapists) from prescribing Part D drugs rather than on applying § 424.535(a)(14).

Response: Section 424.535(a)(14) is not an attempt by CMS to regulate the practice of medicine or to usurp state medical boards' roles in doing so. States remain free to take action against

physicians and practitioners as they deem fit. Again, though, Medicare is a distinct program that is under the purview of CMS, not the states. We must have the ability to remove abusive prescribers from the Medicare program without having to obtain or wait for approval from state licensing boards or other bodies that do not have oversight of Medicare.

As mentioned earlier, we have the authority under sections 1102 and 1871 of the Act to establish requirements for the efficient administration of the Medicare program. We believe this includes ensuring that the Part D program is properly administered, and that Medicare beneficiaries and the Trust Funds are protected. We believe that § 424.535(a)(14) will be an important part of these objectives.

We appreciate the recommendation that we work with the medical community in developing future proposals and will take it under advisement.

As for the final comment, our addition of (c)(6) is aimed at stemming the problem of unqualified prescribers. Yet we disagree with the implication that this issue should be our sole focus. Other matters, such as egregious and dangerous prescribing practices by physicians and eligible professionals, must be addressed as well.

Comment: Several commenters expressed concern about the potential application of § 424.535(a)(14) to hospice and palliative physicians. They stated that medications furnished in a hospice or palliative setting often require doses and indications that are generally not seen in conventional care. Such doses, they contend, are often necessary to relieve pain and furnish comfort to terminally ill patients, noting also that dosages might vary depending on what stage of the dying process the patient is in; terminally ill patients, they state, require different pain management strategies and often higher doses of opioids than those who are not terminally ill. The possible application of § 424.535(a)(14) to hospice and palliative physicians, they asserted, could prevent these physicians from prescribing needed medications to dying patients due to concerns about prescribing outside the usual norms. They requested an exception to § 424.535(a)(14) when the patient is specifically receiving hospice or palliative services. Another commenter suggested exempting from § 424.535(a)(14) those physicians who are ABMS-board certified in hospice and palliative medicine, or medical directors certified by the Hospice Medical Director Certification Board.

Response: We decline to establish a specific exception for hospice or palliative physicians or services, for this would eliminate our ability to take action against truly egregious and dangerous prescribing practices that may occur in such settings. However, as stated earlier, we fully understand that each patient is different, as is his or her specific condition and needs. We will operate under this overriding principle when considering whether § 424.535(a)(14) should be invoked in a particular instance.

Comment: A number of commenters contended that several of the criteria identified by CMS are beyond the expertise of CMS regulators.

Response: We disagree. We have physicians and other medical personnel on staff who we anticipate may be consulted, as needed, in potential § 424.535(a)(14) cases.

Comment: A commenter stated that because of the limited number of certified hospice and palliative physicians, most hospice and palliative patients will be cared for by their primary care physician or mid-level practitioner. The commenter recommended that CMS add an appeals process with peer-review to ensure that good clinicians are not penalized unduly. Other commenters expressed concern that the proposed rule made no mention of appeal rights, while one commenter requested how physicians can defend themselves against a § 424.535(a)(14) revocation.

Response: A physician or eligible professional whose Medicare billing and prescribing privileges are revoked under § 424.535(a)(14) may appeal the revocation per 42 CFR part 498. Also, as already mentioned, we anticipate that physicians and other medical personnel of CMS may be consulted, as needed, in potential § 424.535(a)(14) cases.

Comment: One commenter stated that CMS should clarify the term “necessary evaluation” as it is used in § 424.535(a)(14)(i)(B); the commenter explained that a hospice or palliative physician must often rely on the evaluations of the nurses and is not always able to physically see a homebound patient. The commenter was concerned that he or she would not be able to adjust dosages without seeing the patient. Another commenter stated that in applying this criterion, CMS should focus more on the prescriber’s status than on beneficiaries who may be evaluated outside of their normal residence.

Response: We are not in a position to further clarify or define the term “necessary evaluation” in this rule, for we must retain the flexibility to address

the variety of factual scenarios that could potentially implicate § 424.535(a)(14). However, we recognize the commenter’s concern, and as stated earlier we will account for the patient’s particular needs and circumstances.

We intend to review all aspects of the prescriber’s and the patient’s statuses and physical locations when examining this criterion.

Comment: A commenter recommended that in lieu of adopting its proposed new revocation policy, CMS should use its existing regulatory authority under § 405.371 to suspend Part D prescribing privileges when there is a credible allegation of fraud. If CMS believes it lacks the legal authority to implement a payment suspension that precludes a physician or eligible professional from prescribing, ordering, or certifying services for a Medicare beneficiary when a credible allegation of fraud exists, CMS should consider proposing a new policy that expands on the existing provisions in § 405.371 and allow the public to comment on this policy. Another commenter requested that CMS explain how a revocation under § 424.535(a)(14) is different from an OIG exclusion based on a conviction of fraud. Another commenter contended that CMS, through § 424.535(a)(14), would essentially be making fraud determinations that CMS lacks the statutory authority to undertake.

Response: We disagree with the first commenter’s recommendation and the third commenter’s statement because abusive or inappropriate prescribing does not necessarily involve fraudulent behavior, although it could well involve improper payments. We further believe that revocation is a more appropriate remedy for abusive prescribing than a payment suspension. In the latter situation, the prescriber would remain enrolled in Medicare despite his or her improper prescribing; we believe this goes against the overall objective of § 424.535(a)(14), which is to protect Medicare beneficiaries and the Trust Funds from abusive behavior.

Comment: A commenter suggested that CMS should, prior to finalizing § 424.535(a)(14), solicit comments on a process of notification and opportunity to correct prior to implementing a revocation under § 424.535(a)(14). Other commenters likewise stated that before revoking a supplier under § 424.535(a)(14), CMS should notify the supplier of the potential revocation and enable the supplier to respond.

Response: We disagree. Providing a physician with an opportunity to take corrective action would not be appropriate under these circumstances, given that CMS would have based its

revocation action on a prescriber engaging in a pattern or practice of abusive prescribing over some period of time. One of our goals with § 424.535(a)(14) is to place prescribers on notice that abusive prescribing practices can result in the individual’s losing his or her Medicare billing privileges. To permit an abusive prescriber to avoid revocation by simply modifying his or her behavior temporarily would undermine this objective and, more importantly, would not undo the harm that may have been done to Medicare beneficiaries because of the prescriber’s practices.

Comment: Several commenters suggested that CMS be required to consult with and receive written approval from the OIG and/or the Department of Justice prior to any invocation of § 424.535(a)(14).

Response: We do not agree. As mentioned earlier, CMS administers the Medicare program. We must be able to expeditiously remove abusive prescribers from the Medicare program without having to secure prior approval from law enforcement. Indeed, failure to take such quick action would be inconsistent with the spirit of the two aforementioned OIG reports that urged CMS to exercise greater oversight of the Part D program.

Comment: A commenter opposed the criterion in § 424.535(a)(14)(i)(B) that reads, “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).” The commenter stated that this factor does not address whether the physician or eligible professional is out of the country when the new prescription for a Part D drug was given to a beneficiary. Another commenter stated that the criterion does not: (1) Outline cases where a physician or eligible professional is allowed under state law to prescribe Part D drugs over the phone to a Medicare beneficiary who is on vacation and may need a Part D prescription; and (2) differentiate between a prescription for a new Part D drug a day after the death of a Medicare beneficiary and a refill of an existing Part D medication by the spouse or child after the death of the Medicare patient. This commenter requested that CMS rescind this criterion unless it furnishes more information, such as how it will be used as a factor in making a revocation determination. Another commenter requested the removal of this criterion if it will be based solely on PDE data.

Response: The example cited in § 424.535(a)(14)(i)(B) is not the only one to which the criterion could apply. The term “for example” indicates that multiple factual scenarios are envisioned. Such is the case with § 424.535(a)(14)(i)(B). We will consider the specific facts of each situation in determining whether the resolution of this factor weighs in favor of a revocation under § 424.535(a)(14). In addition, we will consider information besides PDE data when evaluating this criterion.

Comment: A commenter opposed the criterion outlined in § 424.535(a)(14)(i)(D) regarding the number and type(s) of disciplinary actions. The commenter contended that CMS did not indicate whether it would use a particular state licensing board decision (for example, a reprimand or fine) as its basis for taking an action under § 424.535(a)(14). The commenter stated that CMS should rescind this portion of its proposal unless it: (1) Provides more information regarding the state medical board actions that would be used as a factor in making a decision under § 424.535(a)(14); and (2) affords the public an opportunity to comment on CMS’ implementation approach.

Response: We are not in a position to outline every conceivable disciplinary action that a state medical board could impose. Such actions vary widely by state and by magnitude, which is why § 424.535(a)(14)(D) accounts for the specific type of disciplinary action involved.

Comment: Several commenters stated that the term “abusive” should be stricken from the rule because it is too broad and subjective. Others requested that CMS at least provide more clarification and guidance: (1) As to the meaning of the terms “abusive,” “excessive dosage,” “improper prescribing practices,” and “threat to patient health and safety”; and (2) regarding the steps that would be taken if the agency determines that a prescriber’s Medicare enrollment should be revoked; one commenter stated that CMS Publication 100–18, Chapter 9, contains a definition of “abusive” whereas our proposed rule did not. Another commenter recommended that this guidance incorporate evidence-based guidelines and research along with the patient’s history.

Response: We did not define these terms in the proposed rule and decline to do so in this final rule because of the need to retain our flexibility in addressing a variety of factual scenarios. Any revocation under § 424.535(a)(14) would be processed in the same manner as all other revocations, with the

exception that with these revocations, the applicable Part D plan sponsor(s) would also be notified of CMS’ revocation action so that the sponsor can terminate the individual’s prescribing privileges.

Comment: A commenter stated that while CMS noted in its proposed rule that it would conduct a complete and thorough investigation prior to any revocation, there are no safeguards to ensure a full investigation. The commenter added that CMS did not identify who would conduct these investigations. Other commenters requested information as to the process for determining whether abusive prescribing or a threat to patient health and safety exists. Another commenter stressed the need for a clearly defined protocol that would be followed before any revocation decision is made.

Response: We stated in the proposed rule and reiterate here that in every case we will carefully consider all of the relevant factors before invoking § 424.535(a)(14); this will include a review of all of the evidence before us, including the patient’s particular needs, circumstances, and setting. CMS and contractor staff will conduct the investigations, with CMS personnel performing the evaluation of the factors and making the final determination. More detailed information regarding the review process will, as deemed necessary, be disseminated via sub-regulatory or other guidance.

Comment: Several commenters requested clarification regarding whether CMS intends to implement § 424.535(a)(14) retrospectively. They supported a strictly prospective application.

Response: We reserve the right to revoke the billing privileges of a physician or eligible professional enrolled as of the effective date of this rule who has engaged or is engaging in abusive prescribing as described in § 424.535(a)(14). However, the effective date of the revocation would not be earlier than the effective date of this final rule.

Comment: A commenter questioned whether CMS will routinely scour its data for suppliers with suspicious prescribing patterns and, if so, what CMS will then do.

Response: Consistent with our current practices, we will be alert for such prescribing patterns. Once a pattern is detected, we will conduct a review and investigation using our existing procedures. If, based on this review, we believe that a situation involving abusive prescribing may exist, we will determine whether action under § 424.535(a)(14) is warranted.

Comment: A commenter stated that proposed § 424.535(a)(14) is unnecessary because the OIG has the ability to exclude from Medicare (under 42 U.S.C. 1320a–7(b)(6)(B)) any individual who has furnished items or services to patients substantially in excess of the patients’ needs or of a quality that does not meet professionally recognized standards of care.

Response: While we recognize that the OIG has its exclusion authority, CMS is the agency directly responsible for administering the Medicare program and for protecting Medicare beneficiaries and the Trust Funds. Consequently, CMS should be able to use its own authority to pursue administrative actions to address our concerns regarding abusive prescribing. We also reiterate that the OIG has recommended that CMS exercise greater oversight over the integrity of the Part D program and has noted its concern about abusive prescribing. Therefore, we believe it is proper for CMS (and consistent with the OIG’s recommendations) to implement § 424.535(a)(14).

Comment: Several commenters expressed support for our proposed addition of § 424.535(a)(14). One commenter stated that this will allow for more effective monitoring of improper prescribing behaviors. The commenter noted that inappropriate prescribing can result in overutilization of medications that increase program costs without providing any health benefit and can harm beneficiaries. Another commenter stated that § 424.535(a)(14) will enable CMS to exercise greater control over the Part D program.

Response: We appreciate the support of these commenters.

Comment: Several commenters recommended that CMS explain in the final rule whether CMS or Medicare contractors will use clinical staff (physicians and pharmacists) in determining whether Part D prescription drug abuse has occurred and whether a revocation under § 424.535(a)(14) is warranted.

Response: As stated earlier, we may use clinical staff, as needed, in making § 424.535(a)(14) determinations.

Comment: One commenter recommended that CMS, in lieu of finalizing § 424.535(a)(14), revoke the Medicare billing and/or prescribing privileges of individuals under § 424.535(a)(10) when the medical documentation does not support the Part D prescription written by the physician or eligible professional. The commenter believed that this approach

would be easier and more cost-effective to implement and would avoid the need for CMS to make clinical judgments.

Response: Section 424.535(a)(10) does not apply to Part D prescriptions. Consequently, § 424.535(a)(10) cannot be used in lieu of § 424.535(a)(14).

Comment: A commenter requested clarification concerning whether CMS or its Medicare contractors will conduct medical document reviews to determine whether an abusive prescribing pattern exists.

Response: Medical document reviews are one of several actions we may undertake in determining whether an invocation of § 424.535(a)(14) is warranted.

Comment: With respect to the criterion regarding diagnoses to support indications for which the drugs were prescribed, a commenter: (1) Questioned how CMS will cross-reference Part D prescriptions with appropriate diagnoses; and (2) stated that CMS should include all scientifically-supported indications, whether on the FDA labeling or not.

Response: We will, as deemed necessary, furnish sub-regulatory or other guidance to address the commenter's first issue. We agree with the commenter's second comment, and intend to include all scientifically-supported indications irrespective of whether they are on the FDA labeling.

Comment: One commenter expressed concern about the potential impact of § 424.535(a)(14) on pharmacies and their patients. The commenter stated that beneficiaries may see an interruption in the continuity of their health care if their physician is no longer qualified to be a Medicare supplier; the commenter believed there should be options available to ensure that health care is not interrupted.

Response: As explained earlier, we only intend to invoke § 424.535(a)(14) in exceptional circumstances. Consequently, we do not believe that patient access in general will be impacted.

Comment: In referring to the criterion in § 424.535(a)(14) regarding private insurers, a commenter stated that CMS does not have the statutory authority to make enrollment and revocation decisions based upon the actions of commercial health insurers. The commenter urged CMS to explain its legal justification for invoking § 424.535(a)(14) on this ground. The commenter also suggested that CMS explain how it will obtain information regarding private insurer actions taken against physicians and practitioners and whether these insurers will be required to furnish such data to CMS.

Response: We disagree with the commenter's assertion that we do not have the authority to consider the actions of private insurers in determining whether a § 424.535(a)(14) is appropriate. Again, we have the authority under sections 1102 and 1871 of the Act to establish requirements for the efficient administration of the Medicare program. If private insurers have taken actions against a particular physician or practitioner for questionable prescribing activities, we believe it would be appropriate for us to consider this information in light of our obligation to oversee the Part D program in a responsible manner. We will attempt to work with private insurers to facilitate the appropriate exchange of information.

Comment: A commenter opposed the following criterion: "Whether the physician or eligible professional has prescribed controlled substances in excessive dosages that are linked to patient overdoses." The commenter contended that CMS: (1) Did not provide the source or sources that it will use to obtain this information, and (2) already has a similar reason for revocation in § 424.535(a)(3) regarding felony convictions. The commenter stated that if CMS adopts this criterion, CMS should add the following language to the end thereof: "that result in a felony conviction of criminal neglect or misconduct." The commenter also recommended that CMS: (1) Cite the sources it will use to obtain information on patient overdoses; and (2) defer to the state medical boards regarding whether a physician or eligible professional is posing an immediate risk to Medicare Part D beneficiaries (assuming CMS intends to consider state actions in its § 424.535(a)(3) determinations).

Response: We are unclear as to the specific information to which the commenter is referring; namely, whether the commenter is alluding to published clinical data (for example, professional journals) or to information regarding a particular patient's overdose. If it is the latter, as we suspect, we intend to use both publicly available and internal data to determine whether cases of excessive prescribing exist. To the extent this data is obtained from state medical boards, CMS (for reasons alluded to earlier) does not believe a prior determination by the state of an immediate risk to Part D beneficiaries is necessary.

Comment: A commenter suggested that in lieu of revoking an individual under § 424.535(a)(14), CMS should place the physician under a payment suspension and deactivate his or her

Medicare billing privileges. Another commenter recommended that CMS consider a sliding scale to include lower-level consequences (such as suspensions) for less severe occurrences.

Response: We disagree. With a payment suspension, the physician would remain enrolled in Medicare and be able to prescribe Medicare Part D drugs and provide Medicare Part B services (although he or she would have Medicare payments withheld for a period of time). Moreover, there would be no legal basis under § 424.540 to deactivate the supplier's prescribing privileges, which is why revocation is the most appropriate remedy to address these situations.

Comment: A commenter stated that the sole use of PDE data to identify prescriber trends is insufficient to determine abusive practices, for such data cannot distinguish between: (1) Legitimate high dose and frequency of prescriptions; and (2) illegitimate prescribing.

Response: We agree and intend to use various data sources to detect such practices.

Comment: Several commenters stated that prescribers may avoid long-term care practice for fear of being revoked from Medicare.

Response: We disagree. We mentioned earlier that we only intend to invoke § 424.535(a)(14) in exceptional circumstances involving truly abusive behavior. Accordingly, we do not believe that § 424.535(a)(14) will deter prescribers from practicing in long-term care settings.

Comment: A commenter suggested that CMS provide additional data to plans in order to improve a plan's ability to identify inappropriate patterns and to apply claims processing edits correctly/timely.

Response: We agree and are considering various means of doing so.

Comment: One commenter stated that a revocation under § 424.535(a)(14) alone will not suspend or revoke the practitioner's right to prescribe drugs under state law, meaning that patients other than Medicare beneficiaries would still be at risk. This is especially true, the commenter added, considering that § 424.535(a)(14) does not require such CMS revocations to be reported to the state.

Response: It is possible that a prescriber revoked under § 424.535(a)(14) may still be able to retain his or her state license. However, we are currently working with the states to facilitate a closer exchange of information regarding Medicare actions taken against physicians and

practitioners, which may facilitate concomitant action taken by states.

Comment: Several commenters requested clarification as to whether a: (1) Part D plan sponsor would be penalized if it fills a prescription from a terminated supplier when information about the termination is not available (for example, in cases of retroactive termination or an error with CMS records); and (2) whether a pharmacy would be penalized for filling a prescription order that has been approved through the claims adjudication process. The commenter opposed the application of such penalties.

Response: We believe these comments are outside the scope of this final rule.

Comment: A commenter recommended that CMS remove the following as a factor for revocation: "Has a pattern or practice of prescribing for controlled substances outside the scope of the DEA Certificate of Registration." The commenter instead suggested that CMS work with the DEA.

Response: We disagree with the commenter. As previously mentioned, we are responsible for administering the Medicare program and must be able to take quick action against abusive prescribers without the prior approval of another agency.

Comment: A commenter stated that, on its face, each criterion appears reasonable. However, the commenter expressed concern that the rule does not provide guidance on the application and weight given to each factor, which could allow for subjective, contradictory, and discriminate revocation decisions (especially with respect to the last criterion that permits CMS to consider "any other relevant information provided to CMS.>").

Response: We understand the commenter's concern and note that we will, as deemed necessary, be issuing sub-regulatory guidance that explains in more depth the operational details of the § 424.535(a)(14) determination process. In addition, CMS, rather than its contractors, will make all final determinations. This will ensure greater overall uniformity, as well as a more consistent application of the various factors.

Comment: While supporting much of our proposed addition of § 424.535(a)(14), a commenter expressed concerns regarding several criteria. First, the commenter (referring to proposed § 424.535(a)(14)(i)(A)) stated that there are many reasons why a physician might prescribe a particular drug without a formal diagnosis (for instance, the physician may be unable to conduct a full evaluation due to

distance, cultural preference, etc.). Second, the commenter recommended that a statute of limitations be imposed regarding the individual's final adverse action history.

Response: We recognize that there may be instances where a formal diagnosis does not or cannot occur. In applying § 424.535(a)(14)(i)(A), we will consider the reason such a diagnosis did not take place. Regarding the commenter's second concern, we do not favor a statute of limitations for the final adverse action criterion; CMS must be able to retain its flexibility in this regard. Nonetheless, we will take into account when the adverse action occurred when analyzing whether it supports a finding of abusive prescribing.

Comment: A commenter recommended that CMS forgo adopting § 424.535(a)(14) and instead work with the Congress to suspend Coverage and Payment for Questionable Part D Prescriptions, as described in the FY 2015 Department of Health and Human Services performance budget.

Response: We continue to work with the Congress in our efforts to enhance Part D program integrity, and we believe that § 424.535(a)(14) is an important step in this direction.

Comment: With respect to the criterion dealing with state disciplinary actions, a commenter suggested that CMS monitor prescriber licensure statuses and status changes in lieu of state disciplinary actions. The commenter stated that many states do not publish state board disciplinary actions in a standardized format that can be easily used to ascertain a prescriber's practicing privileges.

Response: We recognize that state disciplinary data may not always be available. To the extent that it is, though, we do not believe it should be completely disregarded, even if the action did not result in a licensure suspension or revocation.

Comment: A commenter requested that CMS ensure that innovative abuse-deterrent technologies are employed as a tool in working to curb prescription drug abuse in Medicare. Another commenter recommended that CMS utilize health information technology systems to collect and organize data for measuring performance, supporting clinical decisions, and evaluating quality improvement processes; drug utilization procedures and prescription drug monitoring programs (PDMPs), for instance, could be important tools for improving public health and clinical practice.

Response: We appreciate these suggestions and note that we are

considering various technological and system-based means of enhancing our oversight of the Part D program.

Comment: A commenter offered several suggestions. First, CMS should furnish examples in the final rule as to the process of identifying and quantifying a pattern or practice as well as the actual revocation process of Medicare enrollment. Second, CMS should offer additional educational opportunities for suppliers regarding Medicare prescribing practices, which would place physicians and eligible professionals on notice that they must meet Medicare requirements and must prescribe properly.

Response: We agree with the commenter's second recommendation and, as stated earlier, plan to conduct outreach regarding prescribing practices. As for the first suggestion, we are not in a position in this final rule to furnish specific examples of when we would conclude that abusive prescribing exists and a § 424.535(a)(14) revocation is warranted; again, we must retain our flexibility to address a variety of factual scenarios.

The revocation process will be the same as that which currently exists for all other revocation reasons under § 424.535(a), the lone exception being that Part D plan sponsors will be notified of a revocation action under § 424.535(a)(14).

Comment: One commenter recommended that CMS revise the regulation to permit denial of an enrollment application due to prescribing practices that are either abusive and/or represent a threat to the health and safety of Medicare beneficiaries.

Response: We appreciate this suggestion and may consider it as part of a potential future rulemaking effort.

Comment: One commenter recommended that CMS obtain and consider a recommendation from the plan sponsor's medical director as to whether the prescribing pattern falls outside the standard of care and represents a therapeutic use for which safety and efficacy is not otherwise supported by available scientific evidence.

Response: We appreciate this suggestion, but note that CMS staff includes medical personnel who, as stated earlier, may be consulted as needed in potential § 424.535(a)(14) cases.

Comment: A commenter requested that CMS eliminate the criterion dealing with patterns and practices of prescribing without authority and instead utilize processes already in place to validate prescriptive authority

at the point of sale. The commenter also recommended that CMS work with industry stakeholders to develop a streamlined process for capturing data that will be used in CMS' § 424.535(a)(14) determinations.

Response: We disagree with the first comment. The issue is not the technical or logistical means of validating prescriptive authority but whether the unauthorized prescribing of drugs is indicative of abusive prescribing. As for the second comment, we are somewhat unclear as to the commenter's specific request; nevertheless, we will consult with plan sponsors and pharmacy interest groups as needed to ensure that our new provisions are effectively implemented.

Comment: A commenter expressed support for CMS' decision not to define "abusive" and "threat to the health and safety of Medicare beneficiaries" and to allow CMS the flexibility to address each case on its own merits. However, it urged CMS to review the list of criteria on a periodic basis and consider additions and modifications to reflect advances in clinical best practices and the evolution of abusive prescribing patterns or practices.

Response: We appreciate the commenter's support and intend to regularly review (and, if needed, update via further rulemaking) the criteria in § 424.535(a)(14) to account for changes in the medical field.

Comment: A commenter suggested that in making § 424.535(a)(14) determinations, CMS should: (1) Take into account historical information in the National Practitioner Data Bank (such as past DEA registration suspensions); and (2) consider the relative severity of any state licensure sanctions.

Response: We appreciate this comment. As stated earlier, a physician or eligible professional's final adverse action history (both past and present) will be a criterion for us to consider; the severity of any such actions or sanctions will be taken into account as well.

Comment: A commenter stated that proposed § 424.535(a)(14) may run counter to Medicare regulations that protect patient rights, creating the possibility that systematic limitations on prescribing practices may constitute a violation of patients' rights to pain assessments, palliative care, and the provision of hospice care.

Response: We disagree with the commenter. We do not believe that § 424.535(a)(14) will hinder the ability of Medicare beneficiaries to receive appropriate medications, particularly considering that: (1) § 424.535(a)(14) will only be applied in egregious

instances; and (2) the patient's particular needs, circumstances, and setting will be taken into account.

Comment: A commenter stated that there needs to be additional information in the final rule as to how this information would be provided to PBMs and how PBMs should administer it; for example, guidance is needed on how to manage suppliers that are licensed in multiple states but have an action against them in one state but not the other(s).

Response: We will, as deemed necessary, disseminate sub-regulatory or other guidance that addresses the issues the commenter has raised.

Comment: Several commenters believed that § 424.535(a)(14) could be strengthened even further by permitting revocation of enrollment based on prescribing practices that are abusive and/or represent a threat to the health and safety of Medicare beneficiaries, as opposed to requiring that both of these criteria be met. The commenters stated that some prescribing practices might be fraudulent and abusive but not necessarily representative of a threat to the health and safety of Medicare beneficiaries.

Response: We agree, and will revise § 424.535(a)(14) accordingly. Specifically, the language in § 424.535(a)(14)(i) that reads, "The pattern or practice is abusive and represents a threat to the health and safety of Medicare beneficiaries," will be changed to "The pattern or practice is abusive or represents a threat to the health and safety of Medicare beneficiaries or both." This will give us further flexibility in addressing cases of abusive prescribing, which in turn will enable us to better protect Medicare beneficiaries and the Trust Funds.

Given these comments and our responses, we are finalizing our addition of § 424.535(a)(14) with the exception noted in the previous paragraph.

We also received a number of comments that, in general, either applied to all of our proposed provisions or were not precisely related to any specific proposal. Our summary of the comments and are responses are as follows.

Comment: Several commenters opposed the use of the CMS-855O on various grounds. First, the CMS-855O does not collect practice location or medical storage information, which the commenter believes is a significant vulnerability and is inconsistent with CMS' existing regulations. Second, use of the CMS-855O is inappropriate because proposed and final regulations (in which the notice-and-comment

process is used) regarding its use and implementation were not published in the **Federal Register**. Third, the commenter contended that CMS does not have the statutory or legal basis to use an enrollment application other than for the express purpose of enrolling a provider or supplier; as such, CMS exceeded its legal authority to implement the CMS-855O for the sole purpose of ordering and certifying services and items in the Medicare program. Fourth, the commenter contended that CMS lacks the statutory and regulatory basis to establish a registration process for Medicare. Fifth, the CMS-855O is duplicative of the CMS-855I form, the latter of which was subject to notice-and-comment; also, requiring a physician who is enrolled (via the CMS-855I) solely to order or certify services or items to then complete the CMS-855I if he or she wishes to bill Medicare increases the paperwork burden.

Response: These comments are outside the scope of this final rule.

Comment: A commenter recommended that to improve transparency, CMS should post the name, NPI, and reason for each Medicare enrollment revocation or payment suspension and the duration of the revocation or payment suspension on the Medicare Provider/Supplier Enrollment Web site. The commenter believed that this information would be useful for Medicare Advantage Organizations, Part D sponsors, and the public.

Response: We appreciate this suggestion, and will take it under advisement as we continue our efforts to strengthen the integrity of the Part D program.

Comment: Several commenters recommended that CMS: (1) Explain why it does not believe the inclusion of the practice location on the CMS-855O is essential to identifying the physician or non-physician practitioner; (2) require that all physicians and non-physician practitioners report their practice locations; (3) mandate that only physicians with a defined specialty be permitted to prescribe Part D drugs; (4) remove from the list of physicians and eligible professionals with an approved enrollment record any physician or non-physician practitioner with an undefined or unlisted physician or non-physician specialty code; (5) explain why it did not solicit comments on the use of an electronic signature in the Internet-based versions of the CMS-855O and the CMS-855I; (6) provide the authority to implement and use the CMS-855O beginning in July 2011 and explain why it did not choose to solicit

public comments on changes to regulatory provisions found in §§ 424.502 and 424.505 for almost 3 years after adopting and using the CMS-855O; (7) explain why it is using the CMS-855O rather than the CMS-855I since the CMS-855O, in the commenter's view, essentially duplicates the CMS-855I; (8) modify and use the CMS-855I (rather than continue using the CMS-855O) because CMS cannot verify the practice location of a physician who registers using the CMS-855O; (9) explain why CMS has not proposed to revise § 424.500 to accommodate the registration of physicians and non-physician practitioners for the sole purpose of ordering/certifying services and items in the Medicare program; (10) disenroll all physicians and practitioners enrolled via the CMS-855O and require them to enroll via the CMS-855I; and (11) provide the number of individuals enrolled or registered into the Medicare program using the CMS-855O since July 2011.

Response: These comments are outside the scope of this final rule.

Comment: A commenter suggested that the final rule take action against physicians who report via the Internet that they are board certified when in fact they are not.

Response: We appreciate this suggestion. While we are unable to include such a provision in this final rule because we did not propose it, we will take it under advisement as we continue our efforts to strengthen the integrity of the Part D program.

Comment: A commenter recommended that CMS require physicians and eligible professionals to have an active Medicare enrollment to order Part B drugs.

Response: This comment is outside the scope of this final rule.

Comment: A commenter recommended that CMS not allow physicians and eligible professionals who have opted-out of Medicare to order or certify services and items when they have been suspended or revoked by a state licensing body.

Response: This comment is outside the scope of this final rule.

Comment: A commenter recommended that CMS clarify whether a Part D Medicare beneficiary will need to provide his or her physician's name and NPI to his or her plan sponsor if he or she submits a Part D claim for payment.

Response: We will, as deemed necessary, address this issue via sub-regulatory or other guidance.

Comment: A commenter recommended that CMS exclude

physicians and eligible professionals who have opted out of the Medicare program from prescribing Part D covered drugs because CMS does not have the legal authority in either the Social Security Act or existing regulations to revoke the prescribing privileges of a physician or eligible professional who has opted-out of the Medicare program.

Response: As we stated previously, section 1802(b) of the Act is clear that certain physicians and practitioners may opt-out of the Medicare program and enter into private contracts with Medicare beneficiaries. We believe that to require such individuals to enroll in Medicare would be inconsistent with this statutory provision.

Comment: A commenter recommended that CMS explain why the April 14, 2012 and September 11, 2011 **Federal Register** Notices soliciting comments on the CMS-855O state that physicians and practitioners submitting this form are registering rather than enrolling in Medicare, while the April 2013 proposed rule states that they are enrolling in Medicare; the commenter stated that existing regulations do not provide for a registration process.

Response: This comment is outside the scope of this final rule.

Comment: A commenter stated that diagnosis codes should be placed on prescriptions to assess their appropriateness.

Response: This comment is outside the scope of this final rule.

Comment: A commenter: (1) Requested clarification regarding whether a revocation under our proposed provisions would affect a physician or eligible professional's Medicaid enrollment; (2) requested clarification concerning how a State Medicaid agency would differentiate between one's enrollment via the CMS-855I and an enrollment via the CMS-855O; and (3) suggested that CMS provide a complete list of individuals who can only order, certify or prescribe in the Medicare program.

Response: With respect to the first comment, any Medicare revocation results in the termination of the provider or supplier's Medicaid enrollment pursuant to § 455.416(c). The second comment is outside the scope of this final rule. As for the third comment, and as alluded to in both the proposed rule and in this final rule, we plan to make available to Part D sponsors a list of physicians and eligible professionals who have an approved enrollment record or a valid opt-out affidavit on file with an A/B MAC. We do not intend at this time to modify this list (nor to create a separate list) to

identify those individuals who are enrolled solely to order, certify, or prescribe in the Medicare program. However, we may consider this as part of a future enhancement.

Comment: A commenter suggested that CMS require private insurers in Part D to report suspected fraud, waste and abuse to Medicare's fraud contractor. Another commenter stated that CMS should: (1) Encourage Part D sponsors to voluntarily report suspected instances of physician and eligible professional misconduct or abusive prescribing, and (2) institute measures to ensure a two-way working dialogue between the sponsors and the MEDIC.

Response: We are working to ensure that Part D plans consistently and regularly refer suspected fraud, waste, and abuse to the MEDIC and that there is appropriate communication between them.

Comment: A commenter requested that steps be taken to ensure that a beneficiary is notified when his or her physician's billing privileges have been revoked, and that an exception be made for emergency or urgent care situations. Similarly, another commenter requested clarification as to whether claims will be processed for emergency and urgent care services furnished by opt-out physicians and, if so, how processors will identify claims in that scenario. One commenter requested that CMS furnish guidance regarding: (1) How Part D prescribers can complete an opt-out affidavit; (2) how opt-out prescribers will be identified in the file; (3) which (if any) edits will apply to opt-out prescribers; (4) how various enrollment statuses (for example, an enrollment application or opt-out affidavit is pending) should be handled; (5) how terminations should be handled and whether changes in enrollment (including suspensions and revocations) will be communicated to plan sponsors at least 30 business days in advance; (6) whether the enrollment/opt-out file will be made available to prescriber data vendors; (7) whether an alert process will be established for reinstated or new enrollments that occur between file deliveries; (8) whether override processes will be developed; (9) whether procedures for notifying beneficiaries of a change in an individual's ability to prescribe Part D drugs will be established; (10) whether a special call center for Part D prescribing issues related to enrollment will be created; and (11) how felony convictions, exclusions, debarments, and State Medicaid program prescriber sanctions should be treated for purposes of claim denials and coding (for instance, whether they should be treated

as Medicare revocations or OIG exclusions for purposes of claim denials and coding).

Response: We will, as deemed necessary, address the aforementioned issues via sub-regulatory or other guidance.

Comment: A commenter recommended that CMS reestablish the systematic deactivation of Medicare billing and prescribing privileges if the physician or non-physician practitioner has not billed the Medicare program in more than a year to ensure consistency with an OIG recommendation to this effect. The commenter also recommended that CMS provide the number of physicians and eligible professionals who have completed the CMS-855I and who have not billed the Medicare program in more than a year as of March 7, 2014, the ending comment date for this proposed rule.

Response: These comments are outside the scope of this final rule.

Comment: A commenter stated that a revocation would be too serious a penalty for a DEA registration suspension or revocation or for improper prescribing.

Response: While we recognize commenter's concern regarding the severity of a revocation action, this action will in some cases be necessary to protect Medicare beneficiaries and the Trust Funds.

Comment: A commenter sought clarification regarding whether CMS would notify the prescriber at least 30 days in advance of a forthcoming revocation.

Response: As already stated, the operational procedures for revoking suppliers under §§ 424.535(a)(13) and (14) will be the same as those which currently exist for other revocations under § 424.535(a), the sole exception being that Part D plans will be notified of the revocation.

Comment: A commenter suggested that CMS centralize all exclusion, opt-out, and other lists in one location (to the maximum extent possible), preferably via a format that Part D plans can download and convert into a file format compatible with data analytics programs. This would enable plans to act more quickly against excluded suppliers. Another commenter urged that CMS update such lists expeditiously so that plan sponsors can take action as needed.

Response: We appreciate the first commenter's suggestion and may consider this as part of a future enhancement. We agree with the second commenter's recommendation and stress that CMS attempts to update its existing lists (and will attempt to update

the aforementioned enrolled/opted-out prescriber list) as quickly as possible.

Comment: A commenter requested clarification concerning whether: (1) Plan sponsors are only supposed to deny coverage in the state in which a physician's license is revoked or whether denials should be for all states; and (2) whether CMS will continue to permit a physician with a CMS waiver to continue practicing in rural areas when he or she is the only physician available, even though he or she is revoked.

Response: We believe these comments are outside the scope of this final rule.

Comment: A commenter requested clarification regarding whether a physician who is prohibited from prescribing controlled substances for the treatment of non-cancer related chronic pain or obesity would have their Medicare billing privileges and/or prescribing privileges revoked by the Medicare program.

Response: As stated in § 424.535(a)(13), if the applicable licensing body for any state in which the physician practices suspends or revokes his or her ability to prescribe controlled drugs, we have the discretion to revoke his or her Medicare billing and prescribing privileges. Should we exercise this discretion, the physician would be unable to prescribe covered Part D drugs because he or she would no longer be enrolled in Medicare.

Comment: A commenter recommended that CMS explain the process it uses to identify medical licenses that are surrendered while a formal disciplinary proceeding was pending before a state licensing authority.

Response: This comment is outside the scope of this final rule.

Comment: A commenter encouraged CMS to consider participation in the Council for Affordable Quality Healthcare (CAQH) universal credentialing application process used by many private sector healthcare systems. Having one "portal" for physicians to become credentialed for both Medicare and private sector health plans, the commenter believed, would reduce the administrative burden for physicians.

Response: We appreciate this comment but believe it is outside the scope of this final rule.

Comment: One commenter, while expressing support for §§ 424.530(a)(11) and 424.535(a)(13) and (14), requested that CMS delay its implementation until CMS (1) has fully field-tested the Medicare enrollment and reporting program, and (2) demonstrates that the program will operate at a high level of

accuracy, with frequent updates, and with consistently reliable linkages to and from other federal and state databases. Another commenter recommended that the criterion in § 424.535(a)(14) regarding diagnosis codes be delayed until the effects of the ICD-10 transition are reviewed.

Response: While we appreciate the first commenter's support, we do not believe that the implementation of these provisions (including the criteria in (a)(14)) should be delayed. As explained earlier, CMS must take steps to ensure the integrity of the Part D program and to protect both Part D beneficiaries and the Trust Funds.

We are neither finalizing nor proposing any regulatory changes as a result of these miscellaneous comments.

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

We proposed 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. For background, 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), (1) and (m). 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. 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 for research purposes, CMS indicated in the Part D data final rule 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.

In the preamble to the proposed rule, we stated that we believe the current limitations on the release of certain data elements hinder the use of PDE data in a health care environment that is substantially transforming due to the Affordable Care Act, and that these limitations therefore also inhibit accompanying insights into prescription drug benefit plans that could result from broader release of the data. We further stated that 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. For these reasons, we stated that increased access to prescriber, pharmacy, and plan identifiers by all categories of requestors is of utmost importance and will

facilitate research by entities outside CMS that involves identifiable plans, prescribers, and pharmacies. Furthermore, we stated that we could relax the current policies on the release of this PDE data, while still protecting beneficiary confidentiality and commercially sensitive data of Part D sponsors.

Specifically, we proposed to permit the release of unencrypted prescriber, pharmacy, and 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) 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 noted that because the minimum necessary policy will still apply to all such releases, our proposal was more a formality with respect to HHS entities/Congressional oversight agencies and non-HHS executive branch agencies/states, since this data is available in unencrypted format to these same entities under the current Part D data regulations "if needed." For this reason, in the proposed rule, we focused on the release of unencrypted prescriber, pharmacy, and plan identifiers to external entities as discussed later in this section.

We acknowledged in the preamble to the proposed rule that there still may be concerns about releasing unencrypted prescriber, plan, and pharmacy identifiers to outside entities based on comments that were received in response to our original proposed Part D data regulations, and that were discussed in the Part D data final rule (73 FR 30675). In particular, we addressed concerns that this information could be used by pharmaceutical companies and others who may want to influence physicians' prescribing patterns and interfere with their professional judgment. As we stated in the proposed rule, it is our view today, however, that 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, we stated that there are other measures in place to prevent inappropriate influence by external entities on prescribers, such as section 6002 of Affordable Care Act and the federal Anti-Kickback Law (section 1128B(b) of the Act). We also pointed 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 also noted that it appears prescriber data are already available commercially from pharmacy data aggregators. For these reasons, we stated that we believe that our earlier concerns expressed in the Part D data final rule about the release of unencrypted prescriber identifiers in PDE data to external entities are no longer warranted.

In the proposed rule, in conjunction with our proposal to broaden the release of unencrypted prescriber identifiers, we also highlighted our response to a comment discussed in the Part D data final rule, which 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 (73 FR 30676). We noted that in response to the comment, 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 at the time in an effort to encourage health care providers to furnish high quality health care and to provide cost and quality information to consumers. We also noted that in our response to the comment, we had stated that we intended to use PDE data in those activities, but we declined 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). In this proposed rule, however, we acknowledged that, 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 agree with the commenter regarding the importance of providing access to prescriber-identifiable claims in order to allow researchers to pool them with employer data and conduct broader research.

We noted in the proposed rule that 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, and only in aggregated form.

With respect to our proposal to broaden the release of unencrypted plan

identifiers, we also explained in the proposed rule that 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 Medicare Prescription Drug Plan Finder ("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 contribute to the evaluation and functioning of the Part D program and can be used to improve the public health. Therefore, in light of the fact that plan data is already publicly available and the public policy rationale for increasing access to PDE data by all categories of requestors, we stated that plan identifiers should be available in an unencrypted format.

For the same reasons that we proposed to make prescriber and plan identifiers available for release in an unencrypted format, we explained in the proposed rule that we no longer see a reason that pharmacy identifiers should not be available for release in an unencrypted format. Accordingly, we also proposed to release unencrypted pharmacy identifiers to all categories of requestors.

We addressed one final aspect of our policies governing the release of Part D data in the proposed rule. As discussed previously, in the preamble to the Part D data final rule (73 FR 30664), 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, for the same reasons that we proposed to make changes to our rules governing the release of PDE data, we also solicited comment on the current restriction on the release of PDE data for commercial purposes. We noted that we were not making a specific proposal in this regard, but rather, that we wished to receive comments on this issue for consideration.

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 proposed a few other changes to our regulations governing the submission, use, and release of PDE data, including some

changes intended to clarify our existing policies with respect to several issues related to PDE data. First, we proposed 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. Thus, we indicated that we believe 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 proposed to add this purpose explicitly to the non-exclusive list in § 423.505(f)(3).

Second, we proposed to clarify that non-final action data (for example, information on claims subject to subsequent adjustment) are available to entities outside of CMS. We explained that non-final action data are captured through the data element, "Original versus Adjusted PDE (Adjustment/Deletion code)." We further explained that this is a PDE field which distinguishes original from adjusted or deleted PDE records, which allows sponsors to make adjustments to the original PDE record to ensure accurate payment. The information included in these revised PDE records is thus not point-of-sale data. With the increasing focus on coordination of care, we noted that requests for access to non-final action PDE data have understandably also increased, and that non-final action data are also routinely requested for evaluation and research projects. We noted that 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. Specifically, we noted that 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, we noted that this appendix did not explicitly address the question of whether non-final action data would be available for release to

non-HHS executive branch agencies, states, and external entities, because such data were not expected to be needed by these requestors. However, since it is clear that these entities do need access to non-final data, we proposed to clarify 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.

Due to our proposals to make changes to our policies governing the release of PDE data described previously, we proposed to make corresponding changes to the current applicable regulatory text. In addition, we also proposed 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 stated that we believed this appendix is no longer necessary, as our proposed changes in policy would eliminate most of the distinctions with respect to the PDE data available for release to the different categories of requestors, 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 proposed to revise the regulation at § 423.505(m)(1)(iii)(B) to account for this distinction. We also proposed to revise this provision to clarify that we will continue to exclude sales tax from the aggregation, if necessary for the project. Finally, we proposed 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).

We received the following comments on our proposed revisions to the regulations governing the release of Part D data:

Comment: We received a number of comments regarding these proposed revisions, many of which strongly supported our proposed revisions to the Part D data regulations. Several commenters commended CMS' ongoing work to improve the efficiency of the Medicare program and the clinical care of its beneficiaries, which these commenters asserted will be better facilitated through increased data transparency that facilitates additional research. These commenters stated that releasing unencrypted physician, plan, and pharmacy identifiers in Part D PDE data under the parameters we proposed will allow researchers to answer a broader range of questions about the

program. These commenters further stated that greater access to Part D PDE data will help ensure that this data is used to maximum effect in the creation of knowledge and understanding about the program and around clinical care received by beneficiaries. Commenters additionally noted that the increased availability of PDE data will enable researchers to conduct in-depth comparisons of medications provided through different outlets, which could enable CMS to take proactive measures to achieve cost savings. One commenter also stated that the public has a significant interest in provider, plan, and pharmacy professional conduct, as these entities are government licensed and regulated, and Medicare payments are publicly funded. Finally, these commenters noted that our existing “minimum necessary”, “legitimate researcher”, and “aggregation” policies are sufficient to provide some common sense parameters for release of unencrypted identifiers.

Potential areas of research suggested by the commenters were linking information on Part D plan features (such as premiums, cost-sharing, and formularies) to health outcomes and the quality of health care provided to Medicare beneficiaries. Other commenters asserted that broader access to prescriber, plan, and pharmacy identifiers in PDE data will facilitate research in particular for conditions for which there are very few viable treatments, no available cure, and much more work to be done with respect to researching and developing safe and effective medicines. These commenters welcomed the availability of additional information to spur further knowledge, investigation, and progress on how to best treat—and ensure appropriate coverage for treating—complex health conditions.

Response: We thank these commenters for their comments in support of our proposed changes.

Comment: Other commenters opposed our proposed revisions to the policies governing the release of Part D data. These commenters asserted that the existing framework for release of Part D PDE data fully accommodates the needs of government entities and legitimate researchers, and strikes the appropriate balance between these needs and the legitimate concerns of health care providers and Part D plan sponsors regarding the widespread dissemination of sensitive data, including data that specifically identifies them. One commenter stated that CMS had not articulated a reason for the need to identify specific plans, pharmacies, and prescribers, and that necessary research

can be accomplished with encrypted identifiers. One commenter requested a clarification on the meaning of “new health care environment.” Some commenters asserted that prescriber, plan, and pharmacy identifiers in PDE data are commercially sensitive information, and that release of these identifiers would undermine competition and may lead to higher costs in the Part D program and less choice. A few of these commenters asserted similarly that prescription drug benefit plans could potentially reverse engineer competitively sensitive data regarding other plans, which could have an anti-competitive effect on the Part D bidding process.

Response: We think the preamble to the proposed rule provided a clear description of the ways in which the Affordable Care Act is transforming the health care system in this country—by spearheading the drive toward an information- and value-based system, and the compelling reasons for the release of unencrypted prescriber, plan, and pharmacy identifiers in Part D PDE data to allow for additional research to achieve this goal. Specifically, it is in the interest of public health to share this information with entities outside of CMS, as the work of these entities will assist CMS in evaluating the Medicare Part D program and assessing related policies to improve the clinical care of beneficiaries. We also note that when more data is released about the Medicare Part D program, the potential research topics expand as well. For instance, commenters supportive of the proposed expansion in the release of Part D data offered examples of potential areas of new research, such as linking information on Part D plan features (such as premiums, cost-sharing, and formularies) to health outcomes and the quality of health care provided to Medicare beneficiaries. Such research is not possible with encrypted plan identifiers, because the researchers would not know the specific features of the unidentified plans.

In addition, we are not persuaded that these identifiers are commercially sensitive data. As we stated in the preamble to the proposed rule (79 FR 1990), 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. Moreover, we noted that it appears that prescriber data are already

available commercially from pharmacy data aggregators. These data can currently be manipulated by researchers to reveal information about specific plans, pharmacies and prescribers. For these reasons, we have concluded that prescriber, plan and pharmacy identifiers are not commercially sensitive information, and that it is appropriate to share this information in an unencrypted format when it is needed for a particular study or project.

Comment: Some commenters supported our assertion in the proposed rule that release of unencrypted identifiers in Medicare Part D PDE data subject to our current data release policies, including our minimum necessary and legitimate research policies, will not result in data recipients using the data inappropriately, such as to influence physicians’ prescribing patterns or interfere with physicians’ professional judgment. These commenters stated that physicians are trained to use their best medical judgment in making prescription decisions for their patients.

Other commenters disagreed, asserting that the release of unencrypted identifiers has the potential, for instance, to influence prescribing patterns and physician judgment, or otherwise to be used to draw incorrect or inaccurate conclusions that could be damaging to the reputations of professionals and health care organizations. These commenters asserted that inappropriate influence may adversely affect the quality of care for beneficiaries. One commenter stated that the Affordable Care Act’s additional reporting requirements with respect to physician prescribing do not address this type of influence, and that CMS has assumed that release of this data will not adversely affect beneficiaries, rather than carefully considering the impact of release. Another commenter stated that data and statistics are valuable in observing trends among patient populations, but that they are a blunt instrument when applied to individuals. One commenter opposed the indiscriminate release of data to any requesting external entity, including to data aggregators that have little knowledge of the Medicare Part D program. A few commenters encouraged CMS to present the data in a way that considers the quality of the services provided, including an explanation of the data limitations, and allows for the opportunity to correct information, for instance, to include patient non-compliance in the case of release of prescriber identifiers. Finally, these commenters stated that disputing inaccurate findings takes significant

time, effort, and expense, and even then, it is often impossible to fully mitigate the harm caused.

Response: While we are sensitive to the concerns regarding undue influence raised by the commenters, for the reasons discussed in the proposed rule, we agree with those commenters that did not believe releasing these data would result in improper influence on physician prescribing patterns or otherwise interfere with the exercise of professional judgment. In addition, we believe CMS' current release policies will also limit inappropriate use of the data. In order for a researcher to gain access to CMS data, the researcher must submit a research protocol and receive approval of the protocol from CMS. In addition, all requestors are required to sign a Data Use Agreement with the agency that limits the use of the data to only the approved purposes. The agency carefully considers all data requests to ensure that the use of the data will not exploit or negatively impact Medicare beneficiaries. Furthermore, we do not believe the professional research community would support the dissemination of faulty analyses and would be quick to offer criticisms of poor research, should this happen despite our careful evaluation of all data requests. We also disagree that data and statistics are only valuable in observing trends among patient populations. As we lead the effort to provide high quality care and better health at lower costs, data analysis at various levels of specificity is crucial. For example, analyses at the provider or supplier level, when properly adjusted to account for differences in patient populations, could provide insight into differences in the way a given condition is treated and help develop best practices. In addition, unencrypted prescriber identifiers have valuable uses beyond reporting on individual physician prescribing patterns. For example, unencrypted identifiers in Part D data can be linked to other sources of data, such as claims data from other payers, electronic health records, and clinical data such as lab results, in order to facilitate broader and more complex research projects.

Additionally, we were not persuaded that CMS should release data in a way that considers the quality of the services provided, includes an explanation of the data limitations, or allows for the opportunity to correct information. This is precisely what professional researchers do, and as we previously noted, we think the professional research community would be quick to offer criticisms of poor research, should a project fail to address these issues

appropriately. Moreover, if CMS were to analyze data before its release for research, this practice would undermine the independent nature of the analyses performed by outside researchers.

Comment: Some commenters specifically supported the release of non-final action PDE records, asserting such data would permit researchers to explore data for a better understanding of the Medicare Part D program. The comments included a specific example of how non-final action data can assist researchers in exploring prescription adherence and abandonment by tracking and accounting for adjusted or deleted prescriptions. In contrast, other commenters specifically opposed the release of non-final data, asserting that this information can easily be misinterpreted and may cause false conclusions that impact providers. One commenter opposed our proposed clarification regarding release of non-final action data stating that CMS had failed to articulate a reason for releasing non-final action data other than that it had received requests for it.

Response: We disagree with the commenter that asserted that CMS failed to articulate a reason for releasing non-final action data. We think we did articulate a reason for releasing non-final action data. It is the same as the overarching reason to release Part D PDE data, which we discussed at length in the proposed rule. Specifically, it is in the interest of public health to share this information with entities outside of CMS, as research conducted by these entities may assist CMS in evaluating the Medicare Part D program and assessing related policies to improve the clinical care of beneficiaries. In addition, as we stated in the preamble to the proposed rule, the release of non-final action data is necessary due to the increased focus on coordination of care in the Medicare program and indeed in the health care system as a whole.

Comment: One commenter opposed the proposal to allow release of unencrypted prescriber and pharmacy identifiers stating that the current release policies already allow external entities to link unencrypted identifier elements to another data set.

Response: We disagree. Under our current regulations, the identifiers must be re-encrypted after the link has been made. Under the regulations as finalized, once linked, research at higher levels of specificity can be conducted that is not possible with encrypted identifiers. For instance, a researcher conducting a study on medication adherence will have many more factors to consider and explore when the prescribers, plans, and

pharmacies involved in the research are identifiable. Is adherence related to plan features? Physician location and/or specialty? Pharmacy organization filling the prescription? All three? The research possibilities will expand, as the additional connections that can be explored by researchers expand. Drilling down to higher and higher levels of specificity to understand and potentially solve a problem is the very nature of 21st century data-driven research, and we believe it is essential that the Part D data release policies keep current.

Comment: One commenter opposed our proposal to release unencrypted plan identifiers, asserting that plan information is gathered only for Part D administration purposes.

Response: We disagree. Section 423.505(f)(3) of the regulations states that a plan sponsor agrees to submit to the Secretary all data elements for purposes deemed necessary and appropriate by the Secretary, including, but not limited to conducting evaluations of the overall Medicare program. As we noted previously, commenters offered examples of potential areas of research that will be enabled through access to unencrypted plan identifiers, such as linking information on Part D plan features (including premiums, cost-sharing, and formularies) to health outcomes and the quality of health care provided to Medicare beneficiaries.

Comment: One commenter stated that CMS should more specifically define "legitimate researcher" to ensure that Part D data is not released for competitive or commercial purposes contrary to CMS' current policy.

Response: Under current CMS data sharing policies, the agency evaluates all research requests to ensure that the researcher has the expertise to conduct the proposed study. In addition, we must approve the research protocol before any data is shared with a researcher. We believe that this review process contains appropriate safeguards to prevent inappropriate use of the data and, as such, we do not believe it is necessary to define a "legitimate researcher." Furthermore, we believe a variety of different types of individuals could submit a valid research request.

Comment: Some commenters supported our proposal to broaden the release of Part D data, so long as beneficiary privacy is protected. One commenter suggested that a biostatistician conduct an expert review of the data sets to be released in the context of the permitted use(s) to ensure beneficiary privacy in the context of the permitted uses of the data. Another

commenter stated that our proposed expansion of the available data will compromise beneficiary privacy and requested that an approval process similar to an IRB be established to evaluate requests for such information to weigh the risks and benefits of disclosure. Another commenter stated that CMS should ensure that its efforts to protect beneficiary confidentiality do not create such onerous data request processes that qualified researchers are discouraged from attempting to access Part D data. Another commenter stated that CMS should establish and impose appropriate penalties for any breach of privacy related to beneficiary identifiable information.

Response: All users accessing beneficiary identifiable data are required to sign CMS' Data Use Agreement (DUA), which addresses privacy and security for the data CMS discloses. In addition, the DUA currently does, and will continue to have, enforcement mechanisms, including criminal penalties. CMS would make use of these provisions in the event of any breach or violation of the terms of the DUA. The DUA also contains provisions regarding access to and storage of CMS data to ensure that beneficiary identifiable information is stored in a secure system. We believe these restrictions are necessary in order to ensure that data is only requested in compliance with the requirements of the regulations and CMS data sharing procedures, and that data shared by CMS is appropriately protected and is not reused or redisclosed without the necessary approval. Given that researchers have successfully been accessing to CMS data under the terms of this DUA for years, we do not believe these requirements are too burdensome. With regard to the suggestion that CMS have a bio-statistician review the data sets to be released to ensure beneficiary privacy, we do not believe this is necessary given the beneficiary privacy protections in the DUA. However, to the extent that CMS releases any de-identified, summarized data sets based on the Part D data, the agency carefully reviews the proposed release to ensure that it does not put beneficiary privacy at risk. Finally, we disagree that the expansion of the available data will compromise beneficiary privacy or that additional procedures are necessary in order to safeguard beneficiary privacy. CMS has an established process to evaluate requests for data to ensure that there are appropriate safeguards in place to protect beneficiary privacy. We believe this process contains the

necessary checks to ensure that the risks of the disclosure are minimal.

Comment: One commenter stated that CMS should be as transparent as possible under its data use agreements, asserting that the public, as well as the parties involved, must be able to readily determine the manner in which data are released, the purpose for the release of the data and the parties to whom the data are released.

Response: We are strongly committed to transparency. In particular, we have established processes to ensure that beneficiaries can request information about to whom their protected health information or personally identifiable information has been disclosed, as well as the purpose for the release of the data. Beneficiaries interested in requesting access to this information should contact the CMS Freedom of Information Act (FOIA) Office (<http://www.cms.gov/center/freedom-of-information-act-center.html>).

Comment: One commenter stated that CMS should consider whether a proliferation of analyses of outdated Part D data will truly benefit the Part D program, when CMS has the ability to commission studies and data analysis that would more knowledgeably take into account a comprehensive understanding of the continually changing dynamics of the Part D prescription drug market.

Response: We use Part D data to conduct a variety of studies and analyses. However, this work does not even begin to cover the scope of possible analyses that could be performed using Part D data. We believe that by limiting Part D data analysis to that supported by CMS, the agency would be inhibiting important research and innovation that has the potential to result in higher quality care at lower costs in the Medicare Part D program, and indeed for all Americans.

After review of the comments we received, we are finalizing our proposed changes to the regulations governing the release of Part D data. Specifically, we are finalizing the following revisions to the applicable regulatory text:

- Section 423.505(f)(3) is revised to add supporting program integrity purposes, including coordination with states, as an additional purpose.
- Section 423.505(m)(1)(iii) is revised to remove references to encrypting certain identifiers since prescriber, plan, and pharmacy identifiers are no longer be subject to encryption when released.
- Section 423.505(m)(1)(iii)(A) is 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) is revised to incorporate a note from the appendix that is being eliminated, 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) is deleted as no longer necessary since unencrypted plan identifiers, including the internal plan/pharmacy identification numbers, are available for release.

- Section 423.505(m)(1)(iii)(D) is re-lettered as (C) and references to encryption of pharmacy and prescriber identifiers are deleted, since these identifiers are available for release in unencrypted format. Additional language regarding beneficiary identifiers is added to reflect the current policy on release of this identifier. In addition, we are including the statement, "Public disclosure of research results will not include beneficiary identifying information," at § 423.505(m)(1)(iii)(C)(2), which also reflects current policy as described in the appendix that is being eliminated.

- Section 423.505(m)(3) re-lettered as (m)(3)(i) and (m)(3)(ii) is added to incorporate a note from the appendix that is being 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).

With respect to our policy not to release Part D data for commercial purposes, we did not make a specific proposal but solicited comments for general consideration. We received comments on both sides of this topic, and thank all the commenters. The following is a summary of the comments:

Comment: Commenters that desire a change in the policy applauded CMS for soliciting comment on this topic. These commenters stated that in order to improve and modernize the U.S. health care system, greater alignment of stakeholder incentives is required, and that CMS is keenly aware of this pivotal requirement for success. These commenters stated that the challenge of quantifying greater efficiency and evidence of improvement as part of overall health reform requires more access to the unique data sets in federal data, and that the current restriction on the use of these data for commercial purposes will grow increasingly challenging in the future as Medicare employs more value-based payment incentives, and as Medicare data are

included in broader multi-payer sets, such as those being established by the Patient-Centered Outcomes Research Institute. These commenters further stated that because the quality and efficiency of all physician groups, health plans, hospital systems, and other providers and suppliers can be enhanced using data, any notion that commercial interest is limited and discrete is outdated. They stated that PDE data is a valuable asset to all types of commercial health care entities in limiting the incidence of fraud, obtaining practice pattern feedback, managing health care delivery to deliver value, developing best practice standards, and conducting comparative effectiveness research.

The commenters also stated that eliminating or reducing this current restriction on the release of data for commercial purposes is consistent with CMS' desire to foster transparency and competition in the Part D program during a period of sweeping change to the health care system. These commenters asserted, for example, that suppliers need to incorporate accurate data into their product pricing and discounting strategies to align their approaches with the system-wide drive toward value-based decision-making and high quality care.

Commenters additionally stated that the more access there is to Medicare data, the more dramatically the bandwidth for research will be increased, leading to increased quality of care, system efficiency, and consumer satisfaction in the Medicare programs and health care system in general. These commenters noted that there is deep scientific and analytic expertise within organizations that are currently excluded from accessing CMS data. These commenters asserted that the standard for data release by CMS should be whether the research proposed is of high quality and whether it has the potential to improve program administration or the health of the covered population, rather than financial benefit and profit status of the organization proposing the research. These commenters further noted that CMS has in place strong research merit criteria, rules, and obligations for data use and individual privacy protections, and that these processes and this oversight are sufficient to determine whether a requestor should have access to PDE or other identifiable data, regardless of the researcher's affiliation.

Some commenters stated that broader release of Part D data would not only further public health research and analysis of the Part D program, but also would serve to further educate

consumer organizations, patient advocates, and ultimately beneficiaries about the program generally, as well as coverage and prescribing patterns under various plans.

Some commenters stated that they would support changing the policy on non-release of Part D data for commercial purposes, so long as CMS ensured that release of the data would be conditioned on its use for improvement of one or more aspects of the Part D program, and CMS carefully screened potential recipients of the data for demonstrated expertise in using research data to improve health programs, as well as for any potential conflicts of interest or other concerns.

Commenters that believe that the policy of non-release for commercial purposes should remain unchanged stated that health care entities have legitimate concerns regarding the widespread dissemination of sensitive data, such as data that specifically identifies them. These commenters also stated that strong program oversight and public health and public policy imperatives do not exist to counterbalance these concerns.

One commenter stated that CMS lacks the authority to release Part D data for commercial purposes, because the authority cited by CMS limits releases to those required for program purposes and for improving public health. The same commenter asserted that the right to make data available for purely commercial reasons is a right inherent in the ownership of the data, and that CMS has never previously asserted an ownership over, or right to control the use of, data not obtained through access to a CMS system. This commenter stated that by granting itself this right to release Part D PDE data for purely commercial purposes, CMS would be exercising a right inherent in ownership of the data.

In light of all the comments received on both sides of this particular topic, we continue to believe that the best approach is for our policy regarding the release of Part D data for commercial purposes to remain consistent with the policies for the release of data from Medicare Parts A and B. As we discussed, in the Part D data final rule (73 FR 30672), the procedures that we use to make Part D data available are built upon the practice that was already in place with respect to the release of Part A and B data. Furthermore, absent specific reasons for treating the data differently, we believe it is appropriate to have consistent policies for the release of data across Medicare Parts A, B, and D. Therefore, although we are not changing our policy against releasing

Part D data for commercial purposes at this time, we note that in the event the policy regarding the release of Parts A and B data for commercial purposes were to change, we would also revise our Part D data sharing policies to be consistent with that change.

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

Under section 1857(d)(2) and 1860D-12(b)(3)(c) of the Act, existing regulations at §§ 422.504(i) and 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 to require their FDRs to agree to a 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 proposed 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.

We further proposed 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, this 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.

Finally, we also proposed 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) through (viii) would become paragraphs (iv) through (vii).

We received the following comments and our responses follow:

Comment: Several MA organizations, Part D sponsors, and industry associations (about a dozen organizations all together) raised their opposition to this proposal. The main argument made by these parties is that CMS lacks the legal authority to directly access information from FDRs since our contractual relationship in these situations is with the MA organizations and PDP sponsors, not the FDRs themselves. One physician's group raised the concern that this provision would increase the likelihood of audits.

Response: We acknowledge that we do not have the authority to directly regulate FDRs. However, we believe our proposal allows us to achieve our goal of securing the right of access to FDR records because it relies on our ability to require the sponsors to incorporate such a right of access as part of the contractual relationship between the sponsors and their FDRs. That is, the proposal requires MA organizations and PDP sponsors to require their FDRs to agree to respond to direct requests for information made by CMS. As a practical matter, the mechanism for sponsors to require their FDRs to agree to such a provision is through the contractual relationship between the parties. We do not believe that this proposal in any way changes the likelihood of an audit, but merely affects the flow of information which we would be otherwise requesting.

Comment: The MA organizations and PDP sponsors that commented also maintained that since they are ultimately accountable to CMS for the work performed under their Medicare contracts, they have the right to participate in and manage the information provided to their contracting partner (CMS) on their behalf by their FDRs. The MA organizations and PDP sponsors further asserted that allowing the MEDIC or other government-related entities to circumvent the plan sponsors would lead to the collection of potentially erroneous information since the plan

sponsor would not have the opportunity to properly vet the information flowing from the FDR to CMS. As a result, CMS' and the MEDIC's information collection from FDRs may become less efficient than it is under the current regulatory regime. Several commenters argued that the proposal would in fact increase burden, in contrast to CMS' suggestion in the proposed rule that the proposal would reduce burden.

Response: We maintain that having direct access to information from FDRs is an essential tool in combating fraud, waste, and abuse which we should be authorized to use. That said, we appreciate concerns raised about MA organizations and PDP sponsors' interests in managing information flowing to CMS, and the concern that such information could at times be flawed or erroneous without the quality review performed by the MA organization or PDP sponsor. Consequently, we wish to clarify that CMS and the MEDICs will default to the current practice of requesting information held by FDRs via an initial request to the MA organization or PDP sponsor. However, we will use the "direct access" route in circumstances where either (a) the results of data analytics, complaints, and/or investigations indicate a suspicion of fraud, waste, or abuse in the Medicare Part C or D programs or (b) in the case of an urgent law enforcement matter. We will publish sub-regulatory guidance on CMS' standards for determining when direct requests of FDRs would be appropriate. We believe that this approach promotes CMS' anti-fraud efforts by increasing fraud investigators' access to critical Part C and D program information and will likely increase the speed with which investigators may get access to critical FDR information, but at the same time allows for continued MA organization and PDP sponsor control and review of information in appropriate circumstances. We also wish to provide assurance that CMS' contractor, the MEDIC, would not be permitted to independently determine under what circumstances it would be appropriate to bypass the MA organization or PDP sponsor in favor of requesting information directly from the FDR; CMS would be directly involved in all such determinations. This approach also minimizes any loss of quality or potential for errors in the requested information as well as the placement of any additional burden on sponsors or FDRs.

Comment: Several commenters requested that if CMS finalizes the provision, that we revise the regulatory

language to state that CMS would notify the MA organization or PDP sponsor upon a direct request to one of its FDRs.

Response: While we had previously stated in this final rule discussion that MA organizations and PDP sponsors would be notified when there is a direct request for information made of an FDR, we agree that it is reasonable for us to specify this commitment in regulation. As such, we have added at §§ 422.504(i)(2)(iii) and 423.505(i)(2)(iii) language stating that except in exceptional circumstances, CMS will provide notification to the MA organization or PDP sponsor that a direct request for information has been made to one of its FDRs. The exceptional circumstance exception is included to allow for the possibility that the MA organization or PDP sponsor could be one of the parties to the fraud investigation, in which case it may not be appropriate to provide such notification.

Therefore, we are finalizing this provision with the modification that CMS will provide notification to the MA organization or PDP sponsor that a direct request for information has been made to one of its FDRs, except in exceptional circumstances.

24. Eligibility of Enrollment for Incarcerated Individuals (§§ 417.1, 417.460, 422.74, 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 transfers 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, subject to the narrow exception provided in § 411.4(b). The denial of claims continues until the individual is no longer 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" when those regulatory definitions were adopted (54 FR 41734 and 72 FR 47410). Specifically, "service area," under §§ 422.2 for MA plans and 423.4 for PDPs, is defined so 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 therefore, no Medicare payment. Nonetheless, to ensure that no cost payments are made, we proposed 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 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 an enrollee's status, the plan would then apply the more-general 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. Therefore individuals are currently not disenrolled from cost plans solely because they are determined to be incarcerated.

Given that the data CMS receives from SSA today regarding the incarceration status of Medicare beneficiaries are reliable enough for the purpose of involuntary disenrollment from MA, Part D, and cost plans, we proposed in the preamble of the January 2014 notice of proposed rulemaking 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. Our proposal indicated that CMS, as a part of this change, would review the incarceration data provided by SSA and, where possible, involuntarily disenroll individuals who are incarcerated based on the data provided by SSA and notify the plan in which the individual is enrolled of this involuntary disenrollment. For all such disenrollments under our proposal, the effective date of disenrollment would be the first of the month after the incarceration start date, as reported by SSA. Such disenrolled individuals would maintain Medicare Part A and Part B coverage through FFS, provided they continue to pay premiums, as applicable, and payment of FFS claims would be based upon existing regulations outlined at 42 CFR 411.4(b). In connection with this change, we also proposed to deny enrollment requests for individuals if data received by CMS 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 and 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 indicated our intent to provide operational instructions in subregulatory guidance.

We received the following comments on our proposal:

Comment: We received general support for our proposals. Specifically, commenters appreciated the clarification that individuals released from incarceration are eligible for a

special election period (SEP) to enroll in an MA or Part D plan.

Response: We appreciate the support expressed by the commenters. We note that the SEP related to release from incarceration (that is, change in residence) is not new or tied to this proposal. Details about this SEP can be found in section 30.4.1 of Chapter 2 of the Medicare Managed Care Manual and section 30.3.1 of Chapter 3 of the Medicare Prescription Drug Benefit Manual.

Comment: A few commenters had suggestions for how we should implement this proposal. Specifically, they suggested that we issue updated guidance and develop new model notices. They also suggested that the best vehicle for providing updates to incarcerated status on members would be through the MARx system or daily transaction reply reports (DTRRs).

Response: We agree that manual and operational guidance will be necessary in order for MA, Part D and cost plans to implement this provision appropriately. We will evaluate whether new or revised model notices are needed and we will share these with plans as soon as possible. We also agree that transmission of data through MARx and DTRRs would make the most sense in terms of sharing incarcerated status with plans.

Comment: A commenter requested that CMS notify MA organizations and Part D sponsors of involuntary disenrollments on the day of incarceration. This commenter also suggested that we consider permitting MA and Part D plans to disenroll members as of the incarceration start date (as opposed to the first day of the month following the incarceration start date) to be in line with rules governing Qualified Health Plans (QHPs).

Response: Notification to plans and sponsors on the day that incarceration begins is not possible, since CMS receives the data from SSA once a month, and only after the correctional facility provides it to SSA. We would also note that plan enrollment and the corresponding payment to plans by CMS occurs in full calendar month increments. Even if we were able to provide plans with real time incarceration data, an involuntary disenrollment date other than the last day of the month is not possible.

We understand that QHPs may have different disenrollment effective dates because they can disenroll on days other than the first of the month. However, as previously stated, MA, Part D and cost plan effective dates begin and end on a monthly basis (that is, the first day of the month). Therefore, we cannot use

the date of incarceration as the disenrollment effective date.

Comment: A commenter requested that we clarify if there will be an option for plans to disenroll a member if they receive information from the State Medicaid agency that an individual is incarcerated.

Response: If a plan receives information from an entity other than CMS or receives from CMS, via existing MARx processes, an indication of possible out of area status due to incarceration, there is already a process outlined in sub-regulatory guidance for plans to determine whether an individual is residing outside of the service area, which is what incarceration is considered. For cases in which CMS does not receive data confirming the incarceration of the individual, the MA organization or Part D sponsor must establish that the individual is no longer residing in the plan's service area due to incarceration 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 addition, as outlined in Section 50.2.1 in Chapter 17, Subchapter D of the Medicare Managed Care Manual, cost plans must disenroll individuals who permanently move out of the service area based upon written statement from the beneficiary or other reasonable evidence that establishes the individual no longer resides in the plan's service area. With the change in definition of service area for cost plans as reflected in the proposed change at § 417.1, cost plans must establish that the individual is no longer residing in the plan's service area if they receive information regarding incarceration from CMS or another entity.

Comment: Two commenters suggested creating a Part B SEP to ease the transition for beneficiaries after they are released from incarceration to ensure access to Medicare Part B benefits as they re-enter the community. Oftentimes, the commenters cited, these beneficiaries lose their Medicare Part B coverage because they are unable to pay their premiums during their incarceration and are not eligible for a Part B SEP upon their release. As a result, if these individuals sign up for Part B at a later date, there is the likelihood that they will have to pay a late enrollment penalty.

Response: This comment is outside the scope of this rulemaking. However, we would like to note that SEPs for Part B and premium Part A are outlined in statute and CMS does not have the authority to establish additional SEPs.

After consideration of the public comments received, we are taking the following action on our proposals:

- The definition of service area for cost plans at § 417.1 is finalized without modification.
- To articulate that the geographic area is the HMO or CMP's service area as defined in § 417.1, we are finalizing the language at § 417.460(b)(2)(i) with the minor modification of adding the word "service."
- To articulate that the basis of the disenrollment for incarceration is due to the individual not residing in the plan's service area, the regulation text at §§ 417.460(f)(1)(i), 422.74(d)(4)(i)(A), and 422.74(d)(4)(v) is finalized with modification.
- Due to an inadvertent omission, the proposed regulatory text changes to § 423.44(d)(5)(iii) and (iv) were not published in the proposed rule. Because our preamble was clear that our proposed changes were applicable to Part D, and the comments received demonstrated that readers understood our intent, we are adding and finalizing regulatory text changes at § 423.44(d)(5)(iii) and (iv).
- A proposed change to the definition of "service area" was inadvertently published in the January 2014 proposed rule at § 422.2. That revised definition is not being finalized.

Finally, we recognize that in our discussion of the proposed rule we described our intent that ineligibility for—as well as involuntary disenrollment from—MA, Part D, and cost plans would be based on a period of incarceration of 30 days or more. As we will note in implementing guidance for these final rules, we will determine eligibility based on confirmed incarceration data from SSA, not a 30-day timeframe.

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

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. 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.¹

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 our current guidance. We proposed to amend our regulations to establish parameters for rewards and incentives programs offered to enrollees of MA plans. Because 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, we also proposed to include specific requirements regarding rewards and incentives so as to ensure that such programs do not discriminate against beneficiaries on the basis of health status or disability, or other impermissible bases for discrimination.

Section 1856(b)(1) of the Act provides authority for the establishment of MA standards by regulation that are consistent with and carry out Part C, and section 1857(e)(1) of the Act provides authority to impose contract requirements that CMS finds "necessary and appropriate" and that are not inconsistent with Part C. 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. Furthermore, 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 proposed 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 proposed adding a new provision at § 422.134 that would authorize 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 proposed requiring 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. This proposed requirement would not preclude MA organizations from offering rewards and incentives programs that target a specific disease, chronic condition or preventive service. Rather, the goal of having a non-discrimination requirement is to prevent particularly vulnerable populations from being disproportionately underserved. MA organizations may not use this provision to "cherry pick" healthier enrollees. Therefore, any rewards and incentives program implemented by an MA organization under this proposal must accommodate otherwise qualified beneficiaries who receive services in an institutional setting 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. An MA organization would define what qualifies as an "entire service or activity" within its program design. This proposed requirement is tied to interpreting the value of the service provided as it relates to the value of the reward. 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. As part of our proposal, we indicated the intent to provide guidance on this qualitative standard on a regular basis.

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

We received the following comments and our responses are as follows:

Comment: We received several comments in support of this proposal, approving of our effort to allow MA organizations to make rewards and incentives programs more widely available to enrollees. Several

¹ Ali Shirvani-Mahdavi, Ph.D. & Melissa Haeffner, Ph.D., *Rewarding Wellness: The Science Behind Effective Wellness Incentive Programs* (2014).

commenters noted that facilitating beneficiary engagement in health behaviors and practices will help to achieve better health outcomes.

Response: We thank the commenters for their support.

Comment: Several organizations expressed concern over the requirement that rewards and incentives programs be non-discriminatory and available to all enrollees. They requested clarification that such programs may target specific chronic conditions, diseases and other health care needs.

Response: In response to comments, we have strengthened the regulation to ensure that rewards and incentives programs will not be discriminatory. As revised, the non-discrimination requirement of the provision is based on the substantive requirement of section 1852(b)(1)(A) of the Act (which states that MA organizations may not discriminate against beneficiaries on the basis of health status) and expands upon it by identifying other impermissible bases for discrimination, including race, national origin, and gender. The regulation is meant to prevent rewards and incentives programs from being used to unfairly benefit healthier enrollees while excluding or disadvantaging enrollees who are less healthy or have a disability. MA organizations may establish rewards and incentives for specific chronic conditions, diseases, or other health care needs so long as the rewards and incentives program is not discriminatory.

Comment: We received several comments stating that the requirement that a beneficiary must complete a whole service or activity is too narrow to permit effective program designs and requesting that CMS provide greater flexibility in this area.

Response: We proposed to require that rewards and incentives be offered in connection with an entire service or activity so that CMS and MA organizations can interpret the value of a reward or incentive in relation to the service or activity for which it is being given. MA organizations may reasonably define the scope of the “entire service or activity” in their program design. For example, a MA organization may decide to offer rewards and incentives for participation in a smoking cessation program. The MA organization may decide to give smaller rewards for each class attended or give one larger reward for completing a set number of classes, as long as the value of the reward reflects the value of the service and adheres to the monetary cap designated by CMS. We are revising § 422.134(c)(1)(i) to eliminate the phrase

“completion of” to make it possible for portions of a service or activity to be defined as the “entire service or activity.” We emphasize that the value limitation applies to each “entire service or activity” such that the value of the reward or incentive offered may not be greater than the value of the service or activity itself.

Comment: Several commenters cautioned against rewards and incentive programs because they have the potential to disproportionately penalize low-income, minority beneficiaries, and beneficiaries with disabilities.

Response: We understand the commenters’ concerns and consequently emphasize here (and elsewhere in this preamble) that all rewards and incentives programs must be non-discriminatory and may not disproportionately penalize any groups, specifically the vulnerable. Additionally, as discussed in a previous response, we have revised the regulation text to strengthen the non-discrimination language.

Comment: Several commenters suggested that CMS solicit data from rewards and incentives programs on a regular basis rather than “on request.” Commenters are particularly interested in outcomes data. In addition, one commenter asked about CMS’ requirements for the format of that information.

Response: We have noted these comments and will consider adopting a rewards and incentives program reporting cycle in the future.

Comment: Several commenters do not support rewards and incentive program designs that include increased beneficiary cost-sharing as a penalty for not participating in such a program.

Response: The provision as finalized only allows programs that will provide rewards and incentives to beneficiaries. It does not allow MA organizations to penalize beneficiaries for non-participation by any means, including through increased cost-sharing. We also note that § 422.134(c)(2)(i) prohibits rewards and incentives from being offered in the form of cash or monetary rebates; we would consider a discount on cost-sharing to be such a prohibited reward and incentive. Furthermore, CMS regulations requiring uniformity of benefits (42 CFR 422.100(d)(2)) preclude MA plans from charging enrollees of a plan different premiums or cost-sharing for the same service.

Comment: A few commenters asked how this new provision will impact the rewards and incentives guidance that is currently located in the Medicare Marketing Guidelines.

Response: This provision will supersede any previously issued rewards and incentives program guidance. Upon finalization of this rule, we will update our subregulatory guidance accordingly.

Comment: A few commenters asked CMS to provide more specific information regarding rewards and incentives programs. They asked for guidance on calculating the value of the activities for which the plan would like to offer rewards and incentives, whether the rewards and incentives may be used to decrease cost-sharing or premiums and whether there is a limit on how often an MA organization may offer a reward or incentive.

Response: The provision provides an MA organization with great flexibility in designing its own rewards and incentives program. At this time, we will rely on the MA Organizations to reasonably value the activities/services for which they offer rewards and incentives. In this final rule, we neither identify limits for how often rewards and incentives may be offered nor do we set a maximum monetary value for the rewards and incentives. However, if we determine such guidance is needed to apply the standard in § 422.134(c)(1)(iii) that the reward or incentive be expected to impact enrollee behavior without exceeding the value of the health-related service or activity itself, we will provide it through subregulatory guidance.

Rewards and incentives may never be used to decrease cost-sharing or plan premiums. In addition to the prohibition at § 422.134(c)(2)(i), CMS regulations requiring uniformity of benefits (42 CFR 422.100(d)(2)) preclude MA plans from charging enrollees of a plan different premiums or cost-sharing for the same service. Thus, a MA plan may not offer lower cost-sharing or premiums for plan benefits, as a reward or incentive.

Comment: Two commenters asked that we expand this provision to include Part D plans.

Response: We have noted the comment. At this time, the rewards and incentives program provision only applies to Part C.

Comment: One commenter requested that SNPs be allowed greater flexibility in rewards and incentives program design.

Response: The current provision and the parameters set forth are applied to all types of MA plans, including SNPs. At this time, we do not intend to provide SNP-specific rewards and incentives program rules or guidance.

Comment: Several commenters asked how rewards and incentives will be accounted for in plan bids and one

commenter suggested that the costs should be identified as an administrative cost for care management services in the bid.

Response: A rewards and incentives program would be included in the bid as a non-benefit expense and would not be entered in the PBP. Per CMS OACT Bidding Guidance, (available at: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvgtgSpecRateStats/Bid-Forms-and-Instructions.html>), “non-benefit expenses are all of the bid-level administrative and other non-medical costs incurred in the operation of the MA plan.” We also wish to clarify that the costs of a rewards and incentives program would not necessarily be related only to care management services and that plans must comply with applicable bidding requirements.

Comment: Several commenters requested that CMS clarify whether rewards and incentives programs would be offered as a benefit or otherwise.

Response: Our policy has been, and continues to be, that rewards and incentives programs are not benefits.

Comment: One commenter requested that CMS, in considering additional parameters for reward and incentive programs, consider shared decision-making and tiered networks. The same commenter also stated that our proposal removes a great deal of flexibility for plans to develop these programs and constrains employer group plans from providing these programs to the entire employer group.

Response: We are not clear what is meant by the request that in our consideration of additional parameters we consider shared decision-making and tiered networks. We note that shared decision-making and tiering of medical benefits are strategies that MA organizations may use to influence enrolled beneficiaries’ health care decisions. Rewards and incentives are another tool CMS is making available to MA organizations to encourage enrollees to engage in activities/services that are intended to improve health and/or decrease enrollee risk for illness. MA organizations have the flexibility to use these tools together or as separate programs designed to improve enrollees’ health.

We are not aware of what flexibilities plans may be using currently in providing rewards and incentive programs to enrollees that the commenter believes CMS proposed to remove. We specifically solicited information on this topic from MA organizations in both the proposed rule and in the CY 2014 Call Letter and have received no information that would lead

us to believe that our proposed rewards and incentives program would limit, rather than expand, current plan flexibilities. The current guidance on rewards and incentive programs that may be offered to plan enrollees, included in the Medicare Marketing Guidelines, allows a very limited use of rewards and incentives to promote enrollee use of Medicare-covered preventive services. Therefore, we do not see how our proposed rewards and incentives program framework could remove plans’ flexibilities rather than expand them.

After consideration of the public comments received, we are finalizing the proposed Rewards and Incentives Program Regulations for Part C Enrollees rule with modifications to subparagraph (b)(1) to include “national origin, including limited English proficiency,” and “disability.” In subparagraph (b)(1) we are also changing the text from “institutionalization” to “whether a person resides or receives services in an institutional setting” and from “other impairments” to “other prohibited basis.” These changes clarify the scope of the categories of beneficiaries included in the context of prohibited discrimination and address comments expressing concern about the possible disproportionate impact of rewards and incentives programs.

Additionally, we are modifying paragraph (c)(1)(i) to eliminate the phrase “completion of” from the regulation text to make it possible for smaller increments of service or activity to be defined as the “entire service or activity.” However, we emphasize that the value of any reward must reflect the value of the service and adhere to any monetary cap that has been determined by CMS under § 422.134(c)(1)(iii). Finally, we note that we have made a technical change to delete the phrase “all of the following” from the introductory language at paragraph (c).

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 final rule implements Section 6402 of the Affordable Care Act, which established new section 1128J(d) of the Social Security Act (“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) 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 proposed two new sections, §§ 422.326 and 423.360, respectively, both titled, “Reporting and Returning of Overpayments.” These sections proposed rules for MA organizations and Part D sponsors to report and return an identified overpayment to the Medicare program. We use 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 also proposed 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 proposed 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.” Thus, we proposed to add a requirement that applies after CMS has completed prospective monthly payments for a year, and organizations are no longer “requesting payment” because applicable reconciliation has occurred. Applicable reconciliation, we stated, 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 proposed 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 reminded 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.

In response to the January 10, 2014 proposed rule, we received approximately 30 pieces of correspondence from organizations and individuals. In this section of the final rule, we describe our proposals, respond to the public comments, and state our final policies.

We did not receive any comments on our proposed amendments to §§ 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. We did not receive any comments on our conforming amendments to §§ 422.1, 423.300, and 423.1. Therefore, we are finalizing these amendments as proposed.

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

We proposed definitions of 3 terms. First, we proposed 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 proposed definitions of 2 key terms at §§ 422.326(a) and 423.360(a): “Funds” and “applicable reconciliation.”

We proposed 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. We also noted that MA organizations and Part D sponsors have responsibility for the accuracy, completeness, and truthfulness of data they submit 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 MAOs and Part D sponsors cannot be held accountable for the accuracy of data controlled and submitted to CMS by other entities.

For example, the SSA is the authoritative source for date of death. An MA organization or Part D sponsor generally does 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.

We stated that 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.

We stated that the term “applicable reconciliation” refers to an event or events after which an overpayment can exist under section 1128J(d) of the Act, and we proposed definitions of the term applicable reconciliation that are specific to Part C and Part D.

For Part C, we proposed that applicable reconciliation occurs on the date that CMS announces as the final deadline for risk adjustment data submission. 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). We also stated that the final risk adjustment data submission deadline would function as the Part C applicable reconciliation date.

For Part D sponsors, we proposed 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 selected these events to define the Part D applicable reconciliation because these data are used for the purposes of determining final Part D payment reconciliation. We noted that MA organizations would still have to submit all final risk adjustment

diagnoses for Part D by the final risk adjustment data submission deadline.

In summary, we proposed an approach to defining applicable reconciliation that establishes dates that differ for Part C and Part D. We asked for comment on this approach.

We noted 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 final rule as “applicable reconciliation”, we stated that 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, and we do not consider these errors to be overpayments for the purpose of § 423.360.

Finally, we stated 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 proposed amendments that clarify and strengthen these requirements.

We did not receive any comments on the proposed definitions of the terms “funds” or “overpayment.” (See the next section for comments and responses on the provision regarding “identified overpayment.”) We received the following comment on the term “applicable reconciliation”, and our response follows.

Comment: Some commenters supported CMS’ proposal to have separate applicable reconciliation dates for the Part C and Part D programs,

noting that this approach is simpler and more practical than the alternative CMS described (where there would be 2 applicable reconciliation dates for the Part D program—one for risk adjustment and another for PDE and DIR data).

Response: We appreciate the support. We will finalize our proposal that the Part C applicable reconciliation date will be the same as the final risk adjustment data submission deadline, and the Part D applicable reconciliation date will be the later of: The annual deadline for submitting prescription drug event (PDE) data for the annual Part D payment reconciliation referred to in § 423.343(c) and (d) or the annual deadline for submitting DIR data.

We would like to note that the final risk adjustment data submission deadline will still apply to diagnosis data for both Part C and Part D risk scores for beneficiaries in MA–PD plans.

After consideration of the public comments received, we are finalizing the provisions at §§ 422.326(a) and 423.360(a) as proposed.

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

We proposed 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 proposed 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. We noted that the terms “reckless disregard” and “deliberate ignorance” are part of the definitions of “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)). We stated that 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 provided 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 proposed the

requirements for reporting and returning an identified overpayment. An MA organization or Part D sponsor must report and return any identified 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 proposed 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 proposed to 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).

We also emphasized that an 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.

Finally, we proposed that 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 an overpayment is identified after the final Part D reopening for a contract year has occurred but 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.

We received the following comments on general rules for overpayments and our responses follow.

Comment: Several commenters requested that CMS clarify when the 60-day period begins. Specifically, does the period begin once the MA organization or Part D sponsor has identified that there is an overpayment or once the organization has determined the exact amount of the overpayment? A commenter expressed concern that the proposed rule does not appear to acknowledge that the amount of an overpayment must be quantified before it is “identified.” Another commenter requested that CMS address the situation where an MA organization or Part D sponsor becomes aware of an issue or error that may have resulted in one or more overpayments, but could not determine, with reasonable certainty, the amount of the overpayment(s) within a 60-day period.

Response: It is important to understand the distinctions among identifying, reporting, and returning an overpayment in this rulemaking for the purposes of the MA and Part D programs. Once an organization has identified that it has received an overpayment, the 60-day period for reporting and returning the overpayment begins. Because of the nature of the Part C and Part D programs, we did not propose that “identified” includes completion of the act of quantification of an overpayment amount. Rather, we proposed that identification of an overpayment means knowing that the MA organization or Part D sponsor has submitted erroneous data to CMS that caused CMS to overpay the organization.

An organization can identify or assess that there is a problem with data submitted to CMS, and determine that it is incorrect data, prior to actually calculating what the payment impact is of that erroneous data. For the MA and Part D programs, the relevant factor is identifying that the data is incorrect and will result in an overpayment. For example, a risk adjustment diagnosis that has been submitted for payment but is found to be invalid because it does not have supporting medical record documentation would result in an overpayment. Under this provision, the day after the date on which the organization has confirmed an identified overpayment—because the organization knows that the diagnosis is not supported by documentation—is the first day of the 60-day period for reporting and returning the overpayment. As another example, an

MA organization may find that data used to calculate Healthcare Effectiveness Data and Information Set (HEDIS) measures that the organization submitted to CMS are found to be invalid; when the organization has confirmed that it has identified invalid data leading to an overpayment, this is the first day of the 60-day period for reporting and returning the overpayment.

Then, during the 2-month period for reporting and returning the overpayment, the organization must determine what data should be submitted to CMS to correct the identified overpayment, and then must engage in the reporting and returning process that we will describe in forthcoming guidance. This reporting and returning process will involve: (1) Notifying CMS that an overpayment exists, including notification of the reason and estimated amount for that overpayment; and (2) submitting the corrected data to CMS.

In other words, we believe that the MA organization and Part D sponsor will discover through appropriate payment evaluation procedures when a 60-day period would begin under the requirements of this provision, because “day one” of the 60-day period is the day after the date on which organization has determined that it has identified the existence of an overpayment. Once the organization “starts the clock,” it has 60 days to submit to CMS the corrected data that is the basis of the overpayment. It is the act of submitting the corrected data to CMS, along with a reason and an amount of the overpayment (which may be an estimate), that constitutes fulfillment of the requirement to report and return the overpayment.

As we stated in the January 10, 2014 proposed rule preamble (79 FR 1997), “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 CMS payment processes. That is, payments will continue to be recovered through the established payment adjustment processes and schedules. As a result the payment recovery may not occur within the 60-day window triggered by identifying an overpayment. Rerunning payment reconciliations and conducting payment recovery within CMS payment systems each time an entity identifies an

overpayment that triggers its 60-day clock is simply not feasible for CMS.

We will release operational guidance on the process an organization will use for informing CMS that it has identified a Part C and/or Part D overpayment. This guidance will also address how an organization will be required to provide a reason for and the amount of the overpayment (which may be estimated). We seek to reduce burden and implement an efficient process for administering the reporting and return of overpayments, so we are considering making use of existing procedures for organizations to communicate payment data issues to CMS. For example, MA organizations and Part D sponsors have used the Remedy system for a number of years to inform CMS of payment issues and provide relevant information on that issue.

In the forthcoming operational guidance, we will address the question of how to report the overpayment amount, including estimation of the overpayment amount and updates under certain scenarios.

Comment: A commenter contended that, applying the principles adopted by CMS in the RADV audit context, an overpayment cannot exist for a particular MA contract unless CMS’ payments as a whole to the MA organization pursuant to the contract are inaccurate in light of an appropriate FFS Adjuster applied to the entire contract. Potential overpayments can be determined, therefore, based only on processes such as CMS’ RADV audits, which are designed to measure whether contract-level payments to an MA organization are accurate when compared to an appropriate FFS Adjuster. The commenter further contended that to the extent an MA organization develops processes intended to measure payment accuracy at the contract-level, the MA organization would be required to report and repay inaccuracies calculated after applying CMS’s FFS Adjuster, and consistent with prior CMS guidance, this is the sole instance in which an “overpayment” can be determined for purposes of proposed § 422.326.

Response: We disagree with the commenter. Our RADV methodology does not change our existing contractual requirement that MA organizations must certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the risk adjustment data they submit to CMS. Further, this decision does not change the long-standing risk adjustment data requirement that a diagnosis submitted to CMS by an MA organization for payment purposes must

be supported by medical record documentation.

However, we are clarifying the link between the § 422.326 overpayment provisions and RADV audits under § 422.311 by adding a condition to the requirement at § 422.326(d), as follows: 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. We are adding to paragraph (d) the provision “unless otherwise directed by CMS for the purpose of § 422.311.” Thus, when an MA organization has a contract selected for a RADV audit, during the audit the MA organization will not be allowed to report and return an overpayment under § 422.326 that is due to errors in the data used to risk-adjust payments for the audited contract for the payment year that is the subject of the RADV audit. We will notify the MA organization about the timeline for reporting and returning any overpayments for a contract under a RADV audit. This new provision protects the integrity of the RADV audit process, including the sampling frame of beneficiaries in a selected MA plan, whose diagnoses will be audited.

Comment: A commenter stated that there will be many circumstances and situations where entities receiving an overpayment will not have the ability to repay funds within the 60-day period without undue hardship.

Response: MA organizations and Part D sponsors have an obligation to pay an overpayment owed under Section 1128(d). As noted previously, our recovery of overpayments will occur through routine payment processing cycles and schedules. In most circumstances, MA organizations and Part D sponsors will be submitting corrected data, which will be re-run by CMS and then CMS will recover the overpayment.

Comment: A commenter noted that 60 days is not a sufficient timeframe, as identifying and quantifying overpayments can be a very involved process. Another commenter stated that most overpayments are identified through analyses and studies, such as internal RADV studies; the commenter requested that the 60-day time period begin at the conclusion of the internal study, so that overpayments can be referred to CMS after all issues have been identified and confirmed.

Response: We provide that the 60-day period is the time period for reporting and returning an identified overpayment, after the organization has conducted the activities needed to identify that it has received an

overpayment. As explained previously, for the purposes of the MA and Part D programs, the MA organization or Part D sponsor must report and return the identified overpayment, which is due to incorrect data it has submitted to CMS, no later than 60 days after the date on which the organization identified it received the overpayment. Subsequently and within the 60-day period the MA organization or Part D sponsor is required to report and return the overpayment. Reporting the overpayment involves notifying CMS of the reason for and the amount of the overpayment. Returning the overpayment is deemed to have occurred through the act of correcting the erroneous data submitted to CMS, for example, by deleting incorrect PDEs or risk adjustment data. Note that if an organization identifies one set of erroneous data that has caused an overpayment, the organization must begin the 60-day clock on that date, and if subsequent overpayments are identified, the organization must begin subsequent 60-day reporting and returning periods.

Comment: A commenter questioned whether CMS will be identifying criteria for organizations to use to determine an overpayment.

Response: We have specified in this final rule the specific types of “funds” that are subject to the provisions under this section through the definition of “funds”. Funds are payments an organization has received that are based on data that the organization submitted to CMS for payment purposes. We will not provide additional criteria or a checklist.

Comment: A commenter stated that logically, an MA organization or Part D sponsor cannot return an overpayment until it has calculated the exact amount that it must return. It might take a considerable amount of time for the MA organization or Part D sponsor to audit its records to determine the amount, whether there is an issue in previous years, and whether extrapolation, or case by case analysis, is appropriate. The commenter was concerned that while a plan sponsor might be able to report to CMS that it has identified an issue within 60 days, a plan sponsor may not have enough information after identification to be able to report the exact amount. Therefore, the commenter requested that CMS clarify that the 60 days begins once the organization has identified the exact amount of the overpayment. The commenter suggested, as an alternative, that if the MA organization or Part D sponsor has notified CMS that it believes there is an overpayment, but it will take more than

60 days to determine the exact amount, CMS consider allowing a “tolling” of the 60 days so that the organization may determine the amount it must return to CMS. Under this “tolling” process, the organization would be required to notify CMS within 60 days of identifying that an overpayment likely exists, but would be provided additional time by CMS to determine the exact amount.

Response: We have not used the phrase “exact amount” in this rule-making. For the MA and Part D programs, we define overpayment in the regulation as “funds” the organization has received to which it is not entitled, and then defines “funds” as any payment based on data submitted by an MA or Part D organization. Because of the nature of the Part C and Part D programs, the key focus in implementing these statutory provisions for the MA and Part D programs is thus correcting the incorrect data that the organization submitted to CMS that resulted in an overpayment. We will then run reconciliation on its routine operational schedule to recover overpayment amounts based on the corrected data. The purpose of the 60 days is to provide the MA or Part D organization with sufficient time to correct the incorrect data submitted to CMS using established data correction processes. MA organizations and Part D sponsors are deemed to have returned the overpayment when they have taken the actions to submit the corrected data that is the source of the identified overpayment. Within the 60 days the MA organization and Part D sponsor must also report the overpayment amount (or estimated amount). If an estimated overpayment amount is reported, it may be higher or lower than the actual overpayment amount recovered because additional payment data submitted into the CMS payment system from other sources may be incorporated into the payment calculations.

Comment: A commenter stated that it is unclear what may occur post-reconciliation if both parties have been overpaid. For example, if CMS owes the Part D sponsor \$10 million due to activity post-reconciliation and a \$2 million overpayment is discovered, the commenter questioned whether we will still require that the \$2 million be refunded within 60 days or whether the sponsor will be allowed to offset amounts owed by CMS. The commenter recommended that if an overpayment would be reduced or fully covered by a reopening, that CMS allow sponsors to request a reopening and offset the reopening amount due from the

overpayment pending completion of the reopening.

Response: For both the Part C and Part D programs, the provisions regarding reporting and returning identified overpayments become effective the day after the date of applicable reconciliation. As we have stated, MA organizations and Part D sponsors are deemed to have returned the overpayment when they have submitted corrected data that is the source of the overpayment. We will recover the overpayment amount through routine processing. For Part D, that means that if an overpayment is discovered after the initial reconciliation but prior to the reopening described at § 423.346, a Part D sponsor may request a reopening and submit the corrected data to fulfill its obligation to return the overpayment. The overpayment will be reconciled through the routine reopening process.

Comment: A commenter stated that the onus on plans for the calculation of an overpayment amount creates a risk that CMS may be overpaid/underpaid in the monies returned.

Response: As explained in proposed rule (79 FR 1997), we will recover overpayments through the correction of erroneous data and established payment adjustment processes. Therefore, we believe that the risk the commenter mentions does not exist because CMS' systems will calculate the exact amount to be recovered.

Comment: A few commenters objected to the fact that the proposed rule does not address situations in which a sponsor has overpaid CMS, and requested that this regulation also set forth rules by which CMS handles an organization's overpayments to CMS.

Response: This final rule is intended to implement section 1128J(d) of the Act, which pertains only to overpayments the government made to contracting MA organizations and Part D sponsors.

Comment: A commenter requested that MA organizations and Part D sponsors be able to submit auditable estimates of an overpayment in lieu of determining which data is in error and submitting corrected data, given the fact that the administrative costs of determining a specific set of data deletes is significant relative to the size of the issue. The commenter recommended that CMS permit plans to proactively suggest the use of such tools to resolve potential overpayments.

Response: The use of auditable estimates is intended only for a limited set of circumstances. 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. Therefore, we will not allow, on a routine basis, submission of auditable estimates in lieu of submission of corrected data. By recovering overpayments based on the corrected payment data, we will be more likely to ensure that the most accurate overpayment amounts are returned to the Medicare Trust Fund.

Comment: A commenter expressed concern that this final rule could impose a boundless duty to troll medical records in search of unknown vulnerabilities, and requested that CMS make clear that Part C and Part D plans are not obliged to proactively search for an overpayment without reason to believe that a specific overpayment exists.

Response: The focus of this final rule is on ensuring that MA and Part D organizations return an overpayment when it is identified. For many years organizations have been obliged to submit accurate, complete, and truthful payment-related data, as described at §§ 422.504(l) and 423.505(k). Further, CMS has required for many years that diagnoses that MA organizations submit for payment be supported by medical record documentation. Thus, we have always expected that MA organization or Part D sponsor implement, during the routine course of business, appropriate payment evaluation procedures in order to meet the requirement of certifying the data they submit to CMS for purposes of payment. Therefore, we do not believe that §§ 422.326 and 423.360 represent such a new requirement.

Comment: A commenter requested that CMS confirm that the data submission requirement under this section is based on enrollment data and risk adjustment scores, and thus does not apply to direct overpayments from providers.

Response: Once an overpayment is identified, the MA or Part D organization is responsible for correcting the data that caused the overpayment. This is data that is routinely submitted to CMS for payment purposes, such as, risk adjustment data.

Comment: A commenter requested that CMS clarify if changes in a beneficiary's low income subsidy (LIS) status could result in an overpayment under this provision.

Response: As we stated in the proposed rule, we believe that MA organizations and Part D sponsors cannot be held accountable for the accuracy of the data controlled and

submitted to CMS by other entities. (We emphasize here that the term "other entities" used to discuss these overpayment provisions does not include the following parties referenced in §§ 422.504(i) and 423.505(i): first tier, downstream, and related entities, contractors, or subcontractors to the MA organization or Part D sponsor.) It is the Social Security Administration and the states that notify CMS of individuals whom they have determined to be eligible for the Part D LIS. We in turn provide the subsidy information, including effective date and level of subsidy, to the Part D plan in which the beneficiary enrolls. Although, we will not consider an overpayment to have occurred strictly due to changes in a beneficiary's LIS status, Part D sponsors are required to adjust prescription drug event (PDE) data to accurately reflect the beneficiary's LIS status.

Comment: A commenter supported our proposal for when overpayments have been identified.

Response: We appreciate the commenter's support for our proposal.

Comment: A few commenters requested that CMS provide more clarity or an example of what is meant by "acts in reckless disregard or deliberate ignorance."

Response: We are revising our definition of an identified overpayment to state that an MA organization or Part D sponsor has identified an overpayment when it has determined, or should have determined through the exercise of reasonable diligence, that the MA organization or Part D sponsor has received an overpayment.

As to the circumstances that give rise to a duty to exercise reasonable diligence, we are not able to anticipate all factual scenarios in this rulemaking. MA organizations and Part D sponsors are responsible for ensuring that payment data they submit to CMS are accurate, truthful, and complete (based on best knowledge, information, and belief), and are expected to have effective and appropriate payment evaluation procedures and effective compliance programs as a way to avoid receiving or retaining overpayments. Thus, at a minimum, reasonable diligence would include proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments. However, conducting proactive compliance activities does not mean that the person has satisfied the reasonable diligence standard in all circumstances. In certain circumstances, for example, reasonable diligence might require an investigation conducted in good faith and in a timely manner by

qualified individuals in response to credible information of a potential overpayment.

We note that in discussing the standard term “reasonable diligence” in the preamble, we are interpreting the obligation to “report and return the overpayment” which is contained in section 1128J(d) of the Social Security Act. We are not seeking to interpret the terms “knowing” and “knowingly”, which are defined in the Civil False Claims Act and have been interpreted by a body of False Claims Act case law.

Comment: Some commenters thought that we had an overly broad interpretation of the statute and that there was no statutory basis for CMS to interpret the term “identified” in section 6402 of the Affordable Care Act to include “reckless disregard or deliberate ignorance of the existence of the overpayment.” A commenter stated that the term “knowing” is not actually used in the overpayment standard set forth in section 6402(d) of the Affordable Care Act, so the mere existence of an errant reference to the False Claims Act definition of “knowing” does not give CMS sufficient basis to apply the expansive False Claims Act knowledge standard to the definition of “identified” under section 6402. This commenter noted that in an earlier version of the Affordable Care Act, H.R. 3962, used the False Claims Act knowledge standard in the section on reporting and returning of overpayments. The commenter also stated that the final version of the Affordable Care Act enacted by the Congress used the term “identified,” and not the word “knowledge.” This commenter believed that the Congress’s explicit rejection of the False Claims Act knowledge standard, and use of the term “identified” in the final legislative language weighs against incorporating the False Claims Act knowledge standard into the regulatory provision.

Response: We disagree with the commenters’ arguments. While we acknowledge that the terms “knowing” and “knowingly” are defined but not otherwise used in section 1128J(d), we believe that the Congress intended for section 1128J(d) to apply broadly. If the requirement to report and return overpayments applied only to situations where the MA organization or Part D sponsor has actual knowledge of the existence of an overpayment, then these entities could easily avoid returning improperly received payments and the purpose of the section would be defeated. Thus, we decline to read a narrow actual knowledge limitation into the law as suggested by commenters.

Comment: Several commenters recommended that CMS remove the language relating to “reasonable diligence” from the proposed regulation. These commenters believed that an identified overpayment should be limited to actual knowledge of an overpayment.

Response: For the reasons discussed previously, we decline to read a narrow actual knowledge limitation into the law as suggested by commenters.

Comment: A few commenters were concerned that by adding a reasonable diligence requirement, CMS appears to be suggesting that a much lower level of sponsor behavior—a failure to act reasonably—could trigger potential False Claims Act liability. One commenter stated that the phrase “reasonable diligence” is not a recognized or defined standard and is overly vague as to the obligations of plans to follow through on information received regarding a potential overpayment. The commenters have serious concerns about the implication of such a standard.

Response: We understand the commenters’ concerns. However, we do not believe that it is inappropriate to expect that MA organizations and Part D sponsors act reasonably. We note that it is the statute that establishes liability under the False Claims Act for failure to report and return identified overpayments, pursuant to section 1128J(d)(3).

c. Look-Back Period for Reporting and Returning Overpayments

We proposed 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 proposed 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. We also proposed that overpayments resulting from fraud would not be subject to this limitation of a look-back period.

We received the following comments on the look-back period, and our responses follow.

Comment: We received a few comments recommending that we shorten the 6-year look-back period. A commenter noted that permitting greater finality in overpayment reporting and recovery will decrease administrative costs and free up resources to focus on benefits. This commenter also stated that an organization would have to retain a significant amount of documentation to fully support and justify payments, more than what they would retain under CMS’s 10-year record retention requirement. Several commenters recommended that the look-back period be 3 years to align with the RAC look-back period. A commenter noted that the 3-year period would also be consistent with the federal government’s treatment of government contractors that are subject to the Federal Acquisition Regulation. A couple of commenters recommended that we implement a 4-year look-back period to align with the 4-year period that Medicare Administrative Contractors can reopen Medicare fee-for-service payment determinations.

Response: We disagree with the commenters’ recommendations to shorten the look-back period. We note that section 1128J(d) of the Act has no time limit to the obligation to report and return overpayments received by a provider or supplier. However, as we stated in the preamble to our proposed rule and again in this preamble to our final rule, we proposed 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 is consistent with the CMP provisions, and maintenance of records requirements under the contracts. It is also consistent with the False Claims Act in that 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. We believe that our final rule does not create additional recordkeeping burden or cost. Under § 422.504(d) and § 423.505(d), MA organizations and Part D sponsors are required to maintain for 10 years books, records, documents, and other evidence of accounting procedures and practices related to costs, financial statements, cash flow, etc.

Comment: A commenter requested that CMS clarify the parameters of the 6-year look-back provision.

Response: As we stated in the preamble to the proposed rule and this

final rule and again in §§ 422.326(e) and 423.360(e), MA organizations and Part D sponsors are required to report and return any overpayment that they identify within the 6 most recent completed payment years. That would mean, for example, after the initial reconciliation that takes place for Part D payments (that is, the 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) for contract year 2015 (which will take place at the end of 2016), Part D sponsors are obligated to report and return overpayments under § 423.360 for contract years 2010 through 2015.

Comment: A few commenters recommended that CMS impose the same limitation on the look-back period for all overpayments, even those relating to fraud. A commenter noted that under the statutory scheme set forth in section 6402 of the Affordable Care Act, the existence of an overpayment does not depend on, or otherwise reflect, the existence of fraud. Commenters also requested clarification from CMS whether MA organizations and Part D sponsors that become aware of an overpayment prior to the look-back period have an obligation to investigate and determine whether that overpayment resulted from fraud. These commenters were concerned that MA organizations and Part D sponsors would have to investigate potential overpayments indefinitely, no matter how far in the past they may have occurred, because these organizations would have to determine whether there was any fraud in connection with the potential overpayment in order to determine whether a reporting obligation exists.

Response: Upon further review, we agree with the commenters' suggestion that CMS impose the same limitation on the look-back period for all overpayments. Six years is consistent with the more commonly applicable FCA statute of limitations as well as the statute of limitations under section 1128A of the Act. Therefore, we have elected to establish a 6-year look-back period regardless of the nature of the overpayment, and we have amended the regulation text at §§ 422.326(e) and 423.360(e) accordingly. We note that the government may have other avenues for pursuing the return of overpayments due to false and fraudulent claims outside of these provisions.

Finally, we note that an MA organization's and Part D sponsor's

obligation to investigate and identify false and fraudulent claims is outside the scope of this final rule.

After consideration of the public comments received on the overpayment provisions, we are finalizing as proposed the following provisions: §§ 422.1, 422.300, 422.504(l), 423.1, and 423.505(k). We are finalizing the provisions at § 422.326, with the following modifications. First, we add at the end of paragraph (d) the phrase "unless otherwise directed by CMS for the purpose of § 422.311." Second, we strike the following sentence in the proposed paragraph on the six-year look-back period: "Overpayments resulting from fraud are not subject to this limitation of the lookback period." To increase clarity we also revise paragraph (c) regarding identified overpayments. We also are making a technical correction by redesignating proposed paragraph (d)(3) on enforcement as paragraph (e), and redesignating proposed paragraph (e) on the six-year look-back period as paragraph (f), and revising new paragraph (e) on enforcement to say "Any overpayment retained by an MA organization is an obligation under 31 U.S.C. 3729(b)(3) if not reported and returned in accordance with paragraph (d) above."

Finally, we are finalizing the provisions at § 423.360 with the following modifications. We strike the following sentence in the proposed paragraph on the six-year look-back period: "Overpayments resulting from fraud are not subject to this limitation of the lookback period." To increase clarity we also revise paragraph (c) regarding identified overpayments. We also are making a technical correction by redesignating proposed paragraph (d)(3) on enforcement as paragraph (e), and redesignating proposed paragraph (e) on the six-year look-back period as paragraph (f), and revising new paragraph (e) on enforcement to say "Any overpayment retained by a Part D sponsor is an obligation under 31 U.S.C. 3729(b)(3) if not reported and returned in accordance with paragraph (d)."

2. Risk Adjustment Data Requirements (§ 422.310)

We proposed several amendments to § 422.310 to strengthen existing regulations related to the accuracy of risk adjustment data. We proposed 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). Under our proposal, medical record reviews conducted by an MA organization could not be designed *only* to identify diagnoses that would trigger additional payments by CMS to the MA organization; medical record review methodologies would have to 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.

We also proposed to amend § 422.310(g) regarding deadlines for submission of risk adjustment data; our proposal was to restructure and revise subparagraph (g)(2) and add subparagraph (g)(3). Our current procedures generally permit submission of risk adjustment data after the final risk adjustment submission deadline only to correct overpayments. Thus, we proposed, at § 422.310(g)(2)(ii) to explicitly permit late submissions only to correct overpayments but not to submit diagnoses for additional payment so that the regulation text would be consistent with our procedures.

Finally, we proposed to make two additional changes in paragraph (g). First, we proposed the deletion of the January 31 deadline in paragraph (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. We noted 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, also discussed in this final rule. Second, we proposed adding paragraph (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).

In response to the January 10, 2014 proposed rule, we received approximately 25 pieces of correspondence from organizations and individuals regarding these proposals. We received the following public comments and our responses follow.

Comment: Many commenters expressed concern about the vagueness and overly broad statement of CMS' proposal to amend § 422.310(e) to require that medical record reviews conducted by MA organizations be designed to determine the accuracy of diagnoses they submitted to CMS. Some commenters thought this implied a requirement to verify every diagnosis

submitted by every provider, while others thought this implied a restriction on the ability of plans to identify what medical records to review. Other commenters believed the proposed amendment limited plans' ability to review medical records for operational purposes other than risk-adjusted payment, such as focusing on only a portion of a medical record for a subset of beneficiaries in order to enhance HEDIS scores, conduct contract compliance reviews, and validate claims processing and billing.

Finally, a few commenters argued that CMS should offset the payment impact of diagnoses an MA organization submitted to CMS that were later found through medical record reviews to not be supported by medical record documentation by adjusting the amount of CMS' overpayment to the MA organization for the level of error in equivalent diagnoses in FFS claims data. Specifically, the commenters argued that CMS should give MA organizations a credit for erroneous diagnoses they submitted from their providers' claims up to the rate identified by CMS as the applicable FFS Adjustor in the RADV program. The commenters also argued that there is no reason to require that both MA and FFS diagnosis data be scrutinized for error rates when determining retroactive payment adjustments, while not engaging in a similar adjustment process when paying plans prospectively.

Response: We thank the commenters for their input. We are not finalizing the proposed amendment to § 410.322(e).

However, we emphasize that our decision to not finalize this regulatory proposal does not change CMS' existing contractual requirement that MA organizations must certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the risk adjustment data they submit to CMS. Further, this decision does not change the long-standing risk adjustment data requirement that a diagnosis submitted to CMS by an MA organization for payment purposes must be supported by medical record documentation.

Comment: A few commenters supported CMS' proposal to remove the current date of January 31 as the annual final risk adjustment data submission deadline and replace it with the provision that CMS will announce the deadline annually, with the proviso that CMS' timing of this annual deadline always allows sufficient opportunity for organizations to make final data submissions. Several other commenters stated their concern about this proposed change in deadline, including a concern

that CMS might announce a deadline earlier than January 31 in some years. These commenters requested that CMS clarify that the annual deadline would never be before January 31, and a few commenters suggested that the regulation state that the deadline is January 31 but may be extended. Finally, a few commenters requested that CMS not change the January 31 date to a floating date, in order to allow operational stability.

Response: We are not finalizing this proposal at this time.

Comment: Many commenters disagreed with CMS' proposal under § 410.322(g)(2) that, after the final risk adjustment data submission deadline, CMS would permit submission of data to correct overpayments but not permit late submission of diagnosis data that would result in additional payment, asserting that this asymmetrical approach does not promote CMS' stated goal of improving payment accuracy. The commenters maintained that an MA organization should be allowed to submit additional diagnoses after the final risk adjustment data submission deadline to correct not only an overpayment to the MA organization, but also an underpayment. A commenter recommended that, after the final deadline, MA organizations should be able to submit paired deletions-additions of diagnoses as long as the result is not an increased payment to the organization but a smaller reduction in payment than would otherwise occur if only the deletion were submitted; for example, an MA organization may want to delete the diagnosis code for diabetes with acute complications and replace it with the code for diabetes without complications so that it loses only some of the payment. Finally, a commenter requested that CMS allow exceptions to the general rule that no new diagnoses may be submitted after the final risk adjustment data submission deadline for special circumstances such as system failures, file formatting issues, and other technical problems.

Response: For a given payment year (which is a calendar year), CMS applies diagnoses from the previous year (the data collection year) to calculate beneficiary risk scores used to risk-adjust payments to MA organizations in the payment year. MA organizations must finalize any corrections and new submissions of diagnosis data for a data collection year by January 31 of the year after the payment year. That is, we allow 13 months after the end of the diagnosis year for MA organizations to identify errors in data they have submitted (that is, deleting diagnoses from CMS' systems) and to identify and

submit additional diagnoses that were not submitted during the diagnosis year. We believe that is a very reasonable period of time to finalize risk adjustment data for a diagnosis year.

These risk adjustment processes have been in place for many years, and we believe it is the responsibility of MA organizations to have internal audit processes in place allowing them to finalize their risk adjustment data for a payment year by the conclusion of this 13-month period. Therefore, we are finalizing, as proposed, the provision codified at § 422.310(g)(2)(ii) that, after the final deadline, an MA organization may submit risk adjustment data to correct overpayments but not to add payments.

Comment: A commenter supported CMS' proposal to limit post-deadline modifications to deletions of incorrect diagnoses but requested that CMS offer one additional opportunity to eliminate unsupported diagnosis codes in advance of a RADV audit.

Response: When we are preparing to initiate a RADV audit cycle, all MA organizations are notified that they should eliminate unsupported diagnoses from CMS' systems by a date specified in the notice. Subsequently, we inform the contracts that have been selected for RADV.

In summary, after consideration of the public comments received, we are not finalizing the proposed amendment to § 410.322(e). Also, we are not finalizing at this time our proposal at § 422.310(g)(2)(ii) to remove the current date of January 31 as the annual final risk adjustment data submission deadline and replace it with the provision that CMS will announce the deadline annually. We are finalizing as proposed the restructuring of §§ 422.310(g)(2) and the 422.310(g)(2)(ii) provision to prohibit submission of diagnoses for additional payment after the final risk adjustment data submission deadline. We did not receive any comments on subparagraph (g)(3) and are finalizing it as proposed.

3. RADV Appeals

a. Background

We published final Risk Adjustment Data Validation (RADV) appeals regulations in the April 15 2010 **Federal Register** (75 FR 19677). These rules were proposed and finalized under our authority to establish Medicare Advantage (MA) program standards at section 1856(b)(1) of the Act and are found at § 422.311 et seq. Since finalizing these rules in 2010, we conducted additional RADV audits and determined that some of the appeals

provisions finalized in the 2010 RADV Appeals final rule should be modified to strengthen and streamline the RADV appeals process and to prevent confusion. Therefore, we proposed revisions to the RADV appeals regulations on January 10, 2014. These proposed RADV provisions will apply to any RADV determinations issued on or after the effective date of this regulation.

We proposed changing certain RADV definitions at § 422.2. Specifically, we proposed removing the definition Initial Validation Contractor (IVC); removing the definition of RADV payment error calculation appeal process; and removing the definition of “One Best Medical Record for the purposes of Medicare Advantage Risk Adjustment Data Validation (RADV)”. In addition, we proposed adding one new definition by specifically defining the RADV appeals process. We also proposed revising the definitions of “Risk Adjustment Data Validation (RADV)” and “attestation process” within the RADV appeals context. Furthermore, we proposed amending RADV definitions at § 422.2 to specify that the Secretary, along with CMS, could conduct RADV audits.

At § 422.311, we proposed to update select RADV appeals terminology. We proposed amending the RADV regulations by adopting one common term to refer to RADV audit reports: “RADV Audit Report”. As mentioned earlier, we proposed removing from the RADV regulations the term—“Initial Validation Contractor, or IVC,” since 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 who may be employed by the same or different medical record review contractors.

At § 422.311(c)(1), we proposed to simplify the RADV appeals process by combining the two existing RADV appeal procedures—one for medical record review and one for payment error calculation—into one set of requirements and one process comprised of three administrative steps: Reconsideration, hearing officer review, and CMS Administrator-level review. Combining these existing RADV medical record review determination and payment error calculation appeals policies and processes improves the overall appeals process by simplifying the overall RADV appeals process and reducing burden on all parties involved in the RADV appeals process. We also believed that doing so improves overall

RADV appeals procedures by providing clarity that leads to greater efficiencies in adjudicating RADV appeals. Within this overall framework, we also proposed defining issues that would be eligible for RADV appeal at § 422.311(c)(2) and issues that would not be eligible for RADV appeals under this combined-appeal process at § 422.311(c)(3). We further proposed defining the manner and timing of a request for RADV appeal at § 422.311(c)(2)(iii), a reconsideration process at § 422.311(c)(6), a hearing process at § 422.311(c)(7)(iv), and an Administrator-level review at § 422.311(c)(8).

At § 422.311(a), we proposed that the Secretary, along with CMS, be permitted to conduct RADV audits beginning with the effective date of this regulation. Because of the absence of a clearly-defined burden of proof standard for RADV medical record review determination appeals, at § 422.311(c)(4) we proposed adoption of a burden of proof standard for all RADV determinations—be they payment error calculation or RADV medical record review determinations—whereby the burden would be on MA organizations to prove, based on a preponderance of the evidence, that CMS’s determination(s) was (were) erroneous. At § 422.311(b)(2) we proposed changing 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.

We received comments from health plans, managed care industry trade associations, providers, provider trade associations and other interested parties. These comments have resulted in changes to the previously described proposals, as discussed later in this section. Some of the comments we received did not apply to the proposed RADV appeals processes. However, because some of these comments apply to underlying RADV audit process, we are responding to certain comments because they appear to be relevant to the RADV appeals process. Other comments were clearly outside the scope of our proposed rule, so we have not included responses to those comments.

b. RADV Definitions

We proposed 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.

We received no comments specifically recommending modifications to the proposed definitions as stated, though we did receive comments regarding the policy behind some of these definition changes. The policy comments will be addressed later in this rule, though we are finalizing the specific definitions without modification.

c. Publication of RADV Methodology

In the October 22, 2009 proposed rule, and as reinforced in the April 15, 2010 final rule, we 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 proposed 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.

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. As a result, we proposed 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 invited comment on this proposal.

Comment: A commenter requested that CMS verify that the medical record review error determination standard, which presently requires multiple review determinations by independent coders to confirm a CMS-HCC coding error, remains in effect and is not altered by this proposed rule.

Response: While we did not propose RADV coding changes, we believe the question merits a response. We believe that our proposal to remove the definition of "Initial Validation Contractor" (IVC) may have led some to believe that we were abandoning RADV audit processes that require multiple levels of independent medical record review (coding) by independent reviewers before we will confirm a CMS-HCC coding error. This standard has not changed, notwithstanding the removal of the term IVC from the RADV appeals rules. We continue to utilize medical record reviewers to code medical records undergoing RADV review, though these reviewers may now be employed by the same or different medical record review contractors. The principle of independent review and multiple confirmations of an identified CMS-HCC remain in effect.

e. Proposal To Simplify the RADV Appeals Process

Currently, there are two types of RADV-related appeals processes described in our regulations at § 422.311: 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 proposed 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), that combines the two existing RADV appeal policies and procedures into one set of requirements and one process. We proposed 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 proposed at new § 422.311(c)(1), 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 proposed 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 the proposed policy and procedure follow.

(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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 final rule.

At § 422.311(c)(2)(vi) we proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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).

In proposed § 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 proposed 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, we ensure 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 proposed to replace these provisions with new hearing requirements and procedures at § 422.311(c)(7)(iv).

At § 422.311(c)(7)(i), we proposed 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 proposed 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 proposed 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 proposed RADV appeal hearing procedures. We proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 welcomed comments on these proposals.

We received the following comments and our response follows:

Comment: Several commenters agreed that combining the RADV medical record review determination and payment error calculation appeals policies and processes into one combined appeals process strengthens the overall appeals process and should

reduce administrative burden. A commenter disagreed with this assessment. Another commenter indicated that appealing both a medical record review determination and the payment error calculation concurrently within a 30-day timeframe would be problematic.

Response: We continue to believe the combining two RADV appeals processes into one combined appeals process will improve efficiency and reduce administrative burden. Previously, MA organizations wishing to appeal both medical record review determinations and a RADV payment error calculation would have been required to participate in two hearings and two Administrator-level reviews. Under our proposal, these same organizations need only participate in one hearing and one Administrator review. Regarding the notion that appealing both a medical record review determination and the payment error calculation concurrently within a 30-day timeframe would be problematic, we believe the commenter misunderstood how the proposed process is intended to work. The proposed provision at

§ 422.311(c)(5)(ii)(c) states that for MA organizations that appeal both medical record review determination appeal and RADV payment error calculation appeal—the Secretary adjudicates the request for RADV payment error calculation appeal following conclusion of reconsideration of the MA organization's request for medical record review determination appeal and not concurrently as the commenter asserted. However, to provide additional clarity to the provision, we have amended § 422.311(c)(5)(iii)(B) to state that MA organization's request for appeal of their RADV payment error calculation will not be adjudicated until appeals of RADV medical record review determinations filed by the MA organization have been completed and the decisions are final for that stage of appeal. We trust this clarifies this provision and CMS therefore finalizes this proposal.

Comment: A commenter objected to the proposed provision at § 422.311(c)(2)(ii) 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. This commenter stated procedural issues should not render an appeal invalid unless they undermine the integrity of the audit results or are otherwise significantly prejudicial.

Response: We disagree. RADV is an inherently complex administrative

process and the appeals procedures we have proposed are likewise detailed and comprehensive. Failure by MA organizations to follow RADV audit procedures could compromise the integrity of the administrative record that will serve as the foundational document that will be considered during any appeals process. Moreover, if we were to make subjective case-by-case determinations regarding what defines “undermining the integrity of the audit process,” then we would compromise our ability to establish objective review standards upon which to base appeals determinations. Therefore, we are finalizing this provision as proposed.

Comment: Several commenters requested that CMS allow MA organizations to appeal determinations made on “additional” CMS–HCCs abstracted during the medical record review process. Some commenters asserted that these additional CMS–HCCs are underpayments for which they are entitled payment. These commenters also asserted that MA organizations that do not receive credit for what they believe to be additional CMS–HCCs present in a submitted medical record should be entitled to appeal the fact that they did not receive credit.

Response: We disagree. We note that an additional CMS–HCC is a CMS–HCC that CMS uncovers during the review of the MA organization’s submitted medical record(s) for which it had not received payment. We acknowledge that in certain circumstances when CMS uncovers these additional CMS–HCCs, the MA organization can in fact receive credit for these newly-discovered diagnoses codes to offset the overpayment findings resulting from the medical record review of the audited CMS–HCC. The RADV process addresses additional CMS–HCCs, or “additional,” as they are termed, through the application of rules for crediting a sampled enrollee with additional CMS–HCCs that are identified incidentally, during medical record review. We emphasize that these “additional” diagnoses were not submitted for payment by MA organizations during the data collection period for enrollees selected in the sample, and yet in certain instances we provide audited MA organizations credit through our RADV medical record review process. At its core, RADV is an audit process that is intended to validate the CMS–HCCs that were submitted voluntarily by MA organizations in order to determine whether the risk adjustment portion of payment were properly made. We would note that the data collection period for any given payment year

provides a substantial amount of time for MA organizations to submit and/or correct enrollee diagnoses data to reflect an enrollee’s health status. The RADV audit process is not intended to serve as a de facto mechanism for extending the data collection deadlines under which MA organizations operate. For these reasons, MA organizations will not be permitted to appeal additional CMS–HCC determinations found under the RADV audit for which MA organizations did not receive credit.

Comment: At § 422.311(c)(2)(i), CMS proposed that for each audited CMS–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 CMS–HCC appeal. In response to this proposal, a commenter requested that CMS allow MA organizations to use an attestation to replace a medical record. Another commenter recommended that CMS change the attestation process embedded in the existing RADV audit procedures so that when CMS notifies an MA organization that an audited CMS–HCC was not validated due to lack of signature or credential, CMS would likewise allow, after medical record review, submission of an attestation to cure the identified RADV error.

Response: The purpose of the CMS-generated attestations is to provide MA organizations with an opportunity to cure signature and credential CMS–HCC validation errors for eligible medical records. CMS-generated attestations are not intended to provide an opportunity for a MA organizations, provider or supplier to replace a medical record; or for a provider or supplier to attest that a beneficiary has the medical condition reflected in the CMS–HCC at issue. Risk adjustment rules require that allowable diagnoses be verified in a medical record, not attestation. Regarding the recommendation that CMS notifies an MA organization that an audited CMS–HCC was not validated due to lack of signature or credential pursuant to RADV medical record review, we believe MA organizations bear the responsibility for identifying records that do not contain signature or credentials, and should do so at the same time they submit medical records to CMS for RADV medical record review.

Comment: At § 422.311(c)(2)(iv), CMS proposed a provision which stipulates that notwithstanding these changes, for purposes of appealing a CMS medical record review determination, we will not permit MA organizations to appeal

multiple medical records but will instead require MA organizations to identify one medical record from amongst the records submitted, and submit that record for appeal. For each audited CMS–HCC, MA organizations may appeal only one medical record that has undergone RADV review. Several commenters objected to CMS’s proposal that RADV appeals be limited to one medical record selected by the MA organization. These commenters believe CMS should not require MA organizations to select one medical record to appeal, but should rather permit MA organizations to appeal multiple medical records as part of the proposed RADV appeal process.

Response: We believe these comments are in part responding to information that we provided in February 2012 regarding changes in RADV methodology. At that time, we announced that CMS would allow MA organizations to submit more than one medical record for CMS–HCC validation during the RADV medical record review stage of the RADV audit process. While we now permit MA organizations to submit more than one medical record during the RADV audit process to validate an audited CMS–HCC, only one medical record is required and ultimately utilized by CMS to validate an audited CMS–HCC or conversely, to make a determination that the audited CMS–HCC is not present in the submitted medical record. Since one medical record is sufficient to validate an audited CMS–HCC, we believe it is reasonable to limit MA organizations to selecting one medical record for purposes of RADV appeal. Guidelines set forth in the International Classification of Diseases, Ninth Clinical Revision (ICD–9) specify that the information necessary to abstract a code be contained in entirety in documentation for one encounter (either inpatient or outpatient). Multiple records cannot be combined to obtain sufficient documentation for a diagnosis. Furthermore, risk adjustment rules specify that only one diagnosis submission throughout the entire data collection period initiates a risk score adjustment. Given this, multiple medical record support is not required to confirm the diagnosis. Therefore, the appeal record should be carefully selected to ensure payment is validated. Therefore, we do not accept this recommendation.

Comment: Several commenters objected to CMS’s proposal at § 422.311(c)(3) to not permit MA organizations to appeal either medical record review determination or payment error calculation methodology. A

commenter stated that MA organizations should be allowed to identify and explain their objections to audit and appeals procedures and requirements without losing their ability to pursue the administrative appeals process.

Response: At § 422.311(c)(3)(ii), we proposed that MA organizations would not be permitted to appeal CMS's medical record review determination methodology or CMS's payment error calculation methodology. We proposed this requirement for the same reason that we finalized the RADV appeals requirement in 2010 that MA organizations could not appeal the RADV payment error calculation methodology. The payment error calculation methodology would be known to audited MA organizations before their RADV audit began. MA organizations that questioned or did not otherwise understand the methodology would have an opportunity to seek clarification from CMS regarding the methodology at that time.

In December 2010, in response to questions from the MA industry regarding our RADV payment error calculation methodology, we published a white paper describing our RADV payment error calculation methodologies, and invited public comment. In response to comments received in February 2012, we published a RADV-related notice of methodology specifying the RADV payment error calculation methodology that the agency would utilize on a moving-forward basis.

This same principle applies to the way we conduct medical record review within the RADV audit context. We have long adhered to the International Classification of Diseases, Ninth Revision, Clinical Modification, or ICD-9-CM, system to classify and assign codes to health conditions abstracted from medical records that MA organizations submit to validate audited CMS-HCCs. ICD-9-CM standards are widely available to the public and will be available to MA organizations before RADV audits are initiated. We anticipate continuing to adhere to these standards until such time as new coding standards (for example, ICD-10) are universally adhered to in the United States. We continue to believe that it is essential that CMS adhere to a universally accepted coding classification system that is widely available in the public domain when conducting RADV audits.

We disagree that MA organizations lose their ability to pursue the administrative appeals process described at § 422.311 when they identify and explain objections to audit

and appeals procedures. MA organizations can fully execute their rights to RADV administrative appeals as described at § 422.311 by following applicable regulations. Those rules clearly specify issues that are eligible for RADV appeal at § 422.311(c)(2) and § 422.311(c)(3); and issues that are ineligible for RADV appeal at § 422.311(c)(3). To the extent an MA organization appeals RADV issues that are eligible for RADV appeal that request for appeal will go forward. To the extent an MA organization appeals issues that are ineligible for RADV appeal; we will not act upon that request for RADV appeal. The act of identifying and explaining objections to audit and appeals procedures will not in and of itself nullify an MA organization's request to appeal issues that are eligible for RADV appeal.

Comment: At § 422.311(c)(5)(ii) we proposed 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. At § 422.311(c)(7)(iii), we proposed 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. At § 422.311(c)(8)(i) and (ii), we proposed that a request for CMS Administrator review must be made in writing within 30 days of receipt of the hearing officer's decision. Several commenters requested that CMS consider providing MA organizations additional time at each of these steps within the RADV appeals process to elect to pursue further appeals activity. In most instances, these commenters requested CMS provide a 60-day response time instead of the proposed 30-day response time.

Response: We agree with the commenters' recommendations and will change the proposed response times from 30 days to 60 days at § 422.311(c)(5)(ii), § 422.311(c)(7)(iii), and § 422.311(c)(8)(i) and (ii).

Comment: A commenter recommended that CMS correct a cross-reference error between preamble language and regulation text. The error pertains to language at § 422.311(c)(6)(iv)(C) which references the hearing process in accordance with paragraph (c)(8). As stated in the preamble, we believe this should be a reference to (c)(7), which sets forth the rules for requesting a hearing. Paragraph (c)(8) relates to review by the CMS administrator.

Response: We agree with commenter's recommended edit and have changed the regulation text to specify paragraph (c)(7) and not (c)(8).

Comment: A commenter recommended that CMS clarify the provision at § 422.311(c)(7)(vii)(B)(2)(i) that states that either party be allowed to request a live or telephonic hearing, still subject to the hearing officer's discretion. The commenter recommended that both CMS and the MA organization be allowed to request a live or telephonic hearing, still subject to the hearing officer's discretion.

Response: Proposed § 422.311(7)(vii)(B)(2)(i) specifies that "the parties may request a live or telephonic hearing . . ." The term "the parties" in this instance means CMS or the MA organization, and not either CMS or the hearing officer. Therefore, either organization that is a party of the hearing process may request a live or telephonic hearing. This clarification notwithstanding, the CMS Administrator nevertheless maintains the independent discretion to elect to review the hearing officer's decision or to decline to review the hearing officer's decision. See § 422.311(7)(vii)(B)(2)(iii).

Comment: In proposed § 422.311(c)(8)(i) and (ii), CMS requires that a request for CMS Administrator-level review be filed with the CMS Administrator by either CMS or an MA organization. A commenter recommended that CMS accept adverse decisions by its hearing officers and not be permitted to appeal them to the CMS Administrator. Another requested clarification whether an MA organization would be given a "meaningful opportunity" to appeal a hearing officer's decision that is favorable to CMS (and not to the MA organization) if CMS' inaction allows the hearing officer's decision to become finalized.

Response: We disagree that only MA organizations should be provided an opportunity to appeal a hearing officer's adverse determination to the Administrator. Doing so would provide MA organizations with a level of due process not available to CMS, thus weighing the appeals process in favor of MA organizations. Consequently, we believe that both parties should be able to appeal a hearing officer's unfavorable decision to the Administrator level of review. Regarding the question of whether an MA organization would be given a meaningful opportunity to appeal a hearing officer's decision that is favorable to CMS if CMS' inaction allows the hearing officer's decision to become finalized, we reiterate that a decision that is favorable to CMS would inherently be unfavorable to the MA organization rendering them eligible to request review by the CMS Administrator so long as other appeals-

pre-requisites (for example, following of applicable rules, etc.) have been met. At proposed § 422.311(c)(8)(ii) we specify that an MA organization that has received a hearing officer's decision may request review by the CMS Administrator.

Comment: Several commenters objected to CMS's proposed RADV appeals-related documentation standards. A commenter requested that CMS reconsider its position that the medical record that they designate for RADV appeal be selected from one of the medical records that they originally submitted for medical record review under RADV audit. Another commenter requested that CMS reconsider its position that errors resulting from an outright failure by an MA organization to submit a medical record are not eligible for RADV appeal by the MA organization.

Response: Both of these recommendations suggest that CMS should extend, not have or otherwise not adhere to a medical record submission deadline when conducting RADV audits. It is our position that establishing realistic medical record submission deadlines is essential for conducting RADV audits timely. Conducting any type of audit activity absent the establishment of realistic documentation submission standards increases the burden and costs associated with completing the audit tasks on all parties involved. In fact, in response to industry concerns that we were not providing sufficient time for MA organizations to obtain and submit the medical records necessary to validate CMS-HCCs, we earlier extended the RADV audit medical record submission window from 3 months to 5 months. We believe 5 months is sufficient time for MA organizations to locate and submit medical records necessary to validate an audited CMS-HCC. Therefore, we reaffirm that the medical record that an MA organization selects to support its appeal of an adverse CMS-HCC determination must come from records that the MA organizations submitted to CMS for audit.

Comment: Several commenters objected to what they contend is a burden that RADV audits impose upon the physicians and physician practices that must produce medical records necessary to conduct audits. A provider-based trade association requests that MA organizations requesting medical records for a RADV audit be required to provide documentation on the scope of the audit from CMS, as providers believe there have been abuses in terms of the amount of requests and data

demands which exceed the actual requirements. By requiring MA organizations to provide documentation of the CMS RADV audit request and the specific medical records required, this commenter contended that CMS will ensure it receives all necessary documentation, while also ensuring MA organizations are not using the RADV audit to unduly burden providers. We note that outside of the proposed rule, CMS has also received letters arguing that the burden associated with RADV audits is not limited to the CMS' audits but also extends to internal audit activity undertaken by MA organizations that mimic the RADV audits that we undertake for Medicare payment validation. These commenters raised concerns that MA organizations were misrepresenting their internal audit activity as official CMS RADV audits.

Response: In an effort to minimize the burden associated with this activity, we have developed best practices that we encourage MA organizations to employ in their efforts to gather medical records from providers and hospitals. To the extent MA organizations employ these practices; it is our belief that the impact of RADV audits on providers can be minimized. We also understand the increasing need for providers to be able to distinguish when they are being asked for medical records in association with an MA organization's own audit or in accordance with an official Medicare program RADV audit which is subject to statutory requirements. Therefore, we issue letters on our letterhead that MA organizations must use when requesting medical records from providers when the request is specifically related to an official CMS RADV audit. Providers may rely upon these letters as an indicator that a given medical record request is for CMS' RADV audit process, and providers may request this authorizing letter before responding to requests by an MA organization.

f. Proposal To Expand Scope of RADV Audits

Federal regulations at § 422.311(a) specify that RADV audits are conducted by CMS. We proposed 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 proposed 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 welcomed comment on this proposal.

We received the following comments and our response follows:

Comment: Many commenters objected to proposed § 422.311(a) which specifies that the Secretary, along with CMS, could conduct RADV audits beginning with the date when CMS' proposed RADV appeals rule change became effective. Some of these commenters also objected to CMS's proposal to amend RADV definitions at § 422.2 to specify that the Secretary, along with CMS, could conduct RADV audits. Another commenter requested clarification for the rationale and mechanics of allowing HHS to conduct RADV audits, citing concerns about maintaining consistency in the audit process.

Response: We conduct RADV audits to help ensure the integrity of the Medicare program though activities aimed at determining whether certain payments should have been made by Medicare. The Secretary (including the Office of Inspector General (OIG)—pursuant to OIG's authority under the Inspector General Act of 1978, 5 U.S.C. App.) clearly has the authority to conduct RADV audit activity. Our proposing this provision and the related change in definition simply clarifies what is already an existing statutory authority. In response to the commenters requested clarification on the mechanics of how the Secretary would conduct RADV audits, we would note that the Secretary or OIG, will provide instructions regarding its RADV audit at the time the Secretary or OIG notifies selected organizations of pending RADV audit activity.

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 of proving 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 proposed 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 diagnosis 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 invited comment on this proposal.

We received the following comments and our response follows:

Comment: Several commenters objected to proposed § 422.311(c)(4) which specifies that the burden of proof for all RADV determinations—be they payment error calculation or medical record review determinations—resides with the MA organizations, based on a preponderance of the evidence standard, that CMS's RADV audit determination(s) was erroneous. These commenters recommended revising the regulation to place the burden of supporting an affirmative finding that a payment error has been made, on CMS. A commenter also requested that CMS more clearly define how a “preponderance of the evidence” burden of proof standard would be applied.

Response: In developing this proposal, we reviewed other types of burdens of persuasion, such as the burden to establish by “clear and convincing” evidence that a fact exists or does not exist. First, we based our decision to propose a preponderance of the evidence standard on CMS precedence in other appeals processes. Second, we determined that it may not seem fair to the MA organizations to set a high expectation for persuasion, especially for those MA organizations which have not gone through a RADV appeals process before. We determined that it would not set as high a standard as “clear and convincing” or “beyond a reasonable doubt” for these cases at this time. Proof that evidence as a whole is of a degree which is more probable than not is sufficient to overturn a CMS determination.

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 proposed 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 to CMS. See proposed regulation language at § 422.311(b)(2).

We received no comments on this proposal and therefore are finalizing this provision without modification.

B. Improving Payment Accuracy

4. 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 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 a plan disagrees with the calculated overpayment amounts or whether the overpayments are proper, the plan 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 final rule would apply to all Part C and Part D RAC determinations. As we implement the Part C RAC, we would determine if additional changes to the proposed appeals process are necessary.

Based on the foregoing, we proposed 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 3-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 proposed 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 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 proposed 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 proposed 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 proposed 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 proposed 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. We would notify and send its rebuttal to the plan at the same time it is submitted to the independent reviewer. In paragraph (d), we proposed 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 proposed that the independent reviewer would inform CMS and the plan of its decision in writing. In paragraph (f), we proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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.

We received the following comments and our responses follow:

Comment: Several commenters expressed concern over the proposed 15-day timeframe for plan sponsors to request review by a Hearing Official and also the proposed 15-day timeframe to request review by the Administrator. Commenters believe that a 15-day timeframe for requesting additional review may result in unnecessary appeals and that 30 days is a more appropriate timeframe for plan sponsors to evaluate if additional appeals for review are appropriate. Commenters pointed out that a 30-day timeframe is typical among other similar CMS appeals processes.

Response: We agree with commenters that a 15-day timeframe for requesting additional review by a Hearing Official or the Administrator may not provide enough time for plan sponsors to make an appropriate decision regarding additional appeals for review and we are finalizing this rule with a 30-day timeframe for such requests. This timeframe will also make the Parts C and D RAC Appeals process more structurally similar to existing appeals processes such as the RADV Appeals process.

Comment: A commenter requested that CMS clarify the distinction between "payment methodology" and "findings of the applied methodology" given that CMS proposed that "payment methodology" is not subject to appeal. This commenter believes that this distinction is critical to providing meaningful appeal rights to plan sponsors. The commenter provided an example such as when the RAC determines that a payment received by

the Part D sponsor should have been treated as Direct and Indirect Remuneration (DIR).

Response: We agree with the commenter that this distinction is critical to providing a meaningful appeals process to plan sponsors. In the proposed rule, we indicated that miscalculations and factual or data errors may be appealed as "findings of the applied methodology". If a plan sponsor believes that a Part D RAC incorrectly classified a payment as DIR, for example, this would be a question of fact regarding the findings of the applied methodology that the plan sponsor is entitled to appeal.

Comment: A commenter questioned why new evidence could not be submitted at subsequent levels of appeal after the first level reconsideration and requested that CMS allow new evidence to be submitted at each level of appeal.

Response: We disagree with the commenter. We do not believe it is common for evidence relevant to a RAC determination to be unavailable to a plan sponsor 60 days after a Notice of Improper Payment is received by the plan sponsor. This is the relevant timeframe for requesting a reconsideration and submitting relevant evidence and documentation to the independent reviewer. Also, we do not believe it is generally appropriate for plan sponsors to withhold relevant evidence from the independent reviewer at the Reconsideration stage of appeal and we want to safeguard the program from this type of activity. We have modeled our proposed process after existing CMS appeals processes that do not allow the submission of new evidence at higher levels of appeal, such as the CMS RADV appeals process. We also note that in addition to the plan sponsor not being permitted to submit new evidence at subsequent levels of appeal, we are also precluded from submitting new evidence at subsequent levels of appeal.

Comment: A commenter questioned why CMS did not define "designated independent reviewer" and suggested that in order to ensure that the first level appeals reviewer is both qualified and independent of the RAC, the regulation should specify the necessary qualifications for this position. The commenter further suggested that the regulation contain a specific conflict of interest provision that would disallow any financial or other relationship between the RAC and the independent reviewer.

Response: We agree with the commenter that the integrity of the proposed appeals process is imperative and that the designated independent

reviewer be both qualified and independent of the RAC. We decline to specify the necessary qualifications for this position in the regulation and we decline to add a specific conflict of interest provision in the regulation. We believe that the independence of the reviewer will be self-evident as the reviewer will not be affiliated with the RAC and we have no incentive to select independent reviewers who are lacking the qualifications to fulfill this task.

Comment: A commenter requested that CMS make clear that the Part D sponsor is not required to make any payment with respect to a RAC finding until the sponsor has exhausted the administrative appeals process. The commenter also requested that CMS clarify that any final and binding decision by the Administrator does not preclude judicial review.

Response: We agree that final Part D payment adjustments based on RAC findings will not be made until all administrative appeal rights are exhausted. This is our current practice under the existing appeals process and will continue to be the practice under the formal three-level appeals process being implemented in this final rule. We also agree with the commenter that any final and binding decision by the Administrator under this rule does not preclude judicial review.

After review of the public comments received on these proposals, we are finalizing our proposals with one modification. In §§ 422.2610(a) and 422.2615(a) and § 423.2610(a) and § 423.2615(a), we are revising the timeframe for MA organizations and Part D plan sponsors, respectively, to request review by a Hearing Official or the Administrator from 15 days to 30 days.

C. Implementing Other Technical Changes

1. 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 paragraph (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 paragraph (B) of such section, or insulin described in paragraph (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 are potentially eligible for Part D coverage, in line with the Part D drug definition. We proposed to address this issue in regulation to codify and clarify policy we previously addressed through guidance.

We proposed to add paragraph (vii) under the definition of a Part D drug to further clarify that only those combination products approved and regulated in their 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 1860D–2(e)(1) of the Act.

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.

Comment: A commenter noted it supported the proposed policy regarding combination products.

Response: We appreciate the support for our proposal.

Comment: A commenter requested that CMS provide clarification on what constitutes a vitamin versus what constitutes a dietary supplement.

Response: In the preamble, we provided an example of a Part D drug combined with a vitamin that would be eligible for coverage, if FDA approved in the combined form. We also provided an example of a Part D drug combined with a dietary supplement that would not be eligible for coverage because the FDA had not approved that combination. We did not mean to imply that only approved combinations involving vitamins would be eligible, nor did we mean to distinguish between vitamins as opposed to dietary supplements in that paragraph. Our intent was to distinguish their eligibility for coverage by the fact that one of these combined products was approved as a combination drug product by the FDA and the other was not.

After consideration of the public comments we received, we are finalizing this provision with a technical modification to improve the clarity of the provision.

b. Barbiturates and Benzodiazepines

We also proposed 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 by removing from paragraph (2)(ii) the clause “barbiturates when used to treat epilepsy, cancer, or a chronic mental health disorder; and benzodiazepines.”

We did not receive any comments regarding this proposal.

We note that an error appeared in the corresponding regulations text of the January 10, 2014 proposed rule. In the regulations text (79 FR 2062), we made a typographical error in an amendatory instruction and inadvertently did not remove the previously noted clause from the definition of “Part D drug” at § 423.100(2)(ii). Therefore, we are making the required corrections in the regulations text of this final rule.

c. Medical Foods

We proposed 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 paragraphs 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.

Comment: A commenter that strongly disagreed with the proposal stated that there are medically indicated nutritional supplements such as food thickeners, caloric supplements, and probiotics which should be covered if prescribed by a physician.

Response: The definition of a “covered Part D drug” found in section 1860D–2(e)(1) of the Act does not allow us to cover food thickeners, caloric supplements, and probiotics even if prescribed by a prescription. These items do not meet any of the requirements of that section.

After consideration of the public comment we received, we are finalizing this provision without modification.

2. 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 proposed 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 solicited 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 solicited 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 believed our proposal provides a general framework for when RTS edits must be relaxed, we solicited 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 solicited 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 myriad facility-specific factors. In particular, we solicited 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 solicited 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 stated 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 also stated that we would 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 solicited 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 solicited comment as to whether watch/warnings would require RTS overrides in the whole state, or just areas under the watch or warning. We also stated that we were 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 solicited 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.

Comment: Several commenters supported CMS's proposal. A commenter commended CMS's efforts to ensuring access to critical and other drugs during times of crises.

Response: We thank the commenters for the support.

Comment: Several commenters were concerned that the policy was not clear enough to ensure that Part D sponsors would apply it consistently. A commenter suggested that requiring sponsors to "reasonably conclude" whether a beneficiary would have difficulty obtaining refills would result in an inconsistent relaxation of edits and suggested instead that CMS provide clear direction by exercising its section 1135 waiver authority. Another commenter requested that CMS issue HPMS alerts to advise Part D sponsors on when to relax edits every time a trigger event occurred not only because of the subjective nature of the sponsor assessment but because it also depended on whether a sponsor knew that about a declaration. A commenter requested that we make it clear sponsors would only be obligated to relax edits when operationally possible.

Response: We appreciate the suggestions and will consider them in the future.

Comment: A commenter suggested that CMS allow beneficiaries enrolled in mail order pharmacy programs to use local retail or hospital pharmacies during emergencies when disasters or other emergencies interfere with their receipt of drugs through the mail.

Response: While we appreciate the concerns, we did not propose any changes with respect to mail order during disasters and emergencies and we are not adopting this recommendation at this time.

Comment: Several commenters responded to our request for comment by agreeing that it was appropriate to limit the window for relaxed edits to 30 days after the date of declaration. Another commenter suggested that the 30 day period should start running when the emergency actually occurred because declarations often do not take place until later—in which case the proposed timeframe might actually exceed 30 days.

Response: We appreciate the comments, and will use them to inform possible future rulemaking.

Comment: Several commenters believed use of the NCPDP submission code appropriate, while another concluded it would not work because it was beneficiary specific and not specific to LTC facilities. A commenter stated it was difficult to operationalize RTS overrides by areas and that it was typically done by state. Comments on the feasibility of relying on NWS watches and warnings ranged from several commenters who thought it inappropriate to ever relax edits on account of such warnings because they might never occur, to a commenter who thought it appropriate to limit such application solely to hurricane and tropical storm warnings, to another commenter who thought both types of warnings appropriate triggers and suggested that CMS also rely on advisories from NWS. However, not all commenters discussed warnings and watches in the context of LTC facilities and, in fact, a commenter questioned whether our proposal even applied to non-LTC situations.

Response: We appreciate the comments and will use them to inform possible future rulemaking.

Comment: A few commenters requested that we broaden our policy by allowing sponsors to relax edits more often than proposed. A commenter suggested we allow sponsors make determinations regarding whether to relax edits "well before" declarations were issued rather than wait for their issuance, and other commenters identified specific situations that they felt should prompt such a determination such as local challenges and severe weather (such as tornadoes) and accompanying difficulties (such as power outages extending for multiple days). Another commenter requested that CMS automatically grant special access rules when a state of emergency is declared in a state or region thereof rather than leave the discretion to apply those rules to sponsors.

In contrast, several commenters requested that we revise the regulation so that sponsors would be able to relax edits less often than proposed. Observing that many anticipated snow storms that did not actually take place last winter, a commenter requested that CMS not allow Part D sponsors to relax edits for government declarations that merely announced the possibility, rather than the occurrence, of disasters or emergencies. Another commenter suggested that we limit application of the policy to declarations only from federal and state authorities because it

was difficult for Part D sponsors with large service areas to track declarations by local authorities.

Another commenter recommended that we retain the current guidance.

Response: As a result of the comments we received on this issue, we are not finalizing this proposal. We have concluded that we need to carefully consider our options and consequently have decided to leave in place current guidance. There was simply not a consensus regarding any aspect of the proposed regulation to sufficiently inform a decision to finalize. For instance, a number of commenters expressed opposing views: Some requested that we broaden our policy by allowing sponsors to relax edits more often than proposed, while others suggested that we curtail the circumstances under which sponsors would be permitted to relax edits. Some contractors liked the discretionary aspects of the proposal and the existing guidance while others sought bright line indicators—although sometimes just to trigger the times when discretion might be applied. Several commenters appear to have misunderstood our proposal.

We believe it is important to ensure that beneficiaries receive drugs in the event of disasters or anticipated disasters that might hinder their access to such drugs for a period of time. But we are concerned that if sponsors do not uniformly relax edits under similar circumstances, beneficiaries in different plans will be treated disparately. We hope to prevent situations in which, for instance, two beneficiaries living in the same area are affected by the same disaster, but one beneficiary is able refill a prescription that otherwise would be subject by RTS edits, while the other, who is enrolled in a different plan, is not. The variety of comments and responses suggests that resolving these issues may require more focused inquiry. In the meantime, the current guidance will remain in place (found in Prescription Drug Benefit Manual, Chapter 5, Benefits and Beneficiary Protections, Section 50.12). We again thank all the commenters including those that took the time to respond to our specific solicitations. We will keep their suggestions in mind as we carefully consider our options for the future, including whether to address our regulatory proposals in future rulemaking.

3. 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. 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 proposed 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."

b. Terminology Changes (§§ 422.510 and 423.509)

Sections 1857(c) and 1860D–12(b)(3)(B) of the Act authorize CMS to terminate contracts with 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". Therefore, we proposed to replace the word "days" with "calendar days" in both §§ 422.510 and 423.509.

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 CMS 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." Therefore, we proposed to revise the paragraph heading of § 422.510(b)(2) to read "Immediate termination of contract by CMS". This change will also make it consistent with the corresponding heading for Part D, in § 423.509(b)(2).

d. Terminology Change (§ 423.509(b)(2)(C)(ii))

Sections 1857(c)(2) and 1860D–12(d)(3)(B) of the Act provide CMS 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 proposed to change § 423.509(b)(2)(C)(ii) to appropriately reference Part D plan sponsor; not MA organization, as it currently states.

We received no comments on these proposals and are therefore finalizing these provisions without modification.

4. Technical Changes Regarding Intermediate Sanctions and Civil Money Penalties

Sections 1857(g) and 1860D–12(b)(3)(E) of the Act provide 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". The language in other sections of this subpart refers to receipt of a notice as "days after receipt of this notice." All sections should be consistent. Therefore, we proposed to modify the language at §§ 422.756(a)(2) and 423.756(a)(2) to state "10 calendar days after receipt of the notice". In addition, we proposed to correct grammatical errors in current §§ 422.756(a)(2) and 423.756(a)(2) by revising the language in both §§ 422.756(a)(2) and 423.756(a)(2)² to add the word "the" before notice; as proposed, the second sentence in each paragraph (a)(2) would read "CMS considers receipt of the notice as the day after the notice is sent by fax, email, or submitted for overnight mail."

b. Cross-Reference Changes (§ 422.756(b)(4) and § 423.756(b)(4))

Under § 422.756(b)(4) and § 423.756(b)(4), we reference the procedures MA organizations and Part D plan sponsors must follow for requesting a hearing to appeal the imposition of intermediate sanctions and civil money penalties. MA organizations and Part D sponsors must adhere to hearing procedures promulgated within subpart N of the regulations, not just §§ 422.660 through 422.684 and §§ 423.650 through 423.662, respectively, as currently cited in §§ 422.756(b)(4) and 423.756(b)(4). Therefore, we proposed to modify the language at §§ 422.756(b)(4) and 423.756(b)(4) so that it would read that MA organizations and Part D sponsors "must follow the right to a hearing procedures as specified in subpart N".

c. Technical Changes (§§ 422.756(d) and 423.756(d))

In §§ 422.756(d) and 423.756(d) we provide alternatives to sanctions,

² We note that although the preamble accurately reflected this proposal, the regulation text for § 423.756(a)(2), (79 FR 2070), erroneously did not reflect the proposed grammatical correction.

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 proposed to revise the paragraph heading to "Non-renewal or termination by CMS" in both sections to reflect the content specified within the 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 plan sponsors. However, all of paragraph (b) in §§ 422.506 and 423.507 applies to §§ 422.756(d) and 423.756(d), respectively. Therefore, we proposed to change both provisions §§ 422.756(d) and 423.756(d) to read "\$ 422.506(b)" and "\$ 423.507(b)", respectively.³

Within §§ 422.756(d) and 423.756(d), we refer to the "sanctions described in paragraph (c)" but in each section, paragraph (c) refers to the effective date and duration of sanctions, rather than sanctions which are actually described in §§ 422.750 and 423.750, respectively. Therefore, we proposed 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." to correct this mistake.

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 corresponding sections.

Therefore, we proposed to align the language with that used in paragraphs (b)(1) and (2) from that same section 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) to track the statutory language.

³ In the preamble to our proposal, we mistakenly referred to the language as being deleted by using "and" instead of "through".

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 MA organizations and Part D plan sponsors, respectively. Under §§ 422.1020(a)(2) and 423.1020(a)(2), we discuss our procedures for requesting an appeal of a CMP. The current language in both sections state written requests for appeal “must be filed within 60 calendar days from the receipt of notice of initial determination.” However, this language does not align with the appeal language in subpart N for requesting a hearing.

Therefore, we proposed 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 proposed to change the language in both §§ 422.1020(a)(2) and 423.1020(a)(2) to read “after receipt” instead of “from the receipt”, so it reads “within 60 calendar days after receipt of the notice of initial determination”.

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 proposed 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 . . .” to maintain consistency.

We received no comments on these proposals and therefore are finalizing these provisions without modification.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether 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 solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

A. ICRs Related to Improper Prescribing Practices and Patterns

Our additions of §§ 424.530(a)(11), 424.535(a)(13), and 424.535(a)(14) will likely result in an increase in denials, revocations, and associated appeals. However, we are unable to estimate the number of denials, revocations, and appeals. We do not have data available that can be used to make such projections, as each situation would have to be carefully reviewed and addressed on a case-by-case basis. Therefore, we cannot estimate the potential concomitant increase in the ICR burden, though, as we stated in the proposed rule, we believe any such increase will be minimal.

We received no comments on the potential ICR burden of §§ 424.530(a)(11), 424.535(a)(13), and 424.535(a)(14).

B. 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.

We received no comments on this proposal and therefore are finalizing this provision without modification.

C. ICRs Related to Eligibility of Enrollment for Incarcerated Individuals (§§ 417.460, 422.734, and 423.44)

We proposed 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.

We received no comments on the ICRs for this proposal and therefore are finalizing the ICR assessment without modification.

D. 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.

We received no comments on the ICR assessment for this proposal and therefore are finalizing this assessment without modification.

E. 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 4—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 4 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 5.

TABLE 5—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
§ 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

We received no comments on the ICR assessment for this proposal and therefore are finalizing this assessment without modification.

V. Regulatory Impact Analysis

A. Statement of Need

The purpose of this final 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. This final rule makes changes that are necessary to: Clarify various program participation requirements and 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 final 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. Finally, in accordance with the provision of the Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than \$7.0 million to \$35.5 million in any 1 year). Individuals

and states are not included in the definition of a small entity. This final 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. 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 \$35.5 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 \$35.5 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 will be reached by the requirements in this final rule because this final rule will have minimal impact on small entities. Therefore, an analysis for the RFA will not be prepared because the Secretary has determined that this final rule will not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year by state, local, or tribal governments, in the aggregate, or by the private sector of \$100 million in 1995 dollars, updated annually for inflation. In 2014, that

threshold is approximately \$141 million. This final rule is not expected to reach this spending threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Based on CMS Office of the Actuary estimates, we do not believe that this final rule imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications.

Table 10 details the final 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, and incarcerated individuals 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

We proposed 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, and 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. We are finalizing the provision as proposed, with the revisions specified in our response to public comments earlier in this document.

2. Effects of Authority To Impose Intermediate Sanctions and Civil Money Penalties

We proposed 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 will not result in additional burden to sponsors nor will they have a financial impact on sponsors.

3. 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 proposed to modify the notice timeframe from 90 days to 45 days. We believe these provisions will not result in additional burden to sponsors nor will it have a financial impact on sponsors.

4. Effects of Reducing the Burden of the Compliance Program Training Requirements

We proposed 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 will 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 will not be permitted (or required) to develop or implement organization specific training for FDRs. We anticipate that this will 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 will actually provide savings for sponsors and the FDRs since FDRs will only have to take one training as opposed to the possible numerous trainings they may take under current requirements. Additionally, sponsors will save because they will not be required to provide training materials to each FDR with which they contract.

We believe these provisions will not result in additional burden to sponsors nor will they have a financial impact on sponsors.

5. Effects of Procedures for Imposing Intermediate Sanctions and Civil Money Penalties Under Part C and D

We proposed 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 proposed 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 will not receive any LIS annual or auto facilitated reassignments.

We believe these provisions will not result in additional burden to sponsors nor will they have a financial impact on sponsors.

6. Effects on Timely Access to Mail Order Services

We proposed to establish a fulfillment requirement for mail order prescriptions. We believed it was 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.

Comments persuaded us that we had not considered all relevant implications of this proposal and we decided not to finalize this provision. This in turn means that there will be no financial impact.

7. 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 which ended 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. We proposed revising this existing compensation structure. MA organizations and Part D sponsors will 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 Part D 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 Part D sponsor could pay up to 35 percent of the FMV amount for that year. We are finalizing the provision with an up to 50 percent payment for renewals, instead of the proposed 35 percent. We also proposed that plans not recover compensation when the disenrollment is not a result of the agent's behavior. We are not implementing the changes with respect to the recovery of compensation, but will finalize language to keep the existing situation, which requires full recoupment if a member disenrolls within the first 3 months of enrollment except in limited circumstances. In addition to the agent and broker compensation structures, we are setting limits on referral fees for agents and brokers.

We do not believe that any of these revisions will have a significant increase in burden or financial impact. Our existing compensation rules require that MA organizations and Part D sponsors pay on a calendar year basis, not a rolling year basis. Our regulations are restating existing requirements, to ensure consistency. While some MA organizations and Part D sponsors may have to make significant systems changes to ensure compliance, these changes are not based on this final rule but are required to meet existing requirements. MA organizations and Part D sponsors will likely have to make some systems modifications, such as paying between January 1 and December 31 of each year. However, we do not believe these will be of significant impact. Although some changes will be necessary, we believe the small cost and burden of the changes will outweigh the cost and burden of the existing multi-tier approach by simplifying the compensation structure for independent agent brokers.

8. Effects of Drug Categories or Classes of Clinical Concern

We are not finalizing the proposed criteria or their application to the categories and classes of clinical concern.

9. 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 proposed to broaden the MTM criteria to require that Part D sponsors target beneficiaries who have two or more chronic diseases and are taking two or more covered Part D drugs. We proposed 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 have set the cost threshold at \$620 which is the approximate cost of filling two generic prescriptions. We proposed 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 estimated 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 estimated 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 ($\$70.91/\text{CMR} \times 217,500$ 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.

In the proposed rule, we estimated 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 would be \$111,045,060 ($\$70.91/\text{CMR} \times 1,566,000$ CMRs). This was below previous estimates.

We were unable to definitively score the proposed changes to the eligibility criteria 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 was estimated to cost \$111 million, we cited evidence in the proposed rule that showed that MTM services may generate overall medical savings.

We are not finalizing these proposals. Therefore, the increased burden estimates associated with increasing eligibility from 2.5 million beneficiaries to 18 million beneficiaries are removed.

10. 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 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 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 will 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 will 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.

11. 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 will 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 will 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 will 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.

12. 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.

13. Effects of Limit Stand-Alone Prescription Drug Plan Sponsors To Offering No More Than Two Plans per PDP Region

As this proposal is not being finalized, there will be no financial impact.

14. Effects of Applicable Cost-Sharing for Transition Supplies: Transition Process Under Part D

We proposed 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 will be no cost impact on plans.

15. Effects of Interpreting the Non-Interference Provision

We proposed 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 formally 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. As we are not finalizing this proposal, there is no change in regulatory impact.

16. Effects of Pharmacy Price Concessions in Negotiated Prices

We proposed 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 will preclude the differential reporting that is taking place today in the realm of reporting drug costs and price concessions from network pharmacies. The rule will change current policy that permits sponsors to elect which price concessions from pharmacies to report 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 will 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 will impose a single consistent price concession reporting process on all Part D sponsors. Therefore, it is not clear that any contractual arrangements between a subset of sponsors and network pharmacies will require renegotiation, since only the form of the price concession, rather than its level, will 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 will 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 proposed will lend to Part D bids being more accurately comparable and premiums more accurately reflecting relative plan efficiencies. The lowest premiums will 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 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 are finalizing the provision with modification to require that negotiated prices be inclusive of all price concessions from network pharmacies except those contingent price concessions that cannot reasonably be determined at the point of sale. We expect that the effect of regulation to require consistent and transparent pricing will 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 rule will not change the level of price concessions and therefore costs under the program as a whole, but will apply consistency to how these are reported to CMS and treated in bidding and payment processes. Therefore, we anticipate that there will be no cost impact on plans.

17. Effects of Preferred Cost Sharing

We proposed 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 intended to clarify that preferred cost sharing should consistently be aligned with and accurately signal lower costs. We proposed that by “consistently lower” we meant 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.

After considering the public comments, we are not finalizing the proposal to revise § 423.120(a)(9) to require consistently lower negotiated prices for Part D drugs obtained through pharmacies offering preferred cost sharing than the same Part D drugs when obtained in the rest of the pharmacy.

This proposal will not be finalized and we will not engage in further rulemaking without re-proposing in a future rule, eliminating any estimated costs for implementation at this time.

18. Effects of Maximum Allowable Cost Pricing Standard

We proposed a change to the regulations at §§ 423.501, 423.505(b)(21) and 423.505(i)(3)(vii) 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 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 will have to be adapted to also disclose the prices to pharmacies in advance of their use, which we believe will involve negligible effort for Part D sponsors' existing employees and/or subcontractors. Therefore, we estimate the impact of these provisions to be negligible.

19. 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 expected 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 would have been 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 did not require them to start.

Part D sponsors already negotiate contracts regularly with pharmacies in order to meet network access requirements. We estimated 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 x 10 hours) for revising contract language and 2,000 hours (500 plans x 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 had revised contracts to meet the proposed requirement, no extraordinary additional expenses were anticipated for subsequent years. For a plan not currently offering preferred cost sharing levels, it was 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 was similarly expected to be negligible, as they are already reviewing and implementing terms from contracts, often annually. Pharmacies were not being directed to choose one set of T&C over another, but rather would have gained the option to review and implement terms for preferred cost sharing, if they so choose to accept the applicable negotiated pricing terms. Beneficiaries were expected to benefit from an increased number of pharmacies offering preferred cost sharing levels.

We received the following comments and our response follows:

Comment: Some commenters believed that there would be additional costs not reflected in the impact analysis, resulting from the proposed change to pharmacy contracts. One commenter believed that the estimates provided for revising contract language and especially negotiating new contracts with pharmacies were too low, and a few commenters stated that it would take more than 6 months to implement these changes.

Response: We appreciate the comments. However, this proposal will not be finalized and we will not engage in further rulemaking without re-proposing in a future rule, eliminating any estimated costs for implementation at this time.

20. Effects of Enrollment Requirements for Prescribers of Part D Covered Drugs

We proposed that prescribers must either be enrolled in Medicare or have validly opted-out in order for their prescriptions to be covered 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 is enrolled or in a valid opt-out status in Medicare before paying a claim from a network pharmacy or a 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 § 423.120(c)(6) entails a new requirement for Part D sponsors, we do not believe it will have any new or additional impact because Part D sponsors must already have prescriber validation capabilities to meet the NPI PDE requirement.

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. Solely from this perspective, we do not project any savings from this provision. We believe there will be savings, though, from the fact that certain unqualified individuals will no longer be able to prescribe Part D drugs, for they will be unable to meet Medicare requirements. However, we are unable to estimate a particular savings figure because we do not know how many such individuals there will be.

21. Effects of Improper Prescribing Practices and Patterns

Our additions of §§ 424.530(a)(11) and 424.535(a)(13) will likely result in additional application denials, revocations, and associated appeals. The DEA Web site found at http://www.dea.gov/divisions/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. However, we do not have data available to assist us in calculating the possible costs to physicians and eligible professionals in lost potential billings or the possible costs or savings to the government arising from these two provisions.

Section 424.535(a)(14) will result in an increase in the total number of revocations and associated appeals. Yet we are unable to project the number of providers and suppliers that will 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 possible costs or savings to the government arising from this provision.

We received the following comments regarding the impact of proposed §§ 424.530(a)(11), 424.535(a)(13), and 424.535(a)(14).

Comment: A commenter disagreed with CMS' determination that §§ 424.530(a)(11), 424.535(a)(13), and 424.535(a)(14) do not have federalism implications, contending that these provisions usurp the role of state licensing boards. The commenter recommended that CMS explain: (1) the federalism impacts of these provisions; and (2) the steps that it took to consult with state and local officials early in the process of developing the proposed rule.

Response: We maintain that these three provisions have no federalism implications, for CMS is not usurping the authority of states to take action against a physician or practitioner with respect to his or her licensure status. Moreover, as stated earlier, CMS (not state licensing boards) is the agency responsible for administering the Medicare program. Therefore, we must have the ability to independently take steps to protect Medicare beneficiaries and the Trust Funds.

Comment: One commenter stated that CMS did not furnish reasonable alternatives to the establishment of § 424.535(a)(14).

Response: In light of the very serious problem of abusive prescribing, as outlined by the OIG, CMS did not believe there were any reasonable alternatives to its proposal. Prompt action was necessary to protect Medicare beneficiaries and the Trust Funds.

No modifications are being made to §§ 424.530(a)(11), 424.535(a)(13), and 424.535(a)(14) as a result of these comments.

22. Effects of Broadening the Release of Part D Data

We proposed 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 entities, as well as to make other changes to our policies regarding the use and release of PDE data, as currently codified at § 423.505 (f)(3), (l) and (m). These proposals would 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 used or released in accordance with these proposals. Therefore, although we are finalizing the revisions to the Part D data regulations as proposed, we are not including any assessment of this final

policy for the regulatory impact statement.

23. 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 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 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 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.

24. Effects of Eligibility of Enrollment for Incarcerated Individuals

We proposed 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 incarceration status and disenroll the individual for no longer residing in the plan's service area if the plan confirmed incarceration status. If the MA plan or PDP could not confirm the incarceration status, those plans were to continue to investigate each instance of incarceration for up to 6 or 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 could not verify the incarceration status sooner. As a result, plans received capitated payments when individuals were 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 improper payments made by CMS and would result in a cost savings of \$73 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 \$103 million in 2024, and could save the Part D program (includes the Part D portion of MA PD plans) approximately \$46 million in 2015, increasing to \$153 million in 2024. As cost plans are paid based on the reasonable costs of 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 6—PROJECTED NUMBER OF INDIVIDUALS DISENROLLED DUE TO INCARCERATION AND ESTIMATED SAVINGS TO THE MEDICARE ADVANTAGE PROGRAM BY PROVISION FOR CALENDAR YEARS 2015 THROUGH 2024

	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	Totals (CY's 2015– 2024)
Projected number of incarcerated beneficiaries enrolled in MA plans	6,280	7,750	9,221	10,691	12,162	13,234	13,969	14,704	15,440	16,175
Projected federal impact due to incarcerated individuals disenrolled 6 months sooner	–\$27 million	–\$35 million	–\$43 million	–\$52 million	–\$62 million	–\$70 million	–\$78 million	–\$86 million	–\$94 million	–\$103 million	–\$650 million

Note: Estimates reflect scoring by the CMS, Office of the Actuary, and 2012 incarceration data provided by the SSA.

TABLE 7—PROJECTED NUMBER OF INDIVIDUALS DISENROLLED DUE TO INCARCERATION AND ESTIMATED SAVINGS TO THE MEDICARE PART D PROGRAM BY PROVISION FOR CALENDAR YEARS 2015 THROUGH 2024

	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	Totals (CY's 2015– 2024)
Projected number of incarcerated beneficiaries enrolled in MA plans	52,605	60,076	67,547	75,018	82,489	87,937	91,672	95,408	99,144	102,879
Projected federal impact due to incarcerated individuals disenrolled 6 months sooner	–\$46 million	–\$55 million	–\$65 million	–\$77 million	–\$90 million	–\$102 million	–\$113 million	–\$125 million	–\$138 million	–\$153 million	–\$965 million

Note: Estimates reflect scoring by the CMS, Office of the Actuary, and 2012 incarceration data provided by the SSA.

We received the following comment:
Comment: One commenter requested additional information on the assumptions used to calculate the

savings related to our proposal to disenroll incarcerated individuals, such as the percentage of membership of incarcerated beneficiaries.

Response: The following chart provides the assumptions used to calculate the savings previously outlined:

TABLE 8—ASSUMPTIONS FOR ELIGIBILITY OF ENROLLMENT FOR INCARCERATED INDIVIDUALS

	2015	2024
Expected MAPD Enrollment due to be disenrolled (A)	6,280	16,175
Average Part C per Capita Costs (\$) (B)*	10,024	14,845
Average Length of Stay (years) (C)	0.5	0.5
Gross Savings (\$millions) (A x B x C)	31.5	120.1
Savings from Part A Trust Fund (\$millions) (D)	14.7	53.1
Savings from Part B Trust Fund (\$millions) (E)	16.8	67.0
Savings Net of Member Premium (\$millions) (D + 0.75 x E)	27.3	103.3

* Note: Part C per Capita Costs are derived from the 2014 mid-session review.

After consideration of the public comment received, we are finalizing the policy without modification.

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

This provision permits 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 there may be savings as a result of healthier 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.

26. Effects of Improving Payment Accuracy: Reporting Overpayments, RADV Appeals, and LIS Cost Sharing

This section proposes only technical changes for overpayment reporting, RADV appeals, and CMS' treatment of diagnoses for additional payment after the final risk adjustment data submission deadline. 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.

27. Effects of Part C and Part D RAC Determination Appeals

In section III.B.4. of this final 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 9.

TABLE 9—SUMMARY OF RAC DETERMINATION APPEALS

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.
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.

28. 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.

29. Effects of Special Part D Access Rules During Disasters

In § 423.126(a), we proposed to 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 have resulted 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 provisions would have required 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.

As this proposal is not being finalized, there will be no financial impact.

30. Effects of Termination of a Contract Under Parts C and D

The changes to §§ 422.510 and 423.509 are minor technical and clarifying revisions and include making language consistent, aligning titles and

correcting references. These technical and clarifying changes will not result in additional burden to MA organizations or Part D sponsors nor will they have a financial impact on such entities.

31. Effects of Technical Changes Regarding Intermediate Sanctions and Civil Money Penalties

The changes to §§ 422.756 and 423.756 are minor technical and

clarifying revisions and include making language consistent, aligning titles and correcting references. These technical and clarifying changes will not result in additional burden to MA organizations or Part D sponsors nor will they have a financial impact on such entities.

TABLE 10—ESTIMATED ¹ AGGREGATE SAVINGS TO THE HEALTH CARE SECTOR BY PROVISION FOR CALENDAR YEARS 2015 THROUGH 2024

Provision	Regulation section(s)	Calendar year (\$ in millions)										Total (\$ in millions) CYs 2015– 2019
		2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	
												Federal Government (Medicare) Impacts
A.24. Eligibility of Enrollment for Incarcerated Individuals ² .	§ 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).	-73	-90	-108	-129	-152	-172	-191	-211	-232	-256	-1615
Total (\$ in millions)	-73	-90	-108	-129	-152	-172	-191	-211	-232	-256	-1615

Notes:

¹ Estimates of savings reflect scoring by the CMS, Office of the Actuary. Also, only provisions that are being finalized with savings or cost exceeding \$1,000,000 are listed. Other provisions either have no expected savings or cost, have a savings or cost that is difficult to score, have a cost that is expected to be counterbalanced by savings, have a savings or cost under \$1,000,000, or, were not finalized.

² Supporting 2012 incarceration data provided by the SSA.

D. Expected Benefits

1. Drug Categories or Classes of Clinical Concerns (§ 423.102(b)(2)(v))

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.

However, we are not codifying the propose criteria or applying them to the drug categories and classes of clinical concern. Thus, this does not apply.

2. Medication Therapy Management Program Under Part D

We anticipated that many more beneficiaries would have access to MTM services and believed that the proposed changes would have simplified the MTM criteria and minimized beneficiary confusion when choosing or transitioning between plans. Moreover, we believed the proposed changes would have reduced disparity and allowed more beneficiaries with drug therapy problems to receive MTM services.

However, we are not finalizing these proposals, so these expected benefits are no longer applicable.

E. Alternatives Considered

1. Modifying the Agent/Broker Compensation Requirements

In the preamble of this final rule, we outlined a few alternative compensation schedules. Ultimately we determined that the best approach was a two-tiered payment schedule, incorporating an initial payment and a continuous renewal payment.

2. 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.

We are not finalizing this proposal.

3. Pharmacy Price Concessions in Negotiated Prices

We did not identify any alternatives that both maintained consistent reporting among sponsors leading to comparable bids, and maximized price competition.

4. 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.

We are not finalizing this proposal.

5. Drug Categories or Classes of Clinical Concerns

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.

However, we are not codifying the propose criteria or applying them to the drug categories and classes of clinical concern. Thus, this does not apply.

6. Medication Therapy Management Program (MTM) Under Part D

In the proposed rule, 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 solicited stakeholder comment on where the threshold might alternatively be set.

7. 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 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, we proposed changes 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 1 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. 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.

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 11 we have prepared an accounting statement showing the transfers associated with the provisions of this final rule for CYs 2015 through 2019.

TABLE 11—ACCOUNTING STATEMENT: CLASSIFICATIONS OF ESTIMATED TRANSFERS FROM CALENDAR YEARS 2015 TO 2024

[\$ in millions]

Category	Transfers		
	Discount rate		Period covered
	7%	3%	
Annualized Monetized Transfers (Federal)	–\$150.27	– 156.27	CYs 2015–2024
Whom to Whom?	Federal Government to MA Organizations and Part D Sponsors		

Note: Monetized figures in 2014 Dollars.

G. Conclusion

We estimate the savings to the federal government from implementing these provisions will be \$73 million in CY 2015. The savings will increase

annually. In CY 2024, the federal government savings from implementing these provisions will be \$256 million. For the entire estimated period, CYs 2015 through 2024, we estimate the total

federal government (Medicare) impact to result in savings of approximately \$1.615 billion. We note that these savings do not represent net social benefits because they consist of transfers

of value from drug manufacturers, pharmacies, and incarcerated individuals to the federal government, MA organizations, Part D sponsors and beneficiaries who continue in the programs

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs—health, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping 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 recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as follows:

PART 417—HEALTH MAINTENANCE ORGANIZATION, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 1. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9), and 31 U.S.C. 9701.

■ 2. 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.

* * * * *

■ 3. Section 417.460 is amended by revising paragraph (b)(2)(i) and adding paragraphs (f)(1)(i)(A) through (C) to 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 service area or is incarcerated.

* * * * *

(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 and does not reside in the geographic service area of the HMO or CMP per § 417.1.

(B) *Notification by CMS of incarceration.* When CMS notifies an HMO or CMP of disenrollment due to the individual being incarcerated and not residing in the geographic service area of the HMO or CMP, as per § 417.1, the 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.

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 4. 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).

■ 5. 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 definition of “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. 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

* * * * *

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.

* * * * *

■ 6. Section 422.74 is amended by revising paragraph (d)(4)(i)(A) and adding paragraph (d)(4)(v) to read as follows:

§ 422.74 Disenrollment by the MA organization.

* * * * *

(d) * * *

(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 and does not reside in the service area of the MA plan as specified at § 422.2 or when notified of the incarceration by CMS as specified in 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 the individual being incarcerated and not residing in the service area of the MA plan as per § 422.2, disenrollment is effective the first of the month following the start of incarceration, unless otherwise specified by CMS.

* * * * *

■ 7. 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, national origin, including limited English proficiency, gender, disability, chronic disease, whether a person resides or receives services in an institutional setting, frailty, health status or other prohibited basis;

(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 —

(i) Be offered in connection with 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; and

(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.

§ 422.300 [Amended]

■ 8. 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.”

■ 9. Section 422.310 is amended by revising paragraph (g)(2) and adding paragraph (g)(3) to read as follows:

§ 422.310 Risk adjustment data.

* * * * *

(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 January 31 of the year following the payment year, 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.

■ 10. 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 reads 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 60 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) An MA organization's request for appeal of its RADV payment error calculation will not be adjudicated until appeals of RADV medical record review determinations filed by the MA organization have been completed and the decisions are final for that stage of appeal.

(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)(7) 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 60 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 reconsideration determination, 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 a medical record review determination appeal, the hearing officer reviews 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 a payment error calculation appeal, the hearing officer reviews all of the following:

(1) The reconsideration official's written determination.

(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) of this section, 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) *Written decisions* 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 in accordance with paragraph (c)(7)(x) of this section, 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 60 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 paragraph (c)(7)(vii)(B)(3) 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.

■ 11. 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 when the MA organization has determined, or should have determined through the exercise of reasonable diligence, that the MA organization has received an overpayment.

(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, unless otherwise directed by CMS for purposes of § 422.311.

(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.

(e) *Enforcement.* Any overpayment retained by an MA organization is an obligation under 31 U.S.C. 3729(b)(3) if not reported and returned in accordance with paragraph (d) of this section.

(f) *Look-back period.* An MA organization must report and return any overpayment identified for the 6 most recent completed payment years.

■ 12. Section 422.503 is amended by —

■ A. Adding paragraph (b)(4)(vi)(C)(3).

■ B. Adding reserved paragraph (b)(4)(vi)(G)(4).

■ C. Revising paragraph (b)(4)(vi)(G)(5).

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)(i) Not accept, or share, a corporate parent organization owning a controlling interest in 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.

(ii) Not accept, as either the parent organization owning a controlling interest of, or subsidiary of, 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.

* * * * *

■ 13. Amend § 422.504 by:

■ A. Revising paragraph (i)(2)(i).

■ B. Redesignating paragraph (i)(2)(ii) as (i)(2)(iv).

■ C. Adding new paragraph (i)(2)(ii) and paragraphs (i)(2)(iii) and (1)(5).

The revisions and additions read as follows:

§ 422.504 Contract provisions.

* * * * *

(i) * * *

(2) * * *

(i) HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any books, contracts, computer or other electronic systems, including medical records and documentation of the first tier, downstream, and entities related to CMS' contract with the MA organization.

(ii) HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any records under paragraph (i)(2)(i) of this section directly from any first tier, downstream, or related entity.

(iii) For records subject to review under paragraph (i)(2)(ii) of this section, except in exceptional circumstances, CMS will provide notification to the MA organization that a direct request for information has been initiated.

* * * * *

(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.

* * * * *

■ 14. Amend § 422.510 as follows:

■ A. By redesignating 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 paragraph (a)(4)(xii).

■ F. By revising paragraph (b)(1)(i) through (iii) and the heading for paragraph (b)(2).

■ G. 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”.

■ H. 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) * * *

(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:

* * * * *

(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.* * * *

* * * * *

■ 15. 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).

■ 16. Amend § 422.756 as follows:

■ A. In paragraph (a)(2), by removing the phrase “days from receipt” and adding in its place “days after receipt” and by removing the phrase “considers receipt of notice” and adding in its place “considers receipt of the notice”.

■ B. In paragraph (b)(4), by removing the cross-reference “§ 423.660 through § 423.684 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:

§ 422.756 Procedures for imposing intermediate sanctions and civil money penalties.

(c) * * *

(3) * * *

(ii) * * *

(C) During the limited time period, sanctioned sponsoring organizations

offering Part D plans 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 § 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.

* * * * *

■ 17. 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.

■ 18. 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. * * *

* * * * *

■ 19. 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.

* * * * *

■ 20. 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 paragraph (b).

■ 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 an MA-PD or an 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 an 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 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 50 percent of the current fair market value cut-off amounts published annually by CMS.

(iii) If the MA organization contracts with a third party entity such as a Field Marketing Organization or similar type entity to sell its insurance products, or perform services (for example, training, customer service, or agent recruitment)—

(A) The total amount paid by the MA organization to the third party and its agents for enrollment of a beneficiary into a plan, if any, must be made in accordance with paragraph (b)(1) of this section; and

(B) The amount paid to the third party for services other than selling insurance products, if any, must be fair-market value and must not exceed an amount that is commensurate with the amounts paid by the MA organization to a third party for similar services during each of the previous 2 years.

(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 enrollment year and, if paid at all, must be paid in full by December 31 of the enrollment 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 unless CMS determines that recoupment is not in the best interests of the Medicare program.

(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.

* * * * *

(h) *Finder's (referral) fees.* Finder's (referral) fees paid to all agents and brokers—

(1) May not exceed an amount that CMS determines could reasonably be expected to provide financial incentive for an agent or broker to recommend or enroll a beneficiary into a plan that is not the most appropriate to meet his or her needs; and

(2) Must be included in the total compensation not to exceed the fair market value for that calendar year.

Subpart Y—[Reserved]

■ 21. Part 422 is amended by adding reserved subpart Y.

■ 22. Part 422 is amended by adding subpart Z to read as follows:

Subpart Z—Part C Recovery Audit Contractor Appeals Process

Sec.

422.2600 Payment appeals.
422.2605 Request for reconsideration.
422.2610 Hearing official review.
422.2615 Review by the Administrator.

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 30 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 30 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

■ 23. 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).

■ 24. Amend § 423.1 by adding new references in numerical order to paragraph (a)(1) 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.

* * * * *
■ 25. Amend § 423.44 by adding paragraphs (d)(5)(iii) and (iv) to read as follows:

§ 423.44 Involuntary disenrollment from Part D coverage.

* * * * *

(d) * * *

(5) * * *

(iii) *Incarceration.* The PDP must disenroll an individual if the PDP establishes, on the basis of evidence acceptable to CMS, that the individual is incarcerated and does not reside in the service area of the PDP as specified at § 423.4 or when notified of an incarceration by CMS as specified in paragraph (d)(5)(iv) of this section.

(iv) *Notification by CMS of incarceration.* When CMS notifies the PDP of the disenrollment due to the individual being incarcerated and not residing in the service area of the PDP as per § 423.4, disenrollment is effective the first of the month following the start of incarceration, unless otherwise specified by CMS.

* * * * *

■ 26. In § 423.100, amend the definition of "Part D drug" as follows:

■ A. By adding paragraph (1)(vii).

■ B. By revising paragraph (2) introductory text.

■ C. In paragraph (2)(i), by removing ";" and adding in its place ".".

■ D. In paragraph (2)(ii), by removing the phrase "; barbiturates when used to treat epilepsy, cancer, or a chronic mental health disorder; and benzodiazepines." and adding in its place ".".

■ E. By adding paragraph (2)(iii).

The additions read as follows:

§ 423.100 Definitions

* * * * *

Part D drug * * *

(1) * * *

(vii) A combination product approved and regulated by the FDA as a drug, vaccine, or biologic described in paragraphs (1)(i), (ii), (iii), or (v) of this 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.

* * * * *

■ 27. Section 423.100 is further amended, effective January 1, 2016, by revising the definition of "Negotiated prices" to read as follows:

§ 423.100 Definitions

* * * * *

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 from network pharmacies except those contingent price concessions that cannot reasonably be determined at the point-of-sale; and

(3) Include any dispensing fees; but

(4) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices and cannot reasonably be determined at the point-of-sale.

(5) Must not be rebated back to the Part D sponsor (or other intermediary contracting organization) in full or in part.

* * * * *

■ 28. Amend 423.120 by:

■ A. Revising paragraph (b)(2)(v).

■ B. Adding paragraph (b)(3)(vi).

■ C. Adding paragraph (c)(5) introductory text.

■ D. Adding paragraph (c)(6).

The revisions and additions read as follows:

§ 423.120 Access to covered Part D drugs.

* * * * *

(b) * * *

(2) * * *

(v) Until such time as there are established, through notice and comment rulemaking, criteria to identify, as appropriate, categories and classes of clinical concern, the categories and classes of clinical concern are as specified in section 1860D–4(b)(3)(G)(iv) of the Act.

* * * * *

(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) Before June 1, 2015, the following are applicable:

* * * * *

(6) Beginning June 1, 2015, the following are applicable:—

(i) A Part D sponsor must deny, or must require its pharmaceutical benefit manager (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 (NPI) is not contained on the claim.

(ii) A Part D sponsor must deny, or must require its PBM to deny, a pharmacy claim for a Part D drug if the physician or eligible professional (when permitted to write prescriptions by applicable State law)—

(A) Is not enrolled in the Medicare program in an approved status; and

(B) Does not have a valid opt-out affidavit on file with an A/B Medicare Administrative Contractor (MAC).

(iii) A Part D sponsor must deny, or must require its PBM to deny, a request for reimbursement from a Medicare beneficiary for a drug if the request is not for a Part D drug that was dispensed in accordance with a prescription written by a physician or, when permitted by applicable State law, other eligible professional (as defined in section 1848(k)(3)(B)(i) or (ii) of the Act) who—

(A) Is identified by his or her legal name in the request; and

(B)(1) Is enrolled in Medicare in an approved status; or

(2) Has a valid opt-out affidavit on file with an A/B MAC.

(iv) In order for a Part D sponsor to submit to CMS a prescription drug event

record (PDE), the PDE must contain an active and valid individual prescriber NPI and 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 by applicable State law, an eligible professional (as defined in section 1848(k)(3)(B)(i) or (ii) of the Act) who—

(A) Is enrolled in Medicare in an approved status, or

(B) Has a valid opt-out affidavit on file with an A/B MAC.

* * * * *

■ 29. 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.* The Part D sponsor has identified an overpayment when the Part D sponsor has determined, or should have determined through the exercise of reasonable diligence, that the Part D sponsor has received an overpayment.

(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.

(e) *Enforcement.* Any overpayment retained by a Part D sponsor is an obligation under 31 U.S.C. 3729(b)(3) if not reported and returned in accordance with paragraph (d) of this section.

(f) *Look-back period.* A Part D sponsor must report and return any overpayment identified within the 6 most recent completed payment years.

§ 423.464 [Amended]

■ 35. 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 “.”.

■ 30. Amend § 423.501, effective January 1, 2016, by 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 acquisition cost.
- (3) Average manufacturer price.
- (4) Average sales price.
- (5) Maximum allowable cost.
- (6) Other cost, whether publicly available or not.

* * * * *

■ 31. Amend § 423.503 by adding paragraphs (a)(3) to read as follows:

§ 423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.

(a) * * *

(3) CMS does 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.

* * * * *

■ 32. Amend § 423.504 by adding paragraphs (b)(4)(vi)(C)(4) and (b)(8) and (9) to 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.

* * * * *

■ 33. Amend § 423.505 as follows:

■ A. In paragraph (f)(3)(v), by removing “,” and adding in its place “.”.

■ B. In paragraph (f)(3)(vi), by removing “; and” and adding in its place “.”.

■ C. By adding paragraph (f)(3)(viii).

■ D. In paragraph (i)(2)(i), by removing the phrase “audit, evaluate and inspect” and adding in its place “audit, evaluate, collect, and inspect”.

■ E. By redesignating paragraph (i)(2)(ii) as paragraph (i)(2)(iv).

■ F. By adding new paragraphs (i)(2)(ii) and (i)(2)(iii).

■ G. By removing paragraph (i)(3)(iv).

■ H. By redesignating (i)(3)(v) through (viii) as (i)(3)(iv) through (vii).

■ I. By adding paragraph (k)(7).

■ J. By adding a paragraph (m) heading.

■ K. By revising paragraphs (m)(1)(iii).L. By revising paragraph (m)(3).

The revisions and additions read as follows:

§ 423.505 Contract provisions.

* * * * *

(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 paragraph (i)(2)(i) of this section directly from any first tier, downstream, or related entity.

(iii) For records subject to review under paragraph (i)(2)(ii) of this section, except in exceptional circumstances, CMS will provide notification to the Part D sponsor that a direct request for information has been initiated.

* * * * *

(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) Beneficiary identifier elements on the claim generally are encrypted for release, except in limited circumstances, such as the following:

(1) If needed, in the case of release to other HHS entities, Congressional oversight agencies, non-HHS executive agencies and the States.

(2) 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.

* * * * *

■ 34. Section 423.505 is further amended, effective January 1, 2016, by revising paragraphs (b)(21) and (i)(3)(vii) to read as follows:

§ 423.505 Contract provisions.

* * * * *

(b) * * *

(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.

* * * * *

(i) * * *

(3) * * *

(vii) If applicable, provisions addressing the drug pricing standard requirements of § 423.505(b)(21).

* * * * *

■ 35. Amend § 423.509 as follows:

■ A. By redesignating paragraphs (a)(4), through (7), (a)(8) introductory text, (a)(8)(i) and (ii), and (a)(9) through (14) as paragraphs (a)(4)(i) through (iv), (a)(4)(v) introductory text, (a)(4)(v)(A) and (B), and (a)(4)(vi) through (xi), respectively.

■ 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).

■ 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.

* * * * *

(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 (xi) of this section.

* * * * *

§ 423.642 [Amended]

■ 36. Amend § 423.642(c)(1) by removing the phrase “90 calendar days” and adding in its place “45 calendar days”.

■ 37. 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) of this chapter”.

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) of this chapter.

* * * * *

■ 38. 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” and by removing the phrase “considers receipt of notice” and adding in its place the phrase “considers receipt of the notice”.

■ 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.

(1) Decline to authorize the renewal of an organization’s contract in accordance with § 423.507(b); or

(2) Terminate the contract in accordance with § 423.509.

* * * * *

■ 39. 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 (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.

■ 40. 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. * * *

■ 41. 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.

* * * * *

■ 42. 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 paragraph (b).

■ 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 an MA-PD or an 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 an 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 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 50 percent of the current fair market value cut-off amounts published annually by CMS.

(iii) If the Part D sponsor contracts with a third party entity such as a Field Marketing Organization or similar type entity to sell its insurance products, or perform services (for example, training, customer service, or agent recruitment)—

(A) The total amount paid by the Part D sponsor to the third party and its agents for enrollment of a beneficiary into a plan, if any, must be made in accordance with paragraph (b)(1) of this section; and

(B) The amount paid to the third party for services other than selling insurance products, if any, must be fair-market value and must not exceed an amount that is commensurate with the amounts paid by the Part D sponsor to a third party for similar services during each of the previous 2 years.

(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 enrollment year and, if paid at all, must be paid in full by December 31 of the enrollment 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 unless CMS determines that recoupment is not in the best interests of the Medicare program.

(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.

* * * * *

(h) Finder's (referral) fees. Finder's (referral) fees paid to all agents and brokers—

(1) May not exceed an amount that CMS determines could reasonably be expected to provide financial incentive for an agent or broker to recommend or enroll a beneficiary into a plan that is not the most appropriate to meet his or her needs; and

(2) Must be included in the total compensation not to exceed the fair market value for that calendar year.

Subpart Y—[Reserved]

■ 43. Part 423 is amended by adding reserved subpart Y.

■ 44. Part 423 is amended by adding subpart Z to read as follows:

Subpart Z—Recovery Audit Contractor Part D Appeals Process

Sec.	
423.2600	Payment appeals.
423.2605	Request for reconsideration.
423.2610	Hearing official review.
423.2615	Review by the Administrator.

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 30 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 30 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

■ 45. 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).

■ 46. 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 the physician or eligible professional submits his or her enrollment application to the Medicare contractor.

* * * * *

■ 44. 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 or represents a threat to the health and safety of Medicare beneficiaries or both. 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 eligible professional 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; Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: April 30, 2014.

Marilyn Tavenner,
Administrator, Centers for Medicare & Medicaid Services.

Dated: May 1, 2014.

Kathleen Sebelius,
Secretary, Department of Health and Human Services.

[FR Doc. 2014–11734 Filed 5–19–14; 2:56 pm]

BILLING CODE 4120–01–P